NEVADA STATE
BOARD OF PHARMACY

BOARD MEETING

June 4-5, 2025

HILTON GARDEN INN
7830 S LAS VEGAS BLVD
LAS VEGAS, NV

Zoom
https://zoom.us/j/5886256671
Meeting ID: 5886256671

Please do not remove the book from the meeting room.

STATE OF NEVADA

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

J. DAVID WUEST
Executive Secretary

DEPARTMENT OF BUSINESS AND INDUSTRY

OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS
STATE OF NEVADA BOARD OF PHARMACY

Date Posted: May 15, 2025

FIRST AMENDED AGENDA

◈ PUBLIC NOTICE ◈

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, June 4, 2025, at 9:00 am. The meeting will continue Thursday, June 5, 2025, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hilton Garden Inn
7830 S Las Vegas Blvd
Las Vegas, NV

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Please Note:

In regulating the practice of pharmacy, the Nevada State Board of Pharmacy has a duty to carry out and enforce the provisions of Nevada law to protect the health, safety, and welfare of the public.

Please note that items on this agenda may be taken out of order, two or more agenda items may be combined for consideration, and/or items may be removed from the agenda or delayed for discussion at any time.

The Board may convene in closed session pursuant to NRS 241.030 to consider the character, alleged misconduct, professional competence or physical or mental health of any person named on this agenda.

The Board will take public comment on any matters within their jurisdiction, control, or advisory power. Public comments may be limited to three minutes per person. Public comment may also be submitted to the Board at teambc@pharmacy.nv.gov.

The Board may refuse to consider public comment related to a contested case pursuant to NRS 233B.126 until the Board has rendered a decision in the contested case.

1. Call to Order and Roll Call – Establishment of Quorum

2. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

◈ CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the April 16-17, 2025, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-Appearance (**FOR POSSIBLE ACTION)**

A. Edgepark Medical Supplies – Fort Worth, TX
B. Lymphacare - Lebanon, TN
C. Medline Industries, LP – Salt Lake City, UT
D. Medline Industries, LP – Temecula, CA
E. Medline Industries, LP – Tolleson, AZ
F. RxFunction, Inc – Eden Prairie, MN
G. Sleep Data Holding – San Diego, CA
H. Vantive US Healthcare LLC – Largo, FL

4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-Appearance (**FOR POSSIBLE ACTION**)

Background Check Not Required by Law.

4.2.1 Publicly Traded (NAC 639.593(6)(a))

I. Cardinal Health at Home – Fort Worth, TX
J. Emergent Devices Inc – Plymouth Meeting, PA
K. Henry Schein, Inc – Jacksonville, FL
L. McKesson Medical-Surgical, Inc – Tolleson, AZ
M. McKesson Medical-Surgical, Inc – Houston, TX
N. Nuvaila US, LLC – Etna, OH
O. Surmodics, Inc – Eden Prairie, MN

4.2.2 Publicly Traded and VAWD-Accredited (NAC 639.593(6)(a) and (c))

P. McKesson Drug Company – Jeffersonville, OH

4.2.3 Publicly Traded and Manufacturer (NAC 639.593(6)(a) and (d))

Q. Alpha Cognition USA, Inc – Grapeville, TX
R. Chimerix, Inc – Durham, NC
S. Dentsply North America, LLC – Charlottes, NC
T. Intra-Cellular Therapies, Inc – Towson, MD
U. Ionis Pharmaceuticals, Inc – Carlsbad, CA
V. Precigen, Inc – Germantown, MD
W. Scholar Rock, Inc – Cambridge, MA

4.2.4 VAWD-Accredited (NAC 639.593(6)(c))

4.2.5 Manufacturer (NAC 639.593(6)(d))

X. Apozeal Pharmaceuticals, Inc – Levittown, PA
Y. Armas Pharmaceuticals, Inc – Freehold, NJ
Z. Cepheid – Fremont, CA
AA. Cresilon, Inc – Brooklyn, NY
BB. Fujifilm Irvine Scientific, Inc – Santa Ana, CA
CC. Fusion Orthopedics, USA, Inc – Mesa, AZ
DD. Getinge Group Logistics Americas, LLC – East Windsor, NJ
EE. Glenmark Pharmaceuticals, Inc- Allentown, PA
FF. Harrow Eye, LLC – Nashville, TN
GG. HTL-Strefa, Inc – Woodstock, GA
HH. LXO US, Inc – Landsdale, PA
II. Medisca, Inc – Plattsburgh, NY
JJ. Medtronic Logistics, LLC – Jacksonville, FL
KK. Medtronic Logistics, LLC – Memphis, TN
LL. Medtronic Logistics, LLC – Parker, CO
MM. Otter Pharmaceuticals, LLC – Lake Forest, IL
NN. PAI Pharma – Greenville, SC
OO. Philips Ultrasound, LLC – Reedsville, PA
PP. Premier Dental Products Company, LLC – Plymouth Meeting, PA
QQ. Progenics Pharmaceuticals, Inc – Bedford, MA
RR. Sagent Pharmaceuticals – Schaumburg, IL
SS. Spectrum Vascular – White Plains, NY
TT. Urgo Medical North America, LLC – Fort Worth, TX
UU. Secura Bio – Las Vegas, NV

4.2.6 VAWD-Accredited and Manufacturer (NAC 639.593(6)(c) and (d))

VV. J Knipper & Company, Inc – Lakewood, NJ
WW. J Knipper & Company, Inc – Lakewood, NJ
XX. J Knipper & Company, Inc – Charlestown, IN
YY. Kuehne & Nagel, Inc – Southhaven, MS
ZZ. PI Services, LLC – Erie, PA
AAA. UPS Supply Chain Solutions, Inc – Pedricktown, NJ

4.2.7 Distributor for Single Manufacturer (NAC 639.593(6)(e))

BBB. Axia Medical Solutions – Dallas, TX

4.2.9 <u>Background checks completed in compliance with NRS 639.500.</u>

CCC. Chewy Wholesale DFW5, LLC – Dallas, TX
DDD. Correct Rx Pharmacy Services, Inc – Hanover, MD
EEE. UPS Supply Chain Solutions, Inc – Louisville, KY

4.3 Application for Nevada Pharmacy License (NRS 639.230) – Non-Appearance **(FOR POSSIBLE ACTION)**

4.4 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance **(FOR POSSIBLE ACTION)**

FFF. Adelia Compounding, LLC – Farmers Branch, TX
GGG. Alchemist Pharma – Thonotosassa, FL
HHH. Castleton Pharmacy – Staten Island, NY
III. DCA Pharmacy – Franklin, TN
JJJ. Innovative Compounding Pharmacy – Folsom, CA
KKK. OptioRx – 290 – Columbus, OH

4.5 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-Appearance **(FOR POSSIBLE ACTION)**

LLL. AMRx – Denton. TX
MMM. CareFirst Specialty Pharmacy, LLC – Mount Laurel, NJ
NNN. Flexcare Specialty Services, LLC – Houston, TX
OOO. HealthDyne Specialty Colorado, LLC – Centennial, CO
PPP. HealthDyne Pharmacy Co., LLC – Centennial, CO
QQQ. HealthDyne Specialty Florida, LLC – Lakeland, FL
RRR. LeMed Specialty Pharmacy Arizona, LLC – Gilbert, AZ
SSS. Metro Drugs Pharmacy Department – Hoboken, NJ
TTT. Phoenix Pharmacy – La Palma, CA
UUU. Precision Fulfillment Pharmacy – Boca Raton, FL
VVV. ProCompounding LLC – Johnson City, TN
WWW. Realo Specialty Care Pharmacy – Morrisville, NC
XXX. Seven Hills Pharmacy LLC – Sharonville, PA
YYY. Synergy Apothecare – Wauwatosa, WI
ZZZ. TC Script, LLC – Scottsdale, AZ
AAAA. Triad Rx – Daphne, AL
BBBB. Truepill NY LLC – Brooklyn, NY
CCCC. Truepill – Hayward, CA

4.6 Application for Out-of-State Outsourcing Facility (NAC 639.6915) – Non-Appearance (**FOR POSSIBLE ACTION**)

DDDD. Mark Cuban Cost Plus Manufacturing – Dallas, TX
EEEE. Olympia Pharmacy – Orlando, FL

4.7 Request to Engage in The Practice of Pharmacy at A Site Other Than a Licensed Pharmacy – Non-Appearance **(FOR POSSIBLE ACTION)**

FFFF. Shyla Ann Mariano

4.8 Recommended Denial of Registration/Licensure Due to Material Omissions on Application – Non-Appearance **(FOR POSSIBLE ACTION)**

4.9 Application for Nevada Warehouse (NAC 639.622) – Non- Appearance **(FOR POSSIBLE ACTION)**

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

A. CVS Pharmacy #8824	(22-509-PH-S)
B. Karlo Arceo	(22-509-RPH-S)
C. Rodelyn Arceo	(23-353-CS-S)
D. Hill-Rom	(24-500-MP-S)
E. Partell Specialty Pharmacy	(23-175-PH-S)
F. Partell Specialty Pharmacy	(23-239-PH-S)
G. Jeffrey Lang	(23-239-RPH-S)
H. Partell Specialty Pharmacy	(23-429-PH-S)
I. Robert Seik	(23-429-RPH-A-S)
J. David Whitehouse	(23-429-RPH-B-S)
K. Michael Brogan	(23-183-RPH-S)
L. Gary M. DeShazo	(23-450-CS-S)
M. Mashayla Coleman	(23-505-PT-S)

6. Appeal hearing pursuant to NRS 639.2895(2) **(FOR POSSIBLE ACTION)**

A. FutureCare
B. Rxeed

7. Discussion and possible action to approve Amended Findings of Fact, Conclusions of Law and Order in Case No. 19-012-CS-S, in settlement of Petition for Judicial Review filed in *Festus Ebonka, APRN, Petitioner v. Nevada State Board of Pharmacy, Respondent*, Eighth Judicial District Court Case No. A-24-902608-J. **(FOR POSSIBLE ACTION)**

8. Application for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION)**

A. Inspire Prosthetics & Orthotics – Las Vegas, NV
B. Optimal Embrace – Las Vegas, NV
C. Silver State Medical Supplies, LLC – Las Vegas, NV
D. High Vibes Medical Supply, LLC - Las Vegas, NV

9. Application for Out-of-State Medical Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION)**

    A. The CPAP Shop – West Berlin, NJ

10. Application for Nevada Ambulatory Surgery Center License (NAC 639.4992) – Appearance (**FOR POSSIBLE ACTION)**

    A. Coronado Surgery Center – Henderson, NV
    B. Coronado Surgical Recovery Suites – Henderson, NV
    C. Elkhorn Surgery Center – Las Vegas, NV
    D. Fort Apache Surgery Center, LLC – Las Vegas, NV
    E. Fresenius Vascular Care Henderson ASC, LLC – Henderson, NV
    F. Horizon Ridge Surgery Center, LLC – Henderson, NV
    G. Queensridge Surgery Center – Las Vegas, NV
    H. Queensridge Surgical Recovery Suites – Las Vegas, NV
    I. Sahara Surgery Center – Las Vegas, NV
    J. Summit Surgical Center, LLC – Las Vegas, NV

11. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

    A. Las Vegas Radiopharmacy – Las Vegas, NV
    B. Meta Pharmacy Services – Las Vegas, NV

12. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance – **(FOR POSSIBLE ACTION)**

    A. Polaris Pharmacy Services – Warrington, PA
    B. RLS (USA) Inc. – Livingston, NJ
    C. RLS (USA) Inc. – Wood Dale, IL

13. Request for Approval of Change of Managing Pharmacist pursuant to NRS 639.220 **(FOR POSSIBLE ACTION)**

    A. Thomas Schotik

14. Application for Advance Practice Registered Nurse – Prescribe Registration (NAC 639.850) – Appearance (**FOR POSSIBLE ACTION)**

    A. Leslie Erin Kalyn

15. Discussion of Attorney General Opinion 2025-01 re: Homeopathic physicians authority to possess, administer, prescribe and dispense controlled substances/dangerous drugs.

16. General Counsel Report. Note: The Board may exclude the public for a report on potential or existing litigation pursuant to NRS 241.015(3)(b)(2).

17. Executive Secretary Report:

    A. Financial Report

B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative update
H. Nevada Law Examination Update

18. Date and Location of Next Scheduled Board Meeting:

July 16-17, 2025 – Las Vegas, NV

19. Public Comment: No action may be taken upon a matter raised under this item of the agenda until the matter itself has been specifically included on a future agenda as an item. (NRS 241.020)

20. **Adjournment**

Note: We are pleased to make reasonable accommodations for members of the public who are disabled and wish to attend the meeting. If special arrangements for the meeting are necessary, please notify the Nevada State Board of Pharmacy, 985 Damonte Ranch Parkway, Suite 206, Reno, NV, 89521, or call Darlene Nases at (775) 850-1440, as soon as possible.

Supporting materials or additional information regarding the meeting may be obtained from Darlene Nases at (775) 850-1440, email teambc@pharmacy.nv.gov or 985 Damonte Ranch Parkway, Suite 206, Reno, Nevada, 89521.

Continuing Education credit of 4 hours, including 1 hour of law, will be given per day of in-person Board meeting attendance pursuant to NAC 639.330(1)(b)(2). You are required to attend the board meeting for a full day to receive CE credit including the law credit.

This notice has been posted at www.notice.nv.gov and www.bop.nv.gov pursuant to NRS 241.020 (4).

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Ste 206, Reno, NV 89521

(775) 850-1440 • 1-800-364-2081 • FAX (775) 850-1444

Email: pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

MINUTES

April 16-17, 2025

BOARD MEETING

The Nevada State Board of Pharmacy will conduct a meeting beginning Wednesday, April 16, 2025, at 9:00 am. The meeting will continue Thursday, April 17, 2025, at 9:00 am if necessary or until the Board concludes its business. Pursuant to NRS 241.023(1)(c) the meeting is being conducted by means of remote technology. The public may attend the meeting via live stream remotely or at the following location:

Hyatt Place
1790 E Plumb Lane
Reno, NV 89502

Via Videoconference at Zoom: https://zoom.us/j/5886256671
or
Via Teleconference at 1 (669) 900-6833
Meeting ID: 588 625 6671

Board Members Present:

Helen Park	Krystal Freitas	Richard Tomasso	Adam Porath
Jade Jacobo	Anna Carr		

Board Staff Present:

David Wuest	Gregory Zunino	Brett Kandt	Monica Moazez
Darlene Nases	Erin Miller	Ryan Miller	Jessette Phaynarikone
Yenh Long	Todd Weiss	Laura Tucker	Mui Lee

1. Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. Board members were present, and a quorum was established.

2. Public Comment at April 16, 2025, 9:07 AM

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There was no public comment.

3. Approval of March 5-6, 2025, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

Board Action:

Motion: Jade Jacobo moved to approve the March 5-6, 2025 Board Meeting Minutes.

Second: Krystal Freitas

Action: Passed unanimously.

◈CONSENT AGENDA ◈

The Consent Agenda contains matters of routine acceptance. The Board Members may approve the consent agenda items as written or, at their discretion, may address individual items for discussion or change.

3. Approval of the March 5-6, 2025, Board Meeting Minutes (**FOR POSSIBLE ACTION)**

4. 4.1 Applications for Out-of-State Medical, Devices, Equipment and Gases License (NAC 639.6944) – Non-Appearance (**FOR POSSIBLE ACTION)**

A. Clara Care, Inc – Uniontown, OH
B. Gramatan Health Supplies, LLC – Mount Vernon, NY
C. Graymont Equipment Distribution LLC – Chicago, IL

4.2 Applications for Out-of-State Wholesaler License (NRS 639.233) – Non-appearance (**FOR POSSIBLE ACTION**) **Background Check Not Required by Law.**

4.2.1 Publicly Traded (NAC 639.593(6)(a))

D. Cardinal Health 414, LLC – Lewis Center, OH
E. Infusystem, Inc – Bakersfield, CA

4.2.2 Publicly Traded and VAWD-Accredited (NAC 639.593(6)(a) and (c))

F. Catalent Pharma Solutions, LLC – Philadelphia, PA

4.2.3 Publicly Traded and Manufacturer (NAC 639.593(6)(a) and (d))

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G. Euclid Vision Corporation – Sterling, VA
H. KalVista Pharmaceuticals, Inc – Cambridge, MA
I. Kuna Oncology, Inc – Boston, MA
J. Revance Therapeutics, Inc – Nashville, TN
K. Soleno Therapeutics, Inc – Reedwood City, CA

4.2.4 Publicly Traded, VAWD-Accredited, and Manufacturer (NAC 639.593(6)(a), (c), and (d))

4.2.5 VAWD-Accredited (NAC 639.593(6)(c))

L. Kuehne & Nagel, Inc – Lewisville, TX
M. Kuehne & Nagel, Inc – Memphis, TN

4.2.6 Manufacturer (NAC 639.593(6)(d))

N. Accellence Home Medical – Reno. NV
O. Banner Life Sciences, LLC – High Point, NC
P. Bridge Global Health – Hapeville, GA
Q. Catalent Greenville, LLC – Greenville, NC
R. Catalent Pharma Solutions, LLC – Morrisville, NC
S. Granulation Technology, Inc – Fairfield, NJ
T. Nuclein, LLC – Austin, TX

4.2.7 VAWD-Accredited and Manufacturer (NAC 639.593(6)(c) and (d))

4.2.8 Distributor for Single Manufacturer (NAC 639.593(6)(e))

4.2.9 <u>Background checks completed in compliance with NRS 639.500.</u>

U. Kuehne & Nagel, Inc – Dallas, TX

4.3 Application for Nevada Warehouse (NAC 639.622) – Non-Appearance **(FOR POSSIBLE ACTION)**

4.4 Application for Nevada Pharmacy License (NRS 639.230) – Non-Appearance **(FOR POSSIBLE ACTION)**

V. Renown Regional Medical Center Specialty Care Pharmacy – Reno, NV
W. Ridley's Pharmacy #1144 – Spring Creek, NV

4.5 Application for Out-of-State Compounding Pharmacy License (NRS 639.230) – Non-Appearance – **(FOR POSSIBLE ACTION)**

X. AnazaoHealth – Tampa, FL
Y. Oakstead Infusion Vital Care – Layton, UT

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Z. Optum Infusion Services 308, LLC – Chandler, AZ
AA. Polomar Specialty Pharmacy, LLC – Palm Harbor, FL
BB. Rush Pharmacy – Oviedo, FL

4.6 Application for Out-of-State Pharmacy License (NRS 639.2328) – Non-Appearance –
(FOR POSSIBLE ACTION)

CC. Advanced Diabetes Supply – Carlsbad, CA
DD. AHF Pharmacy – Carson, CA
EE. Aurora Specialty Pharmacy – Menomonee Falls, WI
FF. Get Relief Rx – Billings, MT
GG. Rare Specialty Pharmac – Rahway, NJ
HH. Stellar Rx – Avondale, PA
II. SelectRx KS, LLC – Olathe, KS
JJ. The Art of Medicine – Philadelphia, PA
KK. The Medicine Shoppe – Riverside, CA
LL. US Med, LLC – Miami, FL

4.7 Application for Out-of-State Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

4.8 Request to Engage in The Practice of Pharmacy at A Site Other Than a Licensed Pharmacy – Non-Appearance **(FOR POSSIBLE ACTION)**

4.9 Application for Nevada Ambulatory Surgery Center License (NAC 639.4992) – Non- Appearance **(FOR POSSIBLE ACTION)**

Adam Porath recused himself from Consent Agenda Item 4V from the Consent Agenda.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda with exception of Agenda Item 4V.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to approve the Consent Agenda Item 4V.

Second: Krystal Freitas

Action: Passed unanimously (Porath recused).

◈ REGULAR AGENDA ◈

5. Disciplinary hearings pursuant to NRS 639.247. (**FOR POSSIBLE ACTION**)

N. Lincare, Inc (24-324-MP-N)

Jay DeVoy was present.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging Lincare failed to properly service the respiratory equipment furnished to a patient at least every 24 months as required by the manufacturer's product manual.

The proposed stipulated penalties for Lincare, Inc. License No. MP00015 are the following: 1) Respondent fined $1,000; and 2) Respondent assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Lincare, Inc. as presented by Mr. Zunino.

Second: Jade Jacobo

Action: Passed unanimously.

N. Meta Pharmacy Services (24-125-PH-S)
O. Sean Barclay (24-125-RPH-A-S)

Richard Tomasso has recused himself from these matters.

President Park was familiar with Sean Barclay from Roseman University but could participate in this matter fairly and without bias.

Sean Barclay and William Stilling were present.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Meta Pharmacy Services and Sean Barclay as owner/managing pharmacist, and/or pharmacy employees, filled and dispensed unlawful prescriptions for controlled substances and compounded semaglutide, employed one pharmaceutical

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technician in training (PTT) on an expired registration and another PTT without obtaining a registration to work at Meta Pharmacy.

Mr. Kandt commented that a change of ownership application had been submitted on behalf of Meta Pharmacy. The parties then presented a proposed stipulation to resolve the matter.

Board discussion ensued.

The hearing was recessed so the parties could meet to discuss proposed amendments to the stipulated penalties. The hearing resumed, and the parties presented the following proposed stipulation for the Board's consideration:

Respondent's Barclay's Certificate of Registration No. 17303 is revoked, the revocation is stayed, and respondent is placed on probation for a period of ten (10) years subject to the following conditions: 1) a public reprimand; 2) pay a $10,000 fine for the violations; 3) pay $2,000 in attorney's fees and costs; 4) 12 additional continuing education on pharmacy law and ethics within six months of the Order date; 5) shall not be a managing pharmacist at Meta Pharmacy or any pharmacy licensed by the Board during the probation period; 6) shall divest himself of any ownership interest in Meta Pharmacy within 90 days of the Order and shall not hold any ownership in any pharmacy licensed by the Board during the probation period; and 7) shall not work as a pharmacist for Meta Pharmacy for a period of two years from the effective date of the Order. Respondent Meta fined $10,000 for the violations; $2,000 in attorney's fees and costs; and quarterly inspections for a period of one (1) year not to exceed $500 at owner's expense.

Board Action:

Motion: Jade Jacobo moved to approve the Stipulation and Order for Meta Pharmacy and Sean Barclay, with the amendments presented.

Second: Adam Porath

Action: Motion passed (Tomasso recused).

N. Christopher Peters (24-125-RPH-B-S and 23-175-RPH-S)
O. Michelle Lyn Badten (24-125-RPH-C-S)

Joey Gilbert was present on behalf of Christopher Peters and Michelle Lyn Badten.

Brett Kandt, General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Peters in Case No. 23-175-RPH-S refused to transfer a prescription as requested by a patient and engaged in unprofessional conduct, and he knowingly filled and dispensed unlawful prescriptions for controlled substances in Case No. 24-125-RPH-B-S. It was also alleged that Respondent Badten knowingly filled and dispensed unlawful prescriptions for controlled substances.

Kandt presented proposed stipulations for each respondent.

The proposed stipulated penalties for Michelle Lyn Badten, Certificate of Registration No. 14966-B are the following: 1) Respondent's Certificate of Registration No. 14966-B is suspended for a period of one (1) year, the suspension is stayed, and Respondent is placed on probation for one (1) year subject to the following conditions: 1) public reprimand; 2) Respondent fined $1,000; and 3) Respondent assessed $1,000 in attorney's fees and costs.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the Stipulation and Order for Michelle Lyn Badten, as presented by Mr. Kandt.

Second: Krystal Freitas

Action: Motion passed (Tomasso recused).

The proposed stipulated penalties for Christopher Peters, Certificate of Registration No. 16325 are the following: 1) Respondent's Certificate of Registration No. 16325 is suspended for a period of two (2) years, the suspension is stayed, and Respondent is placed on probation for two (2) years; 2) Respondent fined $2,000; and 3) Respondent assessed $2,000 in attorney's fees and costs.

Board discussion ensued.

The Board proposed that Respondent also complete ten (10) additional continuing education (CE) hours on pharmacy law and ethics within six months of the effective date of the Order.

Mr. Gilbert indicated his client consented to the additional term of the Stipulation and Order.

Board Action:

Motion: Adam Porath moved to approve the prosed Stipulation and Order for Christopher Peters, with the additional requirement that Respondent complete ten (10) additional hours of continuing education on pharmacy law and ethics, due within six (6) months of this order.

Second: Jade Jacobo

Action: Motion passed (Tomasso recused).

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O. Heliodoro Magana (20-070-PR-N)

Heliodoro Magana and Brad Shipley were present.

Todd Weiss disclosed that he previously worked with Brad Shipley but could participate in this matter fairly and without bias.

Gregory Zunino, Senior General Counsel for the Nevada Board of Pharmacy, prosecuted the case alleging that Respondent Magana failed to pay the $10,000 fine and $544.55 in attorney's fees and costs in Case No. 20-070-PR-N ordered on April 17, 2024.

A petition to vacate was filed with the Board on behalf of Mr. Magana by his counsel.

The Board heard testimony and received evidence.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to deny the Petition to Vacate.

Second: Krystal Freitas

Action: Passed unanimously.

Board Action:

Motion: Jade Jacobo moved to uphold the previous terms of the Order with an amendment to include a payment plan option for Respondent Magana.

Second: Richard Tomasso

Aye: Freitas, Tomasso, Park, Jacobo, Carr
Nay: Porath

Action: Motion passed.

13. Discussion and possible action to amend, revise and/or approve proposed FY26 budget **(FOR POSSIBLE ACTION)**

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, and Kiran Bains, Finance Manager for the Nevada Board of Pharmacy, reviewed the monthly budget and gave an overview of the proposed FY26 budget for the Board.

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Board discussion ensued.

Board Action:

Motion: President Park moved to approve the FY26 budget, as presented by Board staff.

Second: Adam Porath

Action: Passed unanimously.

A. Uri Assa Krutilin (18-052-RPH-S)

No one was present on behalf of Uri Assa Krutilin.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the Order to Show Cause alleging that Respondent Krutilin failed to pay the fine of $1,300 and $749 in attorney's fees and costs as ordered on December 1, 2021.

Mr. Kandt called Erin Miller as a witness.

Erin Miller, Administrative Assistant – Board Coordinator II, was sworn in and subject to examination.

Mr. Kandt called Jessette Phaynarikone as a witness.

Jessette Phaynarikone, Administrative Assistant – Board Coordinator I, was sworn in and subject to examination.

Mr. Kandt requested that proof of service of the Order to Show Cause and proof of service of a second notice of the show cause hearing to Respondent Krutilin be admitted into record as Exhibits 1-2.

President Park admitted Exhibits 1-2 into the record.

The Board heard testimony and received evidence.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to find that Uri Assa Krutilin was properly served and was in violation of the original Order by non-payment of the fine and attorney's fees and the violation shall be reported to the National Practitioner Data Bank.

DRAFT

Second: Krystal Freitas

Action: Passed unanimously.

B. Eric Math (19-083-CS-S)

No one was present on behalf of Eric Math.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the Order to Show Cause alleging that Respondent Math failed to pay the fine of $5,000 and $812.50 in attorney's fees and costs as ordered on April 21, 2021.

Mr. Kandt called Erin Miller as a witness and reminded her she was still under oath.

Erin Miller, Administrative Assistant – Board Coordinator II, was subject to examination.

Mr. Kandt called Jessette Phaynarikone as a witness.

Jessette Phaynarikone, Administrative Assistant – Board Coordinator I, was sworn in and subject to examination.

Mr. Kandt requested that proof of service of the Order to Show Cause and proof of service of a second notice of the show cause hearing to Respondent Math be admitted into record as Exhibits 1-2.

President Park admitted Exhibits 1-2 into the record.

The Board heard testimony and received evidence.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to find that Eric Math was properly served and was in violation of the original Order by nonpayment of the fine and attorney's fees and the violation shall be reported to the National Practitioner Data Bank.

Second: Krystal Freitas

Action: Passed unanimously.

L. Alyssa Garcia (25-076-PT-S)

No one was present on behalf of Alyssa Garcia.

Brett Kandt, General Counsel for Nevada Board of Pharmacy, prosecuted the case alleging that the Board filed an Order of Summary Suspension based upon preliminary findings that Respondent Garcia diverted controlled substances.

Mr. Kandt called Erin Miller as a witness and reminded her she was still under oath.

Erin Miller, Administrative Assistant – Board Coordinator II, was subject to examination.

Mr. Kandt called Jessette Phaynarikone as a witness and reminded her she was still under oath.

Jessette Phaynarikone, Administrative Assistant – Board Coordinator I, was subject to examination.

Mr. Kandt requested that proof of service of the Summary Suspension Order and proof of service of a second notice of the summary suspension hearing to Respondent Garcia be admitted into record as Exhibits 1-2.

President Park admitted Exhibits 1-2 into the record.
Board discussion ensued.

Board Action:

Motion: Adam Porath moved to uphold the Order of Summary Suspension, pending the filing of an accusation with charges.

Second: Jade Jacobo

Action: Passed unanimously.

C. McGuff Compounding Pharmacy Services (23-070-PH-O)

This matter was continued.

D. McGuff Company, Inc (23-070-WH-O)

This matter was continued.

E. Revive Rx (23-411-PH-O)

This matter was continued.

F. Injured Workers Pharmacy, LLC (23-428-PH-O)

This matter was continued.

DRAFT

K. Abdollah Assad (24-470-CS-N)

This matter was continued.

M. Pulmonary Solutions, LLC (22-357-MP-N)

This matter was continued.

P. Frank A Shallenberger (23-515-CS-N)

This matter was continued.

6. Application for Nevada Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION)**

B. The Tranzonic Companies – Las Vegas, NV – Background Check completed in compliance with NRS 639.500

Tamer Gerges (West Coast Distribution Director), Justin Nunez (designated representative), Chris Adams (Vice President - North American Firm), and Jaclyn Sittock (General Manager for Controlled Environments Pharma Strategic Business Unit) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the wholesaler license for The Tranzonic Companies.

Second: Jade Jacobo

Action: Passed unanimously.

6. Application for Nevada Medical, Devices, Equipment and Gases License (NAC 639.6944) – Appearance (**FOR POSSIBLE ACTION)**

A. High Vibes Medical Supply, LLC – Las Vegas, NV

Cecily Fernandez, Owner and Administrator, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

DRAFT

President Park asked the applicant if she would like to table her application and resubmit it to later to reappear in front of the Board.

This matter was tabled.

B. Med Way Medical Inc – Las Vegas, NV

Michael Williams (Regional Manager - Nevada), Austin Drushal (Regional Operations Director), Natascha Amster (Compliance), and Diane Segel (Compliance) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the Nevada Medical, Devices, Equipment and Gases license for Med Way Medical, Inc.

Second: Adam Porath

Action: Passed unanimously.

11. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

A. Harsha Nagaraja

Harsha Nagaraja was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the controlled substance registration for Harsha Nagaraja for schedules II-V with the condition that he remains compliant with the monitoring program with the Nevada Medical Board of Medical Examiners and the North Carolina Medical Board and to send quarterly reports to Board staff

Second: Jade Jacobo

Action: Passed unanimously.

DRAFT

B. Rachel Miceli

Rachel Miceli was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the controlled substance registration for Rachel Miceli on the condition that she stays complaint with her monitoring program with the Nevada Board of Medical Examiners.

Second: Richard Tomasso

Action: Passed unanimously.

12. Applications for Advance Practice Registered Nurse – Prescribe Registration (NAC 639.850) – Appearance (**FOR POSSIBLE ACTION)**

A. Jorge Menjivar

Jorge Menjivar was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the prescribing registration for Jorge Menjivar for schedules II-V with the condition that he stays compliant with the monitoring program with the Georgia Board of Nursing as well as the requirements imposed on him by the Nevada State Board of Nursing and to provide quarterly reports to Board staff.

Second: Jade Jacobo

Action: Passed unanimously.

B. Samantha Perkins

Samantha Perkins was present.

DRAFT

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

President Park commented that since there is a pending case with the California Board of Nursing relating to this applicant and asked Ms. Perkins if she would like to table her application until the case is adjudicated.

The matter was tabled.

C. Rebecca Ballinger

Rebecca Ballinger and Craig Perry, Esq. were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: President Park moved to approve the controlled substance prescribing registration for Rebecca Ballinger for dangerous drugs only.

Second: Jade Jacobo

Action: Passed unanimously.

15. General Counsel Report

Gregory Zunino, Senior General Counsel, presented.

9. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

C. Healthy Choice Pharmacy – Las Vegas, NV

Olive Bayle (Pharmacist in Charge), Brandon Catacutan (Owner and Administrator), and Giovanni Bayle (Owner) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

DRAFT

Motion: Jade Jacobo moved to approve the pharmacy license for Healthy Choice Pharmacy pending a favorable inspection.

Second: Adam Porath

Action: Passed unanimously.

E. Renew Care Pharmacy – Las Vegas, NV

Yvonne Nkwen-tamo, managing pharmacist, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the pharmacy license for Renew Care Pharmacy pending a favorable inspection.

Second: Adam Porath

Action: Passed unanimously.

16. Executive Secretary Report

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, presented.

Public comment at April 16, 2025, at 4:15 PM

There was no public comment.

President Park recessed the meeting for the night and reconvened the meeting the next morning at 9:00 AM.

Board Members Present:

Helen Park	Adam Porath	Richard Tomasso	Jade Jacobo
Krystal Freitas	Anna Carr		

Board Staff Present:

David Wuest	Yenh Long	Gregory Zunino	Brett Kandt
Monica Moazez	Laura Tucker	Darlene Nases	Erin Miller
Mui Lee	Jessette Phaynarikone		

DRAFT

Call to Order and Roll Call – Establishment of Quorum

President Park performed the roll call. All Board members were present, and a quorum was established.

Public comment at April 17, 2025, at 9:02 AM

There was no public comment.

◈ WORKSHOP ◈

Thursday, April 17, 2025 – 9:00 am

14. Notice of Proposed Regulation Workshop Pursuant to NRS 233B.061(2) **(FOR POSSIBLE ACTION)**:

    A. **Amendment to Nevada Administrative Code NAC 454.** The proposed amendment revises the ability of an advanced emergency medical technicians to possess and administer dangerous drugs upon the order of a practitioner in a license hospital when practicing under their scope of practice as determined by the State of Nevada Health Department.

David Wuest, Executive Secretary for the Nevada Board of Pharmacy, and Brett Kandt, General Counsel for the Nevada Board of Pharmacy, presented.

President Park opened the floor for public comment.

The following person(s) offered public comment:

Melinda Osborn, Chief Nurse Executive for Renown Health.

Jimmy Lao, Director of Emergency Services for Renown Health.

President Park closed the floor for public comment.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to adopt the proposed amendment to Nevada Administrative Code NAC 454, with the suggested revisions by the Board.

Second: President Park

Action: Passed unanimously.

7. Application for Nevada Wholesaler License (NRS 639.233) – Appearance (**FOR POSSIBLE ACTION)**

    A. Boxout, LLC – McCarran, NV – Background Check completed in compliance with NRS 639.500

Matthew Miller (Compliance Manager), Ken Kramer (Chief Finance Officer), and Dennis Partain (Regional Director) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the wholesaler license for Boxout, LLC.

Second: Jade Jacobo

Action: Passed unanimously.

9. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

    D. Meta Pharmacy Services – Las Vegas, NV

Jade Jacobo, Krystal Freitas, and President Park disclosed that they were familiar with the incoming pharmacist in charge could participate in this matter fairly and without bias.

Rachel Grey (Counsel), Derek O'Leary (President of Operations), Andy Vukadinovich (Vice President of Operations), and Erik Heikkenen (Consultant) were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the change of ownership application for Meta Pharmacy Services with conditions that the pharmacist in charge appears at the next Board Meeting; and quarterly inspections at the owner's expense.

Second: Richard Tomasso

DRAFT

Action: Passed unanimously.

8. Application for Nevada Warehouse (NAC 639.622) – Appearance **(FOR POSSIBLE ACTION)**

A. Kuehne & Nagel, Inc – McCarran, NV

Ria Philip (Director of Healthcare Regulatory Compliance) and Katy Ditmars (Quality Manager) were present.

The Board heard testimony and asked questions of the applicant.

Jade Jacobo was excused from the meeting at 10:20AM.

Jade Jacobo returned to the meeting at 10:21AM.

Board discussion ensued.

Board Action:

Motion: Adam Porath moved to approve the warehouse license for Kuehne & Nagel, Inc.

Second: Krystal Freitas

Action: Passed unanimously.

9. Application for Nevada Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

B. First Choice Pharmacy, LLC – Las Vegas, NV

Kirk Beaulieu, Pharmacist in Charge, was present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the ownership change for First Choice Pharmacy, LLC.

Second: Krystal Freitas

Action: Passed unanimously.

DRAFT

A. AMG Pharmacy – Las Vegas, NV

April Tsai (Owner and Designated Representative) and Terry Kang (Pharmacist in Charge) were present.

President Park disclosed that she is familiar with Dr. Kang from Roseman University but could participate in this matter fairly and without bias.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Jade Jacobo moved to approve the pharmacy license for AMG Pharmacy pending a favorable inspection.

Second: Krystal Freitas

Action: Passed unanimously.

11. Applications for Controlled Substance Registration (NRS 453.226) – Appearance **(FOR POSSIBLE ACTION)**

C. Devendrakumar Patel

Devendrakumar Patel and Lyn Beggs, Esq. were present.

The Board heard testimony and asked questions of the applicant.

Board discussion ensued.

Board Action:

Motion: Krystal Freitas moved to approve the controlled substance registration for Devendrakumar Patel with conditions that he can prescribe Schedules IV and V only and must participate in quarterly PMP training with Board staff for a period of one (1) year.

Second: Richard Tomasso

Aye: Freitas, Tomasso, Carr, Park, Porath
Nay: Jacobo

Action: Motion passed.

DRAFT

10. Application for Out-of-State Pharmacy License (NRS 639.230) – Appearance **(FOR POSSIBLE ACTION)**

D. Wedgewood Pharmacy LLC – Bakersfield, CA

Richard Tomasso was excused from the meeting at 11:38AM.

Samra Wussow, pharmacy and compliance manager, was present.

The Board heard testimony and asked questions of the applicant.

Richard Tomasso returned to the meeting at 11:42AM.

Board discussion ensued.

Board Action:

Motion: Richard Tomasso moved to approve the out-of-state pharmacy license for Wedgewood Pharmacy LLC.

Second: Jade Jacobo

Action: Passed unanimously.

17. Date and Location of Next Scheduled Board Meeting:

June 4-5, 2025 – Las Vegas, NV

18. Public Comment

There was no public comment.

19. Adjournment

DRAFT

4

4A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]**Is the business also a wholesaler? (NRS 639.016)**	■ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	■ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: RGH Enterprises, LLC dba Edgepark Medical Supplies;

MDEG Physical Address: 3000 Mark IV Parkway

City: Fort Worth State: TX Zip: 76106

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin State: OH Zip: 43017

Telephone: 817-740-3224 Website: www.edgepark.com

Email: licensure@cardinalhealth.com

Name of MDEG Administrator (NAC 639.694): Robert Kapela

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
■ Pharmacies[a]	■ Respiratory Equipment**
■ Practitioners[a]	☐ Life-sustaining equipment**
■ Hospitals/Clinics[a]	■ Parenteral and Enteral Equipment**
■ Clinics[a]	■ Assistive Equipment
■ Wholesalers[a]	■ Diabetic Supplies
■ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
Labs	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Please see Attached Explanation
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
▣ Mon: 9:30AM-4:30P	▣ Tue: 9:30AM-4:30P	▣ Wed: 9:30AM-4:30P	▣ Thurs: 9:30AM-4:30	▣ Fri: 9:30AM-4:30P
▣ Sat: 12:00AM-2:30A	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
See Attached

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/a _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: Ohio

Parent Company (if any): Allegiance Corporation

Corporation Name: RGH Enterprises, LLC

Mailing Address: 7000 Cardinal Place

City: Dublin State: OH Zip: 43017

Telephone: 614-553-3420 Email: licensure@cardinalhealth.com

Contact Person Name: LaToyia Martin

Date of SEC Registration: 08/04/1983	SEC Registration Number: 0000721371	Stock Exchange Symbol: CAH

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/a

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: OH Zip: 43017

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: N/a

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/a

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

K Chamberlain

Original signature of Authorized Person (copies or stamps not accepted)

03/25/25

Date

Board Use Only	Date Received: 3/27/25	Amount: $580 ck 1091 24980

CardinalHealth™

June 30, 2024

To whom it may concern:

This is a declaration and confirmation by Cardinal Health, Inc. and its subsidiaries exclusively that:

Cardinal Health is self-insured for products, completed operations liability and pharmacist professional liability. You will not be named as additional insured for any of the self-insured retention limits of the product liability, completed operations liability and pharmacist professional liability coverages. Cardinal Health's self-insurance is backed by its financial strength documented in financial statements found at www.cardinalhealth.com. The existence of self-insurance within Cardinal Health's insurance program does not change any contractual obligation we may have, and shall not be deemed to exceed the scope of coverage and/or limits required, under our written contract or agreement with you.

As respects the Automobile Liability, Automobile Physical Damage, Comprehensive and Collision coverage is self-insured for all owned and leased vehicles.

Please direct any questions or concerns to GMB-DUB-RiskManagement@cardinalhealth.com.

Denise Johnston
Director, Risk Management

JPK/as

enc.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 05/31/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Aon Risk Services Northeast, Inc. Cincinnati OH Office 8044 Montgomery Road Suite 405 Cincinnati OH 45236-2919 USA	**CONTACT NAME:** **PHONE (A/C. No. Ext):** (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105 **E-MAIL ADDRESS:**
INSURED Cardinal Health, Inc. 7000 Cardinal Place Attn: Suzanne Cochran Dublin OH 43017 USA	**INSURER(S) AFFORDING COVERAGE** / **NAIC #** **INSURER A:** Greenwich Insurance Company 22322 **INSURER B:** XL Insurance America Inc 24554 **INSURER C:** XL Specialty Insurance Co 37885 **INSURER D:** Indian Harbor Insurance Company 36940 **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** 570105992993 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR X Liquor Liability Included GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			RGD943716719	06/30/2024	06/30/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG Liquor Liability Lim	$5,000,000 $1,000,000 $5,000,000 $5,000,000 Excluded Included
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY in .			RAD943716819	06/30/2024	06/30/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$5,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION			US00092147LI24A SIR applies per policy terms & conditions	06/30/2024	06/30/2025	EACH OCCURRENCE AGGREGATE Products/Completed O	$5,000,000 $5,000,000 Excluded
B	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** Y/N ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		RWD943512519 (AOS)	06/30/2024	06/30/2025	X PER STATUTE OTH-ER	
B				RWR943512619 (WI)	06/30/2024	06/30/2025	E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$5,000,000 $5,000,000 $5,000,000
D	E&O - Professional Liability - Primary			RGD943797705 E&O SIR applies per policy terms & conditions	06/30/2024	06/30/2025	Loss Limit	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Cardinal Health, Inc.
7000 Cardinal Place
Dublin OH 43017 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc

Holder Identifier :

Certificate No : 570105992993

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AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER: See Certificate Number: 570105992993	
CARRIER: See Certificate Number: 570105992993 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
C		N/A		RWR300142406 (AK)	06/30/2024	06/30/2025		
	OTHER							
C	Excess Workers Compensation			RWE943514319 Xs Work Comp - OH SIR applies per policy terms & conditions	06/30/2024	06/30/2025	EL Each Accident	$4,500,000
							EL Disease - Ea Empl	$4,500,000

ACORD 101 (2008/01)

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER See Certificate Number: 570105992993	
CARRIER See Certificate Number: 570105992993 / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Evidence of Coverage

As respects the Commercial General Liability Policy:
Additional Insured Managers or Lessors of Premises : as required by written contract
Additional Insured Owners, Lessees or Contractors - Scheduled Persons or Organization : as required by written contract
Coverage provided to the additional insured is required by a contract or agreement, the insurance afforded to such additional insured will not be broader than that which you are required by the contract or agreement to provide for such additional insured and shall not increase the applicable Limits of Insurance

As respects the Automobile Liability Policy:
Coverage symbol 1 (Any Auto) applies to Automobile Liability which includes coverage for Hired / Non-Owned Autos
Lessor - Additional Insured: all leased autos.
The policy will pay as interest may appear, you (Cardinal Health) and the lessor named in this endorsement for "loss" to a "leased auto".
Additional Insured Where Required under Written Contract or Agreement Endorsement

As respects General Liability, Automobile Liability, and Workers Compensation Policies:
Waiver of Subrogation is permitted as required by written contract or agreement executed prior to loss and in accordance with the terms, conditions and exclusions of the applicable policies.

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AGENCY CUSTOMER ID: 570000070825
LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570105992993	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570105992993	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insured Listing

Named Insured Listing for June 30, 2024 - June 30, 2025 includes but is not limited to the following:
A+ Secure Packaging, LLC
Abilene Nuclear, LLC
Acuity GPO, LLC
Aero-Med, LLC
Allegiance (BVI) Holding Co. Ltd.
Allegiance Corporation
Allegiance Healthcare (Labuan) Pte. Ltd.
Allegiance I, LLC
Allegiance Labuan Holdings Pte. Ltd.
C. International, Inc.
Cardinal Distribution Holding Corporation - I
Cardinal Distribution Holding Corporation - II
Cardinal Health (Shanghai) Medical Devices Co., Ltd.
Cardinal Health 100, LLC
Cardinal Health 104 LP
Cardinal Health 105, LLC
Cardinal Health 107, LLC
Cardinal Health 108, LLC
Cardinal Health 110, LLC
Cardinal Health 112, LLC
Cardinal Health 113, LLC
Cardinal Health 114, Inc.
Cardinal Health 115, LLC
Cardinal Health 116, LLC
Cardinal Health 118, LLC
Cardinal Health 119, LLC
Cardinal Health 121, LLC
Cardinal Health 122, LLC
Cardinal Health 123, LLC
Cardinal Health 124, LLC
Cardinal Health 125, LLC
Cardinal Health 126, LLC
Cardinal Health 127, Inc.
Cardinal Health 128, LLC
Cardinal Health 130, LLC
Cardinal Health 131, LLC
Cardinal Health 132, LLC
Cardinal Health 133, Inc.
Cardinal Health 134, LLC
Cardinal Health 135, LLC
Cardinal Health 2, LLC
Cardinal Health 200, LLC
Cardinal Health 201 Canada L.P.
Cardinal Health 201, LLC
Cardinal Health 215, LLC
Cardinal Health 222 (Thailand) Ltd.
Cardinal Health 23 Funding, LLC
Cardinal Health 23, LLC
Cardinal Health 242, LLC
Cardinal Health 247, Inc.

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570105992993	
CARRIER / NAIC CODE	EFFECTIVE DATE:
See Certificate Number: 570105992993	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Marin Apothecaries
Medicap Pharmacies Incorporated
Medicine Shoppe Capital Corporation
Medicine Shoppe International, Inc.
Medicine Shoppe Internet, Inc.
Mediquip Sdn. Bhd.
MosaicGPO, LLC
mscripts Holdings, LLC
mscripts, LLC
Nautic Specialty Networks VIII-A Bocker, Inc.
Navista Investments, LLC
Navista Network Holding, LLC
Navista Network, LLC
One Cloverleaf, LLC
Owen Shared Services, Inc.
Pharmacy Operations Of New York, Inc.
Pharmacy Operations, Inc.
Physicians Purchasing, Inc.
Pinnacle Intellectual Property Services, Inc.
Pinnacle Intellectual Property Services-International, Inc.
Precision Point Specialty, LLC
Quiroproductos de Cuauhtemoc S. de R.L. de C.V.
RainTree Administrative Services, LLC
RainTree Care Management, LLC
RainTree GPO, LLC
Red Oak Sourcing, LLC
Renal Purchasing Group, LLC
RGH Enterprises, LLC
RT Oncology Services Corporation
Rxealtime, Inc.
Scalamed (US), Inc.
ScalaMed Pty Ltd
Sierra Radiopharmacy, L.L.C.
SN Buyer, LLC
SN Funding, LLC
SN Intermediate, Inc.
SOAR Network, LLC
Sonexus Health Access & Patient Support, LLC
Sonexus Health Distribution Services, LLC
Sonexus Health Financial Solutions, LLC
Sonexus Health Pharmacy Services, LLC
Sonexus Health, LLC
Specialty Networks Consulting, LLC
Specialty Networks Research, LLC
Specialty Networks Urology Registry, LLC
Specialty Networks, LLC
The Harvard Drug Group, L.L.C.
Traverse GPO, LLC
United Rheumatology NY IPA I, LLC
United Rheumatology, LLC
UR Nice, LLC
UroGPO, LLC
Velocare, LLC
Wavemark Cyprus Pvt. Ltd.
Wavemark Lebanon Offshore s.a.l.
Wavemark, Inc.

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Explanation Regarding Enteral supplies

In addition to any communication and advisement required pursuant to NAC 639.693 to 639.6958, inclusive, a medical products provider who provides medical gas and related equipment, or respiratory equipment, must advise the consumer receiving the medical gas and related equipment, or respiratory equipment, regarding:

(a) Cleaning of the equipment; Business does not clean or service equipment

(b) Potential hazards and warning signs of malfunctioning or inadequately functioning equipment; Information would be provided by the manufacturer of the equipment and if instructed by the manufacturer, business (as a distributor), would notify customers if directed to do so with a communication provided by the manufacturer.

(c) Maintenance procedures for the equipment N/A business does not service equipment

(d) The telephone number, contact name, and contact address for emergency servicing or repair of the equipment, and for routine servicing or repair of the equipment; and N/A would need to contact the manufacturer.

(e) The written materials about the equipment that are available from the medical products provider or the manufacturer of the equipment. Instructions/directions for use are provided in packaging supplied by manufacturer.

6. For the purposes of this section, "material safety data sheet" has the meaning ascribed to it in 29 C.F.R. § 1910.1200.

(Added to NAC by Bd. of Pharmacy by R008-01, eff. 11-1-2001; A by R033-07, 8-26-2008)

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show RGH ENTERPRISES, LLC, an Ohio Limited Liability Company, Registration Number 770802, was organized in the State of Ohio on April 9, 1990, is currently in FULL FORCE AND EFFECT upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 18th day of March, A.D. 2025.

Ohio Secretary of State

Validation Number: 202507702218

CardinalHealth

3000 Mark IV Parkway
Suite #1 (UTAH Only)
Fort Worth, Texas 76106

Officer Name	Title	Percentage of Ownership
Robert Evan Schlissberg	President	0%
Keegan David Chamberlain	Director, Quality Management	0%
John Henry Martin Jr.	SVP, Tax	0%
Brent Mathew Withrow	Assistant Treasurer	0%
Anthony F. Alvarez	Secretary	0%

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CardinalHealth

3000 Mark IV Parkway
Suite #1 (UTAH Only)
Fort Worth, Texas 76106

Officer Name	Title
Robert Evan Schlissberg	President
Keegan David Chamberlain	Director, Quality Management
John Henry Martin Jr.	SVP, Tax
Brent Mathew Withrow	Assistant Treasurer
Anthony F. Alvarez	Secretary

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- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/drug-manufacturers-distributors/applications-forms-drug-manufacturers-distributor**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

RGH ENTERPRISES LLC ORA
7000 CARDINAL PL
DUBLIN OH 43017

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

RGH ENTERPRISES LLC DBA
EDGEPARK MEDICAL SUPPLIES
3000 MARK IV PKWY
FORT WORTH, TX 76106

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

FOOD WHOLESALER & NONPRESCRIPTION DRUG DISTRIBUTOR & DEVICE DISTRIBUTOR

License # 1002244
Expires: December 26, 2026

NON-TRANSFERABLE

Commissioner

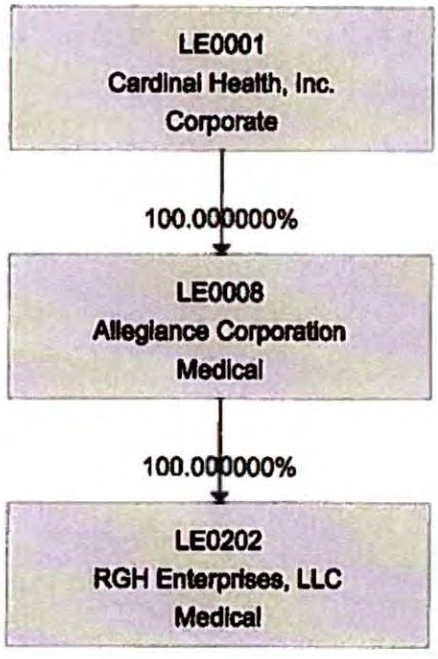
515102

RGH Enterprises, LLC dba Edgepark Medical Supplies		
State	Original Effective Date	Provider No.
Alaska	1/1/2013	1577887
Arkansas	8/26/2013	199742741
Arizona	3/13/2000	496738
California	10/24/2012	1609858729
Colorado	11/27/2013	43128556
District of Columbia	6/22/2012	041270500
Delaware	10/30/2012	20044164
Florida	5/27/2022	114359700
Georgia	7/1/14	003149398A
Hawaii	1/1/2012	005293
Iowa	1/1/2012	1609858729
Idaho	5/25/2012	1609858729
Illinois	3/1/2011	341650951002
Indiana	1/17/2007	200843320A
Kansas	12/23/2019	3003890530002
Kentucky	6/1/2010	7100142060
Louisiana	6/1/2011	2160117
Massachusetts	12/1/2017	1101284818
Maryland	1/1/2012	222516600
Maine	3/1/12	1609858729
Michigan	1/1/2012	1609858729
Minnesota	1/1/2012	1609858729
Missouri	4/2/2012	629969700
Mississippi	12/1/2011	06432701
Montana	3/5/2012	100033173
North Carolina	5/5/2016	1356886030
North Dakota	8/6/2018	1478102
Nebraska	2/21/2014	100258842-00
New Hampshire	1/1/2014	3139129
New Jersey	5/9/2013	0346535
New Mexico	2/6/2012	38920387
Nevada	7/14/2012	100517250
New York	4/19/2012	03450011
Ohio	2/1/1991	0830757
Oklahoma	4/26/12	200428360A
Oregon	7/1/2003	290834
Pennsylvania	4/1/2008	0071120630002
Rhode Island	1/1/2012	6020001
South Carolina	8/1/08	DM1376
South Dakota	1/1/2012	1609858729
Tennessee	10/30/96	4582447
Texas	10/30/96	1921744-01
Utah	1/1/2012	1609858729
Virginia	1/1/2012	30015035600001

Vermont	4/6/2012	1020569
Washington	6/14/2012	2018198
Wisconsin	6/1/2009	1609858729
West Virginia	7/27/2017	1609858729
Wyoming	1/1/2012	208384100

The top four shareholders

1. Blackrock Inc. – 13.33%
2. Vanguard Group Inc. – 12.74%
3. State Street Corporation – 5.72%
4. Geode Capital Management, LLC – 2.43%



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Cardinal Health
Legal Entity
Organization Chart
(Domestic Medical)

Confidential
Not for General Distribution

3/31/2022 SJB

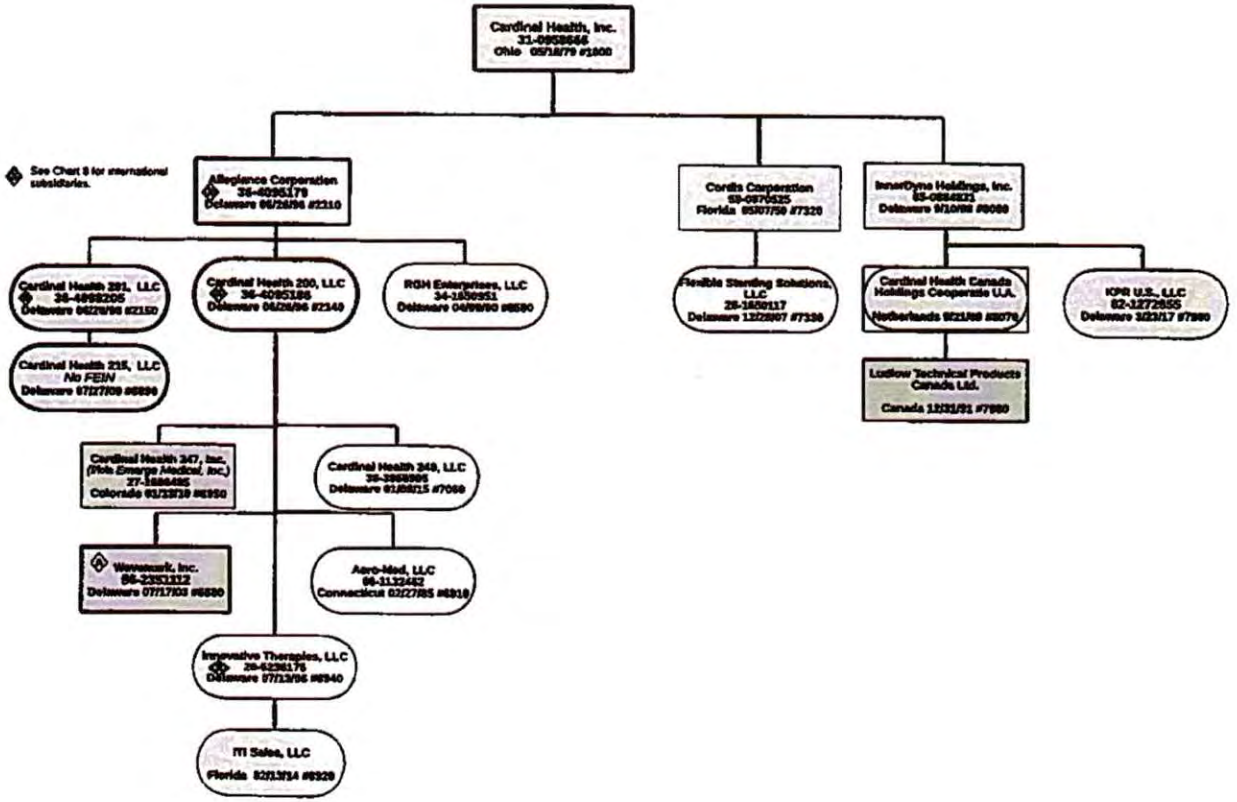


Chart 7

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: RGH Enterprises, LLC dba Edgepark Medical Supplies MDEG License # (if applicable): N/a

Physical Address: 3000 Mark IV Parkway

City: Fort Worth State: TX Zip: 76106

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin State: OH Zip: 43017

Telephone: _____ Website: www.edgepark.com

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: Robert Middle: Allen Last: Kapela

Alias(es, nicknames, name changes, etc.): N/a

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: TX Zip: [redacted]

Telephone: [redacted] Email: robert.kapela@cardinalhealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ballston Spa High School		8/01 - 5/05	
Address	**City**	**State**	**Zip**
220 Ballston Ave	Ballston Spa	NY	12020
Diploma/Degree obtained, if any	Regents High School Diploma		

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]	City	State	[redacted]
07/24- Present		Haslet	TX	
From - To (MM/YY – MM/YY)		City	State	
07/20-07/24		Fort Worth	TX	
From - To (MM/YY – MM/YY)		City	State	
04/19-07/20		Fort Worth	TX	
From - To (MM/YY – MM/YY)		City	State	
04/18-04/19		Fort Worth	TX	
From - To (MM/YY – MM/YY)		City	State	
04/17-04/18		Plainsboro	NJ	
From - To (MM/YY – MM/YY)		City	State	
2001-2017		Mechanicville	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health - RGH Enterprises, LLC			08/2011- Present	
Business Address		**City**	**State**	**Zip**
3550 Roy Orr Blvd.		Grand Prairie	TX	75050
Phone	**Title**		**Number of Employed Hours**	
972-790-7489	Operations Manager		1,500 +	
Description of Duties				
Oversees all aspects of operations including receiving, inventory management, order fulfillment, and shipping. Collaborated with cross-functional teams to ensure on-time delivery and customer satisfaction				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name N/A			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/14/2025
Date

I, Robert Kapela, **certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. RK Have a high school diploma or its equivalent;
2. RK Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RK Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RK Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Kapela
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/14/2025
Date

Board Use Only	Date Received: _____

4B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	☒ Out-of-State
***Is the business also a wholesaler? (NRS 639.016)**	☒ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (Check applicable box)		MDEG Business Type (Check applicable box)
☒ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: LoeCo llc dba Lymphacare

MDEG Physical Address: 1123 N Castle Heights Ave Suite L

City: Lebanon State: TN Zip: 37087

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 615-229-5858 Website: www.lymphacare.com

Email: khayes@lymphacare.com

Name of MDEG Administrator (NAC 639.694): Kimberly Hayes

Entities the MDEG will serve	Type of MDEG products that will be sold (Check all applicable)
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies*	☐ Respiratory Equipment**
☐ Practitioners*	☐ Life-sustaining equipment**
☐ Hospitals/Clinics*	☐ Parenteral and Enteral Equipment**
☐ Clinics*	☐ Assistive Equipment
☐ Wholesalers*	☐ Diabetic Supplies
☐ Other business entities (specify)*:	☐ Orthotics and Prosthetics
	☒ Others: Lymphedema Pumps and Sleeves
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
*If MDEG products will ALSO be sold to the Entities with an (*) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
☒ Mon: 8-5:30	☒ Tue: 8-5:30	☒ Wed: 8-5:30	☒ Thurs: 8-5:30	☒ Fri: 8-5:30
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	YES	NO
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
7739920001 Medicare
Q054325 Medicaid

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and the percent ownership. (NAC 639.6949; NAC 693.6935)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Sole Owner

Owner's Name: Mary Ellen Doran

Business Name: LoeCo llc DBA Lymphacare

Business Address: 1509 LatchString Lane

City: Gwynedd Valley State: PA Zip: 19002

Telephone: 887-799-6863 Email: Medoran@lymphacare.com

Section 3: Provide all the applicable documents with your application based on your business type. Required documents are indicated by an "✓" or "other".	Publicly Traded	Non-Publicly Traded	Partnership	Sole Owner
• List of all Officers and Directors.	✓	✓		
• List of all general and limited partner names and their percent ownership (NAC 639.6942).			✓	
• Certificate of Corporate Status or Certificate of Good Standing obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).	✓	✓	✓	✓
• Copy of proof of insurance (NAC 639.6946). The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• Personal History Record Application must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• MDEG Administrator Application (NAC 639.694). Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• "Wholesaler Application must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person other than the consumer or patient. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kimberly Hayes

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10/4/24

Date

Board Use Only	Date Received: _____	Amount: _____

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 03/28/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATIONIS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER NORTHEAST AGENCIES INC/PHS 01214608 The Hartford Business Service Center 3600 Wiseman Blvd San Antonio, TX 78251	**CONTACT NAME:** **PHONE (A/C, No, Ext):** (866) 467-8730 **FAX (A/C, No):** E-MAIL ADDRESS:
INSURED Loeco, LLC DBA Lymphacare 1123 N CASTLE HEIGHTS AVE STE L LEBANON TN 37087-5725	**INSURER(S) AFFORDING COVERAGE** — **NAIC#** **INSURER A :** Hartford Underwriters Insurance Company — 30104 **INSURER B :** **INSURER C :** **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED.NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/Y YYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR [X] General Liability GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:			01 SBW AV4XDS	12/20/2024	12/20/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $10,000 $1,000,000 $2,000,000 $2,000,000
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] ALL OWNED AUTOS [ ] SCHEDULED AUTOS [ ] HIRED AUTOS [ ] NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/ A					[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE -EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	
A	Data Breach - Defense & Liab Covg			01 SBW AV4XDS	12/20/2024	12/20/2025	Limit	$50,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Those usual to the Insured's Operations.

CERTIFICATE HOLDER

For Informational Purposes
1123 N CASTLE HEIGHTS AVE STE L
LEBANON TN 37087-5725

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Susan L. Castaneda

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Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding: LOECO LLC
Request Type: Certificate of Registration
Request No.: 054593829
Receipt No.: 1592818
Filing Type: Foreign Limited Liability Company
Filing Subtype: Limited Liability Company
Initial Filing Date: April 02, 2025
Status: Active

Issuance Date: April 10, 2025
File No: 0014286239

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

LOECO LLC

is a foreign association duly registered to do business in this Commonwealth as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Certificate of Registration shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written.

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

Kristy Zigenis

From: Kimberly Hayes <khayes@lymphacare.com>
Sent: Tuesday, April 1, 2025 8:34 AM
To: Kristy Zigenis
Subject: No active members

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

No board of directors or officers

Kimberly



Kimberly Hayes
Office and Compliance Manager
1123 N Castle Heights Ave
Lebanon, TN 37087

License No. 1274
No. Beds

State of Tennessee

Health Facilities Commission

Board for Licensing Health Care Facilities

This is to certify that a license is hereby granted by the Health Facilities Commission to LOECO LLC to conduct and maintain a Home Medical Equipment Company

LYMPHACARE
Located at 1123 NORTH CASTLE HEIGHTS AVENUE, SUITE L, LEBANON, TN 37087
County of WILSON, TN.

The license shall expire April 09, 2026 and is subject to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable and shall be subject to revocation at any time by the Health Facilities Commission, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the Health Facilities Commission issued thereunder.

In Witness Whereof, we have hereunto set our hand and seal of the State
this 22nd day April, 2025.

HFC

By Caroline R Ogren, Esq., CHC
Director, Licensure & Regulation

By
Executive Director

State of Tennessee

License No. 0000001274

Health Facilities Commission

Board for Licensing Health Care Facilities

This is to certify that a license is hereby granted by the Health Facilities Commission to LOECO LLC to conduct and maintain a Home Medical Equipment Company LYMPHACARE

Located at 1123 NORTH CASTLE HEIGHTS AVENUE, SUITE L, LEBANON

County of WILSON, Tennessee.

The license shall expire APRIL 09, 2025 and is subject to the provisions of Chapter 11, Tennessee Code Annotated. This license shall not be assignable or transferable and shall be subject to revocation at any time by the Health Facilities Commission, for failure to comply with the laws of the State of Tennessee or the rules and regulations of the Health Facilities Commission issued thereunder.

In Witness Whereof, we have hereunto set our hand and seal of the State this 15TH day MARCH, 2024.

Health Facilities Commission

HFC

By Caroline R. Pyron, Esq., C.H.C.
Director, Licensure & Regulation

By
Executive Director

0070

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: LoCo llc dba Lymphacare

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) [illegible] 1274

Physical Address 1123 N. Castle Heights Ave. Suite L

City Lebanon State TN Zip 37087

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 615-229-5858 Website www.lymphacare.com

Licensing Company Email khayes@lymphacare.com

Section 2: Personal Information

First Mary Ellen Middle _____ Last Dorn

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Gwynedd Valley State PA Zip [redacted]

Telephone [redacted] Email _____

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: St Joseph's University			From - To (MM/YY – MM/YY)	
Address: 5600 City Line Ave	City: Phila		State: PA	Zip: 19131
Diploma/Degree obtained, if any: BS Marketing and Sales Management.				
School Name: North Penn High School			From - To (MM/YY – MM/YY): 9/78 - 6/82	
Address: 1340 S. Valley Forge Road	City: Lansdale		State: PA	Zip: 19446
Diploma/Degree obtained, if any:				
School Name:			From - To (MM/YY – MM/YY)	
Address:	City:		State:	Zip:
Diploma/Degree obtained, if any:				
School Name:			From - To (MM/YY – MM/YY)	
Address:	City:		State:	Zip:
Diploma/Degree obtained, if any:				
School Name:			From - To (MM/YY – MM/YY	
Address:	City:		State:	Zip:
Diploma/Degree obtained, if any:				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 10/23 - current	[redacted]	City: Lower Gwynedd	State: PA	[redacted]
From - To (MM/YY – MM/YY): 8/02 - 10/23		City: North Wales	State: PA	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: MED Supply Cabinet. In			From - To (MM/YY – MM/YY): 10/2000 - Current	
Business Address: 101 Commerce Dr Suite 100	City: Montgomeryville	State: Pa	Zip: 18936	
Phone: 215-987-3718	Title: President			
Description of Duties: Operation of the company.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip	
Phone	Title			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Mary Ellen Dreen

Original Signature (electronic, copies or stamps not accepted)

2/19/2015

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mary Ellen Doran
Print Name (First, Last)

Mary Ellen Doran
Original Signature (electronic, copies or stamps not accepted)

2/24/25
Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Bucks

I, Mary Ellen Doran, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Mary Ellen Doran
Original Signature

2/24/25
Date

Subscribed and Sworn to before me this 24th day of February

Linda K Knecht
Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
LINDA K KNECHT - Notary Public
Bucks County
My Commission Expires February 26, 2026
Commission Number 1281989

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG LoeGo llc dba Lymphacare MDEG License # (if applicable) _____

Physical Address 1123 N. Castle Heights Ave Suite L

City Lebanon State TN Zip 37087

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 615-229-5858 Website lymphacare.com

Licensing Company Email _____

Section 2: Personal Information

First Kimberly Middle A Last HAYES

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☐ F ☐ X

Mailing Address [redacted]

City Lebanon State TN Zip [redacted]

Telephone [redacted] Email khayes@lymphacare.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Marquette Manor			84 - 88	
Address	City		State	Zip
333 75th St.	Downers Grove		IL	60516
Diploma/Degree obtained, if any				
general				
School Name			From - To (MM/YY – MM/YY)	
Bob Jones			89-94	
Address	City		State	Zip
	Greenville		SC	29681
Diploma/Degree obtained, if any				
Speech Eds/English				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019- present	[redacted]	Mt. Juliet	TN	[redacted]
2016-2019		Mt. Juliet	TN	
2007-2016		Mt. Juliet	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: LocGo llc			From - To (MM/YY – MM/YY): 2024 - present.	
Business Address: 1123 N. Castle Heights Ave	City: Lebanon		State: TN	Zip: 37087
Phone: 615-229-5858	Title: Manager		Number of Employed Hours: 500 ↑	
Description of Duties: run office, help employees, assist clients				
Business Name: National Seating & Mobility			From - To (MM/YY – MM/YY): 2020 - 2024	
Business Address: 1610 Elm Hill Pike	City: Nashville		State: TN	Zip: 3721
Phone: 615-880-1819	Title: General Manager		Number of Employed Hours: 1000 ↑	
Description of Duties: run office, help employee, assist clients				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Kimberly Hayes, certify that as the MDEG Administrator for CoeCo Llc,

that I (initial that you have read and meet the following requirements):

1. KH Have a high school diploma or its equivalent;
2. KH Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KH Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KH Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

KIMBERLY HAYES

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/1/25

Date

Board Use Only	Date Received:

4C

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	■ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		■ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Medline Industries, LP

MDEG Physical Address: 264 S 5750 W

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address): Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 847-643-4508 Website: https://www.medline.com/

Email: ralicensing@medline.com

Name of MDEG Administrator (NAC 639.694): Joseph Morozin

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
■ Pharmacies[a]	☐ Respiratory Equipment**
■ Practitioners[a]	☐ Life-sustaining equipment**
■ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
■ Clinics[a]	■ Assistive Equipment
■ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: Catheters, TENS Units, Incontinence Supplies, Manual Wheelchairs, Ostomy/Urologicals
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8a-5p	■ Tue: 8a-5p	■ Wed: 8a-5p	■ Thurs: 8a-5p	■ Fri: 8a-5p
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? This facility has not received any discipline. Please see Attachment A for Medline's corporate disciplinary history.	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
See Attachment B

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Attachment A

Medline Industries, LP- Discipline *Confidential*

Date	Facility	Description of State Action	Corrective Actions
8/3/2005	1401 N. Universal Ave Kansas City, MO 64120	**FILE CLOSED 2010** Medline Industries' Kansas City, MO facility (#2003031660) was disciplined for failure to renew on time and for deficient temperature control procedures. Medline was placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010.	Medline's Regulatory Affairs Department was significantly expanded to include a team of 7 Licensing Specialists that monitor and ensure our licenses are renewed on time. A temperature control room was constructed at the facility to ensure product is stored at the appropriate temperature and humidity. These control rooms are now a standard feature at our distribution centers. We worked closely with NABP to ensure that our temperature control facilities and procedures align with industry best practices throughout our distribution network.
12/7/2006	9101 Riverside Pkwy Lithia Springs, GA 30122	**FILE CLOSED 2008** The Florida Certified Designated Representative at the Georgia facility unexpectedly resigned. The state of Florida suspended Medline's Florida Out of State Rx Drug Wholesale Distributor Permit (#23:1470) until a new licensed Florida CDR was hired at the facility.	To prevent this for occurring in the future, all Florida licensed Medline facilities are required to have multiple Florida Certified Designated Representatives on staff.
11/16/2007	10601 Southport Dr. Orlando, FL 32824 401 Commerce Blvd. Oldsmar, FL 34677 4750 118th Ave N Clearwater, FL 33762	**FILE CLOSED 2008** Medline Industries was cited for several violations. Failure to pass and maintain a Florida compliant pedigree. Maintaining the wrong permit type for the activities performed in the facilities (in addition to a manufacturing permit, Florida required the facility a repackager permit). Distribution of saline to an unauthorized recipient. Additionally an Rx drug item was found at an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. Medline was assessed and paid a fine for these violations. All issues were addressed and resolved to the satisfaction of the FL DOH. After duly notifying state authorities, as required by law, Medline received a fined from New York for out-of-state professional misconduct. (Cal. No. 27278)	To address the pedigree issues, Medline instituted a Florida specific pedigree system. This program ensured that any pedigree shipments within our distribution network with potential to end up in Florida has the required Florida documentation. (Note - these requirements have since been preempted by federal law). To address the issue of the wrong permit type, Medline secured the repackaging permit. To address the sale of saline to an unauthorized person, Medline instituted a new procedure for obtaining and maintaining customer licenses for all Rx Drug purchases- this procedure generates an automatic block for any Rx Drug order by an unlicensed customer. The Rx Drug item unintentionally stored in the raw materials facility was properly disposed of. Waste disposal procedures were updated to ensure that this mistake would not recur.
11/26/2007	2708 NE Waldo Rd. Gainesville, FL 32609	**FILE CLOSED 2008** Medline Industries' FL license (# 22:1022) was suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. In 2010, Medline made an unrelated business decision to close this facility. (Case # 2007-37412)	After this inspection, Medline conducted a thorough review of its policies and procedures. Additionally, Medline implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.
3/5/2008	149 New Camellia Blvd. Covington, LA 70433	**FILE CLOSED 2008** Medline Industries (LA #4318) was cited for failure to properly maintain copies of current customer licenses on-site. Medline was assessed and paid a fine. (Louisiana Administrative Docket #2008006). After duly notifying state authorities, as required by law, Medline received a fine from New York for out-of-state professional misconduct. (Cal. No. 27278)	In addition to storing copies of customers' licenses at headquarters, these licenses are now stored digitally so they can be accessed by our distribution centers.
5/9/2008	5450 W. Stewart Ave. Wausau, WI 54401	**FILE CLOSED 2009** Medline Industries (WI # 1116-045) was cited and fined by the Wisconsin Department of Regulation & Licensing following a facility inspection. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All of the hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state (Case #08	Immediately after the inspection, Medline and the owner of the facility erected a locked fence to divide the faculty. Medline also reviewed all of its other facilities to make sure no similar situations existed. In addition, training on where and how to access current policies and procedures was increased for distribution center personnel. This training is in addition to the training they receive on the policies and procedures themselves.

Attachment A (cont.)

Medline Industries, LP- Discipline *Confidential*

		PHM 037). In 2010, Medline made an unrelated business decision to close this facility. After duly notifying state authorities, as required by law, Medline received a fine from the states of Hawaii (Case #PHA 2009-7-L) and New York (Cal. No. 27278) for out-of-state professional misconduct.	
8/21/2008	94-1420 Moaniani St. Waipahu, HI 96797	**FILE CLOSED 2013** Medline Industries, Inc. (PWD 115) was fined $5000 and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices, but missed the 30-day deadline. The probationary period ended in August 2013. (Case # PHA 2008-17-L)	Medline implemented a new process to notify the necessary licensing boards of future disciplinary actions within the required reporting timelines.
3/19/2010	1401 N. Universal Ave. Kansas City, MO 64120	**FILE CLOSED 2010** Medline Industries, Inc. applied for a Colorado Out-of-State Wholesaler license for the Kansas City, MO distribution center. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See 8/3/2005 discipline). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license.	See 8/3/2005 discipline for corrective actions related to the underlying sanction.
1/6/2021	1501 Harris Rd Libertyville, IL 60048	**FILE CLOSED 2021** Medline Industries, Inc. (OH License #01-1985050) received a fine of $250 from the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file for the physician rather than the TDDD license for the facility. The facility's TDDD license at the time of the sale had expired. The fine was paid on January 21, 2021 and the case was closed. (Case No. A-2020-0054 I-2019-0972-B.) After duly notifying state authorities, as required by law, Medline received a $500 fine from the Alabama State Board of Pharmacy for the same underlying conduct as the Ohio matter. The fine was paid and the matter closed. (Case No:21-L-0048)	Medline takes this matter very seriously. Medline reviewed the customer licensing policies and procedures and updated internal requirements for the type of license required for customers in Ohio. Efforts were taken by Customer Licensing to research, ensure the proper type, and check license status for a large number of existing Ohio licenses. The Ohio TDDD licenses are reviewed on an annual basis to ensure compliance.
11/1/2022	1040 Enterprise Parkway South West Jefferson, OH 43162	**FILE CLOSED 2022** Medline Industries, LP (OH License #01-30000190) entered a settlement agreement and agreed to pay a fine of $1,125.00 to the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file versus a Terminal Distributor (TDDD) license. The TDDD license was added in May 2022- prior to this investigation. During the period of July 2021 to March 2022, the customer's TDDD license lapsed and Medline was unaware. Medline is in the process of notifying states of this fine.	Medline is committed to following all applicable state and federal statutes and regulations, including customer license requirements. Medline updated customer licensing requirements after the 01/06/2021 fine. This incident occurred while Medline was in the process of updating a large number of Ohio accounts. Medline is implementing additional steps to ensure compliance, including, increasing staffing, training, and resources for the customer licensing team.
12/19/2022	9670 NW 112th Ave Miami, FL 33178	**FILE CLOSED 2022** Medline Industries, LP (FL WDD# #2220297) entered a settlement agreement and agreed to pay a fine of $6,000.00 to the FL Dept. Business and Professional Regulation. Medline accepted a physician license for a facility customer, instead of the correct facility license. The second allegation relates to failure to include NDC numbers on outbound packing slips/ invoices. After duly notifying state authorities, as required by law, Medline received a reciprocal fine for disciplinary action by another state from the Hawaii Department of Consumer Affairs. The fine was paid and the matter closed. (Case PHA 2023-9-L).	Medline is addressing the customer licensing issue by expanding the customer licensing team resources and oversight. This process began after the 11/1/2022 Ohio Discipline and has been expanded to address FL and confirming other states. The packing slip/invoice error stemmed for an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A system fix is in progress.

Attachment A (cont.)

Medline Industries, LP- Discipline *Confidential*

07/19/2023 07/25/2023	1040 Enterprise Parkway South West Jefferson, OH 43162 251 Hilton Drive, Jeffersonville, IN 47130	**FILE CLOSED 2023** Medline Industries, LP entered a settlement agreement with the Ohio Board of Pharmacy and agreed to pay fines of $750 and $850 for alleged sales of dangerous drugs to an unlicensed entity from the Jeffersonville, IN (OH License #01-30000158) and West Jefferson, OH locations (OH License #01-30000190). The sales occurred between July 2021 and January 2022. After duly notifying state authorities, as required by law, Medline received a reciprocal fine for disciplinary action by another state from the Hawaii Department of Consumer Affairs. The fine was paid and the matter closed. (Case PHA 2023-9-L).	This underlying issue was previously corrected. These fines related to activities between July 2021 and January 2022. At that time Medline was in the process of updating Ohio customer requirements. Medline updated Ohio customer license requirements and implemented a TDDD verification process in 2021. In addition, Medline reviewed all existing Ohio accounts to verify the correct license was on file. The review process was completed in 2022. Medline also dedicated additional resources and staff for the customer licensing team and remains committed to following all state and federal laws and regulations.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Medline Industries, LP

Mailing Address: Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 847-643-4508 Email: ralicensing@medline.com

Contact Person Name: Kiara Rosado

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).** Attachment C			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**. Attachment D	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable)** Attachment E	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00). Attachment F	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/ N/A No individual owners Refer to Attachment C		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/ ed Attachment G	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/ Attachment H	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lara Simmons, Chief Quality Officer

Print Name of Authorized Person Submitting Application

Lara Simmons

Original signature of Authorized Person (copies or stamps not accepted)

01/31/2025

Date

Board Use Only	Date Received: 2/5/25	Amount: $500.00

Attachment B

Medicare

Enrollment State	Enrollment Status	Medicare ID
AL	Active	0428930008
CA	Active	0428930007
CO	Active	0428930009
GA	Active	0428930012
HI	Active	0428930010
IL	Active	0428930001
MA	Active	0428930006
MI	Active	0428930005
MO	Active	0428930011
OR	Active	0428930003
TX	Active	0428930002

Medicaid

Enrollment State	Enrollment Status	Provider Number
AK	Active	1750309 (new) 1021896 (old)
AK	Active	1704352
AL	Active	216180
AR	Active	194904716
AZ	Active	AHCCCS ID 036021
CA	Active	9449244
CA	Active	1811997638; account ID 800336592
CO	Active	9000161244
CO	Active	1811997638 Location 98000060
DC	Active	19902800
DE	Active	200044726 -Location ID #
FL	Active	119444000
GA	Active	003127194A (Rendering) 305948034A (Payee ID)
HI	Active	008508

Attachment B (cont.)

IA	Active	0715918 HCBS Waiver 0915918 DME
ID	Active	1811997638
IL	Active	362596612001
KS	Active	30003891870001
KY	Active	90032335
LA	Active	2429400
MA	Active	110066936C
MA	Active	110066936A
MD	Active	033388300
MI	Active	1811997638
MO	ACTIVE	620803601
MT	Active	100030893
NC	Active	1649637059
NE	Active	36259661200
NH	Active	3098855;
NJ	Active	5096901
NM	Active	000T0700
NV	Active	1801225354
NY	Active	00680891
OH	Active	0400435
OR	Active	500719754
PA	Active	000905230-0006 (NEW) 000905230-0005 (OLD)
RI	Active	4028930
SC	Active	556712
TN	Active	3539772
TX	Active	3587834-01 (TPI)
UT	Active	1024729 - Prism ID
VA	Active	30015042570002
WA	Active	1024838
WI	Active	100269854
WY	Active	234872100

Attachment C

Medline Industries, LP
FEIN 36-2596612

Limited Partnership Partners:

PARTNERS	Business Address	General or Limited	% of Ownership	FEIN
Mozart GP, LLC	Three Lakes Drive Northfield, IL 60093	General	0%	87-2508203
Medline Borrower, LP	Three Lakes Drive Northfield, IL 60093	Limited	100%	87-2530238

PARENT COMPANY INFORMATION:
Medline Intermediate, LP
FEIN 87-2521736
State of Formation: IL
Managing Members:

BUSINESS ADDRESS AND PHONE NUMBER FOR ALL LISTED HERE:

THREE LAKES DRIVE
NORTHFIELD, IL 60093
PHONE #: 847-949-5500

Title	Name	Address
CEO	James M. Boyle	[redacted]
President / COO	James M. Pigott	[redacted]
CFO	Michael B. Drazin	[redacted]
Chief Quality Officer	Lara N. Simmons	[redacted]

Attachment D

File Number S030704

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

MEDLINE INDUSTRIES, LP, HAVING REGISTERED IN THE STATE OF ILLINOIS ON SEPTEMBER 07, 2021, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE UNIFORM LIMITED PARTNERSHIP ACT (2001) OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LP/LLLP IN THE STATE OF ILLINOIS, HAVING FULFILLED ALL REQUIREMENTS OF SAID ACT WITH REGARD TO PAYMENT OF FEES, THE FILING OF ANNUAL REPORTS (IF APPLICABLE) AND NEITHER HAVING BEEN ADMINISTRATIVELY DISSOLVED BY THE SECRETARY OF STATE NOR HAVING VOLUNTARILY FILED A STATEMENT OF TERMINATION.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 27TH *day of* FEBRUARY ***A.D.*** 2025 .

Authentication #: 2505804876 verifiable until 02/27/2026

Authenticate at: https://www.ilsos.gov

Alexi Giannoulias

SECRETARY OF STATE

Attachment E

STATE OF UTAH
DEPARTMENT OF COMMERCE
ACTIVE LICENSE

Medline Industries LP

EFFECTIVE
01/20/2023

EXPIRATION
09/30/2025

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

13214433-1710 Pharmacy - Class C

Wholesaler

DBA: None Associated

IMPORTANT LICENSURE REMINDERS:

- Your license is valid until the expiration date listed on this form. Approximately 60 days prior to this expiration you will receive a renewal notice in the mail.
- Please note the address listed below. This is your public address of record for the division, and all future correspondence from the division will be mailed to this address. If you move, it is your responsibility to notify us directly of the change. Maintaining your current address with us is the easiest way to ensure continuous licensure.

MEDLINE INDUSTRIES LP
264 S 5750 W
SALT LAKE CITY UT 84104

Please visit our web site at www.dopl.utah.gov should you have any questions in the future.

STATE OF UTAH
DEPARTMENT OF COMMERCE
DIVISION OF OCCUPATIONAL & PROFESSIONAL LICENSING
ACTIVE LICENSE

EFFECTIVE DATE: **01/20/2023**

EXPIRATION DATE: **09/30/2025**

ISSUED TO: **Medline Industries LP**
264 S 5750 W
Salt Lake City UT 84104

REFERENCE NUMBER(S), CLASSIFICATION(S) & DETAIL(S)

13214433-1710 **Pharmacy - Class C** **Wholesaler**

DBAs: **None Associated**

Form #1

Attachment F

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/01/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC. 155 N. WACKER, SUITE 1200 CHICAGO, IL 60661 CN101705524-Stnd-GAWUP-24-25 USA	**CONTACT NAME:** Medline Industries, LP **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:** riskmanagement@medline.com
INSURED Medline Industries, LP 3 Lakes Dr Northfield, IL 60093	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Safety National Casualty Corporation — 15105 **INSURER B :** Endurance Assurance Corporation — 11551 **INSURER C :** Life Science Risk **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-010059544-47 **REVISION NUMBER:** 17

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL 4065036	07/01/2024	07/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 2,000,000 $ 2,000,000 $ 10,000 $ 2,000,000 $ 4,000,000 $ SEE BELOW
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA 6675933	07/01/2024	07/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 2,000,000 $ $ $
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 10,000			ELD10004065211	07/01/2024	07/01/2025	EACH OCCURRENCE AGGREGATE	$ 10,000,000 $ 10,000,000
A A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		LDS 4065032 (AOS) PS 4065034 (WI)	07/01/2024 07/01/2024	07/01/2025 07/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ 1,000,000 $ 1,000,000 $ 1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00561-24	07/01/2024	07/01/2025	Limit	2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569. B56 – 190 Medline Drive, Ste 200, Richmond Hill, GA 31324. C40 – 81 Campanelli Drive, Uxbridge, MA 01569. C42 – 3446 Highway 51 N. Southaven, MS 38672. C59 – 2100 Industrial Park Road, Hammond, LA 70401. D46 – 18601 Christopher Way, Ste 100. Lathrop, CA 95330. MXC – 16415 Cosmos St. Moreno Valley, C 92551. C71- 264 South 5750 West Salt Lake City, UT 84104, Medline Industries, LP 3835 John Wall Drive, Madison, WI 53704.

SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.
Evidence of Insurance.

CERTIFICATE HOLDER

Medline Industries, LP
3 Lakes Dr.
Northfield, IL 60093

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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Attachment F (cont.)

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Branch Locations:

A59 - 19230 S Hi Park LN, Hammond, IN 70403
B01 - 1 Medline Place, Mundelein, IL 60060,
B04 - NPS - 1160 North point Blvd., Waukegan, IL 60085,
B04 - RC - 1710 Lakeside Drive, Waukegan, IL 60085,
B04 - SPT - 1170 North point Blvd., Waukegan, IL 60085,
B06 - 1 Medline Drive, Wilmer, TX 75172
B22 - 9670 NW 112th Ave., Miami, FL 33178,
B24 - 8001 SW 47th Street, Oklahoma City, OK 73179,
B25 - 1401 N. Universal Ave., Kansas City, MO 64120,
B27 - 8005 SW Hunziker St., Tigard, OR 97223,
B28 - 735 County Road 4 East, Prattville, AL, 36067,
B29 - 13115 Brockton Lane N, Rogers, MN 55374-9571,
B30 - 1900 Meadowville Technology Pkwy., Chester, VA 23836,
B31 - 500 Sharkey Drive, Maumelle, AR 72113,
B34 - 6645 Change point Drive, Anchorage, AK 99518,
B36 - 1989 Transit Way, Brockport, NY 14420,
B44 - 2325 W. Louise Avenue, Manteca, CA 95377,
B45 - 1119 W Middlesex Ave., Port Reading, NJ 07064,
B48 - 10401 Harrison, Suite 101, Romulus, MI 48174,
B49 - 42500 Winchester Rd, Temecula, CA 92590,
B51 - 60 Athlete's Way Suite 100, MT Juliet TN 37122
B52 - 974 Main Street, Alamo TN 38001
B58- 198 Commercial Blvd, Blakeslee PA 18610
B80- 2341 Lauwiliwili St, Kapolei HI 96707
B82- 9103 Riverside Parkway, Douglasville, GA
C02 - 2200 Cornerstone Parkway, Grayslake, IL 60030
C03 - 1500 Medline Place, McDonough, GA 30253
C05 - 1062 Old Dixie Highway, Auburndale, FL 33823
C09 - 1960 W Miro Way, Rialto, CA 92376
C11 - 21111 E 36th Drive, Aurora, CO 80011
C37 - 5000 Premier Parkway, Saint Peters, MO 63376
C41- 1040 Enterprise Parkway South, West Jefferson, OH 43162
C46 - 5701 Promontory Parkway, Suite 100, Tracy, CA 95377
C47-239 Belvidere Rd, Perryville MD 21903
C50 - 8787 W Buckeye Rd, Tolleson, AZ 85353
C53 - 100 Highland Dr, Westampton NJ 08060
C75 - 3770 Hogum Bay Rd NE, Lacey, WA 98516
C89-251 Hilton Dr, Jeffersonville IN, 47130
E15 - 30 Germantown Road, Danbury, CT 06810
C54- 494 St. Route 416, Montgomery, NY 12549.
C57 - 5511 W. Ten Road, Mebane, NC 27302.
C71- 264 South 5750 West Salt Lake City, UT 84104
C32 - 29895 US HWY 90 BUS, Katy, TX 77494
Laredo - SPT - 12013 General Milton Drive, Laredo, TX 78045
LRD - 12001 General Milton Drive, Laredo, TX 78045

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Attachment H

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 10/02/2024
Amount: $ 1050.00
Permit #: WH03451

Medline Industries, LP
264 South 5750 West
Salt Lake City UT 84104

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Permit #
WH03451
Active

Wholesaler
Effective Date:11/01/2024
Expires:10/31/2026

Medline Industries, LP
264 South 5750 West
Salt Lake City UT 84104

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Wholesaler

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

Expires: 10/31/2026
STATUS: Active

Permit Type: Wholesaler
Permit #: WH03451
Effective Date: 11/01/2024
DEA #:

Medline Industries, LP
264 South 5750 West
Salt Lake City UT 84104

NONTRANSFERABLE

POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medline Industries, LP MDEG License # (if applicable): _____

Physical Address: 264 S 5750 W

City: Salt Lake City State: UT Zip: 84104

Mailing Address (if different from physical address): Attn: "RA Licensing - 3D" Three Lakes Drive

City: Northfield State: IL Zip: 60093

Telephone: 801-975-6305 Website: www.medline.com

Licensing Company Email: ralicensing@medline.com

Section 2: Personal Information

First: Joseph Middle: Hans Bauer Last: Morozin

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Millcreek State: UT Zip: [redacted]

Telephone: [redacted] Email: jmorozin@medline.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Riverton High School		2003-2007	
Address	**City**	**State**	**Zip**
12476 S 2700 W.	Riverton	UT	84065
Diploma/Degree obtained, if any			
HS Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2017 - Present	[redacted]	Millcreek	UT	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04/2004 - 06/2017		Riverton	UT	
From - To (MM/YY – MM/YY)		City	State	
02/1998 - 03/2004		Riverton	UT	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			01/2023 - Present	
Business Address		**City**	**State**	**Zip**
264 South 5750 West		Salt Lake City	UT	84104
Phone	**Title**		**Number of Employed Hours**	
847-643-4508	Warehouse Manager		600	
Description of Duties				
See Attachment I				

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, Inc.			01/2017 - 01/2023	
Business Address		**City**	**State**	**Zip**
1820 South 5200 West		Salt Lake City	UT	84104
Phone	**Title**		**Number of Employed Hours**	
801-975-6305	Warehouse ~~Manager~~ Supervisor		13,000+	
Description of Duties				
See Attachment I				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
08/29/2009	10/16/2009	ID	Barley	Cassia County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CR-2009-6754	Cassia County Magistrate Court

Reason/Charge
Driving without Privileges

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Joseph Morozin	

Name of Business/Industry/Entity

Provide explanation below:

Drove to Idaho to visit family. Pulled over and cited for driving without privileges.

Original Signature (electronic, copies or stamps not accepted)

02/10/2025
Date

I, Joseph Morozin, **certify that as the MDEG Administrator for**

Medline Industries, LP,

that I (initial that you have read and meet the following requirements):

1. JM Have a high school diploma or its equivalent;
2. JM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Morozin
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/10/2025
Date

Board Use Only	Date Received: 3/5/25

Attachment 1

Job Description

Responsible for the daily administration and operation of the warehouse. Oversee materials are received, stored, shipped and reported in accordance with established procedures. Direct and supervise warehouse staff. Review effectiveness of operating procedures, maintenance, space utilization and protection of equipment.

- Administer and oversee the daily operation of the warehouse including processing, packaging and storage of supplies, materials and equipment. Ensure overtime is maintained within budget allotted.
- Oversee receipt, storage and shipment of materials and related reporting in accordance with established procedures. Ensure the accuracy of the inventory.
- Account for all materials and supplies in the stores facilities. Audit goods received into warehouse.
- Coach and mentor team members in the areas of productivity, quality, safety and Medline Core Values.
- Ensure all routine paperwork is completed on time and are filled out accurately.
- Assist in maintaining a safe work environment for all team members.
- Lead day-to-day activities of employees. Assign, monitor and review progress and accuracy of work, directs efforts and provides technical guidance on more complex issues. Provide input into hiring, firing and performance reviews.
- Work with customer service to resolve warehouse related issues.

CERTIFIED

CASSIA COUNTY MAGISTRATE COURT

CASE SUMMARY

CASE NO. CR-2009-6754

State of Idaho	§	Location:	Cassia County Magistrate Court
vs.	§		
Joseph Hans Morozin	§	Judicial Officer:	Bollar, Rick L.
	§	Filed on:	09/21/2009
	§	Appear by:	09/21/2009

CASE INFORMATION

Offense	Citation	Statute	Deg	Date	Case Type: Criminal
Jurisdiction: State					
1. Driving Without Privileges	1382455	I18-8001	MIS	08/29/2009	

TCN: 1601000953

Statistical Closures
10/03/2014 Closed

Bonds
Surety Bond #FCS3-479603 $2,000.00
10/16/2009 Exonerated
08/31/2009 Posted
Counts: 1

CASE ASSIGNMENT

Current Case Assignment

Case Number	CR-2009-6754
Court	Cassia County Magistrate Court
Date Assigned	09/22/2009
Judicial Officer	Bollar, Rick L.

PARTY INFORMATION

		Lead Attorneys
State	**State of Idaho**	**Cassia County Prosecutor**
Defendant	**Morozin, Joseph Hans**	**Cassia County Public Defender** *Public Defender*

EVENTS & ORDERS OF THE COURT

DATE	EVENTS & ORDERS OF THE COURT	INDEX
08/31/2009	Bond Posted - Surety (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Bond Posted - Surety (Amount 2000.00)*	
09/21/2009	New Case - Criminal (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *New Case Filed - Misdemeanor*	
09/21/2009	Arraignment (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Arraignment Sheet*	
09/21/2009	Order (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Order and Notice of Hearing*	

Printed on 02/14/2023 at 10:44 AM

CASE SUMMARY

CASE NO. CR-2009-6754

09/21/2009	A Plea is entered for Charge:* (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *A Plea is entered for charge - NG (118-8001 Driving Without Privileges)*
09/21/2009	Plea 1. Driving Without Privileges Not Guilty TCN: 1601000953 :
09/22/2009	Affidavit of Probable Cause (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Affidavit Of Probable Cause*
09/22/2009	Hearing Scheduled (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *(Pretrial Conference 10/16/2009 08:30 AM)*
10/16/2009	Court Minutes (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Court Minutes*
10/16/2009	Judgment of Conviction & Order of Commitment (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Judgment of Conviction, Order of Commitment*
10/16/2009	Court Accepts Guilty Plea (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Court Accepts Guilty Plea (118-8001 Driving Without Privileges)*
10/16/2009	Sentenced to Incarceration (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Sentenced To Incarceration (118-8001 Driving Without Privileges) Confinement terms: Jail: 30 days. Suspended jail: 29 days. Credited time: 1 day.*
10/16/2009	Probation Ordered (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Probation Ordered (118-8001 Driving Without Privileges) Probation term: 0 years 12 months 0 days. (Supervised Prob-Level II)*
10/16/2009	Bond Exonerated (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Bond Exonerated (Amount 2,000.00)*
10/16/2009	Miscellaneous (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Written Plea of Guilty*
10/16/2009	Miscellaneous (Judicial Officer: Bollar, Rick L.) Party: Defendant Morozin, Joseph Hans *Pretrial Scheduling Order*
10/16/2009	Disposition 1. Driving Without Privileges Guilty TCN: 1601000953 :
10/16/2009	Sentence (Judicial Officer: Bollar, Rick L.) 1. Driving Without Privileges Misdemeanor Sentence

CASSIA COUNTY MAGISTRATE COURT

CASE SUMMARY

CASE NO. CR-2009-6754

Confinement
- Type: County Jail
- Facility: Mini-Cassia Criminal Justice Center
- Term: 30 Days
- Suspended: 29 Days
- Effective Date: 10/16/2009
- Credit Term: 1 Day

Condition - Adult:
1. ZZZDO NOT USE Sup Probation PRIOR TO 7/1/18, 0Y 12M 0D, 10/16/2009 - 10/16/2010, Closed 10/03/2014

DATE	FINANCIAL INFORMATION	
	Defendant Morozin, Joseph Hans	
	Total Charges	275.50
	Total Payments and Credits	275.50
	Balance Due as of 02/14/2023	0.00

CLERK OF THE DISTRICT COURT CASSIA COUNTY, IDAHO

State of Idaho } ss
County of Cassia }

I hereby certify that the foregoing instrument is a full, true and correct copy of the original as the same appears in this office.

Dated 01-14-23

Clerk of the District Court, Ex-officio Auditor and Recorder, Cassia County, Idaho

By:

Printed on 02/14/2023 at 10:44 AM

4D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	■ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		■ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Medline Industries, LP

MDEG Physical Address: 42500 Winchester Road

City: Temecula State: CA Zip: 92590

Mailing Address (if different from physical address): Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 847-643-4508 Website: https://www.medline.com/

Email: ralicensing@medline.com

Name of MDEG Administrator (NAC 639.694): Cecilia Ramirez

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
■ Pharmacies[a]	☐ Respiratory Equipment**
■ Practitioners[a]	☐ Life-sustaining equipment**
■ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
■ Clinics[a]	■ Assistive Equipment
■ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: Catheters, TENS Units, Incontinence Supplies, Manual Wheelchairs, Ostomy/Urologicals
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8a-5p	■ Tue: 8a-5p	■ Wed: 8a-5p	■ Thurs: 8a-5p	■ Fri: 8a-5p
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? This facility has not received any discipline. Please see Attachment A for Medline's corporate disciplinary history.	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
See Attachment B

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Attachment A

Medline Industries, LP- Discipline *Confidential*

Date	Facility	Description of State Action	Corrective Actions
8/3/2005	1401 N. Universal Ave Kansas City, MO 64120	**FILE CLOSED 2010** Medline Industries' Kansas City, MO facility (#2003031660) was disciplined for failure to renew on time and for deficient temperature control procedures. Medline was placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010.	Medline's Regulatory Affairs Department was significantly expanded to include a team of 7 Licensing Specialists that monitor and ensure our licenses are renewed on time. A temperature control room was constructed at the facility to ensure product is stored at the appropriate temperature and humidity. These control rooms are now a standard feature at our distribution centers. We worked closely with NABP to ensure that our temperature control facilities and procedures align with industry best practices throughout our distribution network.
12/7/2006	9101 Riverside Pkwy Lithia Springs, GA 30122	**FILE CLOSED 2008** The Florida Certified Designated Representative at the Georgia facility unexpectedly resigned. The state of Florida suspended Medline's Florida Out of State Rx Drug Wholesale Distributor Permit (#23:1470) until a new licensed Florida CDR was hired at the facility.	To prevent this for occurring in the future, all Florida licensed Medline facilities are required to have multiple Florida Certified Designated Representatives on staff.
11/16/2007	10601 Southport Dr. Orlando, FL 32824 401 Commerce Blvd. Oldsmar, FL 34677 4750 118th Ave N Clearwater, FL 33762	**FILE CLOSED 2008** Medline Industries was cited for several violations. Failure to pass and maintain a Florida compliant pedigree. Maintaining the wrong permit type for the activities performed in the facilities (in addition to a manufacturing permit, Florida required the facility a repackager permit). Distribution of saline to an unauthorized recipient. Additionally an Rx drug item was found at an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. Medline was assessed and paid a fine for these violations. All issues were addressed and resolved to the satisfaction of the FL DOH. After duly notifying state authorities, as required by law, Medline received a fined from New York for out-of-state professional misconduct. (Cal. No. 27278)	To address the pedigree issues, Medline instituted a Florida specific pedigree system. This program ensured that any pedigree shipments within our distribution network with potential to end up in Florida has the required Florida documentation. (Note - these requirements have since been preempted by federal law). To address the issue of the wrong permit type, Medline secured the repackaging permit. To address the sale of saline to an unauthorized person, Medline instituted a new procedure for obtaining and maintaining customer licenses for all Rx Drug purchases- this procedure generates an automatic block for any Rx Drug order by an unlicensed customer. The Rx Drug item unintentionally stored in the raw materials facility was properly disposed of. Waste disposal procedures were updated to ensure that this mistake would not recur.
11/26/2007	2708 NE Waldo Rd. Gainesville, FL 32609	**FILE CLOSED 2008** Medline Industries' FL license (# 22:1022) was suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. In 2010, Medline made an unrelated business decision to close this facility. (Case # 2007-37412)	After this inspection, Medline conducted a thorough review of its policies and procedures. Additionally, Medline implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.
3/5/2008	149 New Camellia Blvd. Covington, LA 70433	**FILE CLOSED 2008** Medline Industries (LA #4318) was cited for failure to properly maintain copies of current customer licenses on-site. Medline was assessed and paid a fine. (Louisiana Administrative Docket #2008006). After duly notifying state authorities, as required by law, Medline received a fine from New York for out-of-state professional misconduct. (Cal. No. 27278)	In addition to storing copies of customers' licenses at headquarters, these licenses are now stored digitally so they can be accessed by our distribution centers.
5/9/2008	5450 W. Stewart Ave. Wausau, WI 54401	**FILE CLOSED 2009** Medline Industries (WI # 1116-045) was cited and fined by the Wisconsin Department of Regulation & Licensing following a facility inspection. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All of the hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state (Case #08	Immediately after the inspection, Medline and the owner of the facility erected a locked fence to divide the faculty. Medline also reviewed all of its other facilities to make sure no similar situations existed. In addition, training on where and how to access current policies and procedures was increased for distribution center personnel. This training is in addition to the training they receive on the policies and procedures themselves.

Attachment A (cont.)

Medline Industries, LP- Discipline *Confidential*

		PHM 037). In 2010, Medline made an unrelated business decision to close this facility. After duly notifying state authorities, as required by law, Medline received a fine from the states of Hawaii (Case #PHA 2009-7-L) and New York (Cal. No. 27278) for out-of-state professional misconduct.	
8/21/2008	94-1420 Moaniani St. Waipahu, HI 96797	**FILE CLOSED 2013** Medline Industries, Inc. (PWD 115) was fined $5000 and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices, but missed the 30-day deadline. The probationary period ended in August 2013. (Case # PHA 2008-17-L)	Medline implemented a new process to notify the necessary licensing boards of future disciplinary actions within the required reporting timelines.
3/19/2010	1401 N. Universal Ave. Kansas City, MO 64120	**FILE CLOSED 2010** Medline Industries, Inc. applied for a Colorado Out-of-State Wholesaler license for the Kansas City, MO distribution center. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See 8/3/2005 discipline). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license.	See 8/3/2005 discipline for corrective actions related to the underlying sanction.
1/6/2021	1501 Harris Rd Libertyville, IL 60048	**FILE CLOSED 2021** Medline Industries, Inc. (OH License #01-1985050) received a fine of $250 from the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file for the physician rather than the TDDD license for the facility. The facility's TDDD license at the time of the sale had expired. The fine was paid on January 21, 2021 and the case was closed. (Case No. A-2020-0054 I-2019-0972-B.) After duly notifying state authorities, as required by law, Medline received a $500 fine from the Alabama State Board of Pharmacy for the same underlying conduct as the Ohio matter. The fine was paid and the matter closed. (Case No:21-L-0048)	Medline takes this matter very seriously. Medline reviewed the customer licensing policies and procedures and updated internal requirements for the type of license required for customers in Ohio. Efforts were taken by Customer Licensing to research, ensure the proper type, and check license status for a large number of existing Ohio licenses. The Ohio TDDD licenses are reviewed on an annual basis to ensure compliance.
11/1/2022	1040 Enterprise Parkway South West Jefferson, OH 43162	**FILE CLOSED 2022** Medline Industries, LP (OH License #01-30000190) entered a settlement agreement and agreed to pay a fine of $1,125.00 to the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file versus a Terminal Distributor (TDDD) license. The TDDD license was added in May 2022- prior to this investigation. During the period of July 2021 to March 2022, the customer's TDDD license lapsed and Medline was unaware. Medline is in the process of notifying states of this fine.	Medline is committed to following all applicable state and federal statutes and regulations, including customer license requirements. Medline updated customer licensing requirements after the 01/06/2021 fine. This incident occurred while Medline was in the process of updating a large number of Ohio accounts. Medline is implementing additional steps to ensure compliance, including, increasing staffing, training, and resources for the customer licensing team.
12/19/2022	9670 NW 112th Ave Miami, FL 33178	**FILE CLOSED 2022** Medline Industries, LP (FL WDD# #2220297) entered a settlement agreement and agreed to pay a fine of $6,000.00 to the FL Dept. Business and Professional Regulation. Medline accepted a physician license for a facility customer, instead of the correct facility license. The second allegation relates to failure to include NDC numbers on outbound packing slips/ invoices. After duly notifying state authorities, as required by law, Medline received a reciprocal fine for disciplinary action by another state from the Hawaii Department of Consumer Affairs. The fine was paid and the matter closed. (Case PHA 2023-9-L).	Medline is addressing the customer licensing issue by expanding the customer licensing team resources and oversight. This process began after the 11/1/2022 Ohio Discipline and has been expanded to address FL and confirming other states. The packing slip/invoice error stemmed for an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A system fix is in progress.

Attachment A (cont.)

Medline Industries, LP- Discipline *Confidential*

07/19/2023 07/25/2023	1040 Enterprise Parkway South West Jefferson, OH 43162 251 Hilton Drive, Jeffersonville, IN 47130	**FILE CLOSED 2023** Medline Industries, LP entered a settlement agreement with the Ohio Board of Pharmacy and agreed to pay fines of $750 and $850 for alleged sales of dangerous drugs to an unlicensed entity from the Jeffersonville, IN (OH License #01-30000158) and West Jefferson, OH locations (OH License #01-30000190). The sales occurred between July 2021 and January 2022. After duly notifying state authorities, as required by law, Medline received a reciprocal fine for disciplinary action by another state from the Hawaii Department of Consumer Affairs. The fine was paid and the matter closed. (Case PHA 2023-9-L).	This underlying issue was previously corrected. These fines related to activities between July 2021 and January 2022. At that time Medline was in the process of updating Ohio customer requirements. Medline updated Ohio customer license requirements and implemented a TDDD verification process in 2021. In addition, Medline reviewed all existing Ohio accounts to verify the correct license was on file. The review process was completed in 2022. Medline also dedicated additional resources and staff for the customer licensing team and remains committed to following all state and federal laws and regulations.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Medline Industries, LP

Mailing Address: Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 847-643-4508 Email: ralicensing@medline.com

Contact Person Name: Kiara Rosado

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).** Attachment C			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**. Attachment D	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable)** Attachment E	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00). Attachment F	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/ N/A No individual owners Refer to Attachment C		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/ Attachment G	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/ Attachment H	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lara Simmons, Chief Quality Officer

Print Name of Authorized Person Submitting Application

Lara Simmons

Original signature of Authorized Person (copies or stamps not accepted)

01/31/2025

Date

Board Use Only	Date Received: 3/5/25	Amount: $300 CC

Attachment B

Medicare

Enrollment State	Enrollment Status	Medicare ID
AL	Active	0428930008
CA	Active	0428930007
CO	Active	0428930009
GA	Active	0428930012
HI	Active	0428930010
IL	Active	0428930001
MA	Active	0428930006
MI	Active	0428930005
MO	Active	0428930011
OR	Active	0428930003
TX	Active	0428930002

Medicaid

Enrollment State	Enrollment Status	Provider Number
AK	Active	1750309 (new) 1021896 (old)
AK	Active	1704352
AL	Active	216180
AR	Active	194904716
AZ	Active	AHCCCS ID 036021
CA	Active	9449244
CA	Active	1811997638; account ID 800336592
CO	Active	9000161244
CO	Active	1811997638 Location 98000060
DC	Active	19902800
DE	Active	200044726 -Location ID #
FL	Active	119444000
GA	Active	003127194A (Rendering) 305948034A (Payee ID)
HI	Active	008508

Attachment B (cont.)

IA	Active	0715918 HCBS Waiver 0915918 DME
ID	Active	1811997638
IL	Active	362596612001
KS	Active	30003891870001
KY	Active	90032335
LA	Active	2429400
MA	Active	110066936C
MA	Active	110066936A
MD	Active	033388300
MI	Active	1811997638
MO	ACTIVE	620803601
MT	Active	100030893
NC	Active	1649637059
NE	Active	36259661200
NH	Active	3098855;
NJ	Active	5096901
NM	Active	000T0700
NV	Active	1801225354
NY	Active	00680891
OH	Active	0400435
OR	Active	500719754
PA	Active	000905230-0006 (NEW) 000905230-0005 (OLD)
RI	Active	4028930
SC	Active	556712
TN	Active	3539772
TX	Active	3587834-01 (TPI)
UT	Active	1024729 - Prism ID
VA	Active	30015042570002
WA	Active	1024838
WI	Active	100269854
WY	Active	234872100

Attachment C

Medline Industries, LP
FEIN 36-2596612

Limited Partnership Partners:

PARTNERS	Business Address	General or Limited	% of Ownership	FEIN
Mozart GP, LLC	Three Lakes Drive Northfield, IL 60093	General	0%	87-2508203
Medline Borrower, LP	Three Lakes Drive Northfield, IL 60093	Limited	100%	87-2530238

PARENT COMPANY INFORMATION:
Medline Intermediate, LP
FEIN 87-2521736
State of Formation: IL
Managing Members:

BUSINESS ADDRESS AND PHONE NUMBER FOR ALL LISTED HERE:

THREE LAKES DRIVE
NORTHFIELD, IL 60093
PHONE #: 847-949-5500

Title	Name	Address
CEO	James M. Boyle	[redacted]
President / COO	James M. Pigott	[redacted]
CFO	Michael B. Drazin	[redacted]
Chief Quality Officer	Lara N. Simmons	[redacted]

Attachment D

File Number S030704

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

MEDLINE INDUSTRIES, LP, HAVING REGISTERED IN THE STATE OF ILLINOIS ON SEPTEMBER 07, 2021, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE UNIFORM LIMITED PARTNERSHIP ACT (2001) OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LP/LLLP IN THE STATE OF ILLINOIS, HAVING FULFILLED ALL REQUIREMENTS OF SAID ACT WITH REGARD TO PAYMENT OF FEES, THE FILING OF ANNUAL REPORTS (IF APPLICABLE) AND NEITHER HAVING BEEN ADMINISTRATIVELY DISSOLVED BY THE SECRETARY OF STATE NOR HAVING VOLUNTARILY FILED A STATEMENT OF TERMINATION.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 27TH *day of* FEBRUARY *A.D.* 2025 .

SEAL OF THE STATE OF ILLINOIS — AUG. 26TH 1818

Authentication #: 2505804876 verifiable until 02/27/2026

Authenticate at: https://www.ilsos.gov

Alexi Giannoulias

SECRETARY OF STATE

Attachment E

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Medline Industries L.P.
42500 Winchester Rd
Temecula, CA 92590

LICENSE NUMBER: 115265
EXPIRATION DATE: 11/22/2025

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 10/15/2024

OSP 07 102308

Attachment F

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 07/01/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC.
155 N. WACKER, SUITE 1200
CHICAGO, IL 60661

CN101705524-Stnd-GAWUP-24-25 USA

INSURED
Medline Industries, LP
3 Lakes Dr
Northfield, IL 60093

CONTACT NAME: Medline Industries, LP
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS: riskmanagement@medline.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Safety National Casualty Corporation	15105
INSURER B : Endurance Assurance Corporation	11551
INSURER C : Life Science Risk	
INSURER D :	
INSURER E :	
INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** CHI-010059544-47 **REVISION NUMBER:** 17

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL 4065036	07/01/2024	07/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 2,000,000 10,000 2,000,000 4,000,000 SEE BELOW
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA 6675933	07/01/2024	07/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	2,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION $ 10,000			ELD10004065211	07/01/2024	07/01/2025	EACH OCCURRENCE AGGREGATE	$ $	10,000,000 10,000,000
A A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N: Y If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		LDS 4065032 (AOS) PS 4065034 (WI)	07/01/2024 07/01/2024	07/01/2025 07/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00561-24	07/01/2024	07/01/2025	Limit		2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569. B56 – 190 Medline Drive, Ste 200, Richmond Hill, GA 31324. C40 – 81 Campanelli Drive, Uxbridge, MA 01569. C42 – 3446 Highway 51 N. Southaven, MS 38672. C59 – 2100 Industrial Park Road, Hammond, LA 70401. D46 – 18601 Christopher Way, Ste 100. Lathrop, CA 95330. MXC – 16415 Cosmos St. Moreno Valley, C. 92551. C71- 264 South 5750 West Salt Lake City, UT 84104, Medline Industries, LP 3835 John Wall Drive, Madison, WI 53704.

SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.
Evidence of Insurance.

CERTIFICATE HOLDER

Medline Industries, LP
3 Lakes Dr.
Northfield, IL 60093

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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Attachment F(cont.)

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Branch Locations:

A59 - 19230 S Hi Park LN, Hammond, IN 70403
B01 - 1 Medline Place, Mundelein, IL 60060,
B04 - NPS - 1160 North point Blvd., Waukegan, IL 60085,
B04 - RC - 1710 Lakeside Drive, Waukegan, IL 60085,
B04 - SPT - 1170 North point Blvd., Waukegan, IL 60085,
B06 - 1 Medline Drive, Wilmer, TX 75172
B22 - 9670 NW 112th Ave., Miami, FL 33178,
B24 - 8001 SW 47th Street, Oklahoma City, OK 73179,
B25 - 1401 N. Universal Ave., Kansas City, MO 64120,
B27 - 8005 SW Hunziker St., Tigard, OR 97223,
B28 - 735 County Road 4 East, Prattville, AL, 36067,
B29 - 13115 Brockton Lane N, Rogers, MN 55374-9571,
B30 - 1900 Meadowville Technology Pkwy., Chester, VA 23836,
B31 - 500 Sharkey Drive, Maumelle, AR 72113,
B34 - 6645 Change point Drive, Anchorage, AK 99518,
B36 - 1989 Transit Way, Brockport, NY 14420,
B44 - 2325 W. Louise Avenue, Manteca, CA 95377,
B45 - 1119 W Middlesex Ave., Port Reading, NJ 07064,
B48 - 10401 Harrison, Suite 101, Romulus, MI 48174,
B49 - 42500 Winchester Rd, Temecula, CA 92590,
B51 - 60 Athlete's Way Suite 100, MT Juliet TN 37122
B52 - 974 Main Street, Alamo TN 38001
B58- 198 Commercial Blvd, Blakeslee PA 18610
B80- 2341 Lauwiliwili St, Kapolei HI 96707
B82- 9103 Riverside Parkway, Douglasville, GA
C02 - 2200 Cornerstone Parkway, Grayslake, IL 60030
C03 - 1500 Medline Place, McDonough, GA 30253
C05 - 1062 Old Dixie Highway, Auburndale, FL 33823
C09 - 1960 W Miro Way, Rialto, CA 92376
C11 - 21111 E 36th Drive, Aurora, CO 80011
C37 - 5000 Premier Parkway, Saint Peters, MO 63376
C41- 1040 Enterprise Parkway South, West Jefferson, OH 43162
C46 - 5701 Promontory Parkway, Suite 100, Tracy, CA 95377
C47-239 Belvidere Rd, Perryville MD 21903
C50 - 8787 W Buckeye Rd, Tolleson, AZ 85353
C53 - 100 Highland Dr, Westampton NJ 08060
C75 - 3770 Hogum Bay Rd NE, Lacey, WA 98516
C89-251 Hilton Dr, Jeffersonville IN, 47130
E15 - 30 Germantown Road, Danbury, CT 06810
C54- 494 St. Route 416, Montgomery, NY 12549.
C57 - 5511 W. Ten Road, Mebane, NC 27302.
C71- 264 South 5750 West Salt Lake City, UT 84104
C32 - 29895 US HWY 90 BUS, Katy, TX 77494
Laredo - SPT - 12013 General Milton Drive, Laredo, TX 78045
LRD - 12001 General Milton Drive, Laredo, TX 78045

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Attachment H

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 09/20/2024
Amount: $ 1050.00
Permit #: WH01720

Medline Industries, LP
42500 WINCHESTER RD
TEMECULA CA 92590

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Permit #
WH01720
Active

Wholesaler
Effective Date:11/01/2024
Expires:10/31/2026

Medline Industries, LP
42500 WINCHESTER RD
TEMECULA CA 92590

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Wholesaler

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

Expires: 10/31/2026
STATUS: Active

Permit Type: Wholesaler
Permit #: WH01720
Effective Date: 11/01/2024
DEA #:

Medline Industries, LP
42500 WINCHESTER RD
TEMECULA CA 92590

NONTRANSFERABLE

POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medline Industries, LP MDEG License # (if applicable): _____

Physical Address: 42500 Winchester Road

City: Temecula State: CA Zip: 92590

Mailing Address (if different from physical address): Attn:"RA Licensing - 3D" Three Lakes Drive

City: Northfield State: IL Zip: 60093

Telephone: 951-296-2600 Website: www.medline.com

Licensing Company Email: ralicensing@medline.com / krosado@medline.com

Section 2: Personal Information

First: Cecilia Middle: _____ Last: Ramirez

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Temecula State: CA Zip: [redacted]

Telephone: [redacted] Email: crramirez@medline.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lake Elsinore High School		1981-1984	
Address	**City**	**State**	**Zip**
21800 Canyon Dr.	Wildomar	CA	92595
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/1999-Present	[redacted]	Temecula	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			02/2014 - Present	
Business Address		**City**	**State**	**Zip**
42500 Winchester Rd		Temecula	CA	92590
Phone	**Title**		**Number of Employed Hours**	
951-296-2600	Warehouse Manager		20,800+	
Description of Duties				
See Attachment I				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Cecilia Ramirez, **certify that as the MDEG Administrator for**

Medline Industries, LP,

that I (initial that you have read and meet the following requirements):

1. CR Have a high school diploma or its equivalent;
2. CR Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CR Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CR Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cecilia Ramirez
Print Name (First, Last)

Cecilia Ramirez
Original Signature (electronic, copies or stamps not accepted)

02/10/2025
Date

Board Use Only	Date Received: 3/5/25

Attachment 1

Job Description

Responsible for the daily administration and operation of the warehouse. Oversee materials are received, stored, shipped and reported in accordance with established procedures. Direct and supervise warehouse staff. Review effectiveness of operating procedures, maintenance, space utilization and protection of equipment.

- Administer and oversee the daily operation of the warehouse including processing, packaging and storage of supplies, materials and equipment. Ensure overtime is maintained within budget allotted.
- Oversee receipt, storage and shipment of materials and related reporting in accordance with established procedures. Ensure the accuracy of the inventory.
- Account for all materials and supplies in the stores facilities. Audit goods received into warehouse.
- Coach and mentor team members in the areas of productivity, quality, safety and Medline Core Values.
- Ensure all routine paperwork is completed on time and are filled out accurately.
- Assist in maintaining a safe work environment for all team members.
- Lead day-to-day activities of employees. Assign, monitor and review progress and accuracy of work, directs efforts and provides technical guidance on more complex issues. Provide input into hiring, firing and performance reviews.
- Work with customer service to resolve warehouse related issues.

4E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]**Is the business also a wholesaler? (NRS 639.016)**	■ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		■ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Medline Industries, LP

MDEG Physical Address: 8787 W Buckeye Rd

City: Tolleson State: AZ Zip: 85353

Mailing Address (if different from physical address): Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 847-643-4508 Website: https://www.medline.com/

Email: ralicensing@medline.com

Name of MDEG Administrator (NAC 639.694): Scott Fritsche

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
■ Pharmacies[a]	☐ Respiratory Equipment**
■ Practitioners[a]	☐ Life-sustaining equipment**
■ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
■ Clinics[a]	■ Assistive Equipment
■ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: Catheters, TENS Units, Incontinence Supplies, Manual Wheelchairs, Ostomy/Urologicals
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8a-5p	■ Tue: 8a-5p	■ Wed: 8a-5p	■ Thurs: 8a-5p	■ Fri: 8a-5p
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry? This facility has not received any discipline. Please see Attachment A for Medline's corporate disciplinary history.	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
See Attachment B

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Medline Industries, LP

Mailing Address: Three Lakes Drive - 3D

City: Northfield State: IL Zip: 60093

Telephone: 847-643-4508 Email: ralicensing@medline.com

Contact Person Name: Kiara Rosado

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).** Attachment C			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**. Attachment D	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable)** Attachment E	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00). Attachment F	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/ N/A No individual owners Refer to Attachment C		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/ ec Attach	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/ Attachment H	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lara Simmons, Chief Quality Officer

Print Name of Authorized Person Submitting Application

Lara N Simmons

Original signature of Authorized Person (copies or stamps not accepted)

01/31/2025

Date

Board Use Only	Date Received: 3/5/25	Amount: $800.00

Attachment A

Medline Industries, LP- Discipline *Confidential*

Date	Facility	Description of State Action	Corrective Actions
8/3/2005	1401 N. Universal Ave Kansas City, MO 64120	**FILE CLOSED 2010** Medline Industries' Kansas City, MO facility (#2003031660) was disciplined for failure to renew on time and for deficient temperature control procedures. Medline was placed on probation for 5 years. The state conducted multiple inspections of the facility throughout the probationary period and found Medline to comply with all requirements. The probationary period closed in August 2010.	Medline's Regulatory Affairs Department was significantly expanded to include a team of 7 Licensing Specialists that monitor and ensure our licenses are renewed on time. A temperature control room was constructed at the facility to ensure product is stored at the appropriate temperature and humidity. These control rooms are now a standard feature at our distribution centers. We worked closely with NABP to ensure that our temperature control facilities and procedures align with industry best practices throughout our distribution network.
12/7/2006	9101 Riverside Pkwy Lithia Springs, GA 30122	**FILE CLOSED 2008** The Florida Certified Designated Representative at the Georgia facility unexpectedly resigned. The state of Florida suspended Medline's Florida Out of State Rx Drug Wholesale Distributor Permit (#23:1470) until a new licensed Florida CDR was hired at the facility.	To prevent this for occurring in the future, all Florida licensed Medline facilities are required to have multiple Florida Certified Designated Representatives on staff.
11/16/2007	10601 Southport Dr. Orlando, FL 32824 401 Commerce Blvd. Oldsmar, FL 34677 4750 118th Ave N Clearwater, FL 33762	**FILE CLOSED 2008** Medline Industries was cited for several violations. Failure to pass and maintain a Florida compliant pedigree. Maintaining the wrong permit type for the activities performed in the facilities (in addition to a manufacturing permit, Florida required the facility a repackager permit). Distribution of saline to an unauthorized recipient. Additionally an Rx drug item was found at an unlicensed raw materials storage facility. Medline challenged several violations, resulting in most being substantially reduced or removed. Medline was assessed and paid a fine for these violations. All issues were addressed and resolved to the satisfaction of the FL DOH. After duly notifying state authorities, as required by law, Medline received a fined from New York for out-of-state professional misconduct. (Cal. No. 27278)	To address the pedigree issues, Medline instituted a Florida specific pedigree system. This program ensured that any pedigree shipments within our distribution network with potential to end up in Florida has the required Florida documentation. (Note - these requirements have since been preempted by federal law). To address the issue of the wrong permit type, Medline secured the repackaging permit. To address the sale of saline to an unauthorized person, Medline instituted a new procedure for obtaining and maintaining customer licenses for all Rx Drug purchases- this procedure generates an automatic block for any Rx Drug order by an unlicensed customer. The Rx Drug item unintentionally stored in the raw materials facility was properly disposed of. Waste disposal procedures were updated to ensure that this mistake would not recur.
11/26/2007	2708 NE Waldo Rd. Gainesville, FL 32609	**FILE CLOSED 2008** Medline Industries' FL license (# 22:1022) was suspended for violations identified during a Florida BOP facility inspection. Medline, through Counsel, addressed the issues raised in the inspection and established that the suspension was unjustified. The suspension was lifted 3 days later on January 22, 2008. In 2010, Medline made an unrelated business decision to close this facility. (Case # 2007-37412)	After this inspection, Medline conducted a thorough review of its policies and procedures. Additionally, Medline implemented an internal auditing program to ensure that all distribution centers comply with internal policies and procedures and state and federal regulations.
3/5/2008	149 New Camellia Blvd. Covington, LA 70433	**FILE CLOSED 2008** Medline Industries (LA #4318) was cited for failure to properly maintain copies of current customer licenses on-site. Medline was assessed and paid a fine. (Louisiana Administrative Docket #2008006). After duly notifying state authorities, as required by law, Medline received a fine from New York for out-of-state professional misconduct. (Cal. No. 27278)	In addition to storing copies of customers' licenses at headquarters, these licenses are now stored digitally so they can be accessed by our distribution centers.
5/9/2008	5450 W. Stewart Ave. Wausau, WI 54401	**FILE CLOSED 2009** Medline Industries (WI # 1116-045) was cited and fined by the Wisconsin Department of Regulation & Licensing following a facility inspection. Medline managed a portion of a Wisconsin hospital's warehouse. The inspector cited Medline for failure to install a dividing fence between the Medline warehouse and the hospital portion of the facility. All of the hospital products were owned by the hospital. Medline was also cited for failure to access policies and procedures during the inspection. Corrections were made and the facility re-inspected, to the satisfaction of the state (Case #08	Immediately after the inspection, Medline and the owner of the facility erected a locked fence to divide the faculty. Medline also reviewed all of its other facilities to make sure no similar situations existed. In addition, training on where and how to access current policies and procedures was increased for distribution center personnel. This training is in addition to the training they receive on the policies and procedures themselves.

Attachment A (cont.)

Medline Industries, LP- Discipline *Confidential*

		PHM 037). In 2010, Medline made an unrelated business decision to close this facility. After duly notifying state authorities, as required by law, Medline received a fine from the states of Hawaii (Case #PHA 2009-7-L) and New York (Cal. No. 27278) for out-of-state professional misconduct.	
8/21/2008	94-1420 Moaniani St. Waipahu, HI 96797	**FILE CLOSED 2013** Medline Industries, Inc. (PWD 115) was fined $5000 and placed on probation for 5 years for failure to report disciplinary actions within 30 days. Medline submitted all required notices, but missed the 30-day deadline. The probationary period ended in August 2013. (Case # PHA 2008-17-L)	Medline implemented a new process to notify the necessary licensing boards of future disciplinary actions within the required reporting timelines.
3/19/2010	1401 N. Universal Ave. Kansas City, MO 64120	**FILE CLOSED 2010** Medline Industries, Inc. applied for a Colorado Out-of-State Wholesaler license for the Kansas City, MO distribution center. The CO Board of Pharmacy issued a conditional license until the facility's MO probation period ended. (See 8/3/2005 discipline). Medline informed the CO Board when the MO probationary period was completed. Upon completion of probation, the Board issued a full license.	See 8/3/2005 discipline for corrective actions related to the underlying sanction.
1/6/2021	1501 Harris Rd Libertyville, IL 60048	**FILE CLOSED 2021** Medline Industries, Inc. (OH License #01-1985050) received a fine of $250 from the Ohio Board of Pharmacy for the sale of dangerous drugs to an unlicensed entity. Medline maintained a current and valid DEA license on file for the physician rather than the TDDD license for the facility. The facility's TDDD license at the time of the sale had expired. The fine was paid on January 21, 2021 and the case was closed. (Case No. A-2020-0054 I-2019-0972-B.) After duly notifying state authorities, as required by law, Medline received a $500 fine from the Alabama State Board of Pharmacy for the same underlying conduct as the Ohio matter. The fine was paid and the matter closed. (Case No:21-L-0048)	Medline takes this matter very seriously. Medline reviewed the customer licensing policies and procedures and updated internal requirements for the type of license required for customers in Ohio. Efforts were taken by Customer Licensing to research, ensure the proper type, and check license status for a large number of existing Ohio licenses. The Ohio TDDD licenses are reviewed on an annual basis to ensure compliance.
11/1/2022	1040 Enterprise Parkway South West Jefferson, OH 43162	**FILE CLOSED 2022** Medline Industries, LP (OH License #01-30000190) entered a settlement agreement and agreed to pay a fine of $1,125.00 to the Ohio Board of Pharmacy for alleged sales of dangerous drugs to an unlicensed entity. Medline maintained a physician license on file versus a Terminal Distributor (TDDD) license. The TDDD license was added in May 2022- prior to this investigation. During the period of July 2021 to March 2022, the customer's TDDD license lapsed and Medline was unaware. Medline is in the process of notifying states of this fine.	Medline is committed to following all applicable state and federal statutes and regulations, including customer license requirements. Medline updated customer licensing requirements after the 01/06/2021 fine. This incident occurred while Medline was in the process of updating a large number of Ohio accounts. Medline is implementing additional steps to ensure compliance, including, increasing staffing, training, and resources for the customer licensing team.
12/19/2022	9670 NW 112th Ave Miami, FL 33178	**FILE CLOSED 2022** Medline Industries, LP (FL WDD# #2220297) entered a settlement agreement and agreed to pay a fine of $6,000.00 to the FL Dept. Business and Professional Regulation. Medline accepted a physician license for a facility customer, instead of the correct facility license. The second allegation relates to failure to include NDC numbers on outbound packing slips/ invoices. After duly notifying state authorities, as required by law, Medline received a reciprocal fine for disciplinary action by another state from the Hawaii Department of Consumer Affairs. The fine was paid and the matter closed. (Case PHA 2023-9-L).	Medline is addressing the customer licensing issue by expanding the customer licensing team resources and oversight. This process began after the 11/1/2022 Ohio Discipline and has been expanded to address FL and confirming other states. The packing slip/invoice error stemmed for an internal system error. The error was limited to DSCSA exempt products, i.e. IV fluids. A system fix is in progress.

Attachment A (cont.)

Medline Industries, LP- Discipline *Confidential*

07/19/2023 07/25/2023	1040 Enterprise Parkway South West Jefferson, OH 43162 251 Hilton Drive, Jeffersonville, IN 47130	**FILE CLOSED 2023** Medline Industries, LP entered a settlement agreement with the Ohio Board of Pharmacy and agreed to pay fines of $750 and $850 for alleged sales of dangerous drugs to an unlicensed entity from the Jeffersonville, IN (OH License #01-30000158) and West Jefferson, OH locations (OH License #01-30000190). The sales occurred between July 2021 and January 2022. After duly notifying state authorities, as required by law, Medline received a reciprocal fine for disciplinary action by another state from the Hawaii Department of Consumer Affairs. The fine was paid and the matter closed. (Case PHA 2023-9-L).	This underlying issue was previously corrected. These fines related to activities between July 2021 and January 2022. At that time Medline was in the process of updating Ohio customer requirements. Medline updated Ohio customer license requirements and implemented a TDDD verification process in 2021. In addition, Medline reviewed all existing Ohio accounts to verify the correct license was on file. The review process was completed in 2022. Medline also dedicated additional resources and staff for the customer licensing team and remains committed to following all state and federal laws and regulations.

Attachment B

Medicare

Enrollment State	Enrollment Status	Medicare ID
AL	Active	0428930008
CA	Active	0428930007
CO	Active	0428930009
GA	Active	0428930012
HI	Active	0428930010
IL	Active	0428930001
MA	Active	0428930006
MI	Active	0428930005
MO	Active	0428930011
OR	Active	0428930003
TX	Active	0428930002

Medicaid

Enrollment State	Enrollment Status	Provider Number
AK	Active	1750309 (new) 1021896 (old)
AK	Active	1704352
AL	Active	216180
AR	Active	194904716
AZ	Active	AHCCCS ID 036021
CA	Active	9449244
CA	Active	1811997638; account ID 800336592
CO	Active	9000161244
CO	Active	1811997638 Location 98000060
DC	Active	19902800
DE	Active	200044726 -Location ID #
FL	Active	119444000
GA	Active	003127194A (Rendering) 305948034A (Payee ID)
HI	Active	008508

Attachment B (cont.)

IA	Active	0715918 HCBS Waiver 0915918 DME
ID	Active	1811997638
IL	Active	362596612001
KS	Active	30003891870001
KY	Active	90032335
LA	Active	2429400
MA	Active	110066936C
MA	Active	110066936A
MD	Active	033388300
MI	Active	1811997638
MO	ACTIVE	620803601
MT	Active	100030893
NC	Active	1649637059
NE	Active	36259661200
NH	Active	3098855;
NJ	Active	5096901
NM	Active	000T0700
NV	Active	1801225354
NY	Active	00680891
OH	Active	0400435
OR	Active	500719754
PA	Active	000905230-0006 (NEW) 000905230-0005 (OLD)
RI	Active	4028930
SC	Active	556712
TN	Active	3539772
TX	Active	3587834-01 (TPI)
UT	Active	1024729 - Prism ID
VA	Active	30015042570002
WA	Active	1024838
WI	Active	100269854
WY	Active	234872100

Attachment C

Medline Industries, LP
FEIN 36-2596612

Limited Partnership Partners:

PARTNERS	Business Address	General or Limited	% of Ownership	FEIN
Mozart GP, LLC	Three Lakes Drive Northfield, IL 60093	General	0%	87-2508203
Medline Borrower, LP	Three Lakes Drive Northfield, IL 60093	Limited	100%	87-2530238

PARENT COMPANY INFORMATION:
Medline Intermediate, LP
FEIN 87-2521736
State of Formation: IL
Managing Members:

BUSINESS ADDRESS AND PHONE NUMBER FOR ALL LISTED HERE:

THREE LAKES DRIVE
NORTHFIELD, IL 60093
PHONE #: 847-949-5500

Title	Name	Address
CEO	James M. Boyle	[redacted]
President / COO	James M. Pigott	[redacted]
CFO	Michael B. Drazin	[redacted]
Chief Quality Officer	Lara N. Simmons	[redacted]

Attachment D

File Number S030704

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias**, *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

MEDLINE INDUSTRIES, LP, HAVING REGISTERED IN THE STATE OF ILLINOIS ON SEPTEMBER 07, 2021, APPEARS TO HAVE COMPLIED WITH ALL PROVISIONS OF THE UNIFORM LIMITED PARTNERSHIP ACT (2001) OF THIS STATE, AND AS OF THIS DATE IS IN GOOD STANDING AS A DOMESTIC LP/LLLP IN THE STATE OF ILLINOIS, HAVING FULFILLED ALL REQUIREMENTS OF SAID ACT WITH REGARD TO PAYMENT OF FEES, THE FILING OF ANNUAL REPORTS (IF APPLICABLE) AND NEITHER HAVING BEEN ADMINISTRATIVELY DISSOLVED BY THE SECRETARY OF STATE NOR HAVING VOLUNTARILY FILED A STATEMENT OF TERMINATION.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 27TH *day of* FEBRUARY *A.D.* 2025 .

Authentication #: 2505804876 verifiable until 02/27/2026

Authenticate at: https://www.ilsos.gov

SECRETARY OF STATE

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 10/04/2023
Receipt Number: 2023160547
Receipt Amount $: 1000.00

Wholesaler - Full Service

	PERMIT NO	EXPIRES
	W003673	**10/31/2025**
Issued to :	Medline Industries, L.P. Medline Industries, L.P. THREE LAKES DRIVE - 3D NORTHFIELD, IL 60093	Medline Industries, L.P. 8787 W. BUCKEYE ROAD TOLLESON, AZ 85353

Sam Gaddis
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF
PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Medline Industries, L.P.
LICENSE NUMBER : W003673
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

Attachment F

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/01/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER MARSH USA LLC. 155 N. WACKER, SUITE 1200 CHICAGO, IL 60661 CN101705524-Stnd-GAWUP-24-25 USA	**CONTACT NAME:** Medline Industries, LP **PHONE (A/C, No, Ext):** **FAX (A/C, No):** **E-MAIL ADDRESS:** riskmanagement@medline.com
INSURED Medline Industries, LP 3 Lakes Dr Northfield, IL 60093	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A :** Safety National Casualty Corporation — 15105 **INSURER B :** Endurance Assurance Corporation — 11551 **INSURER C :** Life Science Risk **INSURER D :** **INSURER E :** **INSURER F :**

COVERAGES **CERTIFICATE NUMBER:** CHI-010059544-47 **REVISION NUMBER:** 17

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X **COMMERCIAL GENERAL LIABILITY** CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL 4065036	07/01/2024	07/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	2,000,000 2,000,000 10,000 2,000,000 4,000,000 SEE BELOW
A	**AUTOMOBILE LIABILITY** X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			CA 6675933	07/01/2024	07/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	2,000,000
B	X **UMBRELLA LIAB** X OCCUR **EXCESS LIAB** CLAIMS-MADE DED X RETENTION $ 10,000			ELD10004065211	07/01/2024	07/01/2025	EACH OCCURRENCE AGGREGATE	$ $	10,000,000 10,000,000
A A	**WORKERS COMPENSATION AND EMPLOYERS' LIABILITY** ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y / N: Y **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		LDS 4065032 (AOS) PS 4065034 (WI)	07/01/2024 07/01/2024	07/01/2025 07/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000
C	Products/Completed Operations Liability			LSR-PCO-00561-24	07/01/2024	07/01/2025	Limit		2,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Re: C42 - 3446 Highway 51 N Southaven, MS 38672. C40- 81 Campanelli Dr, Uxbridge, MA 01569. B56 – 190 Medline Drive, Ste 200, Richmond Hill, GA 31324. C40 – 81 Campanelli Drive, Uxbridge, MA 01569. C42 – 3446 Highway 51 N. Southaven, MS 38672. C59 – 2100 Industrial Park Road, Hammond, LA 70401. D46 – 18601 Christopher Way, Ste 100. Lathrop, CA 95330. MXC – 16415 Cosmos St. Moreno Valley, C 92551. C71- 264 South 5750 West Salt Lake City, UT 84104, Medline Industries, LP 3835 John Wall Drive, Madison, WI 53704.

SIR applies per policy terms & conditions. The products/completed operations policy evidenced above is subject to self-insured retentions for various perils covered.
Evidence of Insurance.

CERTIFICATE HOLDER

Medline Industries, LP
3 Lakes Dr.
Northfield, IL 60093

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Marsh USA LLC

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Attachment F (cont.)

AGENCY CUSTOMER ID: CN101705524

LOC #: Chicago

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC.	Medline Industries, LP 3 Lakes Dr Northfield, IL 60093
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Branch Locations:
A59 - 19230 S Hi Park LN, Hammond, IN 70403
B01 - 1 Medline Place, Mundelein, IL 60060,
B04 - NPS - 1160 North point Blvd., Waukegan, IL 60085,
B04 - RC - 1710 Lakeside Drive, Waukegan, IL 60085,
B04 - SPT - 1170 North point Blvd., Waukegan, IL 60085,
B06 - 1 Medline Drive, Wilmer, TX 75172
B22 - 9670 NW 112th Ave., Miami, FL 33178,
B24 - 8001 SW 47th Street, Oklahoma City, OK 73179,
B25 - 1401 N. Universal Ave., Kansas City, MO 64120,
B27 - 8005 SW Hunziker St., Tigard, OR 97223,
B28 - 735 County Road 4 East, Prattville, AL, 36067,
B29 - 13115 Brockton Lane N, Rogers, MN 55374-9571,
B30 - 1900 Meadowville Technology Pkwy., Chester, VA 23836,
B31 - 500 Sharkey Drive, Maumelle, AR 72113,
B34 - 6645 Change point Drive, Anchorage, AK 99518,
B36 - 1989 Transit Way, Brockport, NY 14420,
B44 - 2325 W. Louise Avenue, Manteca, CA 95377,
B45 - 1119 W Middlesex Ave., Port Reading, NJ 07064,
B48 - 10401 Harrison, Suite 101, Romulus, MI 48174,
B49 - 42500 Winchester Rd, Temecula, CA 92590,
B51 - 60 Athlete's Way Suite 100, MT Juliet TN 37122
B52 - 974 Main Street, Alamo TN 38001
B58- 198 Commercial Blvd, Blakeslee PA 18610
B80- 2341 Lauwiliwili St, Kapolei HI 96707
B82- 9103 Riverside Parkway, Douglasville, GA
C02 - 2200 Cornerstone Parkway, Grayslake, IL 60030
C03 - 1500 Medline Place, McDonough, GA 30253
C05 - 1062 Old Dixie Highway, Auburndale, FL 33823
C09 - 1960 W Miro Way, Rialto, CA 92376
C11 - 21111 E 36th Drive, Aurora, CO 80011
C37 - 5000 Premier Parkway, Saint Peters, MO 63376
C41- 1040 Enterprise Parkway South, West Jefferson, OH 43162
C46 - 5701 Promontory Parkway, Suite 100, Tracy, CA 95377
C47-239 Belvidere Rd, Perryville MD 21903
C50 - 8787 W Buckeye Rd, Tolleson, AZ 85353
C53 - 100 Highland Dr, Westampton NJ 08060
C75 - 3770 Hogum Bay Rd NE, Lacey, WA 98516
C89-251 Hilton Dr, Jeffersonville IN, 47130
E15 - 30 Germantown Road, Danbury, CT 06810
C54- 494 St. Route 416, Montgomery, NY 12549.
C57 - 5511 W. Ten Road, Mebane, NC 27302.
C71- 264 South 5750 West Salt Lake City, UT 84104
C32 - 29895 US HWY 90 BUS, Katy, TX 77494
Laredo - SPT - 12013 General Milton Drive, Laredo, TX 78045
LRD - 12001 General Milton Drive, Laredo, TX 78045

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Attachment H

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 09/20/2024
Amount: $ 1050.00
Permit #: WH02162

Medline Industries, LP
8787 W BUCKEYE RD
TOLLESON AZ 85353

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Wholesaler
Effective Date:11/01/2024
Expires:10/31/2026

Medline Industries, LP
8787 W BUCKEYE RD
TOLLESON AZ 85353

Permit #
WH02162
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA

STATE BOARD OF PHARMACY

Wholesaler

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

Expires: 10/31/2026
STATUS: Active

Permit Type: Wholesaler
Permit #: WH02162
Effective Date: 11/01/2024
DEA #:

Medline Industries, LP
8787 W BUCKEYE RD
TOLLESON AZ 85353

NONTRANSFERABLE

POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medline Industries, LP — MDEG License # (if applicable): _____

Physical Address: 8787 W Buckeye Rd

City: Tolleson — State: AZ — Zip: 85353

Mailing Address (if different from physical address): Attn:"RA Licensing - 3D" Three Lakes Drive

City: Northfield — State: IL — Zip: 60093

Telephone: 623-936-5443 — Website: www.medline.com

Licensing Company Email: ralicensing@medline.com / krosado@medline.com

Section 2: Personal Information

First: Scott — Middle: Jason — Last: Fritsche

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Buckeye — State: AZ — Zip: [redacted]

Telephone: [redacted] — Email: sfritsche@medline.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Milwaukee Marshall High School		1991 - 1995	
Address	**City**	**State**	**Zip**
4141 N. 64th Street	Milwaukee	WI	53216
Diploma/Degree obtained, if any			
Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2016 - Current	[redacted]	Buckeye	AZ	[redacted]
09/2015 - 06/2016		Buckeye	AZ	
07/2015 - 09/2015		Deatsville	AL	
01/2014 - 06/2015		Prattville	AL	
10/2011 - 01/2014		Romeoville	IL	
10/2009 - 10/2011		Plainfield	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medline Industries, LP			01/2013 - Current	
Business Address		**City**	**State**	**Zip**
8787 W. Buckeye Rd		Tolleson	AZ	85353
Phone	**Title**		**Number of Employed Hours**	
623-936-5443	Sr Director of Operations		21,000+	
Description of Duties				
See Attachment I				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Scott Fritsche, **certify that as the MDEG Administrator for**

Medline Industries, LP,

that I (initial that you have read and meet the following requirements):

1. SF Have a high school diploma or its equivalent;
2. SF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Fritsche
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/10/2025
Date

Board Use Only	Date Received: 2/5/25

Attachment 1

Job Description

Responsible for the daily administration and operation of the warehouse. Oversee materials are received, stored, shipped and reported in accordance with established procedures. Direct and supervise warehouse staff. Review effectiveness of operating procedures, maintenance, space utilization and protection of equipment.

- Administer and oversee the daily operation of the warehouse including processing, packaging and storage of supplies, materials and equipment. Ensure overtime is maintained within budget allotted.
- Oversee receipt, storage and shipment of materials and related reporting in accordance with established procedures. Ensure the accuracy of the inventory.
- Account for all materials and supplies in the stores facilities. Audit goods received into warehouse.
- Coach and mentor team members in the areas of productivity, quality, safety and Medline Core Values.
- Ensure all routine paperwork is completed on time and are filled out accurately.
- Assist in maintaining a safe work environment for all team members.
- Lead day-to-day activities of employees. Assign, monitor and review progress and accuracy of work, directs efforts and provides technical guidance on more complex issues. Provide input into hiring, firing and performance reviews.
- Work with customer service to resolve warehouse related issues.

4F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: RxFunction Inc.

MDEG Physical Address: 6509 Flying Cloud Dr Suite 140

City: Eden Prairie State: MN Zip: 55344

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (888) 382-3518 Website: www.rxfunction.com

Email: info@rxfunction.com

Name of MDEG Administrator (NAC 639.694): Mary E. Anderson

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Wearable Lower Limb Sensory Prosthesis
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8AM-5pm	■ Tue: 8AM-5pm	■ Wed: 8AM-5pm	■ Thurs: 8AM-5pm	■ Fri: 8AM-5pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
N/A

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota

Parent Company (if any): N/A

Corporation/Organization Name: RxFunction Inc.

Mailing Address: 6509 Flying Cloud Drive, Suite 140

City: Eden Prairie State: MN Zip: 55344

Telephone: 888.382.3518 Email: info@rxfunction.com

Contact Person Name: Jim Hanton, Compliance Officer

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James J. Hanton, Compliance Officer

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

12-26-24

Date

Board Use Only	Date Received: 1/2/25	Amount: $500.00

RXFUINC-01 MRAZIDLO

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 3/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Christensen Group, Inc. 9855 W 78th Street Suite 100 Eden Prairie, MN 55344-8004	CONTACT NAME: Matt Razidlo PHONE (A/C, No, Ext): (952) 653-1181 FAX (A/C, No): E-MAIL ADDRESS: mrazidlo@christensengroup.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Atlantic Specialty Ins Co	27154
INSURED Rxfunction, Inc. 6509 Flying Cloud Dr Suite 140 Eden Prairie, MN 55344-3636	INSURER B :	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT LOC OTHER:			711-01-61-24-0007	1/29/2025	1/29/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 500,000 $ 15,000 $ 1,000,000 $ 2,000,000 $
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY			711-01-61-24-0007	1/29/2025	1/29/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			711-01-61-24-0007	1/29/2025	1/29/2026	EACH OCCURRENCE AGGREGATE AGG	$ 5,000,000 $ $ 5,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y / N If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
A	Products Liability			750-00-03-28-0004	1/29/2025	1/29/2026	Aggregate	5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
XXXXXX EVIDENCE OF COVERAGE XXXXXX

CERTIFICATE HOLDER

EVIDENCE OF COVERAGE
XXXXXXXXXXXXXXX
XXXXXXXXXXXXXXX

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	RxFunction, Inc.
Date Filed:	05/17/2010
File Number:	3843734-2
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 10/31/2024

Steve Simon
Secretary of State
State of Minnesota

RxFunction Inc.

6509 Flying Cloud Dr Suite 140, Eden Prairie, MN 55344

OFFICERS

Mary E. Anderson	Chief Executive Officer
Joseph J. Schauer	Chief Operating Officer
Lars I.E. Oddsson	Chief Technology Officer

DIRECTORS

Mary E. Anderson
Lars I.E. Oddsson
Richard E. Offerdahl
Richard J. Nigon
Robert P. Rinek
Kevin H. Roche

MINNESOTA
BOARD OF PHARMACY

Minnesota Board of Pharmacy
335 Randolph Ave; #230
St Paul, MN 55102
Email: pharmacy.board@state.mn.us
Protecting the Public Since 1885

1/29/2024

Regarding: RxFunction Inc. 6509 Flying Cloud Dr; Suite 140; Eden Prairie, MN 55344 which is seeking a license in your jurisdiction

To whom it may concern:

At this time the State of Minnesota does not regulate medical device companies (manufacturers or distributors) through either the Board of Pharmacy or any other health board or division. As there is no statutory reference to this, we provide the following related FAQ information from our official website:

https://mn.gov/boards/pharmacy/resourcesfaqs/faqs/generalfaqs.jsp

Does your Board of Pharmacy license or register medical device or medical supply manufacturers, wholesale distributors, supplies or retailers?
The Board does not license or register companies that exclusively manufacture, distribute, supply or sell medical devices or supplies. If a company that handles medical devices or supplies also manufactures or distributes drugs, it must be licensed as a drug manufacturer or drug wholesaler. Exception if the drug is coated on or embedded in the device (e.g. drug-coated stents) and the resultant product is approved by the FDA as a device, the company does not have to be licensed as a manufacturer or wholesale distributor.

If you have any questions you may reach out to me at the MN Board of Pharmacy any time.

Thank you,

Aaron L Patterson PharmD; RPh **1/29/2024**
Pharmacy Surveyor

Minnesota Board of Pharmacy
335 Randolph Avenue
Suite 230
St. Paul, MN 55102

Direct: 651-201-2838
Office: 651-201-2825
Fax: 651-215-0951

Protecting the Public Since 1885 | mn.gov/boards/pharmacy

Ownership
3/11/2025

Shareholder	3/11/2025
Richard Offerdahl	56.05%
Kevin Roche	2.29%
David B. Johnson	2.03%
Joseph Novogratz	1.91%
David Henderson	1.47%
Lars Oddsson	1.31%
Joseph Daniel Leach	1.28%
Gregory B. Schultz	1.27%
Elden Russell	1.23%
Ronald E. Clark	1.21%
Daniel Nilsson	1.06%
131 shareholders under 1%	28.89%
	100.00%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG RxFunction Inc. MDEG License # (if applicable) n/a

Physical Address 6509 Flying Cloud Dr Suite 140

City Eden Prairie State MN Zip 55344

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone (888) 382-3518 Website www.rxfunction.com

Licensing Company Email info@rxfunction.com

Section 2: Personal Information

First Mary Middle Ernst Last Anderson

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Eden Prairie State MN Zip [redacted]

Telephone [redacted] Email mary.anderson@rxfunction.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Saint Thomas		09/81 - 05/85	
Address	**City**	**State**	**Zip**
2115 Summit Ave	St. Paul	MN	55105
Diploma/Degree obtained, if any			
Bachelor of Science in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Academy of Holy Angels		09/77 - 05/81	
Address	**City**	**State**	**Zip**
6600 Nicollet Avenue	Richfield	MN	55423
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/03 - present	[redacted]	Eden Prairie	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
RxFunction Inc.			02/18 - present
Business Address	**City**	**State**	**Zip**
6509 Flying Cloud Dr Suite 140	Eden Prairie	MN	55344
Phone	**Title**		**Number of Employed Hours**
612.358.2139	CEO		2000+ per year
Description of Duties			
Lead privately-held start-up medical device company in bringing to market an innovative wearable sensory prosthetic device			

Business Name			From - To (MM/YY – MM/YY)
Tactile Medical Inc.			01/05 - 07/17
Business Address	**City**	**State**	**Zip**
3701 Wayzata Blvd Suite 300	Minneapolis	MN	55416
Phone	**Title**		**Number of Employed Hours**
(612) 355-5100	Vice President of Reimbursement and Patient Support		2000+ per year
Description of Duties			
Designed business platform that transferred the patient information collected by sales representatives through the insurance approval, shipment,in-home patient training, billing, and collection process			

Business Name			From - To (MM/YY – MM/YY)
Advanced Respiratory Inc. (nka Hill-Rom® Respiratory Care)			08/90 - 12/03
Business Address	**City**	**State**	**Zip**
1020 County Road F West	St. Paul	MN	55126
Phone	**Title**		**Number of Employed Hours**
(800) 426-4224	Vice President of Internal Operations (Reimbursement)		2000+ per year
Description of Duties			
developed operational strategy and proprietary software systems and reimbursement and patient services teams necessary to execute order with patient, healthcare team, and insurance customers			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. Provide all the following *<u>where applicable</u>*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/23/2024
Date

I, Mary E. Anderson, **certify that as the MDEG Administrator for**

RxFunction Inc.,

that I (initial that you have read and meet the following requirements):

1. MEA Have a high school diploma or its equivalent;
2. MEA Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MEA Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MEA Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mary Anderson

Print Name (First, Last)

Mary Anderson

Original Signature (electronic, copies or stamps not accepted)

12/23/2024

Date

Board Use Only	Date Received: 1/2/25

-55.8%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site RxFUNCTION INC.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) n/a

Physical Address 6509 Flying Cloud Dr Suite 140

City Eden Prairie State MN Zip 55344

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone (888) 382-3518 Website www.rxfunction.com

Licensing Company Email info@rxfunction.com

Section 2: Personal Information

First Richard Middle Edward Last Offerdahl

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City INCLINE VILLAGE State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
North Dakota State University		08/61 - 05/65	
Address	**City**	**State**	**Zip**
1340 Administration Ave	Fargo	ND	58105
Diploma/Degree obtained, if any			
BS Electrical Engineering			

School Name		From - To (MM/YY – MM/YY)	
Ada High School		08/57 - 06/61	
Address	**City**	**State**	**Zip**
604 W Thorpe Ave	Ada	MN	56510
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
1993 - PRESENT	[redacted]	INCLINE VILLAGE	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
RxFUNCTION INC.			12/20 - current	
Business Address		**City**	**State**	**Zip**
6509 Flying Cloud Dr Suite 140		Eden Prairie	MN	55344
Phone	**Title**			
(888) 382-3518	Board Member			
Description of Duties				
Typical advisory role as member of Board including periodic meetings of the Board of Directors.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4and5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

4 and 5. I was CEO of ZYCAD CORP in 1985. ZYCAD CORP sued SILICON SOLUTIONS for patent infringement in about 1985.

4 and 5. Control Data Corporation sued ZYCAD CORP in about 1983 for patent infringement. The lawsuit was settled when ZYCAD purchased the patent in question.

4 and 5. Employee Jane Bersie sued ZYCAD CORP on an employment-related matter in about 1984. ZYCAD CORP prevailed at trial. No money changed hands.

Original Signature (electronic, copies or stamps not accepted)

12/20/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Richard Offerdahl

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/20/24

Date

Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Hennepin

I, Richard Offerdahl, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/20/24

Date

Subscribed and Sworn to before me this 20th day of December, 2024

Notary Public Signature

PAUL W RUTZEN
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES 01/31/30

(Seal)

AFFIDAVIT
REGARDING

Out-Of-State Medical Devices, Equipment and Gases Application of RxFunction Inc.

I, Richard E. Offerdahl, having been duly sworn, provide this Affidavit in support of RxFunction Inc., a Minnesota corporation, and its application to the state of Nevada for an out-of-state MDEG license and state the following:

1. I reside in Incline Village, Nevada.
2. I am a member of the Board of Directors of the Applicant.
3. I own shares in excess of 10% of the outstanding shares of the Applicant.
4. I have submitted a PERSONAL HISTORY APPLICATION dated 12/20/24 in support of the Applicant and as required by the state of Neveda.
5. I responded in the affirmative to questions 4 and 5 of that PERSONAL HISTORY APPLICATION regarding my past involvement in three (3) separate lawsuits. All three (3) lawsuits involved a company identified as ZYCAD CORPORATION.
6. At no time has there ever been any relationship between the Applicant, RxFunction Inc. and ZYCAD CORPORATION.
7. ZYCAD, founded in 1981, was a pioneer in simulation acceleration technology for design verification of integrated circuits.
8. I served as Chief Executive Officer of ZYCAD from June 1981 until June 1986.
9. I retired from ZYCAD in June 1986.
10. Control Data Corporation sued ZYCAD for patent infringement on or about 1983. That lawsuit continued after I retired from ZYCAD. I had no further involvement after I retired.
11. Upon information and belief, ZYCAD eventually settled with Control Data Corporation by purchasing the patent in dispute.
12. ZYCAD sued Silicon Solutions for patent infringement on or about 1985. That lawsuit continued after I retired from ZYCAD. I had no further involvement after I retired.
13. Upon information and belief, ZYCAD eventually settled with Silicon Solutions.
14. A former employee of ZYCAD, Jane F. Bersie, sued ZYCAD on or about 1984. That lawsuit continued after I retired from ZYCAD. I had no further involvement after I retired.
15. The Bersie lawsuit against ZYCAD was ultimately adjudicated. A copy of that court opinion from the Minnesota Court of Appeals has been provided to the Nevada Board of Pharmacy.

16. Upon information and belief, ZYCAD CORPORATION changed its name to GateField Corp. in 1997. Gatefield, the company that was once Zycad, was later acquired by Actel. This all occurred years after I retired from ZYCAD.

I declare under penalty of perjury that everything I have stated in this document is true and correct to the best of my knowledge and recollection.

STATE OF Minnesota)
) SS
COUNTY OF Hennepin)

PRINT FULL NAME: Richard Edward Offerdahl

SIGNATURE: Richard Offerdahl

Sworn to and subscribed before me on (date) 4/17/2025.

Notary Public: _____ Notary Seal

PAUL W RUTZEN
NOTARY PUBLIC - MINNESOTA
MY COMMISSION EXPIRES 01/31/30

Bersie v. Zycad Corp.

417 N.W.2d 288 (1987)

Jane F. BERSIE, Appellant, v. ZYCAD CORPORATION, Respondent.

No. CX-87-1003.

Court of Appeals of Minnesota.

December 29, 1987.

Review Denied May 5, 1988.

Donald E. Horton, Sonja R. Peterson, Minneapolis, for appellant.

Lee A. Bernet, III, St. Paul, for respondent.

Heard, considered and decided by FORSBERG, P.J., and LANSING and NIERENGARTEN, JJ.

OPINION

NIERENGARTEN, Judge.

This is an appeal from a judgment concluding Zycad Corporation did not discharge Jane F. Bersie for reasons based on her sex, or knowingly allow her to endure an intimidating, hostile, or offensive working environment in violation of the Minnesota Human Rights Act. We affirm.

FACTS

Jane Bersie was hired by Zycad Corporation (Zycad) in March 1982 to work as a computer systems analyst/programmer. Most Zycad employees have backgrounds in electrical engineering because of the company's clientele and product focus. Bersie has a masters degree in mathematics and programming experience, but does not have an engineering background.

Bersie was responsible for maintaining some of Zycad's computer operating systems and also was required to perform certain programming tasks which became increasingly sophisticated as the months passed and the company developed. Bersie indicated to her supervisor, Harley Horsager that she felt she was not accorded the same respect as the other employees because *289 she did not have an engineering background.

Horsager concluded during the first few months of 1983 that Bersie's work was unsatisfactory and that she was incapable of performing certain technical tasks. According to Horsager, Bersie was not completing projects in a timely manner, did not relate well to co-employees, and was becoming increasingly difficult to supervise. Horsager testified about Bersie's inability to complete an important programming project despite several new deadlines. He also testified about how Bersie "lost" a bank of computer files which were needed for an important computer show and that he had to spend significant amounts of time assisting Bersie with projects. Horsager decided to change Bersie's work responsibilities so she could work on assignments at which she could succeed and which would help re-establish her self-confidence.

In July 1983, Bersie told Horsager she was having problems at work relating to other employees and that she thought she did not have a future with Zycad because she was not an engineer. Bersie said she was unhappy, indicated that maybe she should quit and suggested Zycad might consider firing her instead so she could qualify for unemployment benefits.

On August 4 Bersie gave Horsager a letter which indicated she considered herself involuntarily terminated. In a reply letter, Zycad agreed Bersie's employment was terminated as of her conversation with Horsager on July 30 and enclosed a check which included two weeks severance pay and accrued vacation pay. Several days later, Bersie's

attorney sent a letter to Zycad in which he stated Bersie had "reluctantly decided that her sex was a significant factor" in her termination.

Bersie summarized incidents of sexual harassment such as an employee calling her "sweetheart" and "doll" several times and placing his hands on her neck and shoulders on a few occasions. The employee engaged in similar conduct with other female employees. According to Bersie, another employee asked Bersie why she did not prostitute herself for a living. Bersie testified that she resented the remarks but admitted they were a failed attempt at humor. Bersie indicated that those individuals and a third employee suggested Bersie and a male customer were "really tight" and asked if they should call her husband, alluding to recent stories about Control Data which had been accused of providing prostitutes for its customers. Bersie cited an incident in which one of those employees allegedly moved his chair close to Bersie's chair and leaned his body in close proximity to Bersie's body. Bersie also referred to an incident in which magazine photographs of nude women were posted on the walls of a male employee's cubicle on that employee's fortieth birthday. The photographs were removed by the next day at the direction of the company president. Although Bersie met with Horsager on numerous occasions to complain or report about job and performance problems, Bersie admitted she never reported any of these incidents to Horsager, who claimed no knowledge of the incidents.

In March 1984, Bersie filed a lawsuit against Zycad alleging sexual discrimination and harassment in violation of the Human Rights Act. She also asserted various contract and tort claims based on fraud, misrepresentation, and defamation. An advisory jury returned a special verdict in Zycad's favor, finding no defamation and no sexual discrimination and/or sexual harassment. The trial court adopted those findings and directed entry of judgment for Zycad. On appeal, this court concluded the trial court's findings were not adequate and remanded for appropriate findings. See Bersie v. Zycad Corp., 399 N.W.2d 141 (Minn.Ct.App.1987).[1]

On remand, the trial court adopted Zycad's proposed findings and conclusions with only minor changes. The court found that Bersie's termination was based on "legitimate *290 non-discriminatory business performance-related reasons justified by the facts and circumstances taken as a whole," including Bersie's "increasing inability to cope with project deadlines and her inability to get along with co-employees and her manager." The

court concluded Bersie "failed to establish by credible evidence" the factors necessary to prove a prima facie case of sexual discrimination and harassment.

Bersie appeals from the February 1987 judgment and the denial of her post-trial motions for amended findings and a new trial.

ISSUE

Did the trial court err by concluding the appellant did not suffer sexual harassment or discrimination and that her employer did not violate the Minnesota Human Rights Act?

ANALYSIS

The trial court's findings "will not be disturbed if they are reasonably supported by evidence in the record considered as a whole." Hubbard v. United Press International, Inc., 330 N.W.2d 428, 441 (Minn. 1983). See Minn.R.Civ.P. 52.01 ("Findings of fact shall not be set aside unless clearly erroneous, and due regard shall be given to the opportunity of the trial court to judge the credibility of the witnesses").

Sexual Harassment and Discrimination Claims

Under the Minnesota Human Rights Act, it is an unfair employment practice for an employer, because of sex,

(b) to discharge an employee; or (c) to discriminate against a person with respect to his [or her] hire, tenure, compensation, terms, upgrading, conditions, facilities, or privileges of employment.

Minn.Stat. § 363.03, subd. 1(2) (1982). Sexual harassment is a form of sex-based discrimination and may include conduct or communication which "has the purpose or effect of substantially interfering with an individual's employment, * * * or creating an intimidating, hostile, or offensive employment * * * environment." See id. § 363.01, subds. 10, 10a. In employment cases, the employer must know or should have known of the harassment and fail to take timely and appropriate action. See id. § 363.01, subd. 10a(3); see also Continental Can Co., Inc. v. State, 297 N.W.2d 241, 249 (Minn.1980).

Since this is a disparate treatment claim under the Minnesota Human Rights Act, we must apply a three-part analysis established in McDonnell Douglas Corp. v. Green, 411 U.S. 792, 93 S. Ct. 1817, 36 L. Ed. 2d 668 (1973). See Sigurdson v. Isanti County, 386 N.W.2d 715, 719-20 (Minn.1986). That analysis requires the complainant to establish a prima facie case of discrimination, the employer to answer that showing, and the complainant to rebut the employer's evidence of nondiscrimination. See McDonnell Douglas, 411 U.S. at 802-04, 93 S. Ct. at 1824-25.

Five factors may demonstrate sexual harassment and may be used to establish a prima facie case.

1. Did the employee belong to a protected class? 2. Was the employee subject to unwelcome sexual harassment? 3. Was the harassment complained of based upon sex? 4. Did the harassment complained of affect a "term, condition, or privilege" of employment? (Or, more exactly, in Bersie's case did the harassment create an "intimidating, hostile, or offensive working environment?") 5. Respondeat superior (did the employer know or should the employer have been aware of the harassment?).

Bersie, 399 N.W.2d at 146 (citing Henson v. City of Dundee, 682 F.2d 897, 903-05 (11th Cir.1982)).

Bersie asserts her sex discrimination claims under the Minnesota Human Rights Act. For the purposes of our analysis, Bersie is a member of a protected class.

While some conduct of Bersie's co-employees was offensive, the evidence supports *291 the trial court's conclusion that Bersie's employment problems were caused in large part by her "increasing inability to cope with project deadlines and her inability to get along with co-employees and her manager." When viewed as a whole, the record indicates Bersie's problems were personal problems unrelated to her status as a female employee. See Continental Can Co., 297 N.W.2d at 249 ("all the circumstances surrounding the conduct alleged to constitute sexual harassment, such as the nature of the incidents and the context in which they occurred, should be examined").

The record indicates that the vast majority of Bersie's "harassment" and interpersonal problems with her co-employees were not based on sex, but were the result of Bersie's apparent lack of the requisite technical skills.[2] After reviewing the entire record, we cannot conclude the conduct of Bersie's co-employees "substantially" interfered with Bersie's employment or that the incidents were not "sufficiently severe or pervasive so as `to alter the conditions of [the victim's] employment and create an abusive working condition.'" See Klink v. Ramsey County, 397 N.W.2d 894, 901 (Minn.Ct.App.1986) pet. for rev. denied (Minn. Feb. 13, 1987) (quoting Meritor Savings Bank v. Vinson, 477 U.S. 57, ___, 106 S. Ct. 2399, 2406, 91 L. Ed. 2d 49 (1986)).

[T]he prohibition against sex discrimination in [the Human Rights Act] includes sexual harassment which impacts on the conditions of employment when the employer knew or should have known of the employees' conduct alleged to constitute sexual harassment and fails to take timely and appropriate action.

Continental Can Co., 297 N.W.2d at 249 (footnote omitted; emphasis added).

Bersie never complained or told Horsager about any of the incidents which Bersie alleges constitute sexual harassment. Horsager denies actual knowledge of the incidents, and the record does not indicate the incidents were so obvious or pervasive the employer should have known of the alleged misconduct. See Minn.Stat. § 363.01, subd. 10a(3) (the employer must know or should have known of the existence of the harassment and failed to take timely and appropriate action).

Since the evidence does not show Zycad had actual or constructive knowledge of the objectionable incidents, Bersie failed to prove a prima facie case of sex discrimination. Bersie's discrimination claims and the factual circumstances of her case were established largely by testimony which the trial court was able to hear and assess firsthand.

Employment discrimination cases often involve intricate factual issues in which only the trial court, with its opportunity to observe the witnesses firsthand, can meaningfully assess the weight and credibility of the evidence. We have traditionally accorded great deference to the trial court in making findings of fact, recognizing that much must necessarily be left to its sound judgment and discretion because it has the advantage of fully hearing the testimony and acquiring a thorough familiarity with all the circumstances of the case. An

appellate court cannot judge the credibility of a witness or the weight, if any, to be given to testimony.

Sigurdson v. Isanti County, 386 N.W.2d 715, 721 (Minn.1986) (citations omitted). Bersie's case was tried before an advisory jury which also determined there was no sexual discrimination or harassment. We must defer to the factfinders' conclusions when the findings "are reasonably supported by evidence in the record considered *292 as a whole." See Hubbard, 330 N.W.2d at 441; see also Tretter v. Liquipak International, Inc., 356 N.W.2d 713, 715 (Minn.Ct. App.1984) (an appellate court does not "weigh the evidence as if trying the matter de novo," but determines "if the evidence as a whole sustains the trial court's findings"). Based on our review of the entire record, we cannot say the trial court erred by concluding Bersie's termination was not based on her sex, or by concluding Zycad did not allow Bersie "to endure an intimidating and hostile employment environment."

Reversible Error Per Se

Bersie contends the trial court improperly adopted Zycad's proposed findings of fact and conclusions of law because the court adopted the findings almost verbatim. Such adoption by itself is not improper if the record supports the findings and shows the trial court conscientiously considered all the issues. See Sigurdson v. Isanti County, 408 N.W.2d 654, 657 (Minn. Ct.App.1987) pet. for rev. denied (Minn. Aug. 19, 1987). The record supports the trial court's findings.

DECISION

The trial court did not err by concluding the appellant did not suffer sexual harassment or discrimination in violation of the Minnesota Human Rights Act. The appellant failed to establish a prima facie case of sex discrimination.

Affirmed.

FORSBERG, Judge (concurring specially):

I concur on the basis that Bersie failed to prove steps 3, 4, and 5 of the Henson test. (See majority opinion, p. 290.)

In steps 3 and 4 reference is made to the "harassment complained of." At no time did Bersie complain to anyone, either formally or informally of the acts alleged to constitute sexual harassment. She did complain about virtually everything associated with her job, including difficulty getting along with female employees. Moreover, it is very unlikely that she would complain about these acts being sexual harassment when she, herself, testified that she was not mistreated because she is a female.

Moreover, in regard to step 5, the acts complained of were committed by co-employees. There may be a question as to Allenbaugh's status. However, Bersie, herself, testified as follows:

Q: And [Allenbaugh] is a coemployee? A: Yes. Q: As is Mr. Gilson is Mr. Olson? A: That is correct. Q: Mr. Olson and Mr. Gilson and Mr. Allenbaugh were all co-employees, correct? A: That is correct. Q: None of them were supervisors or officers of the company? A: That is correct.

In any event, Bersie did not prove Allenbaugh's status as a supervisor; but even if true, he is without doubt not Bersie's supervisor, and an unrelated supervisor is no different than a co-employee for purposes of making the employer aware of sexual acts. And certainly, acts of sexual harassment of co-employees cannot be attributed to the employer, and step 5 is so designed to prevent it. One can imagine on an assembly line the number of lawsuits a company would have to face if it was directly responsible for acts of co-employees toward each other.

LANSING, Judge (dissenting).

The record compels a finding that Jane Bersie was subjected to sexual harassment in violation of the Minnesota Human Rights Act. As a woman, Bersie was clearly a member of a class protected by the Act. Minn.Stat. § 363.03, subd. 1(2)(c) (1982). Moreover, despite the opinion's weak characterization of the facts, the record conclusively indicates that Bersie was subject to sexual harassment. Accordingly, the trial court's judgment should be reversed and the case should be remanded for a new trial.

Sexual harassment includes

*293 unwelcome * * * sexually motivated physical contact or other verbal or physical conduct or communication of a sexual nature when * * * that conduct or communication has the purpose or effect of substantially interfering with an individual's employment * * * or creating an intimidating, hostile, or offensive employment * * * environment.

Minn.Stat. § 363.01, subd. 10(a). To state that "Bersie's problems were personal problems unrelated to her status as a female employee" is to ignore the language of the Act. Under the statute, the issue is whether Bersie was subjected to sexual harassment, not whether this harassment was her primary employment problem.

The record evidences a number of acts of harassment. A Zycad supervisor[1] suggested that Bersie may have been hired only because she was a woman, and asked her why she didn't just become a prostitute for a living. Bersie v. Zycad Corporation, 399 N.W.2d 141, 142 (Minn.Ct.App.1987) (Bersie I). Calling these remarks a "failed attempt at humor" does not negate their sexually harassing character. The Act does not contain an exception for derogatory remarks that are intended to be funny, and creating such an exception here would substantially destroy the Act's purpose of protecting women from offensive conduct affecting employment conditions.

That same Zycad supervisor also participated in an incident in which he and two other employees suggested that Bersie's relationship with a customer was sexual and analogized it to prostitution on behalf of the company. Id. at 143. In addition, a Zycad founder and executive decorated an employee cubicle with pictures of nude women; although the company president saw the pictures in the morning, he did not call them inappropriate until midday and did not direct their removal. The company executive who put up the pictures also failed to intervene and appeared to approve when one of Bersie's male co-employees initiated unwelcome physical contact with Bersie and called her and other female employees "sweetheart" and "doll." Id.

A number of other incidents, set forth in Bersie I, such as turning off the computer, giving Bersie the runaround on projects and blocking her entrance to the laboratory, are less patently sexual harassment, but appear to derive from the same motives, particularly as some of them were perpetrated by the same supervisor who had made the sexually

derogatory comments. Whether or not the performance issues resulted from this atmosphere, these incidents establish that Bersie was subjected to repeated, unwelcome physical and verbal conduct based on her sex, and this conduct was sufficiently pervasive to create an abusive working environment. Compare Minneapolis Police Department v. Minneapolis Commission on Civil Rights, 402 N.W.2d 125, 131 (Minn.Ct.App. 1987), pet. for rev. granted (Minn. May 18, 1987). I cannot agree with the trial court's characterization of these events as "good-natured give and take banter that is part of any working environment."

The opinion is misleading in its characterization of Bersie I as limited to the adequacy of the findings. While the issue was framed that way, Bersie I actually centered on the adequacy of the trial court's analysis of the evidence. As Bersie I notes, a prima facie case of harassment can be established by "showing the `bare essentials' of discrimination or harassment, merely `sufficient' evidence to create the inference of unequal treatment." Id., 399 N.W.2d at 145 (citing Danz v. Jones, 263 N.W.2d 395, 399-400 (Minn.1978)).

In this case, Bersie showed at least the "bare essentials" of harassment. Uncontradicted evidence established a number of overtly sexual incidents in addition to the less patently sexual harassment to which Bersie was subjected. Nonetheless, the majority upholds the trial court's finding *294 that no prima facie case was established because this harassment did not substantially interfere with Bersie's employment or create an abusive working environment. The majority's analysis, however, focuses not on whether the harassment created an abusive environment, but rather on whether the abusive environment could have a legitimate business justification.[2] This analysis improperly places the burden on the plaintiff to prove, as part of her prima facie case, that no legitimate cause for work problems might exist.

The determination whether harassment created a hostile working environment should properly focus on the nature of the harassment rather than on other work problems. See, e.g., Moylan v. Maries County, 792 F.2d 746, 749-50 (8th Cir.1986) (sustained and nontrivial harassment sufficient to create hostile environment); Katz v. Dole, 709 F.2d 251, 254-55 (4th Cir.1983) (evidence of a "pattern of personally directed sexual insult and innuendo" sufficient to show offensive and hostile working environment); Rogers v. E.E.O.C., 454 F.2d 234, 238 (5th Cir.1971) (mere utterance of a single racial epithet would not sufficiently affect environment to support a harassment claim), cert. denied, 406 U.S. 957, 92 S. Ct.

2058, 32 L. Ed. 2d 343 (1972); Klink v. Ramsey County, 397 N.W.2d 894, 901-02 (Minn.Ct.App.1986), pet. for rev. denied (Minn. Feb. 13, 1987) (sporadic exposure to foul language and vulgar materials not directed specifically at the plaintiff not sufficiently severe or pervasive).

Unlike the isolated incident referred to in Rogers, Bersie was subjected to repeated sexually derogatory and offensive behavior. Unlike Klink, the offensive behavior was directed specifically at her. Where sustained and nontrivial sexual harassment is shown, the degree to which other factors may have influenced working conditions is irrelevant to the establishment of a prima facie case. Bersie has met her burden of showing that the acts of sexual harassment created an abusive working environment. The record in this case requires such a finding.

The record also establishes the final element of a sexual harassment claim: that Zycad knew or should have known of the harassment. The Supreme Court in Meritor declined to state a definitive rule on the question of employer liability for harassment by supervisors which creates a hostile working environment. Meritor Savings Bank, FSB v. Vinson, 477 U.S. 57, ___, 106 S. Ct. 2399, 2408, 91 L. Ed. 2d 49 (1986). Under Minnesota law, an employer will be liable if it knows or should have known of the harassment. Minn.Stat. § 363.01, subd. 10a(3); Continental Can Company, Inc. v. State, 297 N.W.2d 241, 249 (Minn. 1980).

A Zycad supervisor and a company executive were not only aware of, but perpetrated, offensive conduct. In March 1983 Bersie told her supervisor that she was treated disrespectfully, but he did not investigate her complaint or ask for any examples. According to Bersie, whenever she went to Horsager with a problem, he would tell her to handle it herself. Where acts of harassment are perpetrated by supervisory agents of an employer in the context of the work environment, the fact that no formal complaint was made to Bersie's immediate supervisor should not insulate the employer, particularly if the employer has not established an express policy against sexual harassment or any procedure for resolving harassment claims.[3]See Meritor, 477 U.S. at ___, 106 S. Ct. at 2408.

*295 The record cannot support the trial court's finding that Bersie failed to establish a prima facie case of sexual harassment based on her sex. The absence of a formal

complaint in these circumstances does not relieve Zycad of liability for these acts. Zycad did not advance, and it would be impossible to construct, a legitimate business motivation for the offensive conduct.

A showing of constructive discharge or other adverse economic impact is not required to maintain a sexual harassment suit. Id. at ___, 106 S. Ct. at 2406. Nonetheless, the trial court's finding that Bersie failed to establish a prima facie case of sexual harassment likely influenced its finding on constructive discharge, and the case should be remanded for a new trial on that issue as well.

NOTES

[1] Although this court suggested Bersie had made a prima facie showing of sex discrimination, the issue on appeal was limited only to whether the trial court's findings were adequate. See Bersie, 399 N.W.2d at 144.

[2] The dissent suggests that this opinion's characterization of the facts is weak. However, a substantial portion of the record deals only with Bersie's job performance and the difficulties she was experiencing while trying to complete tasks which required sophisticated skills she did not necessarily possess. Moreover, according to a letter from Bersie's attorney sent almost three weeks after Bersie's termination, Bersie "reluctantly decided that her sex was a significant factor in the [termination] decision," only after she could not discern other reasons for her termination or her employer's "actual motivation." According to the Human Rights Act, sexual harassment must "substantially" interfere with an individual's employment. See Minn. Stat. § 363.01, subd. 10a(3).

[1] The majority refers to Allenbaugh merely as an "employee," presumably relying on Bersie's general testimony that Allenbaugh, Olson and Gilson were "co-employees." However, Harley Horsager testified in his deposition that Allenbaugh was "responsible for" marketing and demonstrations and at least one other employee "reported to" Allenbaugh. At trial Horsager stated specifically that Allenbaugh "supervised one person at the time."

[2] Although the majority emphasizes Bersie's inability to perform "certain technical tasks," her supervisor never really criticized her work and told her an engineering degree was not

required for her job. She was given a bonus just before she left, and company president Offerdahl publicly commended her in July 1983. The record is not at all conclusive on the extent to which her employment problems resulted from gender-related harassment as opposed to "lack of the requisite technical skills." Her supervisor stated that her work for him at National Computer Systems before they both joined Zycad had been good, timely and accurate and that he was not aware that she had any problems with her co-employees there.

[3] According to Zycad president Offerdahl, Zycad has an "unwritten policy" of treating its employees fairly.

4G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ■ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M P02987	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ■ Non-Publicly Traded (complete sections 1, 2, **3**, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Sleep Data Holdings, LLC dba BetterNight

MDEG Physical Address: 5471 Kearny Villa Rd Suite 200

City: San Diego State: CA Zip: 92123

Mailing Address (if different from physical address): N/A

City: State: Zip:

Telephone: 866-801-9440 Website: betternight.com

Email: dme-licensing@betternight.com

Name of MDEG Administrator (NAC 639.694): Robert Bovee

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions ☐ Pharmacies[a] ☐ Practitioners[a] ☐ Hospitals/Clinics[a] ☐ Clinics[a] ☐ Wholesalers[a] ☐ Other business entities (specify)[a]:	☐ Medical Gases** ■ Respiratory Equipment** ☐ Life-sustaining equipment** ☐ Parenteral and Enteral Equipment** ☐ Assistive Equipment ☐ Diabetic Supplies ☐ Orthotics and Prosthetics ☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription. [a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954): Name: BetterNight Telephone: 866-801-9440

Check the Days the Business will be Opened and provide the Hours of Operation				
▣ Mon: 8am to 5pm	▣ Tue: 8am to 5pm	▣ Wed: 8am to 5pm	▣ Thurs: 8am to 5pm	▣ Fri: 8am to 5pm
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed on major holidays		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
6615780003, 6615780004, 6615780005, 6615780006, 6615780007, 6615780008, 6615780009, 6615780010
1144767542, 9000203704, 003280072A, 006553, IDTPID020631, 300081232, 2576330, 551050300, 110195703B,
200022340, 1002679050, 3146807, 0874612, 63158337, 0474887, 500815636, 103828137-0001, DM1699, 461504901,
30017729900001, 100232650, 234408400, 080133, 2223457

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Sleep Data Services LLC (new owner)

Corporation/Organization Name: Sleep Data Holdings, LLC dba BetterNight

Mailing Address: 5471 Kearny Villa Rd Suite 200

City: San Diego State: CA Zip: 92123

Telephone: 866-801-9440 Email: dme-licensing@betternight.com

Contact Person Name: Roseanne Rodriguez 866-801-9440 ext 2213 rrodriguez@betternight.com

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List of all Officers and Directors.	✓	✓		
• List of all general and limited partner names and their percent ownership (NAC 639.6942).			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient.** The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roseanne Rodriguez

Print Name of Authorized Person Submitting Application

Roseanne Rodriguez

Original signature of Authorized Person (copies or stamps not accepted)

05/14/2025

Date

Board Use Only	Date Received: _____ Amount: _____

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 8/2/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Marsh & McLennan Agency LLC Marsh & McLennan Ins. Agency LLC PO Box 85638 San Diego CA 92186 License#: 0H18131	CONTACT NAME: Tamara Thrasher PHONE (A/C, No, Ext): 858-200-9261 FAX (A/C, No): 858-452-7530 E-MAIL ADDRESS: tamara.thrasher@MarshMMA.com
INSURED Sleep Data Holdings, LLC 5471 Kearny Villa Rd Suite 200 San Diego CA 92123 SLEEPDATA1	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A : Hanover Insurance Company — 22292 INSURER B : Hartford Fire Insurance Company — 19682 INSURER C : The Hanover Atlantic Insurance Co Ltd — 55555 INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** 226528811 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
C	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR X 5,000 GEN'L AGGREGATE LIMIT APPLIES PER: POLICY [ ] PRO-JECT [ ] LOC OTHER:	N		L33H70694604	8/1/2024	8/1/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 100,000 $ 10,000 $ 1,000,000 $ 3,000,000 $ 3,000,000 $
A	AUTOMOBILE LIABILITY X ANY AUTO ALL OWNED AUTOS SCHEDULED AUTOS HIRED AUTOS NON-OWNED AUTOS			AW3H70603303	8/1/2024	8/1/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) Comp & Coll Ded.	$ 1,000,000 $ $ $ $ $1,000
C	UMBRELLA LIAB [X] OCCUR X EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $			L33H70694604	8/1/2024	8/1/2025	EACH OCCURRENCE AGGREGATE $	$ 5,000,000 $ 5,000,000 $
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [ ] N/A **(Mandatory in NH)** If yes, describe under DESCRIPTION OF OPERATIONS below			72WECAP3ADH	12/1/2023	12/1/2024	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ 1,000,000 $ 1,000,000 $ 1,000,000
C	Professional Liability Retro Date 12/1/05			L33H70694704	8/1/2024	8/1/2025	Each Occurence Aggregate Deductible	1,000,000 3,000,000 5,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Sleep Data Holdings, LLC
Including all the following Locations:
*5471 Kearny Villa Rd, Ste 200,
San Diego, CA 92123-1143
*488 E. Valley Parkway, Ste 105
Escondido, CA 92025 -3365
*1415 Ridgeback Rd. Ste 1
Chula Vista, CA 91910-6983
See Attached...

CERTIFICATE HOLDER

Proof of Coverage

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



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Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	SLEEP DATA HOLDINGS, LLC
Entity No.:	201118210119
Registration Date:	07/01/2011
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of January 10, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 283630927

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

Appendix G: Officers/Board Members/Stockholders/Trustees

Officers

Dave French, Chief Executive Officer - only individual with 10% or greater ownership
Member of the Executive team of Sleep Data Services LLC

Business Address:
5471 Kearny Villa Rd. Suite 200
San Diego, CA 92123

Home Address:
[redacted]

Bretton Lane, President/Chief Operating Officer
Member of the Executive team of Sleep Data Services LLC

Business Address:
5471 Kearny Villa Rd. Suite 200
San Diego, CA 92123

Home Address:
[redacted]

Julie Meyer, Chief Financial Officer
Member of the Executive team of Sleep Data Services LLC

Business Address:
5471 Kearny Villa Rd. Suite 200
San Diego, CA 92123

Home Address:
[redacted]

Dr. Dominic Munafo, Chief Medical Officer
Member of the Executive team of Sleep Data Services LLC

Business Address:
5471 Kearny Villa Rd. Suite 200
San Diego, CA 92123

Home Address:
[redacted]

David Guthrie, Chief Technology Officer
Member of the Executive team of Sleep Data Services LLC

Business Address:
5471 Kearny Villa Rd. Suite 200
San Diego, CA 92123

Home Address:
[redacted]

Ownership Interest: 0.18% - pH not needed

Dr. Edward Sall, Medical Director
Member of the Executive team of Sleep Data Services LLC

Business Address:
5471 Kearny Villa Rd. Suite 200
San Diego, CA 92123

Home Address:
[redacted]

Board Members:

Dave French

Business Address:
5471 Kearny Villa Rd. Suite 200
San Diego, CA 92123

Home Address:
[redacted]

Occupation/Relationship:
Chief Executive Officer, Member of the Board of Directors

Mike Caplan (NewSpring)

Business Address:
555 E. Lancaster Ave, 3rd Floor
Randor, PA 10987

Home Address:
[redacted]

Occupation:
Partner, NewSpring Capital

Relationship:
Member of the Board of Directors

Hope Mago (HCAP)

Business Address:
4250 Executive Square Ste 500
San Diego, CA 92037

Home Address:
[redacted]

Occupation: Partner at HCAP Partners

Relationship:
Member of the Board of Directors

David Helgerson (Hamilton Lane)

Business Address:
110 Washington Street, Suite 1300
Conshohocken, PA 19428

Home Address:
[redacted]

Occupation:
Managing Director at Hamilton Lane

Relationship:
Member of the Board of Directors

Sam De Brouwer

Business Address:
255 East Paces Ferry Rd,
Atlanta, GA 30305

Home Address:
[redacted]

Occupation:
Entrepreneur

Relationship:
Member of the Board of Directors

STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

HOME MEDICAL DEVICE RETAIL LICENSE

Sleep Data Holdings, LLC
DBA: BetterNight
5471 Kearny Villa Road,Suite #200
San Diego, CA 92123

LICENSE NUMBER: 95423
EXPIRATION DATE: 2/3/2026

The person named herein is licensed to operate a Home Medical Device Retail Facility through the expiration date of this license. This annual license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee shall be responsible for assuring compliance with all requirements of this article pertaining to Home Medical Device Retail Facilities.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

Printed: 1/8/2025

OSP 07 102308

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Sleep Data Holdings, LLC dba BetterNight

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) MP02987

Physical Address 5471 Kearny Villa Rd Suite 200

City San Diego State CA Zip 92123

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 866-801-9440 Website www.BetterNight.com

Licensing Company Email dme-licensing@betternight.com

Section 2: Personal Information

First David Middle Dale Last French

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City La Jolla State CA Zip [redacted]

Telephone [redacted] Email dfrench@betternight.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.173)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri		09/78 - 05/82	
Address	**City**	**State**	**Zip**
230 Jesse Hall	Columbia	MO	65211
Diploma/Degree obtained, if any			
BSBA in Accounting			

School Name		From - To (MM/YY – MM/YY)	
Warsaw High School		09/74 - 05/78	
Address	**City**	**State**	**Zip**
20363 Lane of Champions	Warsaw	MO	65355
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/25 - Present	[redacted]	La Jolla	CA	[redacted]
06/22- 11/25		La Jolla	CA	
01/15 - 06/22		San Diego	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7. Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Sleep Data Holdings, LLC dba BetterNight			07/11 - Present
Business Address	**City**	**State**	**Zip**
San Diego	San Diego	CA	92123
Phone	**Title**		
866-801-9440	CEO and Former Owner		
Description of Duties			
CEO - oversees business needs and growth of the organization			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

03/28/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David French

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/28/25

Date

Please have this section completed in the presence of a Notary Public.

State of CALIFORNIA, ss. County of San Diego

I, David French, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/28/25

Date

Subscribed and Sworn to before me this 28 day of March.

Notary Public Signature

ROSEANNE MARIA RODRIGUEZ
Notary Public - California
San Diego County
Commission # 2361321
My Comm. Expires Jun 15, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Sleep Data Holdings, LLC dba BetterNight MDEG License # (if applicable) MP02987

Physical Address 5471 Kearny Villa Rd Suite 200

City San Diego State CA Zip 92123

Mailing Address (if different from physical address) N/A

City _____ State _____ Zip _____

Telephone 866-801-9440 Website www.betternight.com

Licensing Company Email dme-licensing@betternight.com

Section 2: Personal Information

First Robert Middle Vernon Last Bovee

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City San Marcos State CA Zip [redacted]

Telephone [redacted] Email rbovee@betternight.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Capella University		09/92 - 05/93	09/16 - 05/17
Address	**City**	**State**	**Zip**
225 South 6th St	Minneapolis	MN	55402
Diploma/Degree obtained, if any			
BS in Business Administration			

School Name		From - To (MM/YY – MM/YY)	
North High School		09/1988 - 05/91	
Address	**City**	**State**	**Zip**
1101 East Thomas Rd	Phoenix	AZ	85014
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/15 - Present	[redacted]	San Marcos	CA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
02/11 - 03/15		San Marcos	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
SLEEP DATA HOLDINGS, IIC DBA BETTERNIGHT			06/2020 - Present	
Business Address		City	State	Zip
5471 Kearny Villa Rd Suite 200		San Diego	CA	92123
Phone	Title		Number of Employed Hours	
866-801-9440	VP OF OPERATIONS		1500	

Description of Duties: Partners with the COO to build and implement operating plans for the clinical, customer service, distribution, and resupply team. Responsible for collaboration with cross functional departments to ensure that the company's financial goals are met. Identifies and implements technological and procedural improvements to ensure that our customers' expectations are met in an efficient and cost effective manner

Business Name			From - To (MM/YY – MM/YY)	
APRIA HEALTHCARE			07/2016 - 05/2020	
Business Address		City	State	Zip
9115 Activity Rd		San Diego	CA	92126
Phone	Title		Number of Employed Hours	
888-492-7742	General Manager		1500	

Description of Duties: Manage the Sales and Operations for the San Diego marketplace through two locations consisting of 8 direct and 51 indirect reports. Prepare and execute the yearly financial budgets and sales targets for the marketplace. Create and maintain relationships with key referrals through the sales team. Develop and implement distribution strategy for the market to achieve service goals at the lowest cost. Execute contracts with local health plans.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties: -

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties:

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	

Description of Duties:

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

03/28/2025
Date

I, Robert Bovee, **certify that as the MDEG Administrator for**

Sleep Data Holdings, LLC dba BetterNight,

that I (initial that you have read and meet the following requirements):

1. RB Have a high school diploma or its equivalent;
2. RB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Bovee
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/28/2025
Date

Board Use Only	Date Received:

Nevada State Board Of Pharmacy

(Firm mailing address for window envelope)

THIS STUB IS YOUR RECEIPT

Date: 10/10/2022
Amount: $ 525.00
Permit #: MP02987

Sleep Data Holdings, LLC
5471 Kearny Villa Rd #200
San Diego CA 92123

(ID Card)

NEVADA STATE BOARD OF PHARMACY

Medical Devices, Equipment, Gas
Effective Date:11/01/2022
Expires:10/31/2024

Sleep Data Holdings, LLC
5471 Kearny Villa Rd #200
San Diego CA 92123

Permit #
MP02987
Active

IDENTIFICATION ONLY
DOES NOT MEET POSTING REQUIREMENTS

Trim ID Card to fit your wallet

Cut Here

NEVADA
STATE BOARD OF PHARMACY
Medical Devices, Equipment, Gas

THE UNDER-NOTED HAVING PAID STATUTORY FEE IS HEREBY LICENCED

Expires: 10/31/2024
STATUS: Active

Permit Type: Medical Devices, Equipment, Gas
Permit #: MP02987
Effective Date: 11/01/2022

Sleep Data Holdings, LLC
5471 Kearny Villa Rd #200
San Diego CA 92123

NONTRANSFERABLE

POST THIS PERMIT PROMINENTLY IN A CONSPICUOUS PLACE

4H

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	☒ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☐ New MDEG ☒ Ownership Change* ☐ Name Change* ☐ Location Change*	* If making a change, provide current license number: M PQ0799	☒ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9) ☐ Partnership (complete sections 1, 2, 3, 4, 7, 9) ☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Vantive US Healthcare LLC

MDEG Physical Address: 7511 114th Avenue North

City: Largo State: FL Zip: 33773

Mailing Address (if different from physical address): 7000 Cardinal Pl, QRA

City: Dublin State: OH Zip: 43017

Telephone: _____ Website: _____

Email: licensure@cardinalhealth.com

Name of MDEG Administrator (NAC 639.694): Michele Preston

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☒ Hospitals/Clinics[a]	☒ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☒ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
☐ Mon: 7am-12am	☐ Tue: 7am-12am	☐ Wed: 7am-12am	☐ Thurs: 7am-12am	☐ Fri: 7am-12am
☐ Sat: Closed	☐ Sun: Closed	☐ Holidays: Closed		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(l))

N/A

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Vantive Health LLC
Corporation Name: Vantive US Healthcare LLC
Mailing Address: One Baxter Parkway
City: Deerfield State: IL Zip: 60015
Telephone: 224.948.2000 Email: licensure@cardinalhealth.com
Contact Person Name: LaTonya Martin

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 8: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LaToya Martin

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01/09/2025

Date

Board Use Only	Date Received: 3/4/25	Amount: $500-CC

Vantive US Healthcare, LLC Disclosures

There are no relevant disciplinary actions taken against the applicant corporation Vantive US Healthcare, LLC ("Vantive US") or the facility related to the license. Vantive US is a subsidiary of Baxter Healthcare Corporation, which in turn is a subsidiary of Baxter International Inc., a publicly traded company listed on the New York Stock Exchange with tens of thousands of employees world-wide. For purposes of transparency, we are providing disclosures pertaining to state disciplinary actions and charges against Baxter Healthcare Corporation. Additional information regarding specific Vantive US or Baxter Healthcare Corporation facilities (e.g., inspection history) can be found on the FDA website.

State Pharmacy License Disciplinary Actions

Utah, License # 12435996-1710, 2023

On February 17, 2023, The Utah Board of Pharmacy issued a citation for failure to timely notify the Board of the change in designated representative at the Baxter Byhalia, MS location. Baxter paid the fine and is waiting for the final signed order.

Utah, Pharmacy Class C License # 9451291-1710, 2022

On May 31, 2022, The Utah Department of Commerce issued a Citation and Order due to a failure to file a timely notification of the change in the designated representative at the Baxter - Hayward (W. Winton) location. Baxter resolved the matter and paid a reduced fine.

Idaho, Out of State Mail Service Pharmacy License # 36855MS, 2022

On March 3, 2022, The Idaho Board of Pharmacy issued an Order and Stipulation for violations stemming from an expired non-resident PIC registration. The registration has since been approved by the Board. Baxter has signed the Stipulation and paid the required fine.

Alabama, Permit #194460, 2022

On May 3, 2022, The Alabama Board of Pharmacy issued a citation for failure to notify the Board of the change in designated representative at the Baxter – Hayward (W. Winton location). Baxter resolved the matter and paid the required fine.

Georgia, Wholesaler Pharmacy License # PHWH001754, 2017

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling,

and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice. This issue is unrelated to Baxter's pharmacy or wholesale activities.

Baxter disclosed this issue on a renewal application for a Georgia wholesale license for its Marion, NC facility, and in October 2017, the state of Georgia issued a disciplinary order against that license (PHWH001754) based on the disclosure.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities.

Iowa, Nonresident Pharmacy License # 4127, 2014

The Iowa Board of Pharmacy (the "Iowa Board") issued a Stipulation for Baxter's Omaha, Nebraska pharmacy due to improperly delegating final verification of prescriptions for peritoneal dialysis solutions to a pharmacy technician. The Omaha facility is licensed in Nebraska under a Delegated Dispensing Permit, and utilized multiple quality checks, including retrospective pharmacist review, to ensure proper dispensing of peritoneal dialysis products to patients. Upon request by the Iowa Board, Baxter promptly modified its operations to ensure pharmacist verification of all orders. Baxter has signed the Stipulation and paid the required fine.

Montana, License #2152, 2010

The Montana Board of Pharmacy (the "Montana Board") issued a Stipulation for violations stemming from the failure of Baxter to notify the Montana Board in the requisite time frame of a change in the designated Person-in-Charge for the Waukegan, IL facility. Baxter has signed the Stipulation and paid the required fine.

Alabama, License #191639, 2009

The Alabama Board of Pharmacy found the Buford, GA facility was in violation of Code of Alabama (1975) Section 34-23-32. The facility continued distribution operations during the time between the valid license expired and when the expired license was renewed. Baxter Healthcare renewed the license, signed a Consent Order and paid the applicable fine.

Florida, Non-Resident Drug Manufacturer Permit No.: 26:4672, 2009

The Florida Department of Health (the "Florida Department") alleged that Baxter (Memphis, TN) sold prescription drugs to an unpermitted facility in Florida in violation of Section 499.005(15), F.S. Specifically, the Florida Department alleged that Baxter sold prescription drugs to Invivo at an unpermitted location. Baxter entered into a settlement agreement, whereby it neither admitted nor denied the allegations, and paid a fine.

Louisiana, License #3691, 2008

Louisiana Board of Wholesale Drug Distributors conducted a routine inspection of the facility operated by Baxter's third party logistics provider. Inspectors concluded Baxter (Round Lake, IL) violated Louisiana Administrative Code 46:XCI.311.D, which requires a licensee to maintain copies of current licenses for its customers who are authorized to obtain and possess legend drugs and devices. Baxter obtained customer licenses, signed a Consent Order, and paid the applicable fine.

Missouri, License #2005002668, 2005

The Missouri Board of Pharmacy (the "Missouri Board") issued a restricted drug distributor license to the facility located in Memphis, TN. The Missouri Board determined the facility violated Section 338.333.1 and 338.337.1 RSMo because the facility shipped legend drugs and/or medical devices into the state without being properly licensed. The proper license was obtained. The probationary period was successfully completed on October 21, 2007 and the restriction on the license was removed.

State Non-Disciplinary Settlements for Memphis Facility

Florida, License #s 26:506 (Memphis, TN) and 26:384 (Marion, NC), 2015

In June 2015, the Florida Department of Business and Professional Regulation (the "Department") sent Notices of Violation to Baxter alleging the shipment of prescription drugs to a Baptist Health South Florida, Inc. ("Baptist"), prior to Baptist receiving its permit to operate as a restricted prescription drug distributor – health care entity. Baxter had shipped products to the Baptist address under the valid medical license of the Medical Director, in reliance on a document evidencing the Medical Director's intent that he serve as the purchaser of the product. In August 2015, Baxter and the Department resolved this matter via a non-disciplinary settlement.

Other Actions: Dismissed Charge of Drug Law Violation

In January 2017, Baxter Healthcare Corporation (Baxter) agreed to resolve claims with the U.S. Department of Justice related to quality and manufacturing practices at Baxter's manufacturing facility in Marion, North Carolina in 2011-2012. Specifically, the government charged that between July 2011 and November 2012, Baxter did not follow cGMP requirements under the Federal Food, Drug, and Cosmetic Act (FDCA) when manufacturing certain large volume intravenous (IV) solutions. Briefly, a Baxter employee reported to plant personnel the presence of mold on HEPA filters installed in the ceiling, and Baxter continued to manufacture IV solutions while those filters remained in place. There was no evidence of any impact on the IV solutions. Copies of the settlement documents, which include a deferred prosecution agreement to resolve a single misdemeanor count of noncompliance with the FDCA, are available on the U.S. Department of Justice's website at https://www.justice.gov/opa/pr/baxter-healthcare-corporation-pay-more-18-million-resolve-criminal-and-civil-liability. The deferred prosecution agreement expired in July 2019, and the misdemeanor charge was dismissed with prejudice.

Please note that this issue is unrelated to Baxter's pharmacy or wholesale activities, or the facility that is the subject of this application.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 04/25/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 16th Floor Philadelphia PA 19103 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Vantive US Healthcare LLC 1 Baxter Parkway Building 6 Deerfield IL 60015 USA	INSURER A: ACE American Insurance Company	22667
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570112264092 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			XSLG48932629	01/31/2025	01/31/2026	EACH OCCURRENCE	$1,900,000
	X CLAIMS-MADE ☐ OCCUR			SIR applies per policy terms & conditions			DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,900,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,900,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$4,000,000
	☐ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	Excluded
	OTHER:							
A	AUTOMOBILE LIABILITY			ISA H11355122	01/31/2025	01/31/2026	COMBINED SINGLE LIMIT (Ea accident)	$5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	
	☐ DED ☐ RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			WLRC72616443	01/31/2025	01/31/2026	X PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N N/A						E.L. EACH ACCIDENT	$1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance.

CERTIFICATE HOLDER

Vantive US Healthcare, LLC
7511 114th Avenue North
Largo FL 33773 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570112264092

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Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "VANTIVE US HEALTHCARE LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE NINTH DAY OF DECEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "VANTIVE US HEALTHCARE LLC" WAS FORMED ON THE NINTH DAY OF OCTOBER, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2462830 8300

SR# 20244426062

Authentication: 205068039

Date: 12-09-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Image not found or type unknown
Cardinal Health

7511 114th Avenue North
Largo, Florida 33773

Officer Name	Title	Percentage of Ownership
Karen L. Leets	Vice President and Treasurer	0%
James William Borzi	EVP, Chief Supply Chain Officer	0%
Ellen K. Bradford	SVP and Corporate Secretary	0%
Daniel James Speciale	VP, Controller – Kidney Care	0%
Christopher Martin Jones	Vice President and Chief Financial Officer	0%

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/index.html (https://www.floridahealth.gov/statistics-and-data/e-forcse/index.html).

- File Transfer Protocol

(http://www.myfloridalicense.com/DBPR/)

— **Division of Drugs, Devices and Cosmetics**

Does my company need a permit?

DDC permitting requirements as regards drugs, (medical) devices and cosmetics fall into two main categories:(a) manufacturing and repackaging of drugs, medical devices and cosmetics conducted in Florida, and (b) distributing drugs, medical devices and cosmetics in and into Florida.

Activity Description	Location	Permit (Generally) Required under Chapter 499?
Manufacturing a Drug, Device or Cosmetic	In Florida	Yes
Repackaging a Drug, Device or Cosmetic	In Florida	Yes
Distributing a Prescription Drug	In or Into Florida	Yes
Distributing an Over-the-Counter Drug	In or Into Florida	No
Distributing a Device	In or Into Florida	No
Distributing a Cosmetic	In or Into Florida	No

- What is a "drug", "device", or "cosmetic"?

Refer to Section 499.003, Florida Statutes: http://www.leg.state.fl.us/statutes /index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections /0499.003.html (http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute& Search_String=&URL=0400-0499/0499/Sections/0499.003.html) Please note that "drug"

Select Year: 2023 Go

The 2023 Florida Statutes

Title XXXIII
REGULATION OF TRADE, COMMERCE, INVESTMENTS, AND SOLICITATIONS

Chapter 499
FLORIDA DRUG AND COSMETIC ACT

View Entire Chapter

499.015 Registration of drugs and devices; issuance of certificates of free sale.—

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(2) The department may require the submission of a catalog and specimens of labels at the time of application for registration of drugs or devices packaged and prepared in compliance with the federal act, which submission constitutes a satisfactory compliance for registration of the products. With respect to all other drugs and devices, the department may require the submission of a catalog and specimens of labels at the time of application for registration, but the registration will not become effective until the department has examined and approved the label of the drug or device. This approval or denial must include written notification to the manufacturer.

(3) Except for those persons exempted from the definition of manufacturer in s. 499.003, a person may not sell any product that he or she has failed to register in conformity with this section. Such failure to register subjects such drug or device to seizure and condemnation as provided in s. 499.062, and subjects such person to the penalties and remedies provided in this part.

(4) Unless a registration is renewed, it expires 2 years after the last day of the month in which it was issued. Any product registration issued or renewed on or after July 1, 2016, shall expire on the same date as the manufacturer or repackager permit of the person seeking to register the product. If the first product registration issued to a person on or after July 1, 2016, expires less than 366 days after issuance, the fee for product registration shall be $15. If the first product registration issued to a person on or after July 1, 2016, expires more than 365 days after issuance, the fee for product registration shall be $30. The department may issue a stop-sale notice or order against a person that is subject to the requirements of this section and that fails to comply with this section within 31 days after the date the registration expires. The notice or order shall prohibit such person from selling or causing to be sold any drugs or devices covered by this part until he or she complies with the requirements of this section.

(5) A product regulated under this section which is not included in the biennial registration may not be sold until it is registered and complies with this section.

(6) The department may issue a certificate of free sale for any product that is required to be registered under this part.

(7) A product registration is valid only for the company named on the registration and located at the address on the registration. A person whose product is registered by the department under this section must

notify the department before any change in the name or address of the establishment to which the product is registered. If a person whose product is registered ceases conducting business, the person must notify the department before closing the business.

(8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; or

(b) The manufacturer subcontracts with a manufacturer of medical devices to manufacture components of such devices.

(9) However, the manufacturer must submit evidence of such registration, listing, or approval with its initial application for a permit to do business in this state, as required in s. 499.01, and any changes to such information previously submitted at the time of renewal of the permit. Evidence of approval, listing, and registration by the federal Food and Drug Administration must include:

(a) For Class II devices, a copy of the premarket notification letter (510K);

(b) For Class III devices, a federal Food and Drug Administration premarket approval number;

(c) For a manufacturer who subcontracts with a manufacturer of medical devices to manufacture components of such devices, a federal Food and Drug Administration registration number; or

(d) For a manufacturer of medical devices whose devices are exempt from premarket approval by the federal Food and Drug Administration, a federal Food and Drug Administration registration number.

History.—s. 34, ch. 82-225; s. 110, ch. 83-218; s. 1, ch. 83-265; s. 3, ch. 84-115; ss. 20, 52, ch. 92-69; s. 587, ch. 97-103; s. 36, ch. 98-151; s. 1, ch. 99-165; s. 41, ch. 2000-242; s. 12, ch. 2000-326; s. 18, ch. 2001-63; s. 33, ch. 2001-89; s. 88, ch. 2004-5; s. 18, ch. 2008-207; s. 63, ch. 2009-21; s. 36, ch. 2014-89; s. 10, ch. 2016-212; s. 33, ch. 2017-3; s. 1, ch. 2017-51; s. 8, ch. 2019-99.

[1]**Note.**—

A. Section 11, ch. 2019-99, provides in part that "[i]mplementation of sections 2 through 10 of this act is contingent upon authorization granted under federal law, rule, or approval." Section 11, ch. 2019-99, was codified as s. 499.02851. Section 12, ch. 2019-99, provides that "[t]his act shall take effect July 1, 2019."

B. Subject to the contingency as to implementation in s. 11, ch. 2019-99, s. 8, ch. 2019-99, amends subsection (1), to read:

(1)(a) Except for those persons exempted from the definition of manufacturer in s. 499.003, any person who manufactures, packages, repackages, labels, or relabels a drug or device in this state must register such drug or device biennially with the department; pay a fee in accordance with the fee schedule provided by s. 499.041; and comply with this section. The registrant must list each separate and distinct drug or device at the time of registration.

(b) The department may not register any product that does not comply with the Federal Food, Drug, and Cosmetic Act, as amended, or Title 21 C.F.R. Registration of a product by the department does not mean that the product does in fact comply with all provisions of the Federal Food, Drug, and Cosmetic Act, as amended.

(c) Registration under this section is not required for prescription drugs imported under the International Prescription Drug Importation Program established in s. 499.0285.

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Vantive US Healthcare LLC. MDEG License # (if applicable) N/A
Physical Address 7511 114th Avenue North
City Largo State FL Zip 33773
Mailing Address (if different from physical address) 7000 Cardinal Pl – Attn: QRA
City Dublin State OH Zip 43017
Telephone 614.757.8789 Website N/A
Licensing Company Email licensure@cardinalhealth.com

Section 2: Personal Information

First Michele Middle Lynn Last Preston
Alias(es, nicknames, name changes, etc.) Womble
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted]
City Saint Petersburg State FL Zip [redacted]
Telephone [redacted] Email Michele_Womble@baxter.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name See Attached			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY)
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY) 12/18 - Present	[redacted]	City St. Petersburg	State FL	[redacted]
From - To (MM/YY – MM/YY) 09/18 - 12/18		City St. Petersburg	State FL	
From - To (MM/YY – MM/YY) 11/04 - 09/18		City St. Petersburg	State FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Vantive US Healthcare LLC (formerly Baxter)			From - To (MM/YY – MM/YY): 12/07-Present
Business Address: 7511 114th Ave. North	City: Largo	State: FL	Zip: 33773
Phone: 727-541-6411	Title: Multiple		Number of Employed Hours: Approx. 35,000
Description of Duties: See Attached Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

01/21/2025
Date

I, Michele Preston, **certify that as the MDEG Administrator for** Vantive US Healthcare LLC,

that I (initial that you have read and meet the following requirements):

1. MP Have a high school diploma or its equivalent;
2. MP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michele Preston
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/21/2025
Date

Board Use Only	Date Received:

Michele Preston

[redacted]

Education: AA, University of Florida, 1993
BS, Animal Science, University of Florida, 1996
Project Management Certification, St Petersburg College, 2020

Experience: **Baxter Healthcare, Largo, FL** (2024-present)
Manager II, Quality, QMR

- Manages the activities of several sections or departments in the Quality organization with responsibility for results in terms of compliance and/or product quality.
- Implements the quality systems procedures in several sections or departments and manages compliance.
- Understands and ensures conformance to regulations applicable to several sections or departments.
- May participate in or manage quality assessments of internal operations and suppliers to analyze compliance and assess risk.
- Interacts frequently with internal subordinate supervisors, functional peer and senior group managers.
- Manages interactions with regulators and auditors (FDA, Health Canada, ISO, Baxter internal/corporate) and customers to represent the company products and processes.
- Identifies and manages continuous improvement projects with the objective of achieving quality, reliability and cost improvements.
- Develops budget for several sections or departments and ensures adherence to the budget.
- Manages coaching, training and development of direct reports and team.
- Adheres to all environmental, health and safety SOP's, equipment, policies and procedures, including any department specific requirements.
- Performs other duties as assigned.
- Support commercial entities in knowledge and navigation of Quality requirements specifically as it related to the Service Organization.
- Participation/Oversite in new product launches and transfer of operations to Service

Baxter Healthcare, Largo, FL (2018-2024)
Quality Lead for U.S. Field Services

- Responsibilities include guiding the US Field team for Quality compliance.
- Monitoring training, complaint evaluations, PM timeliness, FA timeliness, Hold management, complaint trending, & management review metrics.
- Initiating and participating in projects that streamline the processes used in the field for simplification and complianco. Quality representative for new project initiatives and new product launches.
- Own and approve CAPAs and change controls. Assist in writing procedures and developing training plans.
- Guide in high- risk product complaint evaluations. Mentor field technicians in quality applications such as good documentation practices and GMP.
- Interim lead for legacy Hill-rom quality field engineers.
- Qualified lead auditor. SME for auditing for technical services group.
- Back up QMR for Largo Depot. Quality liaison between operations team in the US and manufacturing/complaint trending group in Medolla.
- Support technical specialists in executing improvement projects and communication to the field.
- Proficient in FDA and ISO 13485 regulations. Obtained Project management certification from Saint Petersburg College.

Baxter Healthcare, Largo, FL (2007-2018)

Quality Associate II

- Lead Auditor and manager of internal audit program.
- Coordinator for 483 Gap Analysis project for Baxter Tampa Bay
- Coordinator for Quality Plan activities
- Engineering Quality reviewer for the Product Analysis Lab evaluations within the complaint handling system for devices returned for service.
- Coordinator of metric analysis for Quality System elements.
- Lead Investigator trained for ownership of CAPA's. CAPA Coordinator handling the metrics and monitoring of CAPAs for timeliness and content. Facility SME (Subject Matter Expert) for CAPA elements.
- Trained for technical background of Peritoneal and Hemodialysis devices
- Train the Trainer trained.
- Lead team member for external audits of the Quality system. Coordinate management of external audits to ensure smooth and timely input.
- Owner of EMS (Enterprise Management System) elements. Help ensure lean manufacturing, timely communication of issues, and assist with improvement projects.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30235006

Application/License No. _____

VANTIVE US HEALTHCARE LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 7511 114th Avenue North Largo, FL 33773 (Address of Applicant/Principal), as PRINCIPAL, and WESTERN SURETY COMPANY (Surety Company), a corporation organized under the laws of the state of SD (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 151 N. Franklin Street Chicago, IL 60606 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 20, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of February, 2025.

APPLICANT/PRINCIPAL
VANTIVE US HEALTHCARE LLC

COMPANY

Vantive US Healthcare LLC LIMITED LIABILITY COMPANY SEAL Delaware 2023

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY
WESTERN SURETY COMPANY

Surety Company's Representative

Tara A. Maquinto, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Dafonya Wright

Witness K. Hannigan

Countersigned by:

Nevada Resident Agent Christina L. Sandoval, Non-Resident Nevada Agent

Posted February 20, 2020

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint

Sandra M Winsted, Jennifer L Jakaitis, Christopher P Troha, Derek J Elston, Susan A Welsh, Christina L Sandoval, Judith A Lucky-Eftimov, Bartlomiej Siepierski, Aerie Walton, Nicholas Pantazis, Kristin L Hannigan, Samantha Chierici, Richard Casas, Corinne Chapman, Nicholas Kertesz, Roger Paraison, Jean Torres, Dartonya Wright, Tara A Maquinto, George F Douaire V, Individually

of Chicago, IL, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the Authorizing By-Laws and Resolutions printed at the bottom of this page, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 10th day of September, 2024.

WESTERN SURETY COMPANY

Larry Kasten, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 10th day of September, 2024, before me personally came Larry Kasten, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is a Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires
March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent, Notary Public

CERTIFICATE

I, Paula Kolsrud, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Law and Resolutions of the corporation printed below this certificate are still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 20th day of February, 2025.

WESTERN SURETY COMPANY

Paula Kolsrud, Assistant Secretary

Authorizing By-Laws and Resolutions

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

This Power of Attorney is signed by Larry Kasten, Vice President, who has been authorized pursuant to the above Bylaw to execute power of attorneys on behalf of Western Surety Company.

This Power of Attorney may be signed by digital signature and sealed by a digital or otherwise electronic-formatted corporate seal under and by the authority of the following Resolution adopted by the Board of Directors of the Company by unanimous written consent dated the 27th day of April, 2022:

"RESOLVED: That it is in the best interest of the Company to periodically ratify and confirm any corporate documents signed by digital signatures and to ratify and confirm the use of a digital or otherwise electronic-formatted corporate seal, each to be considered the act and deed of the Company."

VANTIVE US HEALTHCARE LLC

POWER OF ATTORNEY

As contemplated by the resolutions adopted by the Board of Directors of Vantive US Healthcare LLC, a Delaware limited liability corporation ("the Corporation"), effective October 20, 2023 ("Resolutions"), a copy of such Resolutions is attached hereto as Exhibit A, the undersigned Matthew Rice, Assistant Secretary, an Authorized Representative of Vantive US Healthcare LLC, hereby delegates to Keegan Chamberlain, Director of Quality Management and LaToyia Martin, Manager, Quality Compliance, employees of Cardinal Health 200 LLC, the authority to sign for all documents, applications, submissions and other related instruments required for the state pharmacy, wholesale distribution, and manufacturing licenses and legally required permits filed on behalf of Vantive US Healthcare LLC.

This power of attorney shall be effective until December 31, 2024 and is subject to revocation by any officer of Vantive US Healthcare LLC at any time and shall occur automatically when Keegan Chamberlain or LaToyia Martin ceases to be an employee of Cardinal Health 200 LLC.

The undersigned further approves and ratifies any and all actions taken by Keegan Chamberlain and LaToyia Martin prior to this date, solely in connection with the execution of the above-referenced matters.

Effective: October ___, 2023

Vantive US Healthcare LLC

Matthew Rice
Assistant Secretary
Authorized Representative

EXHIBIT A

VANTIVE US HEALTHCARE LLC
MISCELLANEOUS RESOLUTIONS
Adopted October 20, 2023

VANTIVE US HEALTHCARE LLC

WRITTEN CONSENT
OF THE MANAGERS

Effective as of October 20, 2023 ("Effective Date")

THE UNDERSIGNED, being all of the managers (the "Managers") of Vantive US Healthcare LLC, a Delaware limited liability company (the "Company"), do hereby, pursuant to the provisions of Section 18-404 of the Delaware Limited Liability Company Act, approve, adopt, consent to and vote for the following actions and resolutions and each and every action effected thereby:

APPROVAL OF THE FORMATION AND FORMATION ACTIONS

****

MISCELLANEOUS

RESOLVED, that any Manager or officer of the Company, or such other individuals that the Company shall, by power of attorney or otherwise, determine to be necessary, appropriate or advisable (together, the "Authorized Representatives" and each, an "Authorized Representative"), be and each hereby is authorized, empowered and directed, acting jointly with one or more other Authorized Representatives, to do or cause to be done all things and acts, to negotiate, approve, execute, acknowledge, sign, deliver, file and perform or cause to be negotiated, approved, executed, acknowledged, signed, delivered, filed and performed on behalf of the Company any such agreements, instruments or other documents, make all filings, issue powers of attorney, and otherwise take any further action, which in the judgment of the Authorized Representatives are necessary, appropriate or advisable to consummate the foregoing resolutions and perform its obligations thereunder and otherwise to carry out and comply with the intent and purposes of the resolutions herein;

FURTHER RESOLVED, that all of the past acts and transactions of any Authorized Representative (or other representative or agent of the Company), including, but not limited to, preparation, execution, deliveries and filings of agreements, instruments, certificates and other documents in the name of and on behalf of the Company or any of its affiliates, and all fees and expenses (including taxes) incurred or paid by any Authorized Representative (or other representative or agent of the Company) having been deemed necessary, proper or advisable to carry out the intent and effectuate the purposes hereof, prior to the execution of these resolutions, taken in good faith in the name and on behalf of the Company or any of its affiliates pursuant to and consistent with the resolutions contained herein, be and hereby are consented to, adopted, authorized, approved, confirmed and ratified in all respects; and

FURTHER RESOLVED, that these resolutions may be executed in any number of counterparts, each of which when so executed and delivered shall be deemed an original, but all such counterparts

IN WITNESS WHEREOF, the undersigned have duly executed this Written Consent effective as of the Effective Date.

Christopher Toth, Manager

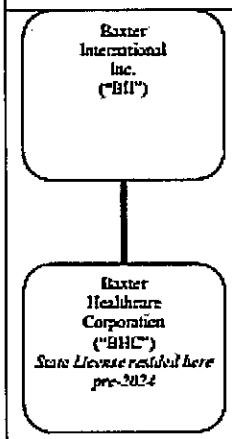
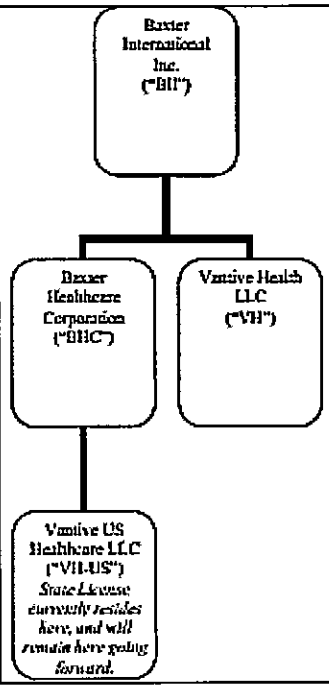
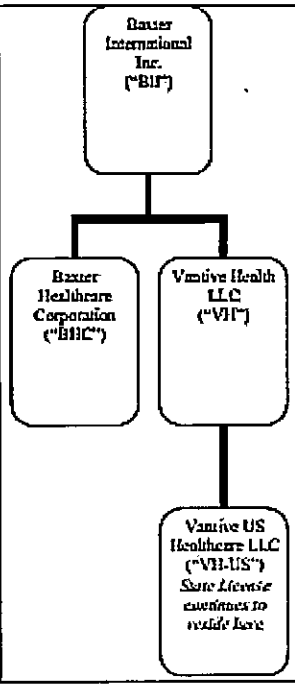
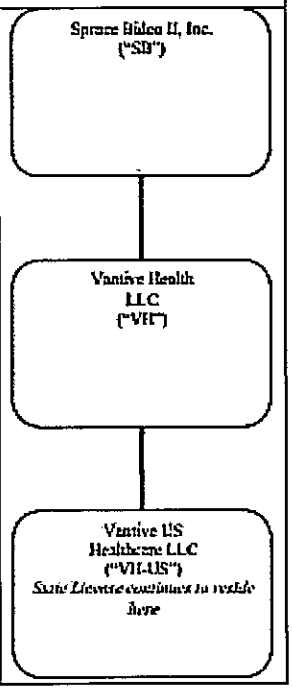
David S. Rosenbloom, Manager

Joel T. Grade, Manager

412992826

(Signature page to Manager Resolutions of Vantive US Healthcare LLC)

ATTACHMENT A

CHART A	CHART B	CHART C	CHART D
Previous Corporate Structure (pre-Feb. 2024)	Current Corporate Structure (as of November 1, 2024)	Corporate Structure Planned On or Around December 31, 2024. NOTE: VH-US becomes a direct subsidiary of VH; however, BII continues to be the ultimate owner as the 'grandparent' company	Final Corporate Structure. NOTE: VH-US continues to be a direct subsidiary of VH; however, there is now a complete corporate separation from all Baxter entities at this stage. This marks the final separation of Vantive from Baxter.
			

Vantive US Healthcare LLC

1 Baxter Parkway, Building 6
Deerfield IL
1-800-333-0887

November 12, 2024

Dave Wuest
Executive Secretary
Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy Ste 206
Reno, NV, 89521

RE: Notification of Pending Ownership Changes for Vantive US Healthcare LLC
Medical Devices – License Number MP00799

Dear Sir/Madam:

This letter is intended to notify you of two upcoming changes in the ownership of Vantive US Healthcare LLC ("VH-US"), which currently holds the following license(s) issued by Nevada State Board of Pharmacy:

- Medical Devices – License Number MP00799

These upcoming ownership changes, which are further described below, are anticipated to happen in close succession. As such, we would like to request that the two changes (i) be treated as a single change of ownership for licensing purposes, (ii) be processed through the submission of a single change of ownership application (for each license referenced above), and (iii) upon approval, result in the issuance of a single new license to VH-US or continuation of existing VH-US license.

In support of these requests, we have provided below specific details regarding the two planned ownership changes as well as relevant background information.

Background

The upcoming ownership changes that are the focus of this letter follow certain corporate changes involving VH-US that have occurred over the last year. These changes are illustrated by the corporate structure charts included in Attachment A (**See Charts A and B**). In summary:

- In early 2023, Baxter International Inc. ("BII"), the parent company of Baxter Healthcare Corporation ("BHC"), publicly announced its intention to separate its Kidney Care (renal and acute therapies) business into a new, independent publicly traded company.

- In executing this separation, two new legal entities were formed: (i) Vantive Health LLC ("VH"), which was established as a direct subsidiary of BII, and (ii) VH-US, which was established as a direct subsidiary of BHC.

- Steps were then initiated to transfer all relevant state licenses previously held by BHC to VH-US, which is the current license holder.

Details of Upcoming Ownership Changes

Two ownership changes involving VH-US are now contemplated:

- Ownership Change #1 (direct change): On or around December 31, 2024, VH-US (which is currently a direct subsidiary of BHC) will become a direct subsidiary of VH (**See Chart C** in Attachment A). Accordingly, VH will be the new "parent" of VH-US, with BII remaining the "grandparent" of VH-US.

- Ownership Change #2 (indirect change): While the initial plan (as noted above) was for BII's Kidney Care business to be a public spin-off, in August 2024, BII announced that it had executed a definitive agreement to sell the Kidney Care business to funds affiliated with the global investment firm, The Carlyle Group. As a result of this transaction, which is expected to close by the end of 2024 or early 2025, Spruce Bidco, II, Inc. ("SB"), a Delaware corporation that is part of The Carlyle Group , will obtain 100% ownership in VH, thus replacing BII as the "grandparent" (i.e., indirect owner) of VH-US (**See Chart D** in Attachment A).

Of note, VH-US, the current license holder, will remain the license holder following Ownership Changes #1 and #2. In addition, these upcoming changes will not result in any change to the EIN of VH-US, nor will there be any changes to VH-US's day-to-day facility operations or the products/services currently provided.[42]

Request

Given that these upcoming ownership changes are expected to occur in close succession, we request that the two changes (i) be treated as a single change of ownership for licensing purposes, (ii) be processed through the submission of a single change of ownership application (for each license referenced above), and (iii) upon approval by Nevada State Board of Pharmacy, result in the issuance of a single new license to VH-US.

We plan to begin the license application submission process in the next ten (10) days. We therefore respectfully request that you let us know at your earliest convenience—within the next ten (10) days—if you have any concerns granting these requests, or if you require any additional information regarding the proposed ownership changes to make such determination. Otherwise, we will proceed with filing the necessary licensing application(s) and supporting document(s), as applicable, in accordance with the applicable deadlines.

[42] Although occasional and periodic changes in the VH-US Officers slate may occur, VH-US will notify Nevada State Board of Pharmacy of any such changes in accordance with the requisite state notification process.

****

We are committed to ensuring compliance with applicable statutory and regulatory licensing requirements, and look forward to aligning on our proposed approach to handling the ownership changes described in this letter. To the extent any of the timelines noted above are materially delayed and/or there is a material change to the anticipated transaction structure outlined above (and in Attachment A), we will promptly update you.

Thank you in advance for your consideration of our requests. Please do not hesitate to contact me if there are any questions or concerns.

Sincerely,

LaToyia M. Martin
Manager, Quality Compliance

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: RGH Enterprises, LLC dba Cardinal Health at Home

Physical Address: 3000 Mark IV Parkway

City: Fort Worth State: TX Zip: 76106

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin State: OH Zip: 43017

Telephone: 817-740-3224 Website: www.edgepark.com

Name of Designated Representative (DR): Robert Kapela

Licensing Company Email: licensure@cardinalhealth.com DR Email: robert.kapela@cardinalhealth.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Patients, Labs		☒ Others: wholesale Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case # N/A	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

[signature] 3/25/25

Original Signature (electronic, copies or stamps not accepted) Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Dexcom
Address: 6290 Sequence Dr City: san Diego State: CA Zip: 92121

Name: Coloplast
Address: 1601 W. River Road N City: Minneapolis State: MN Zip: 55411

Name: Convatec
Address: 1160 Route 22 East City: Bridgewater State: NJ Zip: 08807

Name: Hollister
Address: 2000 Hollister Dr City: Libertyville State: IL Zip: 60048

Section 4: Publicly Traded Corporation

State of Incorporation: Ohio
Parent Company (if any): Allegiance Corporation
Corporation Name: RGH Enterprises, LLC
Mailing Address: 7000 Cardinal Place
City: Dublin State: OH Zip: 43017
Telephone: 614-757-5000 Email: licensure@cardinalhealth.com
Contact Person Name: LaToyia Martin

Date of SEC Registration: 08/04/1983 | SEC Registration Number: 0000721371 | Stock Exchange Symbol: CAH

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/a
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/a
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/a
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

RGH Enterprises, LLC dba Cardinal Health at Home

Facility Name

Keegan Chamberlain

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

03/25/25

Date

Board Use Only	Date Received: _____ Amount: _____

CardinalHealth

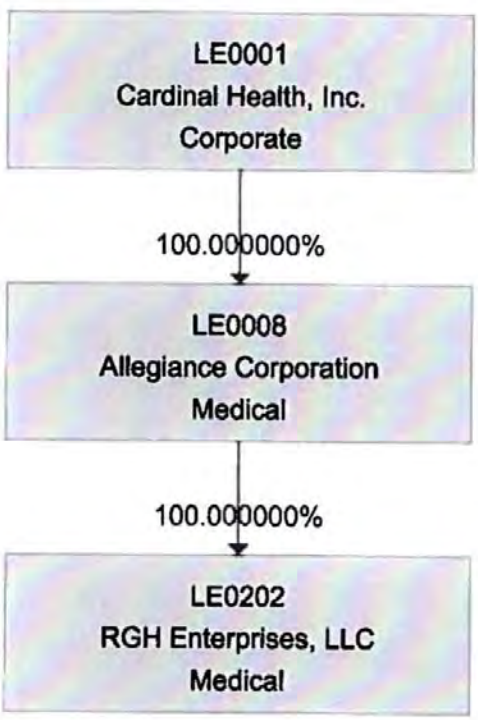
3000 Mark IV Parkway
Suite #1 (UTAH Only)
Fort Worth, Texas 76106

Officer Name	Title
Robert Evan Schlissberg	President
Keegan David Chamberlain	Director, Quality Management
John Henry Martin Jr.	SVP, Tax
Brent Mathew Withrow	Assistant Treasurer
Anthony F. Alvarez	Secretary

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The top four shareholders

1. Blackrock Inc. – 13.33%
2. Vanguard Group Inc. – 12.74%
3. State Street Corporation – 5.72%
4. Geode Capital Management, LLC – 2.43%



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UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show RGH ENTERPRISES, LLC, an Ohio Limited Liability Company, Registration Number 770802, was organized in the State of Ohio on April 9, 1990, is currently in FULL FORCE AND EFFECT upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 18th day of March, A.D. 2025.

Ohio Secretary of State

Validation Number: 202507702218

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/drug-manufacturers-distributors/applications-forms-drug-manufacturers-distributor**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

RGH ENTERPRISES LLC ORA
7000 CARDINAL PL
DUBLIN OH 43017

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

RGH ENTERPRISES LLC DBA
CARDINAL HEALTH AT HOME
3000 MARK IV PKWY
FORT WORTH, TX 76106

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

FOOD WHOLESALER & NONPRESCRIPTION DRUG DISTRIBUTOR & DEVICE DISTRIBUTOR

License # 1002245
Expires: December 26, 2026

NON-TRANSFERABLE

Commissioner

515101

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY)
04/18/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Northeast, Inc. Cincinnati OH Office 8044 Montgomery Road Suite 405 Cincinnati OH 45236-2919 USA	PHONE (A/C, No, Ext): (866) 283-7122	FAX (A/C, No): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE		NAIC #
Cardinal Health, Inc. (See Additional Page) 7000 Cardinal Place Dublin OH 43017 USA	INSURER A:	Greenwich Insurance Company	22322
	INSURER B:	XL Insurance America Inc	24554
	INSURER C:	XL Specialty Insurance Co	37885
	INSURER D:	XL Bermuda Ltd	AA3190757
	INSURER E:	Markel Bermuda Limited	AA3190829
	INSURER F:		

COVERAGES **CERTIFICATE NUMBER:** 570105126776 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS,

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER			RGD943716718	06/30/2023	06/30/2024	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$5,000,000 $1,000,000 $5,000,000 $5,000,000 Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			RAD943716818	06/30/2023	06/30/2024	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$5,000,000
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED X RETENTION			US00092147LI23A SIR applies per policy terms & conditions	06/30/2023	06/30/2024	EACH OCCURRENCE AGGREGATE Products/Completed O	$5,000,000 $5,000,000 Excluded
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			RWD943512518 AOS	06/30/2023	06/30/2024	X PER STATUTE OTH-ER	
C	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH) N / N/A If yes, describe under DESCRIPTION OF OPERATIONS below			RWR300142405 AK	06/30/2023	06/30/2024	E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$5,000,000 $5,000,000 $5,000,000
E	Products Liability			186777015810UMB2023 Prod Comp Ops & Pharm Lia	06/30/2023	06/30/2024	Limit SIR	$15,000,000 $150,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

As respects to Products Liability policies evidenced herein, Aon Risk Solutions (U.S.) is generating and distributing this certificate in an administrative. As respects to Products Liability policies evidenced herein, Aon Risk Solutions (U.S.) is generating and distributing this certificate in an administrative capacity. Aon Bermuda Ltd. is the broker for the defined policy. RGH Enterprises, LLC dba Edgepark Medical Supplies facilities: 1360 Madeline Lane, Suite 500, Elgin, IL 60124 & 5400 Sandshell Drive, Suite 160, Ft. Worth, TX 76137 & 3980 Earlstone St., Ontario, CA 91761 & 4234 Surles Court, Suite 100, Durham, NC 27703 & 1810 Summit Commerce Park, Twinsburg, OH 44087 & 1265 South River Road, Suite 200, Cranbury, NJ 08512 & 2854 NE 181st Ave., Bldg F, Portland, OR 97230 & 12075 Pritchard Road, Jacksonville, FL 32220 & 6335 Seeds Road, Grove City, OH 43123.

CERTIFICATE HOLDER

Florida Agency For Health
Care Administration
Long Term Care Services Unit
2727 Mahan Drive
Tallahassee FL 32308 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast Inc.

Holder Identifier :

Certificate No : 570105126776

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Numbe 570105126776	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Numbe 570105126776	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Ludlow Technical Products Canada, Ltd.
Marin Apothecaries
Medicap Pharmacies Incorporated
Medicine Shoppe Capital Corporation
Medicine Shoppe International, Inc.
Medicine Shoppe Internet, Inc.
Mediquip Sdn. Bhd.
Mirixa Corporation
MosaicGPO, LLC
MSCRIPTS HOLDING, LLC
MSCRIPTS, LLC
One Cloverleaf, LLC
Outcomes Incorporated
Owen Shared Services, Inc.
Pharmacy Operations Of New York, Inc.
Pharmacy Operations, Inc.
Physicians Purchasing, Inc.
Pinnacle Intellectual Property Services, Inc.
Pinnacle Intellectual Property Services-International, Inc.
Quiroproductos de Cuauhtemoc S. de R.L. de C.V.
RainTree Administrative Services, LLC
RainTree Care Management, LLC
RainTree GPO, LLC
Red Oak Sourcing, LLC
Renal Purchasing Group, LLC
RGH Enterprises, LLC
RT Oncology Services Corporation
Rxealtime, Inc.
Scalamed (US), Inc.
ScalaMed Pty Ltd
Sierra Radiopharmacy, L.L.C.
SOAR Network, LLC
Sonexus Health Access & Patient Support, LLC
Sonexus Health Distribution Services, LLC
Sonexus Health Financial Solutions, LLC
Sonexus Health Pharmacy Services, LLC
Sonexus Health, LLC
TelePharm, LLC
The Harvard Drug Group, L.L.C.
Traverse GPO, LLC
Velocare, LLC
Wavemark Cyprus Pvt. Ltd.
Wavemark Lebanon Offshore s.a.l.
Wavemark, Inc.

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER: See Certificate Numbe 570105126776	
CARRIER: See Certificate Numbe 570105126776 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 FORM TITLE: Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
B		N/A		RWR943512618 WI	06/30/2023	06/30/2024		
	OTHER							
D				XLUMB1827365 SIR applies per policy terms & conditions	06/30/2023	06/30/2024		

ACORD 101 (2008/01)

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Number: 570105126776	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Number: 570105126776	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Additional Description of Operations / Locations / Vehicles

110 Exchange Logistics Park Dr., Piedmont, SC 29673.

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Numbe 570105126776	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Numbe 570105126776	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Coverage Details

Products Completed Ops Continued

Policy Number: 186777015810UMB2023
Underwriting Company: Markel Bermuda Limited
Limit: 15M p/o 40M xs SIR
Effective Dates: 6/30/2023 - 6/30/2024

Policy Number: XLUMB1827365
Underwriting Company: XL Bermuda Ltd
Limit: 25M p/o 40M xs SIR
Effective Dates: 6/30/2023 - 6/30/2024

As respects to Products Liability policies evidenced herein, Aon Risk Solutions (U.S.) is generating and distributing this certificate in an administrative capacity. Aon Bermuda Ltd. is the broker for the defined policy

ACORD 101 (2008/01)

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Numbe 570105126776	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Numbe 570105126776	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insured Listing

Cardinal Health 3, LLC
Cardinal Health 414, LLC
Cardinal Health 418, Inc.
Cardinal Health 5, LLC
Cardinal Health 500, LLC
Cardinal Health 524, LLC
Cardinal Health 529, LLC
Cardinal Health 6, Inc.
Cardinal Health 7, LLC
Cardinal Health 8, LLC
Cardinal Health Australia 503 Pty Ltd.
Cardinal Health Austria 504 GmbH
Cardinal Health Belgium 505 BVBA
Cardinal Health Canada Holdings Cooperatie U.A.
Cardinal Health Canada Inc.
Cardinal Health Capital Corporation
Cardinal Health Cardiology Solutions, LLC
Cardinal Health Chile Limitada
Cardinal Health Colombia S.A.S.
Cardinal Health Commercial Technologies, LLC
Cardinal Health Corporate Solutions, LLC
Cardinal Health D.R. 203 II Ltd.
Cardinal Health Denmark ApS
Cardinal Health do Brasil Ltda.
Cardinal Health Finance
Cardinal Health Finland Oy
Cardinal Health Foundation
Cardinal Health France 506 SAS
Cardinal Health Funding, LLC
Cardinal Health Germany 507 GmbH
Cardinal Health Germany Manufacturing GmbH
Cardinal Health Holding International, Inc.
Cardinal Health Holdings Hungary Kft.
Cardinal Health International India Pvt. Ltd.
Cardinal Health International Philippines, Inc.
Cardinal Health IPS, LLC
Cardinal Health Ireland 419 Designated Activity Company
Cardinal Health Ireland 508 Limited
Cardinal Health Ireland Manufacturing Limited
Cardinal Health Ireland Unlimited Company
Cardinal Health Italy 509 S.r.l.
Cardinal Health Korea Limited
Cardinal Health Luxembourg 420 S.a.r.l.
Cardinal Health Luxembourg 522 S.à.r.l.
Cardinal Health Malaysia 211 Sdn. Bhd.
Cardinal Health Malta 212 Limited
Cardinal Health Managed Care Services, LLC
Cardinal Health Mexico 514 S. de R.L. de C.V.
Cardinal Health Middle East FZ-LLC
Cardinal Health MPB, Inc.
Cardinal Health Napoleon Holding, LLC
Cardinal Health Netherlands 502 B.V.
Cardinal Health Netherlands 525 Coöperatie U.A.
Cardinal Health Netherlands 528 B.V.

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Numbe 570105126776	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Numbe 570105126776	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds Continued

Cardinal Health P.R. 120, Inc.
Cardinal Health P.R. 218, Inc.
Cardinal Health P.R. 220, LLC
Cardinal Health P.R. 436, Inc.
Cardinal Health Panama, S. de R.L.
Cardinal Health Pharmaceutical Contracting, LLC
Cardinal Health Pharmacy Services, LLC
Cardinal Health Singapore 225 Pte. Ltd.
Cardinal Health Spain 511 S.L.
Cardinal Health Sweden 512 A.B.
Cardinal Health Switzerland 515 GmbH
Cardinal Health Systems, Inc.
Cardinal Health Technologies Switzerland GmbH
Cardinal Health Technologies, LLC
Cardinal Health U.K. 418 Limited
Cardinal Health U.K. 432 Limited
Cardinal Health U.K. Holding Limited
Cardinal Health U.K. International Holding LLP
Cardinal Health, Inc.
Cardinal MED Equipment Consulting (Shanghai) Co., Ltd.
Cirpro de Delicias S.A. de C.V.
Clinic Pharmacies III, LLC
Clinic Pharmacies, LLC
Community Pharmacy Enterprises, LLC
Convertors de Mexico S.A. de C.V.
Cordis Corporation
Cornerstone Rheumatology LP
Covidien Manufacturing Solutions, S.A.
Dutch American Manufacturers II (D.A.M. II) B.V.
Ellipticare, LLC
EPIC Insurance Company
Especialidades Medicas Kenmex S.A. de C.V.
Experience East, LLC
Flexible Stenting Solutions, Inc.
Generic Drug Holdings, Inc.
GetOutcomes, LLC
Griffin Capital, LLC
HDG Acquisition, Inc.
imgRx Healdsburg, Inc.
imgRx Salud, Inc.
imgRx SJ Valley, Inc.
imgRx SLO, Inc.
imgRx Sonoma, Inc.
InnerDyne Holdings, Inc.
Innovative Therapies,LLC
Instant Diagnostic Systems, Inc (Inactive - Aug 2018)
InteCardia-Tennessee East Catheterization, LLC
ITI Sales, LLC
Kendall-Gammatron Limited
Killilea Development Company, Ltd
Kinray I, LLC
KPR Australia Pty. Ltd
KPR U.S., Inc.
KPR U.S., LLC
Leader Drugstores, Inc

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AGENCY CUSTOMER ID: 570000070825

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Cardinal Health, Inc.
POLICY NUMBER	
See Certificate Numbe 570105126776	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Numbe 570105126776	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insured Listing

Named Insured Listing for June 30, 2023 - June 30, 2024 includes but is not limited to the following:

A+ Secure Packaging, LLC
Abilene Nuclear, LLC
Acuity GPO, LLC
Aero-Med, LLC
Allegiance (BVI) Holding Co. Ltd.
Allegiance Corporation
Allegiance Healthcare (Labuan) Pte. Ltd.
Allegiance I, LLC
Allegiance Labuan Holdings Pte. Ltd.
API (Suppliers) Limited
Blue Robin, LLC
C. International, Inc.
Cardinal Distribution Holding Corporation - I
Cardinal Distribution Holding Corporation - II
Cardinal Health (Shanghai) Medical Devices Co., Ltd.
Cardinal Health 100, Inc.
Cardinal Health 104 LP
Cardinal Health 105, LLC
Cardinal Health 107, LLC
Cardinal Health 108, LLC
Cardinal Health 110, LLC
Cardinal Health 112, LLC
Cardinal Health 113, LLC
Cardinal Health 114, Inc.
Cardinal Health 115, LLC
Cardinal Health 116, LLC
Cardinal Health 118, LLC
Cardinal Health 119, LLC
Cardinal Health 121, LLC
Cardinal Health 122, LLC
Cardinal Health 123, LLC
Cardinal Health 124, LLC
Cardinal Health 125, LLC
Cardinal Health 126, LLC
Cardinal Health 127, Inc.
Cardinal Health 128, LLC
Cardinal Health 130, LLC
Cardinal Health 131, LLC
Cardinal Health 132, LLC
Cardinal Health 133, Inc.
Cardinal Health 2, LLC
Cardinal Health 200, LLC
Cardinal Health 201 Canada L.P.
Cardinal Health 201, LLC
Cardinal Health 215, LLC
Cardinal Health 222 (Thailand) Ltd.
Cardinal Health 242, LLC
Cardinal Health 247, Inc.
Cardinal Health 249, LLC
Cardinal Health 250 Dutch C.V.

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Cardinal Health Legal Entity Organization Chart (Domestic Medical)

Confidential
Not for General Distribution

3/31/2022 SJB

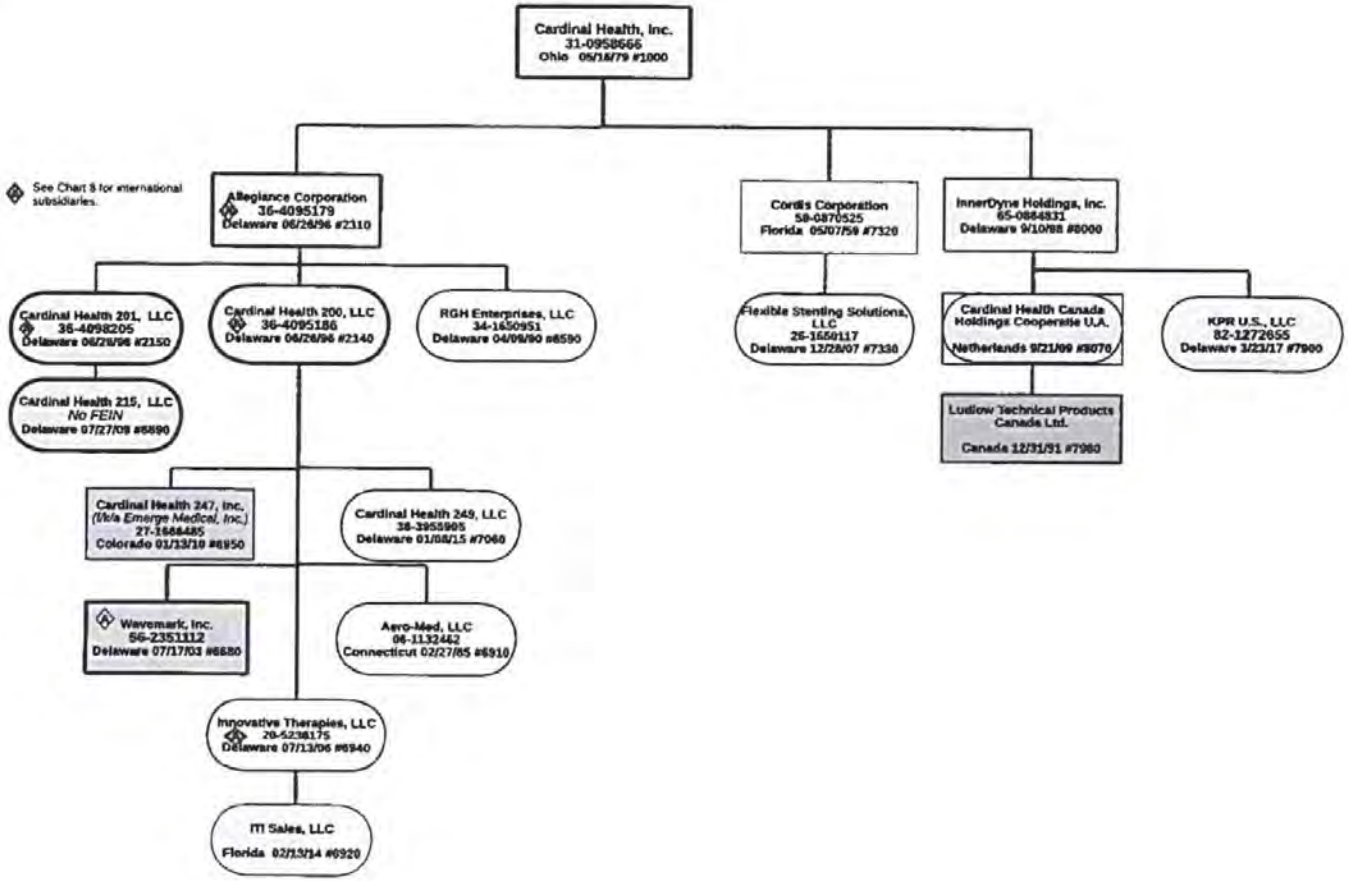


Chart 7

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: RGH Enterprises, LLC dba Edgepark Medical Supplies — MDEG License # (if applicable): N/a

Physical Address: 3000 Mark IV Parkway

City: Fort Worth — State: TX — Zip: 76106

Mailing Address (if different from physical address): 7000 Cardinal Place, QRA

City: Dublin — State: OH — Zip: 43017

Telephone: _____ — Website: www.edgepark.com

Licensing Company Email: licensure@cardinalhealth.com

Section 2: Personal Information

First: Robert — Middle: Allen — Last: Kapela

Alias(es, nicknames, name changes, etc.): N/a

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] — State: TX — Zip: [redacted]

Telephone: [redacted] — Email: robert.kapela@cardinalhealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ballston Spa High School			
Address	**City**	**State**	**Zip**
220 Ballston Ave	Ballston Spa	NY	12020
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/24- Present	[redacted]	[redacted]	TX	[redacted]
From - To (MM/YY – MM/YY)			State	
07/20-07/24			TX	
From - To (MM/YY – MM/YY)			State	
04/19-07/20			TX	
From - To (MM/YY – MM/YY)			State	
04/18-04/19			TX	
From - To (MM/YY – MM/YY)			State	
04/17-04/18			NJ	
From - To (MM/YY – MM/YY)			State	
2001-2017			NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Maria Herrera

From: GMB-HSCS-Facility Licensure <licensure@cardinalhealth.com>
Sent: Wednesday, April 2, 2025 12:18 PM
To: Maria Herrera; GMB-HSCS-Facility Licensure
Subject: RE: Nevada out-of-state Wholesaler Application-RGH Enterprises, LLC dba Cardinal Health at Home Fort Worth, TX

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Hi Maria,

The Fort Worth location is a new facility, so he does not have experience there until the facility goes live. His experience is at the RGH location in Grand Prairie and then will be moving to the Fort Worth location.

Thanks,

Cara Belinske
Sr. Specialist, Quality Compliance
7200 Cardinal Place, QRA, Dublin, OH 43017
614.757.9495 tel

CardinalHealth

I am Essential to care

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Wednesday, April 2, 2025 3:05 PM
To: GMB-HSCS-Facility Licensure <licensure@cardinalhealth.com>
Subject: Nevada out-of-state Wholesaler Application-RGH Enterprises, LLC dba Cardinal Health at Home Fort Worth, TX

External Email – Please use caution before opening attachments or clicking links

The Nevada State Board of Pharmacy received a Wholesaler application from RGH Enterprises, LLC dba Cardinal Health at Home. The application is incomplete due to the following missing item(s).

- Please note the MDEG Administrator does not list the Fort Worth, TX location on section 7?

All items must be received to move forward with processing your application.

Please let me know if you have any questions.

Thank you,

Maria Herrera
Licensing Specialist
Nevada State Board of Pharmacy
775-850-1440
m.herrera@pharmacy.nv.gov

This information is provided as a courtesy on behalf of the Nevada State Board of Pharmacy. This information does not constitute legal advice and does not override the specific provisions of Nevada law as applied to a particular set of facts.

CONFIDENTIALITY NOTICE: This message and any accompanying documents are intended only for the use of the individual or entity to which they are addressed. They may contain information that is proprietary, privileged, confidential or exempt from disclosure under applicable Federal or State law. If the reader of this message is not the intended recipient, you are hereby notified that you are strictly prohibited from reading, using, sharing or copying this communication or its contents. If you have received this email in error, please notify the sender immediately and destroy the original transmission.

This message is for the designated recipient only and may contain privileged, proprietary or otherwise private information. If you have received it in error, please notify the sender immediately and delete the original. Any other use of the email by you is prohibited.

Dansk - Deutsch - Espanol - Francais - Italiano - Japanese - Nederlands - Norsk - Portuguese - Chinese Svenska: http://www.cardinalhealth.com/en/support/terms-and-conditions-english.html

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Cardinal Health - RGH Enterprises, LLC			08/2011- Present	
Business Address		**City**	**State**	**Zip**
3550 Roy Orr Blvd.		Grand Prairie	TX	75050
Phone	**Title**		**Number of Employed Hours**	
972-790-7489	Operations Manager		1,500 +	

Description of Duties

Oversees all aspects of operations including receiving, inventory management, order fulfillment, and shipping. Collaborated with cross-functional teams to ensure on-time delivery and customer satisfaction

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/14/2025
Date

I, Robert Kapela, **certify that as the MDEG Administrator for**

_____,

that I (initial that you have read and meet the following requirements):

1. RK Have a high school diploma or its equivalent;
2. RK Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RK Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RK Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Kapela
Print Name (First, Last)

Rob Kapela
Original Signature (electronic, copies or stamps not accepted)

03/14/2025
Date

Board Use Only	Date Received: 3/27/25

RGH ENTERPRISES, LLC
3000 Mark IV Parkway
Fort Worth, TX 76106
817-740-3224

Employee List

Robert Kapela, *Manager, Warehouse Operations*
Courtney James, *Senior Coordinator, Office Services*
Charlton Lane Long, *Director, Operations Management*

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 7, 2025

Cardinal Health, Inc.

(Exact Name of Registrant as Specified in Charter)

Ohio	1-11373	31-0958666
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

7000 Cardinal Place, Dublin, Ohio 43017
(Address of Principal Executive Offices) (Zip Code)

(614) 757-5000
(Registrant's telephone number, including area code)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common shares (without par value)	CAH	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On March 7, 2025, the Board of Directors (the "Board") of Cardinal Health, Inc. (the "Company") elected Robert W. Musslewhite and Sudhakar Ramakrishna to the Board, effective immediately. Messrs. Musslewhite and Ramakrishna will serve until the 2025 annual meeting of shareholders and until their successors are elected and qualified or until their earlier resignation, removal from office, or death. The Board has appointed Mr. Musslewhite to serve on the Audit and Human Resources and Compensation Committees and has appointed Mr. Ramakrishna to serve on the Audit and Risk Oversight Committees. Mr. Musslewhite is the former Chief Executive Officer of Definitive Healthcare Corp., a provider of healthcare commercial intelligence. Mr. Ramakrishna is the President and Chief Executive Officer of SolarWinds Corporation, a provider of observability and information technology management software.

The Board has affirmatively determined that each of Messrs. Musslewhite and Ramakrishna is "independent" under the rules of the New York Stock Exchange and the rules and regulations under the U.S. Securities Exchange Act of 1934, as amended (the "Exchange Act").

Messrs. Musslewhite and Ramakrishna will receive compensation consistent with that received by the Company's other non-employee directors, as described in the Company's proxy statement on Schedule 14A for the 2024 annual meeting of shareholders, filed with the U.S. Securities and Exchange Commission on September 16, 2024.

There are no arrangements or understandings between either Messrs. Musslewhite or Ramakrishna and any other person pursuant to which they were appointed as a director. At this time, there are no transactions in which either Messrs. Musslewhite or Ramakrishna has or will have an interest that would be required to be disclosed pursuant to Item 404(a) of Regulation S-K under the Exchange Act.

Item 7.01. Regulation FD Disclosure.

The Company issued a news release on March 10, 2025 announcing the election of Messrs. Musslewhite and Ramakrishna to the Board, which is being furnished as Exhibit 99.1 to this Form 8-K.

Item 9.01. Financial Statements and Exhibits.

(d) *Exhibits.*

99.1	News release issued by the Company on March 10, 2025
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the Registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Cardinal Health, Inc.
(Registrant)

Date: March 10, 2025

By: /s/ Jessica L. Mayer
Name: Jessica L. Mayer
Title: Chief Legal and Compliance Officer

CardinalHealth

Robert Musslewhite and Sudhakar Ramakrishna to join Cardinal Health Board of Directors

DUBLIN, Ohio, March 10, 2025 – Cardinal Health (NYSE:CAH) announced today that its Board of Directors has elected Robert Musslewhite, former Chief Executive Officer of Definitive Healthcare Corp., and Sudhakar Ramakrishna, President and Chief Executive Officer of SolarWinds Corporation, as independent directors, effective March 7, 2025.

With more than 20 years of leadership experience, including serving as CEO for two publicly traded companies, Mr. Musslewhite brings to the board unique expertise in advanced analytics, data, and technology across the healthcare ecosystem. Mr. Musslewhite is also an experienced board member, currently serving on the Board of Directors of CoStar Group, Inc., and previously serving as a board member for companies within the healthcare industry, including Definitive Healthcare Corp., The Advisory Board Company and Evolent Health, Inc. Mr. Musslewhite will serve as a member of the board's Audit and Human Resources and Compensation Committees.

Mr. Ramakrishna is an experienced CEO and global technology leader with more than two decades of technology and business expertise. Mr. Ramakrishna has a history of helping matrixed organizations implement effective cybersecurity measures and navigate crises. Mr. Ramakrishna currently serves on the Board of Directors of SolarWinds Corporation and previously served on the Board of Directors of other technology companies, including Enterprise 4.0 Technology Acquisition Corp., SailPoint Technologies Holdings, Inc., Mitel Networks Corporation and Meru Networks, Inc. Mr. Ramakrishna will serve as a member of the Audit and Risk Oversight Committees.

"Robert brings decades of experience in leading technology-oriented healthcare companies and successfully driving rapid growth and innovation," said Gregory Kenny, Chairman of the Board for Cardinal Health. "Robert's expertise in strategic uses of data across healthcare systems and navigating complex business environments will be a great contribution to the board. Likewise, Sudhakar's proven leadership in both technology and business strategy, combined with his ability to collaborate and drive results, will be a tremendous asset to the company. We are pleased to welcome them to our board and look forward to their valuable insights."

"Robert and Sudhakar bring extensive experience and proven leadership with strong backgrounds in technology, which will be instrumental in helping us navigate complex and rapidly evolving environments," said Jason Hollar, CEO of Cardinal Health. "Their track records of delivering results align with our culture, and we look forward to the contributions they will make to Cardinal Health."

Robert Musslewhite – Brief Bio

Mr. Musslewhite currently serves as an advisor to a private equity firm and previously served as Chief Executive Officer of Definitive Healthcare Corp. Prior to that, he served as the Chief Executive Officer of OptumInsight, a division of UnitedHealth Group Incorporated, and before that was the Chair and Chief Executive Officer of The Advisory Board Company. He also previously held multiple positions at McKinsey & Company.

Mr. Musslewhite holds a degree in Economics from Princeton University and is a graduate of Harvard Law School.

Sudhakar Ramakrishna – Brief Bio

Mr. Ramakrishna currently serves as the President and Chief Executive Officer of SolarWinds Corporation. He previously served as the Chief Executive Officer of Pulse Secure, LLC, and prior to that he served in senior leadership roles at Citrix Systems, Inc. Mr. Ramakrishna also has held senior leadership roles at a variety of other technology companies, including Polycom, Inc., Motorola, Inc., Stoke, Inc., 3COM Corporation and U.S. Robotics Corporation.

Mr. Ramakrishna holds a Bachelor of Engineering in Computer Science and Engineering from Osmania University, a Master of Science in Computer Science from Kansas State University and a Master of Management from Northwestern University.

About Cardinal Health

Cardinal Health is a distributor of pharmaceuticals and specialty products; a global manufacturer and distributor of medical and laboratory products; a supplier of home-health and direct-to-patient products and services; an operator of nuclear pharmacies and manufacturing facilities; and a provider of performance and data solutions. Our company's customer-centric focus drives continuous improvement and leads to innovative solutions that improve people's lives every day. Learn more about Cardinal Health at cardinalhealth.com and in our Newsroom.

Contacts

Media: Erich Timmerman, erich.timmerman@cardinalhealth.com and 614.757.8231
Investors: Matt Sims, matt.sims@cardinalhealth.com and 614.553.3661

4J

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☑ New Wholesaler	* If making a change, provide current license number:	☑ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Emergent Devices Inc.

Physical Address: 401 Plymouth Road, Suite 400

City: Plymouth Meeting State: PA Zip: 19462

Mailing Address (if different from physical address): (Same)

City: _____ State: _____ Zip: _____

Telephone: 844-232-7811 Website: www.emergentbiosolutions.com

Name of Designated Representative (DR): Amanda Becker

Licensing Company Email: statelicenses@ebsi.com DR Email: statelicenses@ebsi.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [8]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Please see attached.		☑ Others: Virtual Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	☐	☒
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?	☐	☒
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	☐	☒
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?	☐	☒
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?	☐	☒

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/05/25
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Renaissance Lakewood LLC (Formerly DPT Lakewood, LLC)
Address: 1200 Paco Way City: Lakewood State: NJ Zip: 08701
Name: Cardinal Health Specialty Pharmaceutical Services (3PL)
Address: 15 Ingram Boulevard City: La Vergne State: TN Zip: 37086
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): Emergent BioSolutions, Inc.
Corporation Name: Emergent BioSolutions, Inc.
Mailing Address: 400 Professional Drive, Suite 400
City: Gaithersburg State: MD Zip: 20879
Telephone: 240-631-3430 Email: statelicenses@ebsi.com
Contact Person Name: GM: Douglas White

Date of SEC Registration: 2006	SEC Registration Number: 001-33137	Stock Exchange Symbol: EBS

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Emergent Devices Inc.

Facility Name

Paul Anthony Williams, Jr.

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

03/05/25

Date

Board Use Only	Date Received: 3/26/25	Amount: $500.00 - CC

Attachment to Emergent Devices Inc.'s Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Description of Operations

Emergent Devices Inc. ("Emergent") is an OTC virtual manufacturer headquartered in Plymouth Meeting, Pennsylvania.

Emergent is also a (virtual) distributor of a non-controlled Rx drug through a marketing agreement with Hikma Pharmaceuticals for the (virtual) distribution in the US of Hikma's Rx product.

Emergent sells the Rx prescription and OTC drug products to state, local and county government agencies, federal agencies, nonprofit organizations, pharmacies, licensed practitioners, wholesalers, retailers, and business to business customers, schools, law enforcement, treatment center and community-based organizations.

These products are manufactured by contract manufacturers and then shipped directly to a third-party logistics provider for warehousing and distribution. No drugs are or will be manufactured, stored, or distributed at the Plymouth Meeting, Pennsylvania, facility.

The Plymouth Meeting, Pennsylvania, facility is the corporate headquarters for Emergent Devices Inc. Hours of operation are Monday – Friday from 9:00 a.m. to 5:30 p.m.

Parent Company

Emergent BioSolutions, Inc. (publicly traded on NYSE: EBS)
400 Professional Drive, Suite 400
Gaithersburg, MD 20879

Corporate Officers

Name	Title	Address
Paul Anthony Williams, Jr.	President	[redacted]
Richard Lindahl	Treasurer	
Frank Vargo	Assistant Treasurer	
Jessica Perl	SVP, General Counsel and Corporate Secretary	

Delaware

The First State

I, KRISTOPHER E. KNIGHT, ACTING SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "EMERGENT DEVICES INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SEVENTH DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "EMERGENT DEVICES INC." WAS INCORPORATED ON THE SIXTH DAY OF NOVEMBER, A.D. 2013.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Kristopher E. Knight, Acting Secretary of State

5417832 8300

SR# 20250260164

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202782334

Date: 01-27-25

Pennsylvania
Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

Emergent Devices Inc. 401 Plymouth Road Suite 400; Plymouth Meeting, PA 19462
Certificate(s): **9000000307** issued: 04/18/2025 expires: 5/31/2026

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version 4.0.0.0

Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

Certificate of Record

Certificate No. 9500000061

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:
Office/Corporate Location
No product onsite

EMERGENT DEVICES, INC.
401 PLYMOUTH RD, SUITE 400
PLYMOUTH MEETING, PA 19462

The above business is recognized by the Department of Health as an entity that is doing business in the Commonwealth of Pennsylvania related to pharmaceuticals, medical devices, or cosmetics for which said entity **does not** physically handle, possess, transfer, manufacture, distribute, or retail pharmaceuticals, medical devices or cosmetics at the location on the certificate of record.

Issuance Date: May 13, 2015
Expiration Date: The Last Day of May, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Acting Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Emergent Devices Inc.

Pharmacy/Wholesaler License # (if applicable) Being applied for

Physical Address 401 Plymouth Road, Suite 400

City Plymouth Meeting State PA Zip 19462

Mailing Address (if different from physical address) (Same)

City _____ State _____ Zip _____

Telephone 844-232-7811 Website www.emergentbiosolutions.com

Licensing Company Email statelicenses@ebsi.com

Section 2: Personal Information

First Amanda Middle Sidman Last Becker

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address 401 Plymouth Road, Suite 400

City Plymouth Meeting State PA Zip 19462

Telephone 844-232-7811 Email statelicenses@ebsi.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	☐	☑

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	☐	☑
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	☐	☐

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Leigh University		09/99-05/03	
Address	**City**	**State**	**Zip**
27 Memorial Dr W	Bethlehem	PA	18015
Diploma/Degree obtained, if any			
Bachelor of Science- Chemistry			

School Name		From - To (MM/YY – MM/YY)	
McLean High School		09/95-06/99	
Address	**City**	**State**	**Zip**
1633 Davidson Rd	McLean	VA	22101
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20- Current	[redacted]	[redacted]	PA	[redacted]
08/16-7/20			PA	
08/13-8/16			PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Emergent Devices Inc			12/19- Current	
Business Address		City	State	Zip
401 Plymouth Road, Suite 400		Plymouth Meeting	PA	19462
Phone	Title		Number of Employed Hours	
844-232-7811	VP, Marketing		26,000	
Description of Duties				
Leads the development and commercialization of Narcan Nasal Spray franchise in public interest, HCP, retail and consumer segments.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	☐	☑
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	☐	☐
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	☐	☑
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	☐	☑
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	☐	☑
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	☐	☑
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?	☐	☑
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.	☐	☑
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).	☐	☑
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?	☐	☑

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Amanda Becker
Original Signature (electronic, copies or stamps not accepted)

3/13/25
Date

I, Amanda Sidman Becker, **certify that as the designated representative for**

Emergent Devices Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AB I am at least 21 years of age;
3. AB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Amanda Sidman Becker
Print Name (First, Last)

Amanda Becker
Original Signature (electronic, copies or stamps not accepted)

3/13/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amanda Sidman Becker

Print Name (First, Last)

Amanda Becker — 3/13/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Amanda Sidman Becker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Amanda Becker — 3/13/25

Original Signature — **Date**

Subscribed and Sworn to before me this 13th day of March.

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
RUSHABH R SHAH - Notary Public
Montgomery County
My Commission Expires August 31, 2028
Commission Number 1300609

(Seal)

Emergent Devices, Inc., List of Employees

Name	Position Title
Yabor, Timothy	Sr. Customer Experience Specialist
Reese, Sarah	Customer Experience Specialist
LaBerge, Rebecca	Manager, Retail Marketing
Hellmer, Assal	VP, Communications
Rodriguez, Mario	Sr. Director, Medical Affairs
Owens, Gay	Sr Director, Medical Affairs
Kilduff, Erin	Director, Customer Experience
Ales Rice, Ashley	Sr. Director, Trade & Distribution
Ward, Jason	Sr Director, B2B Sales
Rafa, John	Sr. Director, Insights & Analytics
Anwar-Viveros, Kashfi	Head of Sales - Public Interest
Becker, Amanda	VP, Marketing
White, Mark	Director, Products Governance & Pricing
Di Blasi, Joseph	Director, Logistics and Fulfillment Ops
Sanders, Marlene	Director, Community Health Solutions
Hunter McDade, Alexandra	Director, Community Health Solutions
Lancaster, Stephanie	Director, Community Health Solutions
Leach, Diane	Director, Community Health Solutions
Sharrar, Shauna	Director, Community Health Solutions
Gagnon, Clinton	Director, Community Health Solutions
Allen, Lizabeth	Director, Community Health Solutions
Goldberg, Laura	Director, Community Health Solutions
Jacobson, Robert	Sr. Director, Field Operations
Palaschak, Christa	Sr. Director, PIP Regional Sales
Perez Vega, Edna	Sr. Director, PI Regional Sales Lead
Geiger, Courtney	Director, State & Strategic Accounts
Bannister, Ella	Director, Strategic Programs
Lick, Amanda	Sr Director, National Strategy & Innovation
Rosenthal, Joseph	Sr. Director, Corp Dev & Strat Analysis
Doyle, Katherine	Director, Omnichannel Growth Strategy
Hinton, Carmen	Director, Payor Consumer Access & Inter Lead
Thomas, Meghan	Manager, Marketing Operations
McGill, Rachel	Sr. Analyst, Insights & Analytics
Sherlock, Madison	Manager, Marketing
Sindhwani, Maughan	Director, Medical Affairs
Shertzer, Amy	Director, Medical Affairs
Swingle, Debra	Director, Medical Affairs
Mendoza, Mark	Sr Director, State Govt. Affairs

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: **001-33137**

EMERGENT

EMERGENT BIOSOLUTIONS INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**14-1902018**
(State or Other Jurisdiction of Incorporation or Organization)	*(I.R.S. Employer Identification No.)*

300 Professional Drive		
(Address of Principal Executive Offices)		
Gaithersburg,	**MD**	**20879**
(City)	(State)	(Zip Code)

Registrant's Telephone Number, Including Area Code: (240) 631-3200

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	*Trading Symbol(s)*	*Name of Each Exchange on Which Registered*
Common stock, $0.001 par value per share	**EBS**	**New York Stock Exchange**

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "non-accelerated filer", "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ☐ Accelerated filer ☒ Non-accelerated filer ☐ Smaller reporting company ☐ Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. Yes ☒ No ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of voting and non-voting common equity held by non-affiliates of the registrant as of June 30, 2023 was approximately $380.7 million based on the price at which the registrant's common stock was last sold on that date as reported on the New York Stock

Exchange.

As of February 28, 2024, the registrant had 52,203,433 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2024 annual meeting of stockholders which is expected to be filed with the Securities and Exchange Commission not later than 120 days after the end of the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K. With the exception of the portions of the registrant's definitive proxy statement for its 2024 annual meeting of stockholders that are expressly incorporated by reference into this Annual Report on Form 10-K, such proxy statement shall not be deemed filed as part of this Annual Report on Form 10-K.

EMERGENT BIOSOLUTIONS INC. AND SUBSIDIARIES
Annual Report on Form 10-K
Fiscal Year Ended December 31, 2023

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the documents we incorporate by reference include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical fact, including statements regarding the future performance of Emergent BioSolutions Inc. or any of our businesses, our business strategy, future operations, future financial position, future revenues and earnings, projected costs, prospects, plans and objectives of management, are forward-looking statements. We generally identify forward-looking statements by using words like "anticipate," "believe," "continue," "could," "estimate," "expect," "forecast," "future", "goal," "intend," "may," "plan," "position," "possible," "potential," "predict," "project," "should," "target", "will," "would," and similar expressions or variations thereof, or the negative thereof, but these terms are not the exclusive means of identifying such statements. These forward-looking statements are based on our current intentions, beliefs, assumptions and expectations regarding future events based on information that is currently available. You should realize that if underlying assumptions prove inaccurate or unknown risks or uncertainties materialize, actual results could differ materially from our expectations. You are, therefore, cautioned not to place undue reliance on any forward-looking statement contained herein. Any forward-looking statement speaks only as of the date on which such statement is made and, except as required by law, we do not undertake any obligation to update any forward-looking statement to reflect new information, events or circumstances.

There are a number of important factors that could cause our actual results to differ materially from those indicated by such forward-looking statements, including, among others:

- the availability of U.S. Government ("USG") funding for contracts related to procurement of our medical countermeasures ("MCM"), including CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted), previously known as AV7909, BioThrax® (Anthrax Vaccine Adsorbed) and ACAM2000® (Smallpox (Vaccinia) Vaccine, Live) among others, as well as contracts related to development of medical countermeasures;
- the availability of government funding for our other commercialized products, including Ebanga™ (ansuvimab-zykl), BAT® (Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)) and RSDL® (Reactive Skin Decontamination Lotion Kit);
- our ability to meet our commitments to quality and compliance in all of our manufacturing operations;
- our ability to negotiate additional USG procurement or follow-on contracts for our MCM products that have expired or will be expiring;
- the commercial availability and acceptance of over-the-counter NARCAN® (naloxone HCl) Nasal Spray;
- the impact of a generic and competitive marketplace on NARCAN® Nasal Spray and future NARCAN® Nasal Spray sales;
- our ability to perform under our contracts with the USG, including the timing of and specifications relating to deliveries;
- our ability to provide bioservices for the development and/or manufacture of product and/or product candidates of our customers at required levels and on required timelines;
- the ability of our contractors and suppliers to maintain compliance with current good manufacturing practices and other regulatory obligations;
- our ability to negotiate further commitments related to the collaboration and deployment of capacity toward future commercial manufacturing under our existing Bioservices contracts;
- our ability to collect reimbursement for raw materials and payment of service fees from our Bioservices customers;
- the results of pending stockholder litigation and government investigations and their potential impact on our business;
- our ability to comply with the operating and financial covenants required by our revolving credit facility (the "Revolving Credit Facility") and our term loan facility (the "Term Loan Facility" and, together with the Revolving Credit Facility, the "Senior Secured Credit Facilities") under a senior secured credit agreement, dated October 15, 2018, between the Company and multiple lending institutions, as amended from time to time, as well as our 3.875% Senior Unsecured Notes due 2028 ("Senior Unsecured Notes");
- our ability to remediate a material weakness in our internal control over financial reporting and to prepare accurate financial statements in a timely manner;

- our ability to resolve the going concern qualification in our consolidated financial statements and otherwise successfully manage our liquidity in order to continue as a going concern;
- the procurement of our product candidates by USG entities under regulatory authorities that permit government procurement of certain medical products prior to United States Food and Drug Administration ("FDA") marketing authorization, and corresponding procurement by government entities outside of the United States;
- our ability to realize the expected benefits of the sale of our travel health business to Bavarian Nordic;
- the impact of the organizational changes we announced in January 2023 and August 2023;
- the success of our commercialization, marketing and manufacturing capabilities and strategy;
- our ability to identify and acquire companies, businesses, products or product candidates that satisfy our selection criteria;
- the impact of cybersecurity incidents, including the risks from the unauthorized access, interruption, failure or compromise of our information systems or those of our business partners, collaborators or other third parties; and
- the accuracy of our estimates regarding future revenues, expenses, capital requirements and needs for additional financing.

The foregoing sets forth many, but not all, of the factors that could cause actual results to differ from our expectations in any forward-looking statement. When evaluating our forward-looking statements, you should consider this cautionary statement along with the risk factors identified in the sections entitled "Risk Factor Summary," "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K and the risk factors identified in our other periodic reports filed with the SEC when evaluating our forward-looking statements. New factors emerge from time to time, and it is not possible for management to predict all such factors, nor can it assess the impact of any such factor on the business or the extent to which any factor, or combination of factors, may cause results to differ materially from those contained in any forward-looking statement.

NOTE REGARDING COMPANY REFERENCES

References in this report to "Emergent," the "Company," "we," "us," and "our" refer to Emergent BioSolutions Inc. and its consolidated subsidiaries.

NOTE REGARDING TRADENAMES

Emergent®, BioThrax®, BaciThrax®, RSDL®, BAT®, Trobigard®, Anthrasil®, CNJ-016®, ACAM2000®, NARCAN®, CYFENDUS®, TEMBEXA® and any and all Emergent BioSolutions Inc. brands, products, services and feature names, logos and slogans are trademarks or registered trademarks of Emergent BioSolutions Inc. or its subsidiaries in the United States or other countries. All other brands, products, services and feature names or trademarks are the property of their respective owners.

PART I

ITEM 1. BUSINESS

OVERVIEW

We are a global life sciences company focused on providing innovative preparedness and response solutions addressing accidental, deliberate and naturally occurring public health threats ("PHTs"). Our solutions include a product portfolio, a product development portfolio, and a Bioservices portfolio. The types of PHTs we are currently addressing are focused on the following four categories:

- chemical, biological, radiological, nuclear and explosives ("CBRNE");
- emerging infectious diseases ("EID");
- public health crises (such as the opioid crisis); and
- acute, emergency and community care.

Our revenues are derived from a combination of the sale and procurement of our product/product candidate portfolio (described below), the provision of our bioservices to external customers, and non-dilutive contract and grant funding for research and development ("R&D") projects from various third-party sources.

OUR OPERATING SEGMENTS

In the fourth quarter of 2023, we realigned our reportable operating segments to reflect recent changes in our internal operating and reporting process. The revised reporting structure reflects the internal reporting and review process used by our Chief Operating Decision Maker, for making decisions and assessing performance, and is consistent with how we currently manage the business.

We now manage our business with a focus on three reportable segments:

- our Commercial Products Segment consisting of NARCAN® and other commercial products which were sold as part of our travel health business in the second quarter of 2023;
- our MCM Products Segment consisting of Anthrax—MCM products, Smallpox—MCM products and Other Products (as discussed below); and
- our Services Segment consisting of our Bioservices portfolio.

Additionally, we have a centralized R&D organization and an enterprise-wide governance approach to managing our portfolio of R&D projects.

Commercial Products Segment

In the U.S. and international markets, our Commercial business primarily focuses on sales of NARCAN® (naloxone HCl) Nasal Spray. NARCAN® Nasal Spray is sold commercially over-the-counter at retail pharmacies and digital commerce websites as well as through physician-directed or standing order prescriptions at retail pharmacies, health departments, local law enforcement agencies, community-based organizations, substance abuse centers and other federal agencies.

On May 15, 2023, we completed the sale of our products segment's travel health business, including rights to Vivotif®, the licensed typhoid vaccine; Vaxchora®, the licensed cholera vaccine; the development-stage chikungunya vaccine candidate CHIKV VLP; the Company's manufacturing site in Bern, Switzerland; and certain of its development facilities in San Diego, California. In connection with the divestiture, the Company entered into a Transition Services Agreement ("TSA") with Bavarian Nordic to help support its ongoing operations. Under the TSA, the Company provides certain transition services to Bavarian Nordic, including information technology, finance and enterprise resource planning, research and development, human resources, employee benefits and other limited services. Services pursuant to the TSA remain ongoing. For additional information, refer to Note 3, "Divestiture."

MCM Products Segment

Our Government - MCM business focuses primarily on procurement of MCM products and procured product candidates by domestic and international government customers, with an emphasis on the United States ("U.S.") Government ("USG"), which is our largest customer. We also sell MCM products and procured product candidates to domestic and international non-government organizations and to governments outside of the U.S.

Services Segment

Our portfolio of Bioservices consists of three distinct but interrelated service pillars: development services (process and analytical development); drug substance manufacturing; and drug product manufacturing (fill/finish). These services, which we collectively refer to as a "molecule-to-market" offering, employ diverse technology platforms across a network of development and manufacturing sites operated by us. These Bioservices support all phases of the drug development life cycle, from pre-clinical development programs through commercial manufacturing of approved pharmaceutical products. The customer base for Bioservices is primarily innovators in the biotechnology and pharmaceutical segments.

OUR STRATEGY

The Company continues to execute the three-year strategic plan (2023-2025) adopted by management to strengthen the Company's financial position and adapt to new strategic priorities. We expected this strategy would refocus the business and increase the Company's ability to make more aggressive investments for future growth.

Specifically, throughout 2023 the Company has taken significant steps to strengthen our financial position and de-risk the business. We have executed the travel health divestiture, implemented actions intended to save over $160 million of annualized operating expense, and announced a strategic shift to de-emphasize our CDMO business as a source of growth. At the same time, we have achieved a number of positive milestones in our core products business, including the receipt of approximately $250 million of USG orders for ACAM2000® (discussed more fully below), VIGIV CNJ-016® and BAT®, the FDA approvals of CYFENDUS® and NARCAN® over-the-counter, new long-term contracts for RSDL® and Ebanga™ and the growth of NARCAN® Nasal Spray.

PRIMARY PRODUCTS AND PRODUCT CANDIDATES

Government - MCM Products

The current portfolio of our Government - MCM business consists of the following products:

GOVERNMENT - MCM PRODUCTS		
Product	**Indication(s)**	**Regulatory Approvals, Licensures or Clearances**
ACAM2000®, (Smallpox (Vaccinia) Vaccine, Live)	Vaccine for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection.	United States, Australia, Singapore, Canada
ANTHRASIL® [Anthrax Immune Globulin Intravenous (human)]	Treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs.	United States, Canada
BAT® [Botulism Antitoxin Heptavalent (A,B,C,D,E,F,G)-(Equine)]	Treatment of symptomatic botulism following documented or suspected exposure to botulinum neurotoxin serotypes A, B, C, D, E, F, or G in adults and pediatric patients.	United States, Canada, Ukraine, Singapore
BioThrax® (Anthrax Vaccine Adsorbed)	Vaccine for active immunization for the prevention of disease caused by *Bacillus anthracis* in persons 18 through 65 years of age. BioThrax® is approved for: 1. Pre-exposure prophylaxis of disease in persons at high risk of exposure. 2. Post-exposure prophylaxis of disease following suspected or confirmed *Bacillus anthracis* exposure, when administered in conjunction with recommended antibacterial drugs.	United States, Canada, France (where it is known as BaciThrax®), Germany, Italy, the Netherlands, Poland, Singapore and UK
CYFENDUS® (Anthrax Vaccine Adsorbed Adjuvanted)	Previously known as AV7909, approved by the FDA for post-exposure prophylaxis of disease following suspected or confirmed exposure to Bacillus anthracis in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs.	United States
Ebanga™ (ansuvimab-zykl), for injection	Treatment of infection caused by *Zaire ebolavirus* in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for *Zaire ebolavirus* infection.	United States
Raxibacumab injection	Treatment of adult and pediatric patients with inhalational anthrax due to *Bacillus anthracis* in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or are not appropriate.	United States
RSDL® (Reactive Skin Decontamination Lotion Kit)	Intended to remove or neutralize chemical warfare agents and T-2 Toxin from the skin.	United States (510k), Australia, Canada, European Union and Israel
TEMBEXA® (brincidofovir), (tablet and oral suspension)	Treatment of human smallpox disease caused by variola virus in adult and pediatric patients, including neonates.	United States, Canada
Trobigard® Auto-injector atropine sulfate, obidoxime chloride auto-injector	Indicated for the emergency treatment of known or suspected exposure to nerve agents or toxic organophosphates in adults > 18 years of age.	Belgium*
VIGIV CNJ-016® [Vaccinia Immune Globulin Intravenous (Human)]	Treatment of complications due to vaccinia vaccination, including: • Eczema vaccinatum • Progressive vaccinia; • Severe generalized vaccinia; • Vaccinia infections in individuals who have skin conditions; and • Aberrant infections induced by vaccinia virus (except in cases of isolated keratitis). VIGIV is not indicated for postvaccinial encephalitis.	United States, Canada
**TROBIGARD® is not approved by the FDA. It is only approved by the Belgian Health Authority but has been procured by various government entities for emergency preparedness purposes.*		

Description of MCM Products

ACAM2000® (Smallpox (Vaccinia) Vaccine, Live). ACAM2000® vaccine is a smallpox vaccine licensed by the FDA for active immunization against smallpox disease for persons determined to be at high risk for smallpox infection and comprises the largest percentage of the current USG stockpile in the Strategic National Stockpile ("SNS") designated for use in a bioterrorism emergency. On December 5, 2023, ACAM2000® vaccine received a Notice of Compliance from Health Canada for its Extraordinary Use New Drug Submission (EUNDS) for the indication of active immunization against smallpox disease for persons determined to be at high risk for smallpox infection. On October 27, 2023, Emergent submitted a supplemental Biological License Application (sBLA) to the US FDA seeking approval for the expansion of the indication for ACAM2000® to include immunization against mpox virus. ACAM2000® vaccine is currently stockpiled both in the U.S. and internationally. Smallpox is a highly contagious disease caused by the Variola virus. According to the Centers for Disease Control and Prevention ("CDC"), smallpox is a devastating disease, with a mortality rate as high as 30%. The vaccine stimulates a person's immune system to develop antibodies and cells in the blood and elsewhere that can then help the body fight off a smallpox infection if exposure to smallpox occurs. On September 3, 2019, we announced the award by the USG of a contract valued at up to approximately $2 billion over 10 years for the continued supply of ACAM2000® vaccine into the SNS, assuming all contract options are exercised. This multiple-year contract is intended to support the replacement of the smallpox vaccine stockpile and included a one-year base period of performance in 2019 valued at approximately $170.0 million, and nine option years. The number of doses under the base period were delivered by year end 2019. On May 28, 2020, we announced the exercise by the U.S. Department of Health and Human Services ("HHS") of the first contract option, valued at $176.0 million, to procure doses of ACAM2000® vaccine. The number of doses under the first contract option were delivered by year end 2020. On July 13, 2021, we announced the exercise by HHS of the second contract option, valued at $182.2 million, to procure doses of ACAM2000® vaccine. We completed the delivery of all ACAM2000® doses in 2022. The USG chose to not exercise its option year in 2022. On May 26, 2023, the Company, through its wholly-owned subsidiary, Emergent Product Development Gaithersburg Inc., received a contract modification from the Office of the Assistant Secretary for Preparedness and Response ("ASPR"), an agency of the U.S. Department of Health and Human Services ("HHS"), exercising and funding the third of nine annual contract term extension options (the "Third Option Exercise") for Emergent to supply ACAM2000® to the SNS. The Third Option Exercise is valued at approximately $120 million and was made under a bilateral modification of Emergent's existing 10-year contract awarded by ASPR on August 30, 2019. The period of performance under the Third Option Exercise required Emergent to deliver doses of ACAM2000® into the SNS by June 30, 2023 and the Company achieved delivery in this period.

ANTHRASIL®. ANTHRASIL® (Anthrax Immune Globulin Intravenous (human)) is the only polyclonal antibody therapeutic licensed by the FDA for the treatment of inhalational anthrax in adult and pediatric patients in combination with appropriate antibacterial drugs. We currently have two contracts with HHS for Anthrasil Anthrax IGIV: 1) a development and procurement contract which has been extended to expire in September 2024 for possible additional scope, and 2) a multiple award, indefinite delivery/indefinite quantity contract for the collection of anti-anthrax plasma, as well as the manufacture of such plasma into bulk drug substance and finished drug product; such contract covered extended plasma storage, and the options for manufacturing and delivery of finished product into the SNS to be exercised by HHS through September 2023. We anticipate that the direct disposition of the plasma and close out activities will be completed before July 31, 2025. In addition to domestic USG sales, Anthrasil solution has been sold to several foreign governments, including the Canadian government.

BAT® [Botulism Antitoxin Heptavalent (A, B, C, D, E, F, G) – (Equine)]. BAT® antitoxin is the only equine plasma antitoxin licensed by the FDA and Health Canada for the treatment of all seven botulinum neurotoxin serotypes. BAT® antitoxin is licensed by the FDA for the treatment of symptomatic botulism following suspected or documented exposure to botulinum neurotoxin serotypes A, B, C, D, E, F or G in adults and pediatric patients. It is also licensed in Canada pursuant to Health Canada's Extraordinary Use New Drugs regulations. BAT® antitoxin is the only heptavalent botulism antitoxin available in the U.S. and Canada for treating naturally occurring botulism in adults or pediatric patients. Botulinum toxin is a nerve toxin produced by the bacterium Clostridium botulinum that causes botulism, a serious paralytic illness. On May 8, 2020, we announced the finalization of a previously announced contract with HHS, valued at up to $550.0 million, if all options under the contract are exercised. The contract has two deliverables. The first deliverable, negotiated in September 2019 and valued at up to approximately $90.0 million, is to supply annual doses of BAT® antitoxin into the SNS for 10 years by converting existing bulk drug substance into final drug product. This deliverable also includes options for additional doses valued at up to approximately $94.0 million over 10 years. The second deliverable, valued at up to approximately $366.0 million, is for the production of additional doses of bulk drug substance over 10 years to maintain the plasma collection and production capability for botulism response planning. In addition to domestic government sales, BAT® antitoxin continues to be sold internationally, with deliveries to 15 foreign governments in 2023.

BioThrax® (Anthrax Vaccine Adsorbed). BioThrax® vaccine is the only vaccine licensed by the FDA for pre-exposure prophylaxis of anthrax disease in persons at high risk of exposure. BioThrax® vaccine is also approved by the FDA for post-exposure prophylaxis administration in combination with antimicrobial therapy in the event of suspected or confirmed exposure to *Bacillus anthracis*. Anthrax is a potentially fatal disease caused by the spore-forming bacterium, *Bacillus anthracis*. Inhalational anthrax is the most lethal form of anthrax. In the U.S., BioThrax® vaccine is administered in a pre-exposure prophylaxis setting by intramuscular

injection as a three-dose primary series over a six-month period. Per the U.S. label, booster doses are administered six and 12 months after completion of the primary series and at 12-month intervals thereafter. BioThrax® vaccine is administered in a post-exposure prophylaxis setting as three subcutaneous injections two weeks apart in conjunction with recommended antibacterial drugs following suspected or confirmed *Bacillus anthracis* exposure. When we report the revenue associated with "anthrax vaccines," it reflects the combined revenue from the procurement and sale of BioThrax® vaccine as well as CYFENDUS® vaccine (formerly known as AV7909, described below).

In December 2016, we signed a follow-on contract with the CDC for the supply of up to approximately 29.4 million doses of BioThrax® vaccine for delivery into the SNS, over a five-year period ending in September 2021. On September 29, 2021, we were granted a no-cost contract extension, which extended the date through which the USG procured BioThrax® vaccine to March 31, 2022. On June 16, 2022, the contract's period of performance was extended to June 30, 2022. All deliveries under this contract were completed in August 2022. On January 11, 2024, the Company announced that it has secured an indefinite-delivery, indefinite-quantity ("IDIQ") procurement contract with a maximum value up to $235.8 million to supply BioThrax® vaccine for use by all branches of the U.S. military as Pre-Exposure Prophylaxis (PrEP) for anthrax disease. The new contract with the U.S. Department of Defense ("DoD") and led by the Joint Program Executive Office for Chemical, Biological, Radiological and Nuclear Defense, is comprised of a five-year base agreement ending on September 30, 2028, and an additional five-year option that would extend the contract to September 30, 2033.

CYFENDUS® (Anthrax Vaccine Adsorbed, Adjuvanted) (known as AV7909 prior to FDA approval in July 2023). CYFENDUS® vaccine was approved by the FDA for post-exposure prophylaxis of disease following suspected or confirmed exposure to Bacillus anthracis in persons 18 through 65 years of age when administered in conjunction with recommended antibacterial drugs. In 2021, AV7909 was granted orphan drug designation by the FDA. Studies have shown that CYFENDUS® elicits a stronger immune response using fewer doses than BioThrax® vaccine, which is expected to allow patients to reach a protective level of immunity more rapidly. CYFENDUS® is designed to provide protection with a two-dose regimen (versus the BioThrax® three-dose regimen) for post-exposure prophylaxis of anthrax disease, when administered in combination with the recommended antibacterial drugs. In September 2016, we signed a combination development and procurement contract with Biomedical Advanced Research and Development Authority ("BARDA"), which included a five-year base period of performance to develop CYFENDUS® for post-exposure prophylaxis of anthrax disease and to deliver to the SNS an initial two million doses, subsequently modified to three million doses in March 2017. The contract also includes procurement options for the delivery of an additional 7.5 million to 50.0 million doses of CYFENDUS® into the SNS and options for an additional clinical study and post marketing commitments. In 2019, we initiated and completed enrollment of a Phase 3 study; the 3,850 subject trial evaluating safety, immunogenicity and lot consistency was completed in 2020. In collaboration with us, the CDC filed with the FDA a pre-EUA submission package related to CYFENDUS®. Following this submission, BARDA began procuring CYFENDUS® , exercising its first contract option in July 2019 (valued at approximately $261.0 million) to procure doses to be delivered to the SNS through June of 2020, its second contract option in July 2020 (valued at $258.0 million) to procure additional doses of CYFENDUS® for delivery into the SNS over 12 months, in September 2021 funding another contract option (valued at approximately $399.0 million) to deliver doses of CYFENDUS® to the SNS over 18 months. Two contract modifications (each valued at $75 million) were executed with BARDA in 2023; the first modification was filled during 2023 and the second modification expires in March 2024. In April 2022, we completed our submission of a Biologics License Application ("BLA") for CYFENDUS® to the FDA and received BLA approval in July 2023. When we report the revenue associated with "anthrax vaccines," it reflects the combined revenue from the procurement and sale of CYFENDUS® as well as BioThrax® (described above).

Ebanga™ (ansuvimab-zykl), for injection. Ebanga™ (ansuvimab-zykl) is a monoclonal antibody with antiviral activity provided through a single IV infusion (over 60 minutes) for the treatment of Zaire ebolavirus in adult and pediatric patients, including neonates born to a mother who is RT-PCR positive for Zaire ebolavirus. On July 1, 2022, we entered into an asset purchase agreement and a license agreement with Ridgeback Biotherapeutics ("Ridgeback") to expand the availability of Ebanga™ (ansuvimab-zykl). This included a license to the Ebanga™ trademark and to certain patent rights related to Ebanga™ (ansuvimab-zykl). We will be responsible for manufacturing, selling and distributing Ebanga™ (ansuvimab-zykl) in the U.S. and Canada and Ridgeback will serve as the global access partner. In July 2023, the Company announced it was awarded a 10-year contract by BARDA, valued at up to a maximum of $704 million, for advanced development, manufacturing scale-up, and procurement of Ebanga™.

Raxibacumab injection. Our raxibacumab product is the first fully human monoclonal antibody therapeutic licensed by the FDA for the treatment and prophylaxis of inhalational anthrax due to *Bacillus anthracis*. Our raxibacumab product is indicated for the treatment of adult and pediatric patients with inhalational anthrax in combination with appropriate antibacterial drugs and for prophylaxis of inhalational anthrax when alternative therapies are not available or appropriate.

RSDL® (Reactive Skin Decontamination Lotion Kit). RSDL® kit is cleared by the FDA and is intended to remove or neutralize chemical warfare agents from the skin, including tabun, sarin, soman, cyclohexyl sarin, VR, VX, mustard gas and T-2 toxin. RSDL® kit has also been cleared as a medical device by Health Canada, has a current European Conformity ("CE") mark under European Directives, and is licensed by the Israel Ministry of Health and by Australia's Therapeutic Goods Administration. To date, the

principal customers for RSDL® kits have been agencies of the USG, including the DoD and the National Guard. Our current contract with the DoD awarded in December 2022 is a five-year contract including a base year period and four single year option periods, valued at up to $379.6 million to supply RSDL® kits for use by all branches of the U.S. military. We also sold RSDL® kits to ten foreign countries outside the U.S. in 2023. In November 2022, three lots of our RSDL® kits was recalled due to leakage, which could cause the product not to perform as effectively as intended. There have been no reports of injuries or death related to this recall of which we are aware. We identified and remediated the cause leading to the November 2022 recall, as well as completed all required actions, notices and report submissions related to the recalled batch. We are currently awaiting formal closure of the recall from FDA.

TEMBEXA® (brincidofovir) tablets and oral suspension. TEMBEXA® is the first oral antiviral approved by the FDA for the treatment of smallpox disease caused by variola virus in adult and pediatric patients, including neonates. On September 26, 2022, we acquired exclusive worldwide rights to brincidofovir from Chimerix Inc. for the treatment of any human smallpox disease or any other disease caused by any orthopox virus. Following the acquisition, the 10-year contract with BARDA, valued at up to $680.0 million, to supply up to 1.7 million tablet and suspension formulations of TEMBEXA® was novated to the Company. On December 11, 2023, Emergent received a Notice of Compliance from Health Canada for its Extraordinary Use New Drug Submission (EUNDS) for indication of the treatment of human smallpox disease in adults and pediatric patients, including newborn infants. The Company has 2 patent families relating to the TEMBEXA® product including but not limited to, those listed in the Orange Book: 8,962,829, 9,303,051, 9,371,344, 10,112,909, and 10,487,061. The latest expiring United States composition of matter patents expires in 2034.

TROBIGARD® atropine sulfate, obidoxime chloride auto-injector. TROBIGARD® auto-injector was approved by the Federal Agency for Medicines and Health Products of the Belgium Health Authority on February 18, 2021. TROBIGARD® auto-injector is not currently approved or cleared by the FDA. TROBIGARD® auto-injector is only distributed to authorized government buyers for use outside the U.S. In Belgium, the TROBIGARD® auto-injector is indicated for the emergency treatment of known or suspected exposure to nerve agents or toxic organophosphates in adults (> 18 years of age). In February 2019, Emergent was awarded a 10-year contract, valued at up to approximately $100.0 million, by the U.S. Department of State, to procure our TROBIGARD® product, training auto-injectors and RSDL® kits for emergency use outside of the U.S. The contract consists of a five-year base period of performance with five one-year option periods.

VIGIV CNJ-016® (Vaccinia Immune Globulin Intravenous (Human)). VIGIV is the only polyclonal antibody therapeutic licensed by the FDA and Health Canada to address certain complications from replicating virus smallpox vaccination. The principal customer for VIGIV is the USG, specifically HHS. In June 2019, we announced a contract award by HHS valued at approximately $535.0 million over 10 years for the continued supply of VIGIV into the SNS for smallpox preparedness. VIGIV has also been procured by a limited number of foreign governments.

Commercial Products

Our current Commercial portfolio consists of the following products:

COMMERCIAL PRODUCTS		
Product	**Indication(s)**	**Regulatory Approvals**
NARCAN® (naloxone HCl) Nasal Spray	Emergency treatment of known or suspected opioid overdose as manifested by respiratory and/or central nervous system depression.	United States, Canada

Description of Commercial Products

NARCAN® Nasal Spray. NARCAN® Nasal Spray, a product we obtained in connection with our acquisition of Adapt Pharma Inc. in 2018, is an intranasal formulation of naloxone approved by the FDA and Health Canada for the emergency treatment of known or suspected opioid overdose as demonstrated by respiratory and/or central nervous system depression. We have rights to formulations of naloxone used in NARCAN® Nasal Spray from Indivior PLC (f/k/a Opiant Pharmaceuticals Inc.). The primary customers for NARCAN® Nasal Spray are state health departments, local law enforcement agencies, community-based organizations, substance abuse centers, federal agencies, and consumers. We completed two important product life cycle improvements in 2020. First, we launched the Generation II NARCAN® Nasal Spray device, which has a claim for enhanced temperature excursions and storage below 25°C. Second, we gained FDA approval for an extension of the shelf life of NARCAN® Nasal Spray from 24 months to 36 months. On January 18, 2024, the Company announced that the FDA has acknowledged the shelf-life extension of NARCAN® Nasal Spray from 36 months to 48 months based on the company's four-year stability data.

In the fourth quarter of 2022, we filed our supplemental New Drug Application ("sNDA") for NARCAN® Nasal Spray, as an over-the-counter ("OTC") emergency treatment for known or suspected opioid overdose. The FDA accepted the application and also granted Priority Review. On February 15, 2023, the U.S. Food and Drug Administration (FDA) Nonprescription Drugs Advisory Committee and the Anesthetic and Analgesic Drug Products Advisory Committee unanimously voted in favor (a total of 19 votes) that the benefit-risk profile of NARCAN® Nasal Spray was supportive of its use as a nonprescription opioid overdose reversal agent.

NARCAN® Nasal Spray was approved as an OTC medication on March 29, 2023. It was the first 4 mg naloxone nasal spray available OTC in the U.S. The new OTC product was shipped out to retailers and e-commerce providers nationwide in August of 2023. Emergent is prepared to supply all segments and customers of the business with OTC product.

Product Candidates

The table below highlights our current portfolio of product candidates:

PRODUCT CANDIDATES	
Product Candidate	**Target Indication**
CGRD-001 (Pralidoxime chloride/atropine auto-injector)	Treatment of poisoning by organophosphorus nerve agents or organophosphorus compounds.
EBS-LASV (rVSV-vectored vaccine for Lassa fever)	Active immunization to prevent Lassa fever.
EBS-MARV (rVSV-vectored vaccine for Marburg virus disease)	Active immunization to prevent Marburg virus disease.
EBS-SUDV (rVSV-vectored vaccine for Sudan virus disease)	Active immunization to prevent Sudan virus disease.
Pan-Ebola mAbs	Treatment of ebola virus disease caused by infection in patients with confirmed Sudan virus.
SIAN (stabilized isoamyl nitrite)	Antidote for initial treatment of certain or suspected acute cyanide poisoning.
UniFlu (Universal influenza vaccine)	Intended to induce broad and supra-seasonal immunity against influenza A and B viruses.
WEVEE-VLP	To prevent disease caused by Western, Eastern, and Venezuelan equine encephalitis virus infections.

Description of Product Candidates

CGRD-001. The CGRD-001 auto-injector is being developed for treatment of poisoning by organophosphorus nerve agents, as well as organophosphorus compounds for use by military personnel. CGRD-001 is being developed as an auto-injector for delivery of 600 mg of pralidoxime and 2 mg of atropine for intramuscular injection following nerve agent exposure. The product is being designed for injection by non-medical personnel, including self-injection or buddy aid by service members.

EBS-LASV. This vaccine candidate is a recombinant, vesicular stomatitis virus vectored, monovalent vaccine encoding the surface glycoprotein precursor gene of Lassa virus. The development program is partnered with the Coalition for Epidemic Preparedness Innovations ("CEPI"). We have completed our Phase 1 clinical trial and are currently analyzing the data.

EBS-MARV. This vaccine candidate is a recombinant, vesicular stomatitis virus vectored, monovalent vaccine encoding the surface glycoprotein precursor gene of Marburg virus. The development program is partnered with Auro Vaccines and is currently in IND-enabling stage. NIAID is funding Auro Vaccines program with contract options through Phase 1 development.

EBS-SUDV. This vaccine candidate is a recombinant, vesicular stomatitis virus vectored, monovalent vaccine encoding the surface glycoprotein precursor gene of Sudan virus. The development program is partnered with Auro Vaccines and is currently in IND-enabling stage. NIAID is funding Auro Vaccines program with contract options through Phase 1 development.

Pan-Ebola mAbs. IBT-T02 is a cocktail comprised of two chimeric mAbs, FVM04 and CA45. The mAb cocktail candidate targets two highly conserved and non-overlapping epitopes on the glycoprotein of Sudan ebolavirus (SUDV) and other ebolaviruses. The preclinical program is in partnership with Integrated Biotherapeutics with a BARDA funded non-human primate study in progress.

SIAN. We are developing SIAN (stabilized Isoamyl nitrate) as an antidote for initial treatment of acute poisoning of cyanide that is judged to be serious or life threatening. The USG consistently identifies cyanide ("CN") as a high-priority threat, most recently in the Public Health Emergency Medical Countermeasure Enterprise 2022 Strategy and Implementation Plan. Historically, CN has been used as a chemical warfare agent and could be an agent for a terrorist attack. CN also represents a threat from accidental poisoning, such as industrial accidents or exposure during building fires. The SIAN program is funded by BARDA and is focused on the development of a single-use intranasal spray device that can be rapidly deployed and easily dispensed so that it will deliver SIAN following a cyanide incident or in a mass exposure setting. We have completed our Phase 1 clinical trial to assess the safety, tolerability, pharmacokinetics and pharmacodynamics, and are currently analyzing the data.

UniFlu. We are developing a universal influenza vaccine candidate based on a nanoparticle technology involving a cross-reactive hemagglutinin (HA) antigen for active immunization against influenza virus A and B. The nanoparticle technology was developed by and licensed from the NIAID Vaccine Research Center. Using this technology, we are seeking to develop a universal influenza

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vaccine designed to confer protection against numerous strains and subtypes of influenza virus. We have completed our Phase 1 clinical trial to assess safety, tolerability, and immunogenicity and are currently analyzing the data.

WEVEE-VLP. WEVEE VLP vaccine is a recombinant VLP vaccine. The development program is in partnership with NIAID Vaccine Research Center (VRC), who has already completed a Phase 1 clinical trial of the trivalent vaccine, in addition to a monovalent Phase 1 clinical study of the VEEV VLP component only.

Description of Services

Bioservices. Our Bioservices are based on our established development and manufacturing infrastructure, technology platforms and expertise, as well as continuing capital expenditure projects to expand our capabilities and increase capacity.

Our Bioservices consist of development services, bulk drug substance manufacturing, fill, finish, and packaging of final drug product. Collectively, this portfolio of services provides "molecule-to-market" solutions to clients engaged in all stages of drug development and commercialization. These services are provided to innovator biopharmaceutical companies and non-governmental organizations ("NGOs").

We currently have 8 development and manufacturing sites located in the U.S. and Canada. These sites allow us to meet our internal manufacturing needs as well as performing services for our external customers. Six of these sites currently provide bioservices to customers.

- Our Winnipeg and Gaithersburg sites house our development services expertise;
- Our Lansing and Winnipeg sites house our drug substance expertise; and
- Our Camden, Winnipeg, Rockville and Hattiesburg sites house our drug product and packaging expertise.

We currently have over 55 active Bioservices customers.

Marketing and Sales

We have dedicated sales channels for each of our products and service offerings.

Government - MCM Products

We partner with stakeholders in the USG and domestic NGOs to support procurement of our MCM products and procured product candidates.

We also partner with foreign governments and international NGOs to support procurement of MCM products and procured product candidates internationally.

Our specialized team has expertise and experience in the public and private sector, dealing with counter terrorism, CBRNE preparedness and public health.

The following table lists the registered trademarks for our MCM products:

Trademark	Country of Origin
ACAM2000®	Australia, Brazil, Canada, EU, Hong Kong, Israel, Singapore, United Kingdom, U.S.
Anthrasil®	Australia, Canada, Egypt, EU, Israel, Lebanon, Republic of Korea, Qatar, Saudi Arabia, Singapore, Turkey, United Kingdom, United Arab Emirates, U.S.
	U.S.
	EU, UK
BAT®	Canada, China, EU, Japan, Mexico, Republic of Korea, United Kingdom, U.S.
BioThrax®	Australia, Brazil, Canada, EU, India, Malaysia, Saudi Arabia, Singapore, United Kingdom, U.S.
CYFENDUS®	U.S.
RSDL®	Australia, EU, United Kingdom, U.S.
TEMBEXA®	Argentina, Australia, Brazil, Canada, Chile, China, EU, Hong Kong, India, Israel, Japan, Mexico, New Zealand, Norway, Russia, Singapore, Switzerland, Taiwan, Turkey, Ukraine, United Kingdom, U.S.
CNJ-016®	U.S.

4K

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Henry Schein, Inc.

Physical Address: 4925 Bulls Bay Hwy

City: Jacksonville State: FL Zip: 32219

Mailing Address (if different from physical address): 135 Duryea Rd, E-355

City: Melville State: NY Zip: 11747

Telephone: 631-843-5500 Website: www.henryschein.com

Name of Designated Representative (DR): Sierra Suarez

Licensing Company Email: licensure@henryschein.com DR Email: sierra.suarez@henryschein.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Please see below for details. Exhibits attached.				
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Question 3: Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?

Response: Yes. Based on currently available records/information, and although not necessarily responsive or applicable to the question, Henry Schein, Inc. discloses the following information:

In May 2008, Henry Schein, Inc. resolved a matter with the Florida Department of Health ("DOH") (Case No. 2008-08770; prescription drug wholesaler permit # 22:1315) in connection with a Notice of Violation, alleging that Henry Schein, Inc. sold and/or shipped prescription drugs to an unauthorized recipient, in violation of Chapter 499, Florida Statutes. Henry Schein, Inc. entered into a settlement agreement which resolved the matter without any admission of liability and agreed to make a payment of $5,000. The matter was closed by order dated May 15, 2008.

In July 2011, Henry Schein, Inc. resolved a matter with the Colorado Board of Pharmacy ("BOP") which alleged that Henry Schein, Inc. did not timely submit an application for a change of designated representative in violation of Colorado state statutes and BOP rules (Case No. 2011-1806; non-resident prescription drug wholesaler registration # WHO 7115). Henry Schein, Inc. made a payment of $5,000 to resolve the matter plus a $500 surcharge.

In November 2011, the Iowa Board of Pharmacy alleged that Henry Schein, Inc. violated Iowa state statutes and regulations in connection with the sale of controlled substances to Des Moines University, whose Iowa Controlled Substances Registration had expired at the time of shipment. (Case No. 2010-35; Wholesale Drug License No. 5328) Henry Schein, Inc. denied the allegations. Henry Schein, Inc. agreed to a Citation and Warning, resolving the matter in April 2012 without any admission of liability and agreed to make a payment of $5,000.

Original Signature (electronic, copies or stamps not accepted)

3/24/25
Date

HSI EXHIBIT A

Final Order No. DOH-08-1017-S-MDA
FILED DATE: 5-19-08
Department of Health
By: Rachel Brooks
Deputy Agency Clerk

STATE OF FLORIDA
DEPARTMENT OF HEALTH

DEPARTMENT OF HEALTH,

Petitioner,

Case No.: 2008-08770

vs.

HENRY SCHEIN, INC.,

Respondent.
_____/

FINAL ORDER

A Notice of Violation letter was sent to the Respondent by the Department on April 17, 2008. Having received an Offer of Settlement, which is attached hereto as Exhibit A, this matter is before the Department of Health for the entry of a final order.

The Offer of Settlement was executed on or about May 13, 2008 and submitted together with the payment.

The Offer of Settlement is accepted and incorporated by reference. The parties are directed to comply with the terms of the Agreement.

It is, therefore, ORDERED that this matter and proceeding be CLOSED.

DONE and ORDERED this 15 day of May 2008, in Tallahassee, Leon County, Florida.

ANA M. VIAMONTE ROS, M.D., M.P.H.
State Surgeon General

By: Rebecca R. Poston
Rebecca R. Poston, R.Ph.
Executive Director
Drugs, Devices and Cosmetics

CERTIFICATE OF SERVICE

I HEREBY CERTIFY that a true and correct copy of the foregoing Final Order has been furnished via U.S. mail to: Henry Schein, Inc., 8691 Jesse B. Smith Court, Jacksonville, Florida 32219, this 19 day of May, 2008.

Rachel Blue
Deputy Clerk

cc: Lynne Quimby-Pennock, DOH 4052 Bald Cypress Way, Bin #C-65 Tallahassee, FL 32399
Richard Sands, DOH 4052 Bald Cypress Way, Bin #C-70

SETTLEMENT AGREEMENT
Henry Schein
Case No: 2008-08770

Pursuant to S. 120.57(4), Florida Statutes, the above named party hereby enters into this stipulation as disposition of the attached administrative action, in lieu of any other administrative proceedings authorized in Chapter 120, Florida Statutes. The terms herein become effective upon rendition of the final order which shall incorporate the Settlement Agreement.

STIPULATED FACTS

1) Henry Schein, neither admits nor denies the violations alleged in the Notice of Violation.

2) During the time the violations allegedly occurred, Henry Schein was a permitted Prescription Drug Wholesaler within the state of Florida having been issued permit number 22:1315.

3) The Department is charged with regulating Drugs, Devices, and Cosmetics pursuant to Section 20.43, Florida Statutes and Chapter 499, Florida Statutes.

CONCLUSIONS OF LAW

4) Henry Schein, by and through its undersigned agent, admits that it is subject to the provisions of Chapter 499, Florida Statutes, and the jurisdiction of the Department.

5) Henry Schein, admits that the findings set forth in the Notice of Violation, if proven, would constitute a violation of Chapter 499, Florida Statutes.

6) Henry Schein, agrees that the Department's acceptance of the Settlement Agreement constitutes disciplinary action within the meaning of Section 499.066, Florida Statutes and Rule 64F-12.024, Florida Administrative Code.

SETTLEMENT

7) Henry Schein, agrees to pay a fine of FIVE THOUSAND DOLLARS ($5,000.00), and acknowledges that the total payment is enclosed with this agreement.

8) Henry Schein, affirms the alleged violations cited the Notice of Violation letter issued under this case number have not continued and that it has taken corrective actions to prevent a recurrence.

EXHIBIT
A

9) Henry Schein, affirms that it shall comply with all provisions of the Florida Drug and Cosmetic Act, Chapter 499, Florida Statutes, and the rules adopted thereunder.

10) It is expressly understood that a violation of the terms of this Settlement Agreement shall be considered a violation of Chapter 499, Florida Statutes, for which disciplinary actions may be taken in compliance with Chapters 120 and 499, Florida Statutes.

11) Henry Schein, expressly waives all further procedural steps and expressly waives all rights to seek judicial review of, or to otherwise challenge or contest the validity of, this Settlement Agreement incorporated in the Final Order.

12) Henry Schein, waives the right to seek any attorney's fees or costs from the Department in connection with this disciplinary proceeding.

Corporate Seal:
Henry Schein Inc.
By: _____ 5/13/08
Sr. Vice President (or authorized agent) Date

Attested by: _____ 5/13/08
Corporate Secretary Date
[Note this line only applies if the respondent is a corporation.]

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case No. 2011-1806

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATION OF HENRY SCHEIN, INC., REGISTRATION NO. WHO 7115,

Respondent Wholesaler.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Henry Schein, Inc. ("Respondent Wholesaler") to resolve all matters pertaining to Board Case Number 2011-1806, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Wholesaler, its registration as a non-resident prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Stipulation") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Respondent Wholesaler was originally registered as a non-resident prescription drug wholesaler in the State of Colorado on January 5, 2007, being issued registration number WHO 7115, and has been so registered at all times relevant to this case.

3. Respondent Wholesaler admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

4. Respondent Wholesaler failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, 76 days transpired between the date the previous designated representative ceased the position and the date the application and fee were received.

5. The parties agree that the following Board statutes and rules are relevant to this case:

12-22-802. Wholesaler license requirements.

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3)(VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

* * *

Pharmacy Board Rules

15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

... (8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803.

b. Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

* * *

6. The parties agree that the following disposition is just and appropriate under the circumstances.

DISPOSITION

7. Pursuant to §12-22-806, C.R.S., Respondent Wholesaler shall remit Five Thousand Dollars and No Cents ($5,000.00). Respondent Wholesaler understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 10%. Respondent Wholesaler shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Wholesaler submits this signed Stipulation to the Board.

8. **Compliance.** Respondent Wholesaler shall submit all future applications detailing a change in designated representative and fee to the Board within fourteen (14) days, or as otherwise required by the then-controlling provisions of Board statute, rule or policy, of the previous designated representative ceasing the position.

9. **Other Requirements.** Respondent Wholesaler acknowledges and agrees that, as a condition of this Stipulation, Respondent Wholesaler shall:

   a. promptly pay all its own fees and costs associated with this Stipulation;

   b. comply fully with this Stipulation; and

   c. comply fully with the Pharmaceuticals and Pharmacists Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

10. **Advisements and Waivers.** Respondent Wholesaler enters into this Stipulation freely and voluntarily, after having consulted with legal counsel. Respondent Wholesaler acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

d. to appeal this Stipulation.

Respondent Wholesaler freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Wholesaler to the actions imposed herein.

11. **Acknowledgments.** Respondent Wholesaler has read this Stipulation in its entirety and acknowledges, after having consulted with legal counsel, that Respondent Wholesaler understands its legal consequences and agrees that none of its terms or conditions is unconscionable. Respondent Wholesaler is not relying on any statements, promises or representations from the Board other than as may be contained in this Stipulation. Respondent Wholesaler further acknowledges that it is not entering into this Stipulation under any duress.

12. **Violations.** Time is of the essence in this Stipulation. It is the responsibility of Respondent Wholesaler to take all appropriate steps to comply fully with this Stipulation. Respondent Wholesaler acknowledges and agrees that any violation of this Stipulation may constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Wholesaler's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Stipulation shall not affect the obligation of Respondent Wholesaler to comply with all terms and conditions of this Stipulation.

13. **Integration and Severability.** Upon execution by all parties, this Stipulation shall represent the entire and final agreement of and between the parties. In the event any provision of this Stipulation is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Stipulation shall be given full force and effect.

14. **Public Record.** Upon execution by all parties, this Stipulation shall be a public record, maintained in the custody of the Board and handled as a discipliney document.

15. **Effective Date.** This Stipulation shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Wholesaler

Leonard David Dated: 7/11/11

Authorized Representative / Title
Leonard David / SVP

Subscribed and sworn to before me in the County of Suffolk, State of New York, this 11 day of July, 2011 by Leonard David, authorized representative of Henry Schein, Inc.

Lisa Marie Laletta
Notary Public, State of New York
No. 01LA6199083
Qualified in Nassau County
Commission Expires January 1, 2013

My commission expires:

Lisa Marie Laletta
Notary Public

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 22nd day of July, 2011.

State Board of Pharmacy

BY: For
Wendy Anderson
Program Director

APPROVED AS TO FORM

GREENBERG TRAURIG, LLC

PENFIELD TATE, #11518*
Greenberg Traurig, LLP

Attorneys for Respondent Wholesaler

1200 17th Street, Suite 2400
Denver, Colorado 80202
Telephone: (303) 572-6500
FAX: (720) 904-6142
TateP@gtlaw.com
*Counsel of Record

JOHN W. SUTHERS
Attorney General

JOANNA LEE KAYE, #20486*
Assistant Attorney General
Business and Licensing Section

Attorneys for State Board of Pharmacy

1525 Sherman Street, 5th Floor
Denver, Colorado 80203
Telephone: (303) 866-6170
FAX: (303) 866-5395
jo.kaye@state.co.us
*Counsel of Record

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 22nd day of July 2011, addressed as follows:

Penfield Tate
Greenberg Traurig, LLC
1200 17th Street, Suite 2400
Denver, Colorado 80202

and via interagency mail to:

Jo Kaye
Assistant Attorney General

Linda Acosta

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	
Wholesale Drug License of	)	Case No. 2010-35
HENRY SCHEIN, INC.,	)	
License No. 5328,	)	**CITATION AND**
Respondent.	)	**WARNING**

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), the Iowa Board of Pharmacy (hereinafter, the "Board") and Henry Schein, Inc. (hereinafter, "Respondent"), have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on November 10, 2011 and the licensee disciplinary proceeding shall be resolved without a hearing, as the Board and Respondent stipulate to the following:

1. Respondent's license to operate as a wholesale distributor of drugs in Iowa is evidenced by Wholesale Drug License Number 5328, recorded in the permanent records of the Board.

2. Wholesale Drug License Number 5328 was renewed November 21, 2010, for the year 2011.

3. The Board has jurisdiction over the parties and the subject matter herein.

4. A Statement of Charges was filed against Respondent on March 8, 2011. The Statement of Charges contained two charges: Count I, "Unauthorized Delivery," and Count II, "Violations of Controlled Substance Laws."

5. Respondent denies the allegations contained in the Statement of Charges and hereby enters into this Citation and Warning to resolve the charges without making any admission against its interests. Respondent acknowledges, however,

that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

6. Upon the Board's approval of this Citation and Warning, (a) Count II of the Statement of Charges ("Violations of Controlled Substance Laws) shall be dismissed with prejudice and (b) Respondent shall be assessed a civil penalty in the amount of $5,000. The civil penalty payment shall be made payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Citation and Warning. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

7. Respondent represents that it shall, in the future, comply with all provisions of Iowa law, including the administrative rule prohibiting shipment of controlled substances to persons not authorized to possess the controlled substances.

8. Should Respondent violate or fail to comply with any of the terms or conditions of this Citation and Warning, the Board may initiate further action to impose licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

9. This Citation and Warning is the resolution of a contested case. By entering into this Citation and Warning, Respondent waives all rights to a contested case hearing on the allegations contained in the Statement of Charges, and waives any objections to this Citation and Warning.

10. This proposed settlement is subject to approval by a majority of the full Board. If the Board fails to approve this settlement, it shall be of no force or effect to either party. If the Board approves this Citation and Warning, it shall be the full and final resolution of this matter.

11. The State's counsel may present this Citation and Warning to the Board.

12. The Board's approval of this Citation and Warning shall constitute a FINAL ORDER of the Board in a disciplinary action.

This Citation and Warning is voluntarily submitted by Henry Schein, Inc., to the Iowa Board of Pharmacy for its consideration on this 17th day of April 2012.

HENRY SCHEIN, INC.,
Respondent

Subscribed and sworn to before me by Marjorie Hahn, who has stated to me that he/she is authorized to sign this Citation and Warning on behalf of Henry Schein, Inc., on this 17 day of April 2012.

Lisa Marie Laletta
Notary Public, State of New York
No. 01LA6199083
Qualified in Nassau County
Commission Expires January 1, 2013

NOTARY PUBLIC

This Citation and Warning is accepted by the Iowa Board of Pharmacy on this 27th day of April 2012.

SUSAN M. FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck

Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

Andrew Anderson
Faegre & Benson
801 Grand Avenue, Suite 3100
Des Moines Iowa 50309

Henry Schein settle 11-11.doc

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - No Pharmaceutical Products Distributed

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): N/A

Corporation Name: Henry Schein, Inc.

Mailing Address: 135 Duryea Road

City: Melville State: NY Zip: 11747

Telephone: 643-843-5500 Email: licensure@henryschein.com

Contact Person Name: Regulatory Affairs

Date of SEC Registration: see 10-K | SEC Registration Number: see 10-K | Stock Exchange Symbol: HSIC

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	X	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Henry Schein, Inc.

Facility Name

Michael Ettinger

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/24/25

Date

Board Use Only	Date Received: 3/31/25	Amount: $1600 TH 00820073301

HENRY SCHEIN®

GENERAL BUSINESS: 1-631-843-5500
FAX: 1-631-843-5680
www.henryschein.com

HENRY SCHEIN, INC.
F.E.I.N 11-3136595
Corporate Executive Officers:

Stanley M. Bergman	Chief Executive Officer	135 Duryea Road Melville, NY 11747 Work Phone # 631-843-5910
James P. Breslawski	Vice Chairman and President Henry Schein Inc.	135 Duryea Road Melville, NY 11747 Work Phone # 631-390-8050
Ronald N. South	Senior Vice President Chief Financial Officer	135 Duryea Road Melville, NY 11747 Work Phone # 631-845-2802
Mark E. Mlotek	Executive Vice President Chief Strategic Officer	135 Duryea Road Melville, NY 11747 Work Phone # 631-843-5906
Michael S. Ettinger	Executive Vice President Chief Operating Officer	135 Duryea Road Melville, NY 11747 Work Phone # 631-843-5993

Incorporated Delaware 12/23/1992

HENRY SCHEIN®

135 DURYEA RD
MAIL STOP E-355
MELVILLE, NY 11747
DIRECT LINE 631-843-5847
FAX: 631-843-5557

HENRY SCHEIN, INC.
F.E.I.N 11-3136595
Board of Directors

Stanley M. Bergman	Chairman of the Board and Chief Executive Officer
Mohamad Ali	Senior Vice President and Chief Operating Officer, IBM Counseling
Deborah Derby	President & CEO, Carrols Restaurant Group, Inc.
Carole T. Faig	Former U.S. Health Sector Leader, Ernst & Young LLP (now known as EY LLP)
Joseph L. Herring	Former Chief Executive Officer Covance. Inc.
Robert J. Hombach	Former Executive Vice President, CFO and COO, Baxalta, Inc.
Kurt P. Kuehn	Former Chief Financial Officer, United Parcel Service, Inc.
Philip A. Laskawy	Lead Director, Henry Schein, Inc.; and Retired Chairman, Ernst & Young, LLP (now known as EY LLP)
Anne H. Margulies	Former Vice President and Chief Information Officer, Harvard University
Mark E. Mlotek	Executive Vice President, Chief Strategic Officer
Carol Raphael	National Advisor, Manatt Health Solutions; and Former President and Chief Executive Officer, Visiting Nurse Service of New York
Scott Serota	Former President and Chief Executive Officer of Blue Cross Blue Shield Association
Bradley T. Sheares, Ph.D.	Former Chief Executive Officer, Reliant Pharmaceuticals, Inc.; and Former President of U.S. Human Health, Merck & Co.
Reed V. Tuckson, M.D., FACP	Managing Director of Tuckson Health Connections, LLC, Co-Founder, Black Coalition Against COVID-19, and Co-Founder Coalition For Trust in Health & Science

HENRY SCHEIN®

GENERAL BUSINESS: 1 631 843 5500
FAX: 1 631 843 5680
www.henryschein.com

HENRY SCHEIN, INC
F.E.I.N - 11-3136595
Publicly Traded - NASDAQ: HSIC

Shareholders:

Name	FEIN#	Address	City	State	Zip	% of Shares
The Vanguard Group, Inc.	23-1945930	100 Vanguard Blvd V26	Malvern	PA	19355	11.82
Artisan Partners Limited Partnership	45-0969585	875 E. Wisconsin Avenue, Suite 800	Milwaukee	WI	53202	5.26
BlackRock Institutional Trust Company, N.A.	32-0174431	400 Howard Street	San Francisco	CA	94105	5.23
State Street Global Advisors (US)	90-0337987	Channel Center, 1 Iron Street	Boston	MA	02110	4.92

As of 2/19/25

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HENRY SCHEIN, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SECOND DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HENRY SCHEIN, INC." WAS INCORPORATED ON THE TWENTY-THIRD DAY OF DECEMBER, A.D. 1992.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2320192 8300

SR# 20250008913

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 202610534

Date: 01-02-25

Maria Herrera

From: Licensure <Licensure@henryschein.com>
Sent: Monday, April 7, 2025 1:24 PM
To: Maria Herrera; Licensure
Subject: RE: Nevada out-of-state Wholesaler Application-Henry Schein, Inc.-Jacksonville, FL
Attachments: FL DBPR License Not Required for Devices_02.06.25.pdf

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Maria,

In response to the Deficiency Notice, at this time we are only seeking a license to distribute devices that do not contain a drug. Please see the attached statement from FL DBPR stating a Florida resident license is not required.

Regards,

Pamela Griffin
US Regulatory Compliance Specialist
Phone: 631-247-1875

HENRY SCHEIN®

From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Thursday, April 3, 2025 12:33 PM
To: Licensure <Licensure@henryschein.com>
Subject: [EXTERNAL] Nevada out-of-state Wholesaler Application-Henry Schein, Inc.-Jacksonville, FL

This Message Is From an External Sender
This message came from outside your organization.

- "FTP" File Transfer Protocol

— Division of Drugs, Devices and Cosmetics

– Does my company need a permit?

DDC permitting requirements as regards drugs, (medical) devices and cosmetics fall into two main categories:(a) manufacturing and repackaging of drugs, medical devices and cosmetics conducted in Florida, and (b) distributing drugs, medical devices and cosmetics in and into Florida.

Activity Description	Location	Permit (Generally) Required under Chapter 499?
Manufacturing a Drug, Device or Cosmetic	In Florida	Yes
Repackaging a Drug, Device or Cosmetic	In Florida	Yes
Distributing a Prescription Drug	In or Into Florida	Yes
Distributing an Over-the-Counter Drug	In or Into Florida	No
Distributing a Device	In or Into Florida	No
Distributing a Cosmetic	In or Into Florida	No

- What is a "drug", "device", or "cosmetic"?

Refer to Section 499.003, Florida Statutes: http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html (http://www.leg.state.fl.us/statutes/index.cfm?App_mode=Display_Statute&Search_String=&URL=0400-0499/0499/Sections/0499.003.html)

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 01/27/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Aon Risk Services Northeast, Inc.
New York NY Office
One Liberty Plaza
165 Broadway, Suite 3201
New York NY 10006 USA

CONTACT NAME:
PHONE (A/C. No. Ext): (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Liberty Insurance Corporation	42404
INSURER B:	Liberty Mutual Fire Ins Co	23035
INSURER C:	ProAssurance Specialty Insurance Company	17400
INSURER D:	Berkshire Hathaway Specialty Ins Company	22276
INSURER E:	QBE Specialty Insurance Company	11515
INSURER F:		

INSURED
Henry Schein, Inc.,
Subsidiaries & Affiliates
135 Duryea Road
Melville NY 11747 USA

COVERAGES **CERTIFICATE NUMBER:** 570110601626 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT X LOC OTHER:			TB2621093363034	06/01/2024	06/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $100,000 $5,000 $1,000,000 $5,000,000 Excluded
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			AS2-621-093363-044	06/01/2024	06/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$2,000,000
A	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION			TH7621093363074	06/01/2024	06/01/2025	EACH OCCURRENCE AGGREGATE	$5,000,000 $5,000,000
A A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH) Y/N: N N/A If yes, describe under DESCRIPTION OF OPERATIONS below			WA762D093363014 AOS WC7621093363024 WI	06/01/2024 06/01/2024	06/01/2025 06/01/2025	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000
C	Products Liability			N24NY380027 Claims Made	06/01/2024	06/01/2025	Each Occurrence Aggregate	$10,000,000 $10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Insurance.

CERTIFICATE HOLDER

Henry Schein, Inc.
and its Subsidiary and Affiliated
Companies
135 Duryea Road
Melville NY 11747 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Northeast, Inc.

Holder Identifier : EOC

Certificate No : 570110601626

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER: See Certificate Number: 570110601626	
CARRIER: See Certificate Number: 570110601626 / NAIC CODE:	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	OTHER							
E	E&O - Miscellaneous Professional-Primary			130003732 Cyber Liab/Tech& E&O SIR applies per policy terms & conditions	12/01/2024	12/01/2025	Limit of Liability	$10,000,000
D	Fiduciary Liability - Prima			47EPC31399304 SIR applies per policy terms & conditions	11/01/2024	11/01/2025	Aggregate Limit	$10,000,000

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AGENCY CUSTOMER ID: 570000025511

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Northeast, Inc.	Henry Schein, Inc.,
POLICY NUMBER	
See Certificate Number: 570110601626	
CARRIER / NAIC CODE	EFFECTIVE DATE
See Certificate Number: 570110601626	

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

Named Insureds

Ace Southern Surgical Solutions
Ace Surgical Supply Company, Inc.
AEP MPE Holdings, LLC
All Star Orthodontics
BIOHORIZONS IMPLANT SYSTEMS, INC.
Camlog
CB Healthcare Consulting GmbH
DenMat Holdings, LLC
Dental Instrument Sales & Service, LLC
Dental Practice Transitions
Dentrix Dental Systems
eAssist Inc.
eAssist Publishing LLC
Edge Endo
Exan Enterprises
Firefly Supply LLC
G.I.V. Inc.
General Injectibles & Vaccines, Inc.
Hand Piece Parts & Repair, Inc.
Hayes Handpiece Franchises, Inc.
HealthFirst
Henry Schein, Inc
Henry Schein and Schvadent
Henry Schein Dental, Inc.
Henry Schein Global Sourcing, Inc.
Henry Schein Medical
Henry Schein One, LLC
Henry Schein Practice Solutions
Henry Schein Services GmbH
Henry Schein, Supply
HF Acquisition Co. LLC
HSG-S Corp
Impromed, LLC.
Insource, Inc.
Lighthouse 360, Inc.
Midway Dental Supply LLC
NAR Medical Depot LLC
NAR Training LLC
North American Rescue LLC and TQM, LLC
ORTHO2 LLC
Ortho Organizers, Inc.
Ortho Technology, Inc.
Precision One
Prism Medical Products
RXWORKS, INC.
Sesame Communications
Southern Anesthesia & Surgical Inc.
Shield HealthCare
TDSC, Inc.
The Custom Milling Center, Inc.
US Endodontics
Vulcan Custom Dental
Zahn Dental Company, Inc.
Zahn/Darby Lab

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Henry Schein, Inc. MDEG License # (if applicable): _____

Physical Address: 4925 Bulls Bay Hwy

City: Jacksonville State: FL Zip: 32219

Mailing Address (if different from physical address): 135 Duryea Rd, E-355

City: Melville State: NY Zip: 11747

Telephone: 631-843-5500 Website: www.henryschein.com

Licensing Company Email: licensure@henryschein.com

Section 2: Personal Information

First: Sierra Middle: Marielle Last: Suarez

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: FL Zip: [redacted]

Telephone: [redacted] Email: sierra.suarez@henryschein.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
FLORIDA MEMORIAL UNIVERSITY		08/03 - 05/04	
Address	City	State	Zip
15800 NW 42ND AVE	MIAMI GARDENS	FL	33054
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
WESTSIDE HIGH SCHOOL		08/02 - 05/03	
Address	City	State	Zip
5530 FIRESTONE RD.	JACKSONVILLE	FL	32244
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/22-CURRENT	[redacted]	[redacted]	FL	[redacted]
04/19 – 08/22			FL	
09/16 – 04/19			FL	
05/14 – 09/16			FL	
From - To (MM/YY – MM/YY)		City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Henry Schein		2022 - Present	
Business Address	**City**	**State**	**Zip**
4925 Bulls Bay Hwy	Jacksonville	FL	32219
Phone	**Title**	**Number of Employed Hours**	
904-380-3546	Team Lead	3,000+	
Description of Duties			
Manage the employees responsible for nonprescription drug and medical device distribution, including inventory control and processing customer orders.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5-26-25
Date

I, SIERRA MARIELLE SUAREZ, **certify that as the MDEG Administrator for**

Henry Schein, Inc.,

that I (initial that you have read and meet the following requirements):

1. SMS Have a high school diploma or its equivalent;
2. SMS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SMS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SMS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sierra Suarez
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3.26.25
Date

Board Use Only	Date Received: 3/31/25

HENRY SCHEIN®

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Jacksonville, Florida

A list containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.

Sierra Suarez	Team Lead/DC
Donnie Smith	Bulk Receiver/Material handler
Talon Clairmont	Bulk Receiver/Material Handler
Russell Hollister	Team Lead/DC
Shirl Johnson	Security and Safety Lead
Dalia Fernandez	Security and Safety Officer

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the fiscal year ended December 30, 2023

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934
For the transition period from _____ to _____

Commission file number 0-27078

HENRY SCHEIN, INC.

(Exact name of registrant as specified in its charter)

Delaware	**11-3136595**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

135 Duryea Road
Melville, New York
(Address of principal executive offices)
11747
(Zip Code)
(631) 843-5500
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $.01 per share	HSIC	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
YES: ☒ NO: ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
YES: ☐ NO: ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
YES: ☒ NO: ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
YES: ☒ NO: ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.
Large accelerated filer: ☒ Accelerated filer: ☐ Non-accelerated filer: ☐ Smaller reporting company: ☐
Emerging growth company: ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).
YES: ☐ NO: ☒

The aggregate market value of the registrant's voting stock held by non-affiliates of the registrant, computed by reference to the closing sales price as quoted on the Nasdaq Global Select Market on July 1, 2023, was approximately $10,506,752,000

As of February 20, 2024, there were 128,505,719 shares of registrant's Common Stock, par value $.01 per share, outstanding.

Documents Incorporated by Reference:

Portions of the Registrant's definitive proxy statement to be filed pursuant to Regulation 14A not later than 120 days after the end of the fiscal year (December 30, 2023) are incorporated by reference in Part III hereof.

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PART I

ITEM 1. Business

General

Henry Schein, Inc. is a solutions company for health care professionals powered by a network of people and technology. We believe we are the world's largest provider of health care products and services primarily to office-based dental and medical practitioners, as well as alternate sites of care. Our philosophy is grounded in our commitment to help customers operate a more efficient and successful business so the practitioner can provide better clinical care.

With more than 91 years of experience distributing health care products, we have built a vast set of small, mid-sized and large customers in the dental and medical markets, serving more than one million customers worldwide across dental practices, laboratories, physician practices, and ambulatory surgery centers, as well as government, institutional health care clinics and other alternate care clinics.

We are headquartered in Melville, New York and employ more than 25,000 people. Approximately 55% of our workforce is based in the United States and approximately 45% is based outside of the United States. We have operations or affiliates in 33 countries and territories. Our broad global footprint has evolved over time through our organic success as well as through contribution from strategic acquisitions.

We stock a comprehensive selection of more than 300,000 branded products and Henry Schein corporate brand products through our main distribution centers. Our infrastructure, including over 5.3 million square feet of space in 36 strategically located distribution and 22 manufacturing facilities around the world, enables us to historically provide rapid and accurate order fulfillment, better serve our customers and increase our operating efficiency. This infrastructure, together with broad product and service offerings at competitive prices, and a strong commitment to customer service, enables us to be a single source of supply for our customers' needs.

We conduct our business through two reportable segments: (i) health care distribution and (ii) technology and value-added services. These segments offer different products and services to the same customer base. Our dental businesses serve office-based dental practitioners, dental laboratories, schools, government and other institutions. Our medical businesses serve physician offices, urgent care centers, ambulatory care sites, emergency medical technicians, dialysis centers, home health, federal and state governments and large enterprises, such as group practices and integrated delivery networks, among other providers across a wide range of specialties.

The health care distribution reportable segment, combining our global dental and medical operating segments, distributes consumable products, small equipment, laboratory products, large equipment, equipment repair services, branded and generic pharmaceuticals, vaccines, surgical products, dental specialty products (including implant, orthodontic and endodontic products), diagnostic tests, infection-control products, personal protective equipment products ("PPE") and vitamins. While our primary go-to-market strategy is in our capacity as a distributor, we also market and sell under our own corporate brand portfolio of cost-effective, high-quality consumable merchandise products, and manufacture certain dental specialty products in the areas of oral surgery, implants, orthodontics and endodontics.

The technology and value-added services reportable segment provides software, technology and other value-added services to health care practitioners. Henry Schein One, the largest contributor of sales to this category, offers dental practice management solutions for dental and medical practitioners. In addition, we offer dentists and physicians a broad suite of electronic health records, patient communication services including electronic marketing and website design, analytics and patient demand generation. Our value-added practice solutions include practice consultancy, education, integrated revenue cycle management and the facilitation of financial service offerings (on a non-recourse basis) to help dentists and physicians operate and expand their business operations, e-services, practice technology, network and hardware services, as well as consulting, and continuing education services for practitioners. We believe our hands-on consultative approach to provide solutions to support practice decision-making is a key differentiator for our business.

Recent Developments

See "Management's Discussion and Analysis of Financial Condition and Results of Operations – Recent Developments" herein for a discussion related to recent Company developments.

Industry

The global health care distribution industry, as it relates to office-based health care practitioners, is fragmented and diverse. The industry ranges from sole practitioners working out of relatively small offices to mid-sized and large group practices ranging in size from a few practitioners to several hundred practices owned or operated by dental support organizations ("DSOs"), medical group purchasing organizations ("GPOs"), hospital systems or integrated delivery networks.

Due in part to the limited capacity of office-based health care practitioners to store and manage large quantities of supplies in their offices, the distribution of health care supplies and small equipment to office-based health care practitioners has been characterized by frequent, small quantity orders, and a need for rapid, reliable and substantially complete order fulfillment. The purchasing decisions within an office-based health care practice are typically made by the practitioner, hygienist or office manager. Supplies and small equipment are generally purchased from more than one distributor, with one generally serving as the primary supplier.

The health care distribution industry continues to experience growth due to demand driven by the aging population, increased health care awareness and the importance of preventative care, an increasing understanding of the connection between good oral health and overall health, improved access to care globally, the proliferation of medical technology and testing, new pharmacology treatments and expanded third-party insurance coverage, partially offset by the effects of unemployment on insurance coverage and technological improvements, including the advancement of software and services, prosthetic solutions and telemedicine. In addition, the non-acute market continues to benefit from the shift of procedures and diagnostic testing from acute care settings to alternate-care sites, particularly physicians' offices and ambulatory surgery centers.

We believe that consolidation within the industry will continue to result in a number of distributors, particularly those with limited financial, operating and marketing resources, seeking to combine with larger companies that can provide growth opportunities. This consolidation also may continue to result in distributors seeking to acquire companies that can enhance their current product and service offerings or provide opportunities to serve a broader customer base.

In addition, customer consolidation will likely lead to multiple locations under common management and the movement of more procedures from the hospital setting to the physician or alternate care setting as the health care industry is increasingly focused on efficiency and cost containment. This trend has benefited distributors capable of providing a broad array of products and services at low prices. It also has accelerated the growth of health maintenance organizations ("HMOs"), group practices, other managed care accounts and collective buying groups, which, in addition to their emphasis on obtaining products at competitive prices, tend to favor distributors capable of providing specialized management information support. We believe that the trend towards cost containment has the potential to favorably affect demand for technology solutions, including software, which can enhance the efficiency and facilitation of practice management.

Competition

The distribution and manufacture of health care supplies and equipment is highly competitive. Many of the health care products we sell are available to our customers from a number of suppliers. In addition, our competitors could obtain exclusive rights from manufacturers to market particular products. Manufacturers also could seek to sell directly to end-users, and thereby eliminate or reduce our role and that of other distributors. In certain parts of the dental end market, such as those related to dental specialty products, and medical end market manufacturers already sell directly to end customers.

In North America, we compete with other distributors, as well as several manufacturers, of dental and medical products, primarily on the basis of price, breadth of product line, e-commerce capabilities, customer service and

value-added products and services. In the dental market, our primary competitors in the U.S. are the Patterson Dental division of Patterson Companies, Inc. and Benco Dental Supply Company. In addition, we compete against a number of other distributors that operate on a national, regional and local level. Our primary competitors in the U.S. medical market, which accounts for the large majority of our global medical sales, are McKesson Corporation and Medline Industries, Inc., which are national distributors. We also compete with a number of regional and local medical distributors, as well as a number of manufacturers that sell directly to physicians and patients in their homes. With regard to our dental software, we compete against numerous companies, including the Patterson Dental division of Patterson Companies, Inc., Carestream Health, Inc., Carestream Dental LLC, Centaur Software Development Co Pty Ltd. (d.b.a. dental4windows, dental4web), Open Dental Software, Inc., PlanetDDS LLC, Good Methods Global Inc. (d.b.a. CareStack) and Curve Dental, LLC. In other software end markets, including revenue cycle management, patient relationship management and patient demand generation, we compete with companies such as Vyne Therapeutics Inc., EDI-Health Group, Inc. (d.b.a. Dental X Change, Inc.), Weave Communications, Inc., and Solutionreach, Inc. The medical practice management and electronic medical records market is fragmented and we compete with numerous companies such as the NextGen division of Quality Systems, Inc., eClinicalWorks, Allscripts Healthcare Solutions, Inc. and Epic Systems Corporation.

Outside of the U.S., we believe we are the only global distributor of supplies and equipment to dental practices and our competitors are primarily local and regional companies. We also face significant competition internationally, where we compete on the basis of price and customer service against several large competitors, including the GACD Group, Proclinic SA, Lifco AB, Planmeca Oy and Billericay Dental Supply Co. Ltd., as well as a large number of other dental and medical product distributors and manufacturers in international countries and territories we serve.

Competitive Strengths

We have more than 91 years of experience in distributing products to health care practitioners resulting in strong awareness of the Henry Schein® brand. Our competitive strengths include:

A focus on meeting our customers' unique needs. We are committed to providing customized solutions to our customers that are driven by our understanding of the end markets we serve and reflect the technology-driven products and services best suited for their practice needs. We are committed to continuing to enhance these offerings through organic investment in our products and our teams, as well as through the acquisition of new products and services that may help us better serve our customers.

Direct sales and marketing expertise. Our sales and marketing efforts are designed to establish and solidify customer relationships through personal or virtual visits by field sales representatives, frequent direct marketing and telesales contact, emphasizing our broad product lines, including exclusive distribution agreements, competitive prices and ease of order placement, particularly through our e-commerce platforms. The key elements of our direct sales and marketing efforts are:

- *Field sales consultants.* Our field sales consultants, including equipment sales specialists, covering major North American, European and other international markets. These consultants complement our direct marketing and telesales efforts and enable us to better market, service and support the sale of more sophisticated products and equipment.

- *Marketing.* We market to existing and prospective office-based health care providers through a combination of owned, earned and paid digital channels, tradeshows, as well as through catalogs, flyers, direct mail and other promotional materials. Our strategies include an emphasis on educational content through webinars and content marketing initiatives. We continue to enhance our marketing technology to improve our targeting capability and the relevance of messaging and offers.

- *Telesales.* We support our direct marketing effort with inbound and outbound telesales representatives, who facilitate order processing, generate new sales through direct and frequent contact with customers and stay abreast of market developments and the hundreds of new products, services and technologies introduced each year to educate practice personnel.

- *Electronic commerce solutions.* We provide our customers and sales teams with innovative and competitive e-commerce solutions. We continue to invest in our e-commerce platform to offer enhanced content management so customers can more easily find the products they need and to enable an engaging purchase experience, supported by excellent customer service.

- *Social media.* Our operating entities and employees engage our customers and supplier partners through various social media platforms, which are an important element of our communications and marketing efforts. We continue to expand our social media presence to raise awareness about issues, engage customers beyond a sale and deliver services and solutions to specialized audiences.

Broad product and service offerings at competitive prices. We offer a broad range of products and services to our customers, at competitive prices, in the following categories:

- *Consumable supplies and equipment.* We distribute consumable products, small equipment, laboratory products, large equipment, equipment repair services, branded and generic pharmaceuticals, vaccines, dental specialty products, diagnostic tests, infection-control products and vitamins. We stock a comprehensive selection of more than 300,000 branded products and Henry Schein corporate brand products through our main distribution centers. We also market and sell our own corporate brand portfolio of cost-effective, high-quality consumable merchandise products and manufacture certain dental specialty products in the areas of implants, orthodontics and endodontics.

- *Technology and other value-added products and services.* We sell practice management, business analytics, patient engagement and patient demand creation software solutions to our dental customers. Our practice management solutions provide practitioners with electronic medical records, patient treatment history, analytics, billing, accounts receivable analyses and management, appointment calendars, electronic claims processing and word processing programs, network and hardware services, e-commerce and electronic marketing services, sourcing third party patient payment plans, transition services and training and education programs for practitioners. We also sell medical software for practice management, certified electronic health records ("EHR") and e-Prescribe medications and prescription solutions. We have technical representatives supporting customers using our practice management solutions and services. As of December 30, 2023, we had an active user base of approximately 110,000 practices and 350,000 consumers, including users of AxiUm, Dentally®, Dentrix Ascend®, Dental Vision®, Dentrix® Dental Systems, Dentrix® Enterprise, Easy Dental®, EndoVision®, Evolution® and EXACT®, Gesden®, Jarvis Analytics™, Julie® Software, Oasis, OMSVision®, Orisline®, PBS Endo®, PerioVision®, Power Practice® Px, PowerDent, and Viive® and subscriptions for Demandforce®, Sesame, and Lighthouse360® for dental practices and DentalPlans.com® for dental patients.

- *Repair services.* We have 119 equipment sales and service centers worldwide that provide a variety of repair, installation and technical services for our health care customers. Our technicians provide installation and repair services for dental handpieces, dental and medical small equipment, table-top sterilizers and large dental equipment.

- *Financial services.* We offer our customers solutions in operating their practices more efficiently by providing access to a number of financial services and products provided by third party suppliers (including non-recourse financing for equipment, technology and software products, non-recourse practice financing for leasehold improvements, business debt consolidation and commercial real estate, non-recourse patient financing and credit card processing) at rates that we believe are generally lower than what our customers would be able to secure independently. We also provide staffing services, dental practice valuation and brokerage services.

Commitment to superior customer service. We maintain a strong commitment to providing superior customer service. We frequently monitor our customer service through customer surveys, focus groups and statistical reports. Our customer service policy primarily focuses on:

- *Exceptional order fulfillment.* We ship an average of approximately 141,000 cartons daily.

- *Comprehensive ordering process*. Customers may place orders 24 hours a day, 7 days a week via e-commerce solutions, telephone, fax, e-mail and mail.

Integrated management information systems. Certain of our information systems generally allow for centralized management of key functions, including accounts receivable, inventory, accounts payable, payroll, purchasing, sales, order fulfillment and financial and operational reporting. These systems allow us to manage our growth, deliver superior customer service, properly target customers, manage financial performance and monitor daily operational statistics.

Cost-effective purchasing. We believe that cost-effective purchasing is a key element to maintaining and enhancing our position as a competitively priced provider of health care products. We continuously evaluate our purchase requirements and suppliers' offerings and prices in order to obtain products at the lowest possible cost. In 2023, our top 10 health care distribution suppliers and our single largest supplier accounted for approximately 24% and 4%, respectively, of our aggregate purchases.

Efficient distribution. We distribute our products from our 36 strategically located distribution centers. We strive to maintain optimal inventory levels in order to satisfy customer demand for prompt delivery and complete order fulfillment. These inventory levels are managed on a daily basis with the aid of our management information systems. Once an order is entered, it is electronically transmitted to the distribution center nearest the customer's location for order fulfillment.

Products and Services

The following table sets forth the percentage of consolidated net sales by principal categories of products and services offered through our health care distribution and technology and value-added services reportable segments:

	December 30, 2023	December 31, 2022	December 25, 2021
Health care distribution:			
Dental products [1]	61.1%	59.1%	60.8%
Medical products [2]	32.4	35.2	34.0
Total health care distribution	93.5	94.3	94.8
Technology and value-added services:			
Software and related products and other value-added products [3]	6.5	5.7	5.2
Total	100.0	100.0	100.0

(1) Includes infection-control products, handpieces, preventatives, impression materials, composites, anesthetics, teeth, dental implants, gypsum, acrylics, articulators, abrasives, dental chairs, delivery units and lights, X-ray supplies and equipment, PPE products, equipment repair and high-tech and digital restoration equipment.

(2) Includes branded and generic pharmaceuticals, vaccines, surgical products, diagnostic tests, infection-control products, X-ray products, equipment, PPE products and vitamins.

(3) Consists of practice management software and other value-added products, which are distributed primarily to health care providers, and financial services on a non-recourse basis, e-services, continuing education services for practitioners, consulting and other services.

Business Strategy

Our mission is to provide innovative, integrated health care products and services; and to be trusted advisors and consultants to our customers - enabling them to deliver the best quality patient care and enhance their practice management efficiency and profitability. Our BOLD+1 Strategic Plan consists of the following:

- **Build ("B")** Complementary software, specialty, and services businesses for high growth
- **Operationalize ("O")** One Distribution to deliver exceptional customer experience, increased efficiency, and growth
- **Leverage ("L")** One Schein to broaden and deepen relationships with our customers
- **Drive ("D")** Drive digital transformation for our customers and for Henry Schein
- **+1** Create Value for our stakeholders

To accomplish this, we apply our competitive strengths in executing the following strategies:

- *Increase penetration of our existing customer base.* We have over one million customers worldwide and we intend to increase sales to our existing customer base and enhance our position as their primary supplier. We believe our offering of a broad range of products, services and support, including software solutions that can help drive improved workflow efficiency and patient communications for practices, coupled with our full-service value proposition, helps us to retain and grow our customer base.

- *Increase the number of customers we serve.* This strategy includes increasing the productivity of our field sales consultants and telesales team, as well as using our customer database to focus our marketing efforts in all of our operating segments. In the dental business, we provide products and services to independent practices, mid-market groups, and large DSOs as well as community health centers and government sites of care. Leveraging our broad array of assets and capabilities, we offer solutions to address these new markets. In the medical business, we have expanded to serve customers located in settings outside of the traditional office, such as urgent care clinics, retail, occupational health and home health settings. As settings of health care shift, we remain committed to serving these practitioners and providing them with the products and services they need.

- *Leverage our value-added products and services.* We continue to increase cross-selling efforts for key product lines utilizing a consultative selling process. In the dental business, we have significant cross-selling opportunities between our dental software users and our dental customers. In the medical business, we have opportunities to expand our vaccine, injectables and other pharmaceuticals sales to health care practitioners, as well as cross-selling EHR systems and software when we sell our core products. Our strategy extends to providing health systems, integrated delivery networks and other large group and multi-site health care organizations, including physician clinics, these same value added products and services. As physicians and health systems closely align, we have increased access to opportunities for cross-marketing and selling our product and service portfolios.

- *Pursue strategic acquisitions and joint ventures.* Our acquisition strategy is focused on investments in companies that add new customers and sales teams, increase our geographic footprint (whether entering a new country, such as emerging markets, or building scale where we have already invested in businesses), and finally, those that enable us to access new products and technologies.

Markets Served

Demographic trends indicate that our markets are growing, as an aging U.S. population is increasingly using health care services. According to the U.S. Census Bureau's International Database, between 2023 and 2033, the 45 and older population is expected to grow by approximately 11%. Between 2023 and 2043, this age group is expected to grow by approximately 21%. This compares with expected total U.S. population growth rates of approximately 6% between 2023 and 2033 and approximately 11% between 2023 and 2043.

In the dental industry, there is predicted to be a rise in oral health care expenditures as the 45-and-older segment of the population increases. There is increasing demand for new technologies that allow dentists to increase productivity, and this is being driven in the U.S. by lower insurance reimbursement rates. At the same time, there is an expected increase in dental insurance coverage.

In the medical market, there continues to be a migration of procedures from acute-care settings to physicians' offices and home health settings, a trend that we believe provides additional opportunities for us. There also is the continuing use of vaccines, injectables and other pharmaceuticals in alternate-care settings. We believe we have established a leading position as a vaccine supplier to the office-based physician practitioner.

We support our dental and medical professionals through the many SKUs that we offer, as well as through important value-added services, including practice management software, electronic claims processing, financial services and continuing education, all designed to help maximize a practitioner's efficiency.

Additionally, we seek to expand our dental full-service model and medical offerings in countries where opportunities exist. We do this through both direct sales and by partnering with local distribution and manufacturing companies.

For information on revenues and long-lived assets by geographic area, see Note 4 – Segment and Geographic Data of "Notes to Consolidated Financial Statements."

Seasonality and Other Factors Affecting Our Business and Quarterly Results

We experience fluctuations in quarterly earnings. As a result, we may fail to meet or exceed the expectations of securities analysts and investors, which could cause our stock price to decline.

Our business is subject to seasonal and other quarterly fluctuations. Sales and profitability generally have been higher in the third and fourth quarters due to the timing of sales of seasonal products (including influenza vaccine), purchasing patterns of office-based health care practitioners for certain products (including equipment and software) and year-end promotions. Sales and profitability may also be impacted by the timing of certain annual and biennial dental tradeshows where equipment promotions are offered. In addition, some dental practices delay equipment purchases in the U.S. until year-end due to tax incentives. We expect our historical seasonality of sales to continue in the foreseeable future.

Governmental Regulations

We strive to be compliant in all material respects with the applicable laws, regulations and guidance described below, and believe we have effective compliance programs and other controls in place to ensure substantial compliance. However, compliance is not guaranteed either now or in the future, as certain laws, regulations and guidance may be subject to varying and evolving interpretations that could affect our ability to comply, as well as future changes, additions and enforcement approaches, including political changes. When we discover situations of non-compliance we seek to remedy them and bring the affected area back into compliance. President Biden's administration (the "Biden Administration") has indicated that it will be more aggressive in its pursuit of alleged violations of law, and has revoked certain guidance that would have limited governmental use of informal agency guidance to pursue potential violations, and has stated that it is more prepared to pursue individuals for corporate law violations, including an aggressive approach to anti-corruption activities. Federal, state and certain foreign governments have also increased enforcement activity in the health care sector, particularly in areas of fraud and abuse, anti-bribery and corruption, controlled substances handling, medical device regulations and data privacy and security standards.

Changes to applicable laws, regulations and guidance described below, as well as related administrative or judicial interpretations, may require us to update or revise our operations, services, marketing practices and compliance programs and controls, and may impose additional and unforeseen costs on us, pose new or previously immaterial risks to us, or may otherwise have a material adverse effect on our business.

Government

Certain of our businesses involve the distribution, manufacturing, importation, exportation, marketing, sale and promotion of pharmaceuticals and/or medical devices, and in this regard, we are subject to extensive local, state, federal and foreign governmental laws and regulations, including as applicable to our wholesale distribution of pharmaceuticals and medical devices, manufacturing activities, and as part of our specialty home medical supply businesses that distribute and sell medical equipment and supplies directly to patients. Federal, state and certain foreign governments have also increased enforcement activity in the health care sector, particularly in areas of fraud and abuse, anti-bribery and anti-corruption, controlled substances handling, medical device regulations and data privacy and security standards.

Certain of our businesses involve pharmaceuticals and/or medical devices, including in vitro diagnostic devices, that are paid for by third parties and must operate in compliance with a variety of burdensome and complex coding, billing and record-keeping requirements in order to substantiate claims for payment under federal, state and commercial healthcare reimbursement programs.

Government and private insurance programs fund a large portion of the total cost of medical care, and there have been efforts to limit such private and government insurance programs, including efforts, thus far unsuccessful, to seek repeal of the entire United States Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act, each enacted in March 2010 (as amended, the "ACA").

Certain of our businesses are subject to various additional federal, state, local and foreign laws and regulations, including with respect to the sale, transportation, importation, storage, handling and disposal of hazardous or potentially hazardous substances; "forever chemicals" such as per-and polyfluoroalkyl substances; and safe working conditions. In addition, activities to control medical costs, including laws and regulations lowering reimbursement rates for pharmaceuticals, medical devices, medical supplies and/or medical treatments or services, are ongoing. The Centers for Medicare & Medicaid Services ("CMS") recently released the 2024 durable medical equipment, prosthetics, orthotics and supplies ("DMEPOS") reimbursement schedule, which, effective January 1, 2024, reduced the DMEPOS reimbursement rates for non-rural suppliers, such as us, by removing the Coronavirus Aid, Relief, and Economic Security (aka CARES) Act relief rates in effect during the COVID-19 pandemic. This and other laws and regulations are subject to change and their evolving implementation may impact our operations and our financial performance.

Our businesses are generally subject to numerous laws and regulations that could impact our financial performance, and failure to comply with such laws or regulations could have a material adverse effect on our business.

Operating, Security and Licensure Standards

Certain of our businesses are subject to local, state and federal governmental laws and regulations relating to the distribution of pharmaceuticals and medical devices and supplies. Among the United States federal laws applicable to us are the Controlled Substances Act, the Federal Food, Drug, and Cosmetic Act, as amended ("FDC Act"), Section 361 of the Public Health Service Act and Section 401 of the Consolidated Appropriations Act of the Social Security Act, as well as laws regulating the billing of and reimbursement from government programs, such as Medicare and Medicaid, and from commercial payers. We are also subject to comparable foreign regulations.

The FDC Act, the Controlled Substances Act, their implementing regulations, and similar foreign laws generally regulate the introduction, manufacture, advertising, marketing and promotion, sampling, pricing and reimbursement, labeling, packaging, storage, handling, returning or recalling, reporting, and distribution of, and record keeping for, pharmaceuticals and medical devices shipped in interstate commerce, and states may similarly regulate such activities within the state. Furthermore, Section 361 of the Public Health Service Act, which provides authority to prevent the introduction, transmission or spread of communicable diseases, serves as the legal basis for the United States Food and Drug Administration's ("FDA") regulation of human cells, tissues and cellular and tissue-based products, also known as "HCT/P products."

The Federal Drug Quality and Security Act of 2013 brought about significant changes with respect to pharmaceutical supply chain requirements. Title II of this measure, known as the Drug Supply Chain Security Act ("DSCSA"), was enacted in November 2013, and had a planned "phase in" schedule over a period of ten years, resulting in a national electronic, interoperable system to identify and trace certain prescription drugs as they are distributed in the United States that went into effect on November 27, 2023. Those DSCSA requirements that were scheduled to change on November 27, 2023, and include requiring trading partners to provide, receive and maintain documentation about products and ownership only "electronically" (and not via paper) are now subject to a one-year "stabilization period" announced by FDA through two guidance documents in late August 2023. FDA is permitting the stabilization period to accommodate an additional year, until November 27, 2024, to allow trading partners to implement, troubleshoot and mature their electronic (versus paper), interoperable systems, during which time the FDA does not intend to take action to enforce the requirements for the interoperable, electronic, package level product tracing. Additionally, the FDA announced that it does not intend to take action to enforce the portion of the FDC Act with respect to drug product that is introduced in a transaction into commerce by the product's manufacturer or repackager before November 27, 2024, and for subsequent transactions of such product through the product's expiry. FDA states this stabilization period is intended to avoid disruption to the supply chain, and ensure continued patient access to drug products as trading partners move towards full implementation of the DSCSA's enhanced drug security requirements. The law's track and trace requirements applicable to manufacturers, wholesalers, third-party logistics providers (e.g., trading partners), repackagers and dispensers (e.g.,

pharmacies) of prescription drugs took effect in January 2015, and, as stated, continues to be implemented. The DSCSA product tracing requirements replace the former FDA drug pedigree requirements and pre-empt certain state requirements that are inconsistent with, more stringent than, or in addition to, the DSCSA requirements.

The DSCSA also establishes certain requirements for the licensing and operation of prescription drug wholesalers and third-party logistics providers ("3PLs"), and includes the eventual creation of national wholesaler and 3PL licenses in cases where states do not license such entities. The DSCSA requires that wholesalers and 3PLs distribute drugs in accordance with certain standards regarding the recordkeeping, storage and handling of prescription drugs. The DSCSA requires wholesalers and 3PLs to submit annual reports to the FDA, which include information regarding each state where the wholesaler or 3PL is licensed, the name and address of each facility, and contact information. According to FDA guidance, states are pre-empted from imposing any licensing requirements that are inconsistent with, less stringent than, directly related to, or covered by the standards established by federal law in this area. Current state licensing requirements concerning wholesalers will remain in effect until the FDA issues new regulations as directed by the DSCSA. FDA issued a proposed rule establishing wholesaler and 3PL national standards for licensing and other requirements in February 2022, but that rule has not yet been finalized. In addition, with respect to our specialty home medical supply business, we are subject to certain state licensure laws (including state pharmacy laws), and also certain accreditation standards, including to qualify for reimbursement from Medicare and other third-party payers.

The Food and Drug Administration Amendments Act of 2007 and the Food and Drug Administration Safety and Innovation Act of 2012 amended the FDC Act to require the FDA to promulgate regulations to implement a unique device identification ("UDI") system for medical devices. The UDI rule phased in the implementation of the UDI regulations, generally beginning with the highest-risk devices (i.e., Class III medical devices) and ending with the lowest-risk devices. Most compliance dates were reached as of September 24, 2018, with a final set of requirements for low risk devices being reached on September 24, 2022, which completed the phase in. However, in May 2021, the FDA issued an enforcement policy stating that it does not intend to object to the use of legacy identification numbers on device labels and packages for finished devices manufactured and labeled prior to September 24, 2023. The UDI regulations require "labelers" to include unique device identifiers ("UDIs"), with a content and format prescribed by the FDA and issued under a system operated by an FDA-accredited issuing agency, on the labels and packages of medical devices (including, but not limited to, certain software that qualifies as a medical device under FDA rules), and to directly mark certain devices with UDIs. The UDI regulations also require labelers to submit certain information concerning UDI-labeled devices to the FDA, much of which information is publicly available on an FDA database, the Global Unique Device Identification Database. On July 22, 2022, the FDA posted the final guidance regarding the Global Unique Device Identification Database called Unique Device Identification Policy Regarding Compliance Dates for Class I and Unclassified Devices, Direct Marketing, and Global Unique Device Identification Database Requirements for Certain Devices. The UDI regulations and subsequent FDA guidance regarding the UDI requirements provide for certain exceptions, alternatives and time extensions. For example, the UDI regulations include a general exception for Class I devices exempt from the Quality System Regulation (other than record-keeping requirements and complaint files). Regulated labelers include entities such as device manufacturers, repackagers, reprocessors and relabelers that cause a device's label to be applied or modified, with the intent that the device will be commercially distributed without any subsequent replacement or modification of the label and include certain of our businesses.

As a distributor of controlled substances, we are required, under the Controlled Substances Act, to obtain and renew annually registrations for our facilities from the United States Drug Enforcement Administration ("DEA") permitting us to handle controlled substances. We are also subject to other statutory and regulatory requirements relating to the storage, sale, marketing, handling, reporting, record-keeping and distribution of such drugs, in accordance with the Controlled Substances Act and its implementing regulations, and these requirements have been subject to heightened enforcement activity in recent times. We are subject to inspection by the DEA. Certain of our businesses are also required to register for permits and/or licenses with, and comply with operating and security standards of, the DEA, the FDA, the United States Department of Health and Human Services ("HHS"), and various state boards of pharmacy, state health departments and/or comparable state agencies as well as comparable foreign agencies, and certain accrediting bodies, depending on the type of operations and location of product distribution, manufacturing or sale. These businesses include those that distribute, manufacture, relabel, and/or repackage prescription pharmaceuticals and/or medical devices and/or HCT/P products, or own pharmacy operations, or install, maintain or repair equipment.

In addition, Section 301 of the National Organ Transplant Act, and a number of comparable state laws, impose civil and/or criminal penalties for the transfer of human organs, as defined in the regulations, for valuable consideration, while generally permitting payments for the reasonable costs incurred in their procurement, processing, storage and distribution. We are also subject to foreign government regulation of such products. The DEA, the FDA and state regulatory authorities have broad inspection and enforcement powers, including the ability to suspend or limit the distribution of products by our distribution centers, seize or order the recall of products and impose significant criminal, civil and administrative sanctions for violations of these laws and regulations. Foreign regulations subject us to similar foreign enforcement powers.

EU Regulation of Medicinal and Dental Products

European Union ("EU") member states regulate their own healthcare systems, as does EU law. The latter regulates certain matters, most notably medicinal products and medical devices. Medicinal products are defined, broadly, as substances or combinations of substances having certain functionalities and may not include medical devices. EU "regulations" apply in all member states, whereas "directives" are implemented by the individual laws of member states.

On medicines for humans, we are regulated under Directive No. 2001/83/EC of 6 November 2001, as amended by Directive 2003/63/EC of 25 June 2003, and EU Regulation (EC) No. 726/2004 of 31 March 2004. These rules provide for the authorization of products, and regulate their manufacture, importation, marketing and distribution. It implements requirements which may be implemented without warning, as well as a national pharmacovigilance system under which marketing authorizations may be withdrawn, and includes potential sanctions for breaches of the rules, and on other bases such as harmfulness or lack of efficacy.

EU Regulation No. 1223/2009 of 30 November 2009 *on cosmetic products* requires that cosmetic products (which includes dental products) be safe for human health when used under normal or reasonably foreseeable conditions of use and comply with certain obligations which apply to manufacturer, importer and distributor. It includes market surveillance, and non-compliance may result in the recall or withdrawal of products, along with other sanctions.

In the EU, the EU Medical Device Regulation No. 2017/745 of 5 April 2017 ("EU MDR") covers a wide scope of our activities, from dental material to X-ray machines, and certain software. It was meant to become applicable three years after publication (i.e., May 26, 2020). However, on April 23, 2020, to allow European Economic Area ("EEA") national authorities, notified bodies, manufacturers and other actors to focus fully on urgent priorities related to the COVID-19 pandemic, the European Council and Parliament adopted Regulation 2020/561, postponing the date of application of the EU MDR by one year (to May 26, 2021).

The EU MDR significantly modifies and intensifies the regulatory compliance requirements for the medical device industry as a whole. Among other things, the EU MDR:

- strengthens the rules on placing devices on the market and reinforces surveillance once they are available;
- establishes explicit provisions on manufacturers' responsibilities for the follow-up of the quality, performance and safety of devices placed on the market;
- improves the traceability of medical devices throughout the supply chain to the end-user or patient through a unique identification number;
- sets up a central database to provide patients, healthcare professionals and the public with comprehensive information on products available in the EU;
- strengthens rules for the assessment of certain high-risk devices, such as implants, which may have to undergo an additional check by experts before they are placed on the market; and
- identifies importers and distributors and medical device products through registration in a database (EUDAMED, which is not fully functional for the time being and might not be so before the end of 2027 at the earliest; therefore, the use of this database is only possible through a voluntary basis and, by a way of consequence, is currently not mandatory).

In particular, the EU MDR imposes strict requirements for the confirmation that a product meets the regulatory requirements, including regarding a product's clinical evaluation and a company's quality systems, and for the distribution, marketing and sale of medical devices, including post-market surveillance.

Regulation 2023/607 of the European Parliament and of the Council of *amending Regulations (EU) 2017/745 and (EU) 2017/746 as regards the transitional provisions for certain medical devices and in vitro diagnostic medical devices* has, notably, extended the EU MDR transitional periods applicable to certain medical devices that have been assessed and/or certified under the Directive No. 93/42/EEC of 1993 *concerning medical devices* ("EU Medical Device Directive"). Subject to certain conditions, medical devices that (i) obtained a certificate under the EU Medical Device Directive from May 25, 2017, (ii) which was still valid on May 26, 2021, and (iii) has not been subsequently withdrawn may, for the moment, continue to be placed on the market or put into service until December 31, 2027 for higher risk devices or December 31, 2028 for medium and lower risk devices. Nevertheless, EU MDR requirements regarding the distribution, marketing and sale including quality systems and post-market surveillance have to be observed by manufacturers, importers and distributors as of the application date (i.e., since May 26, 2021).

Other EU regulations that may apply under appropriate circumstances include EU Regulation No. 1907/2006 of 18 December 2006 *concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals*, which requires importers to register substances or mixtures that they import in the EU beyond certain quantities, and the EU Regulation No. 1272/2008 of 16 December 2008 *on classification, labelling and packaging of substances and mixtures* (currently under revision), which sets various obligations with respect to the labelling and packaging of concerned substances and mixtures.

Furthermore, compliance with legal requirements has required and may in the future require us to delay product release, sale or distribution, or institute voluntary recalls of, or other corrective action with respect to products we sell, each of which could result in regulatory and enforcement actions, financial losses and potential reputational harm. Our customers are also subject to significant federal, state, local and foreign governmental regulation, which may affect our interactions with customers, including the design and functionality of our products.

Certain of our businesses are subject to various additional federal, state, local and foreign laws and regulations, including with respect to the sale, transportation, storage, handling and disposal of hazardous or potentially hazardous substances, and safe working conditions. In addition, certain of our businesses must operate in compliance with a variety of burdensome and complex billing and record-keeping requirements in order to substantiate claims for payment under federal, state and commercial healthcare reimbursement programs.

Certain of our businesses also maintain contracts with governmental agencies and are subject to certain regulatory requirements specific to government contractors.

Antitrust and Consumer Protection

The federal government of the United States, most U.S. states and many foreign countries have antitrust laws that prohibit certain types of conduct deemed to be anti-competitive, as well as consumer protection laws that seek to protect consumers from improper business practices. At the U.S. federal level, the Federal Trade Commission oversees enforcement of these types of laws, and states have similar government agencies. Violations of antitrust or consumer protection laws may result in various sanctions, including criminal and civil penalties. Private plaintiffs may also bring civil lawsuits against us in the United States for alleged antitrust law violations, including claims for treble damages. EU law also regulates competition and provides for detailed rules protecting consumers. The Biden Administration has indicated increased antitrust enforcement and has been more aggressive in enforcement activities, including investigation and challenging non-compete restrictions and other restrictive contractual terms that it believes harm workers and competition.

Health Care Fraud

Certain of our businesses are subject to federal and state (and similar foreign) health care fraud and abuse, referral and reimbursement laws and regulations with respect to their operations. Some of these laws, referred to as "false claims laws," prohibit the submission or causing the submission of false or fraudulent claims for reimbursement to federal, state and other health care payers and programs. Other laws, referred to as "anti-kickback laws," prohibit soliciting, offering, receiving or paying remuneration in order to induce the referral of a patient or ordering, purchasing, leasing or arranging for, or recommending, ordering, purchasing or leasing of, items or services that are paid for by federal, state and other health care payers and programs. Certain additional state and federal laws, such

as the federal Physician Self-Referral Law, commonly known as the "Stark Law," prohibit physicians and other health care professionals from referring a patient to an entity with which the physician (or family member) has a financial relationship, for the furnishing of certain designated health services (for example, durable medical equipment and medical supplies), unless an exception applies. Violations of Anti-Kickback Statutes or the Stark Law may be enforced as violations of the federal False Claims Act.

The fraud and abuse laws and regulations have been subject to heightened enforcement activity over the past few years, and significant enforcement activity has been the result of "relators" who serve as whistleblowers by filing complaints in the name of the United States (and if applicable, particular states) under applicable false claims laws, and who may receive up to 30% of total government recoveries. Penalties under fraud and abuse laws may be severe, including treble damages and substantial civil penalties under the federal False Claims Act, as well as potential loss of licenses and the ability to participate in federal and state health care programs, criminal penalties, or imposition of a corporate integrity agreement or corporate compliance monitor which could have a material adverse effect on our business. Also, these measures may be interpreted or applied by a prosecutorial, regulatory or judicial authority in a manner that could require us to make changes in our operations or incur substantial defense and settlement expenses. Even unsuccessful challenges by regulatory authorities or private relators could result in reputational harm and the incurring of substantial costs. Most states have adopted similar state false claims laws, and these state laws have their own penalties, which may be in addition to federal False Claims Act penalties, as well as other fraud and abuse laws.

With respect to measures of this type, the United States government (among others) has expressed concerns about financial relationships between suppliers on the one hand and physicians, dentists and other healthcare professionals on the other. As a result, we regularly review and revise our marketing practices as necessary to facilitate compliance.

We also are subject to certain United States and foreign laws and regulations concerning the conduct of our foreign operations, including the U.S. Foreign Corrupt Practices Act, the U.K. Bribery Act, German anti-corruption laws and other anti-bribery laws and laws pertaining to the accuracy of our internal books and records, which have been the focus of increasing enforcement activity globally in recent years.

While we believe that we are substantially compliant with applicable fraud and abuse laws and regulations, and have adequate compliance programs and controls in place to ensure substantial compliance, we cannot predict whether changes in applicable law, or interpretation of laws, or changes in our services or marketing practices in response to changes in applicable law or interpretation of laws, or failure to comply with applicable law, could have a material adverse effect on our business.

Affordable Care Act and Other Insurance Reform

The ACA increased federal oversight of private health insurance plans and included a number of provisions designed to reduce Medicare expenditures and the cost of health care generally, to reduce fraud and abuse, and to provide access to increased health coverage. The ACA also materially expanded the number of individuals in the United States with health insurance.

The ACA has faced frequent legal challenges, including litigation seeking to invalidate and Congressional action seeking to repeal some of or all of the law or the manner in which it has been implemented. In 2012, the United States Supreme Court, in upholding the constitutionality of the ACA and its individual mandate provision requiring that people buy health insurance or else face a penalty, simultaneously limited ACA provisions requiring Medicaid expansion, making such expansion a state-by-state decision. In addition, one of the major political parties in the United States remains committed to seeking the ACA's legislative repeal, but legislative efforts to do so have previously failed to pass both chambers of Congress. Under President Trump's administration, a number of administrative actions were taken to materially weaken the ACA, including, without limitation, by permitting the use of less robust plans with lower coverage and eliminating "premium support" for insurers providing policies under the ACA. The Tax Cuts and Jobs Act enacted in 2017, which contains a broad range of tax reform provisions that impact the individual and corporate tax rates, international tax provisions, income tax add-back provisions and deductions, also effectively repealed the ACA's individual mandate by zeroing out the penalty for non-compliance. An ACA lawsuit decided by the federal Fifth Circuit Court of Appeals found the individual mandate to be

unconstitutional, and returned the case to the District Court for the Northern District of Texas for consideration of whether the remainder of the ACA could survive the excision of the individual mandate. The Fifth Circuit's decision was appealed to the United States Supreme Court. The Supreme Court issued a decision on June 17, 2021. Without reaching the merits of the case, the Supreme Court held that the plaintiffs in the case did not have standing to challenge the ACA. Any outcomes of future cases that change the ACA, in addition to future legislation, regulation, guidance and/or Executive Orders that do the same, could have a significant impact on the U.S. healthcare industry. For instance, the American Rescue Plan Act of 2021 enhanced premium tax credits, which has resulted in an expansion of the number of people covered under the ACA. These changes were time-limited, with some enhancements in place for 2021 only and others available through the end of 2022.

An ACA provision, generally referred to as the Physician Payments Sunshine Act or Open Payments Program (the "Sunshine Act"), imposes annual reporting and disclosure requirements for drug and device manufacturers and distributors with regard to payments or other transfers of value made to certain covered recipients (including physicians, dentists, teaching hospitals, physician assistants, nurse practitioners, clinical nurse specialists, certified registered nurse anesthetists, and certified nurse midwives), and for such manufacturers and distributors and for group purchasing organizations, with regard to certain ownership interests held by covered recipients in the reporting entity. CMS publishes information from these reports on a publicly available website, including amounts transferred and physician, dentist, teaching hospital, and non-physician practitioner identities. The Sunshine Act pre-empts similar state reporting laws, although we or our subsidiaries may be required to report under certain state transparency laws that address circumstances not covered by the Sunshine Act, and some of these state laws, as well as the federal law, can be unclear. We are also subject to foreign regulations requiring transparency of certain interactions between suppliers and their customers.

In the United States, government actions to seek to increase health-related price transparency may also affect our business. For example, hospitals are currently required to publish online a list of their standard charges for all items and services, including discounted cash prices and payer-specific and de-identified negotiated charges, in a publicly accessible online file. Hospitals are also required to publish a consumer-friendly list of standard charges for certain "shoppable" services (i.e., services that can be scheduled by a patient in advance) and associated ancillary services or, alternatively, maintain an online price estimator tool. CMS may impose civil monetary penalties for noncompliance with these price transparency requirements. Additionally, the No Surprises Act ("NSA"), generally effective January 1, 2022, imposes additional price transparency requirements. The NSA is intended to reduce the number of "out-of-network" patients. This will result in fewer out-of-network payments to physicians and other providers, which may cause financial stress to those providers who are dependent on higher out-of-network fees.

Another notable Medicare health care reform initiative, the Medicare Access and CHIP Reauthorization Act of 2015 ("MACRA"), enacted on April 16, 2015, established a new payment framework, which modified certain Medicare payments to "eligible clinicians," including physicians, dentists and other practitioners. Under MACRA, certain eligible clinicians are required to participate in Medicare through the Merit-Based Incentive Payment System ("MIPS") or Advanced Alternative Payment Models, through which Medicare reimbursement to eligible clinicians includes both positive and negative payment adjustments that take into account quality, promoting interoperability, cost and improvement activities. Data collected in the first MIPS performance year (2017) determined payment adjustments that began January 1, 2019. MACRA standards and payment levels continue to evolve, and reflect a fundamental change in physician reimbursement that is expected to provide substantial financial incentives for physicians to participate in risk contracts, and to increase physician information technology and reporting obligations. The implications of the implementation of MACRA are uncertain and will depend on future regulatory activity and physician activity in the marketplace. New state-level payment and delivery system reform programs, including those modeled after such federal programs, are also increasingly being rolled out through Medicaid administrators, as well as through the private sector, which may further alter the marketplace and impact our business.

Recently, in addition to other government efforts to control health care costs, there has been increased scrutiny on drug pricing and concurrent efforts to control or reduce drug costs by Congress, the President, executive branch agencies and various states. At the state level, several states have adopted laws that require drug manufacturers (including relabelers and repackagers) to provide advance notice of certain price increases and to report information relating to those price increases, while others have taken legislative or administrative action to establish prescription drug affordability boards or multi-payer purchasing pools to reduce the cost of prescription drugs. At

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 1717 South 91st Ave

City: Tolleson State: AZ Zip: 85353

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 602-606-6706 Website: www.mckesson.com

Name of Designated Representative (DR): Joseph Bradshaw

Licensing Company Email: mckessonlicensing@mckesson.com DR Email: joseph.bradshaw@mckesson.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

See attached

Original Signature (electronic, copies or stamps not accepted)

0304-2025
Date

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its wholly owned subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 100 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. ***The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.***

On January 7, 2020, **McKesson Corporation** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

On January 14, 2020, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,000 was imposed and paid on January 14, 2020.

On February 20, 2020, in response to the DEA Settlement, **McKesson Corporation** entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 29, 2020, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of $1,150 was imposed and paid on July 1, 2020.

On April 20, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,125 was imposed and paid on April 20, 2021.

On May 05, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Maine Board of Pharmacy, regarding its Roseville, CA distribution center, in relation to the late reporting of a disciplinary action that was imposed by the Colorado Board of Pharmacy, for failure to report a change of designated representative within the required timeframe. A $500 civil penalty/fine was paid on 5/7/2021.

On May 27, 2021, **McKesson Corporation** entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the

Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

On June 6, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on June 8, 2021.

On June 15, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $3000.00 was imposed and paid on June 15, 2021.

On June 23, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $125 was imposed and paid on June 23, 2021.

On October 1, 2021, **McKesson Corporation** ("McKesson") entered into a non-disciplinary agreement with the Connecticut Department of Consumer Protection, regarding its Memphis, TN distribution center. The agreement resolves allegations that, from January 2015 – January 2021, McKesson sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration. McKesson made no admission of liability and there were no findings of any violation of law. A monetary penalty of $4,500 was imposed.

On October 14, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a Settlement Agreement with the Ohio Board of Pharmacy (the "WCH Ohio Settlement"). The WCH Ohio Settlement applies to the McKesson distribution center located in Washington Court House, Ohio. The Ohio Settlement also resolved allegations of suspicious order reporting violations related to sales occurring between 2011 and 2017. Under the terms of terms of the WCH Ohio Settlement, there were no findings of any violation of law and McKesson made no admissions to the same. McKesson was subject to a reprimand and a fine of twenty-thousand dollars ($20,000).

On December 20, 2021, **McKesson Corporation** entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

On January 18, 2022, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on January 18, 2022.

On March 24, 2022, **McKesson Corporation** and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and there are no findings of any violation of state or federal laws.

On May 20, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On July 19, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a settlement agreement with the Alabama Board of Pharmacy. The Alabama discipline was in response to discipline the facility received from the Ohio Board of Pharmacy in 2021 McKesson paid a $3,000 fine under the Alabama settlement.

On September 16, 2022, **McKesson Medical-Surgical Inc.'s** Leetsdale, PA facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Roseville, CA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Complaint from November 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Corporation**'s Aurora, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Complaint from September 2022. The Administrative Complaint is a result of alleged failure comply with certain licensing requirements required to maintain a license in violation of Rule 680-X-2.23(g)(3). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Manteno, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Compliant from September 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On April 14, 2023, **McKesson Corporation**'s Memphis, TN facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023, upon compliance with the Deferral Agreement and payment of $4,000.00 costs to the Board.

On July 10, 2023, **McKesson Medical-Surgical Inc.**'s Bethlehem, PA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an alleged discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $5,000.00 costs to the Board.

On July 22, 2023, **McKesson Corporation**'s Santa Fe Springs, CA distribution center entered into a Consent Order with the Alabama Board of Pharmacy. The Consent Order constitutes reciprocal disciplinary action that was based entirely on a February 22, 2022, Decision and Order from the California Board of Pharmacy. There were no new facts giving rise to the Alabama Consent. Your office was notified of the California Order on or about 03/25/2022. Pursuant to the terms of the Alabama Consent, McKesson agreed to pay a fine of $25,000.

On August 29, 2023, **McKesson Medical-Surgical Inc.**'s Hanover Park, IL's facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with failing to provide notice of a change of ownership on a permit that the Board itself has deemed unnecessary. Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023, upon compliance with the Deferral Agreement and payment of $4,000 costs to the Board.

On April 12, 2024, **McKesson Corporation**'s Duluth, GA distribution center entered into a Public Consent Agreement with the Georgia State Board of Pharmacy. McKesson Corporation was disciplined for failure to maintain prescription drugs securely and assessed a fine of $10,000.

On May 29, 2024, **McKesson Medical-Surgical Inc.**'s Jacksonville, FL facility entered into a Consent Agreement with the Georgia State Board of Pharmacy due to the facility changing ownership and updating their licensure prior to receiving board approval. Under O.C.G.A § 26-4-40, the Georgia State Board of Pharmacy is authorized to deny Applicants application for licensure due to changing ownership without Board Approval. Based on the Consent Agreement, McKesson Medical-Surgical Inc shall submit a payment of One-Thousand Seven-Hundred Dollars ($1,700) for the violation. The Board agrees to grant the ownership change and licensure update once the terms and conditions of the agreement are met.

On August 29, 2024, the Ohio Board of Pharmacy issued a Final Order to **McKesson Corporation** for activities that occurred at McKesson's former distribution center previously located in Washington Courthouse, OH for purchases of dangerous drugs from an unlicensed entity from July 2019 to April 2021. The Board imposed a monetary fine in the amount of $2,750.00.

On August 30, 2024, **McKesson** (in addition to Cardinal Health, Inc. and Cencora, Inc. (f/k/a AmerisourceBergen Corporation) (collectively, the "Distributors")) has agreed to enter into a settlement agreement with third party payor ("TPP") plaintiffs to resolve certain opioid-related claims.

On September 12, 2024, the Idaho Board of Pharmacy ("BOP") entered into a Stipulation and Consent Order with **McKesson Medical-Surgical Inc.** ("MMS") whereby the parties mutually agree to settle two separate matters from MMS' Chino, CA and Roseville, CA distribution centers in 2020 and 2021 involving a deficient Designated Representative application and failure to timely renew its license application, respectively. The parties agree that sufficient mitigating factors exist (including the COVID-19 pandemic and various stay-at-home orders) to warrant resolution of these matters via the Stipulation and Consent Order without an admission of guilt by MMS and whereby the Stipulation and Consent Order requires MMS to pay a fine to the BOP in the amount of $6,000 and to reimburse the BOP for investigative costs in the amount of $5,200.

On September 25, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of One Thousand Five Hundred Dollars ($1,500) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

On November 14, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of Five Thousand Dollars ($5,000) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: This facility is not yet operational

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Virginia

Parent Company (if any): McKesson Medical-Surgical Holdings Inc - ultimate owner McKesson Corporation publicly traded

Corporation Name: McKesson Medical-Surgical Inc.

Mailing Address: 6555 N State Highway 161

City: Irving State: TX Zip: 75039

Telephone: 972.446.4800 Email: mckessonlicensing@mckesson.com

Contact Person Name: Steven Tarantino III

Date of SEC Registration: 07/07/1994 | SEC Registration Number: 2417015 | Stock Exchange Symbol: MCK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Top RA Suppliers

All	ADDRESS_1	ADDRESS_2	CITY	STATE	ZIP
PFIZER	BANK OF AMERICA	P.O. BOX 100539	ATLANTA	GA	30384
ABBOTT RAPID DX N AMERICA LLC	30 S KELLER ROAD	SUITE 100	ORLANDO	FL	32810
NESTLE HEALTHCARE NUTRITION IN	ATTN REBATE ANALYST 9THFLOOR	800 N.BRAND BLVD	GLENDALE	CA	91203

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

McKesson Medical-Surgical Inc

Facility Name

Steven Tarantino III

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

03-04-2025

Date

Board Use Only	Date Received: 3/31/25	Amount: $1000-cc

Title	Name	Work Address	Work Phone	% Ownership
President; Director	Stanton J. McComb	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-553-2311	0%
VP & CFO	Willard C. Station	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	314-302-2862	0%
Corporate Secretary	Saralisa C. Brau	505 9th St. NW Washington DC 20001	202-904-7031	0%
Vice President	Steven Tarantino III	9954 Mayland Drive, Suite 4000 Richmond, VA 23233	804-640-0035	0%


Ownership
McKesson Corporation
Federal ID 94-3207296
6555 State Highway 161
Irving, TX 75039
McKesson Medical-Surgical Top Holdings Inc.
Federal ID 59-2280364
9954 Mayland Drive Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Holdings Inc.
Federal ID 13-3734754
9954 Mayland Drive Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Inc.
Federal ID 94-2640465
9954 Mayland Drive, Suite 4000
Richmond, VA 23233

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

January 16, 2025

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 20250116212722 36

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 12/12/2024
Receipt Number: 2024193972
Receipt Amount $: 1000.00

Wholesaler - Full Service

PERMIT NO	EXPIRES
W003972	10/31/2026

Issued to :

McKesson Medical-Surgical Inc.
McKesson Medical-Surgical Inc.
1717 SOUTH 91ST AVE
TOLLESON, AZ 85353

McKesson Medical-Surgical Inc.
1717 SOUTH 91ST AVE
TOLLESON, AZ 85353

EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : McKesson Medical-Surgical Inc.
LICENSE NUMBER : W003972
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

McKesson Medical-Surgical Inc. located at 1717 South 91st Ave, Tolleson, AZ 85353 is a wholesale distributor of prescription drugs, devices, over the counter medications and medical supplies and equipment to the primary care and extended care markets.

The facility is approximately 300,000 square feet. The entire facility is temperature controlled and utilizes the Vaisala Continuous Monitoring System to monitor temperature and humidity on a 24/7 basis. The security system is a Honeywell system which includes access controlled gates and doors, electrified door hardware, video surveillance with interior and exterior IP cameras, intercom, and alarm monitoring including door contacts, motion and glass break detection, and audible sounder strobes for emergency notification of unauthorized egress. The system is monitored and serviced by Everon Solutions, who is also the installation vendor, and by the McKesson SOC located in Atlanta.

McKesson Medical-Surgical Inc.
9954 Mayland Drive, Suite 4000
Richmond, VA. 23233

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/21/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Insurance Services West, Inc. San Francisco CA Office 425 Market Street Suite 2800 San Francisco CA 94105 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
McKesson Corporation and all its subsidiaries 6555 North State Highway 161 Irving TX 75039 USA	INSURER A: Old Republic Insurance Company	24147
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570106560155 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY317743	07/01/2024	07/01/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
	X Contractual Liability						MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$2,000,000
	OTHER:							
A	AUTOMOBILE LIABILITY			MWTB 317742 Self Insured for Phys Dam	07/01/2024	07/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / HIRED AUTOS ONLY / SCHEDULED AUTOS / NON-OWNED AUTOS ONLY						BODILY INJURY (Per accident)	
							PROPERTY DAMAGE (Per Accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			MWC31382624	07/01/2024	07/01/2025	X PER STATUTE OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N / N/A						E.L. EACH ACCIDENT	$1,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

EVIDENCE OF INSURANCE

CERTIFICATE HOLDER

MCKESSON CORPORATION
6555 State Hwy 161
Irving TX 75039 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West, Inc.

Holder Identifier :

Certificate No : 570106560155

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG McKesson Medical-Surgical Inc. MDEG License # (if applicable) _____

Physical Address 1717 South 91st Ave

City Tolleson State AZ Zip 85353

Mailing Address (if different from physical address) 1717 South 91st Ave

City Tolleson State AZ Zip 85353

Telephone 602-606-6706 Website www.mckesson.com

Licensing Company Email danna.sturgill@mckesson.com and mckessonlicensing@mckesson.com

Section 2: Personal Information

First Joseph Middle _____ Last Bradshaw

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1717 South 91st Ave

City Tolleson State AZ Zip 85353

Telephone [redacted] Email joseph.bradshaw@mckesson.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
See attached resume			
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20-Current	[redacted]	Phoenix	AZ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
08/18-07/20		Phoenix	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
McKesson Medical-Surgical Inc.			08/20-Current	
Business Address		**City**	**State**	**Zip**
7343 S. Hardy Drive, Suite 101		Tempe	AZ	85283
Phone	**Title**		**Number of Employed Hours**	
(602) 293-2700	Manager, Operations		4+ years	
Description of Duties				
Oversee daily operations, see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Joseph Bradshaw

[redacted]

SUMMARY OF EXPERIENCE

A professional and exceptional employee, with extensive experience in PPSD, quality assurance, shipping lead, and outbound supervisor duties. Other skills include replying to company inquiries (via phone and email) in a timely fashion, pipeline management, fulfillment requests, and safety/security. A detail oriented and effective team player in a non-stop competitive environment.

EXPERIENCE

McKesson — Jan. 2022 – Present
Outbound Supervisor

- Supervise packers and dock workers on their day-to-day duties. Manage payroll, PTO, and flex time. Conduct regional QA and Safety calls for the western region. Manage LUM and Bulk QA.

McKesson — Feb. 2021 – Jan. 2022
Bulk/Shipping Dock Lead

- Help Bulk and Shipping team members do their day-today duties. Help train new hires and or struggling team members.
- Print work for the Bulk team and ensure they are working in a timely manner. Move team members around to different areas to ensure all our work is completed each day.

McKesson — Feb. 2021 – Jan. 2022
Quality Assurance

- Setup a quality assurance process to hold accurately track discrepancies in our shipping processes.
- Review previous days customer complaints and compare them to our RF page to determine who caused a shipping error. Follow up with the team's supervisor and leads for a coaching opportunity with the team member.

McKesson — Aug. 2020 – Feb. 2021
Material Handler

- Operated PIT equipment to help pick Bulk cases.
- Helped pack out and sort on the shipping dock.

EDUCATION

Ex'pression College for Digital Arts, Emeryville, CA — Graduated
Bachelor of Applied Science, Sound Arts — Jun. 2012
Received Honors and Salutatorian

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

MARCH 5 2025
Date

I, Joseph Bradshaw, **certify that as the MDEG Administrator for**

McKesson Medical-Surgical Inc,

that I (initial that you have read and meet the following requirements):

1. JB Have a high school diploma or its equivalent;
2. JB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Bradshaw
Print Name (First, Last)

Original signature (electronic, copies or stamps not accepted)

MARCH 5 2025
Date

Board Use Only	Date Received: 3/3/25

Last Name	First Name	Worker Type	Company	Location ID	Work State
Quihuis	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Brown	Joshua	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Fleming	Micah	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Reber	Krystal	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Deeds	Cameron	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Rodriguez	Amalia	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Blackwell	Jeffrey	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Diaz-Mejia	Elmer	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Gebhardt	Justin	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Ramirez	David	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Riggs	Janet	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Garcia	Benjamin	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cash	Jennifer	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Matuz	Hector	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Wilson	Kyle	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Burns	Damon	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Vallese	Joseph	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Terry	Devon	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Markley	Justin	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cisneros	Eduardo	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Valenzuela	Paris	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Amstutz	Charles	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Valenzuela	Bryan	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Bastida	Victor	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Ruiz	Ryan	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Tsosie	Orien	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Chavarin-Esparza	Ramiro	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Santiago Barajas	Alicia	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
George	Danielle	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Thayer	Andrew	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Doerning	Douglas	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Reed	Damon	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cuevas	Mike	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Standley	Dylan	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Johnson	Erica	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Perez	Monique	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Shipman	Jason	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Moreno	Anthony	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Swearengen	Andria	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Gallardo	Beth	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Mietlowski	Maribel	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Salazar	Chris	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Dearing	Cheryl	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Thang	Do	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Diaz	Omar	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Sandoval	Isaias	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Sandoval	Jesus	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Valdez	Luis	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Lopez Sanchez	Milka	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Matuz	Michelle	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Almasaeed	Abdelkareem	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Mung	Joseph Nang	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hechel	Eric	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Nevares	Jose	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Nicklin	David	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hall	Dylan	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Serden	James	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cox	Autumn	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Nevares	Francisco	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona

Colter	Edward	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Bradshaw	Joseph	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Matuz	Alexandra	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Thompson	Charles	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Bedolla	Anacristina	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Conde	Janae	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hernandez	Jacklyn	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Galloway	Adam	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Valdez Ramos	Fausto	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Valencia	Johnny L	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Mack	Devin	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Toma	Genina	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Lashi	Ahshan	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Te	Rebecca Sung	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Gomez	Marisela	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Zavala	Mayra	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Kmon	Paul	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Aguirre	Jesus	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Castillo	Roque	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Brambila	Jose	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Par	Lian	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Sum	Thawngluai	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hayes	Dechavon	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Ko	Gabriel	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Kyaw	Aung	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Saldivar	Viridiana	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Mendez	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Treverrow	Shannon	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Rodriguez	Maria	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
DeMoss	Barry	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Bachara	Beata	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Paw	Win	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Say	Eh d.	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Chamnankool	Steven	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Fernandez	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Martinez	Anthony	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Davenport	Robert	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Reh	Mee	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Pe	Than	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Zakely	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Rencher	John R	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Dauz	David	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Bolanos	Jorge	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Thein	Aye	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Manchenton	Anthony	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cooper	Jill	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hall	Jeffrey	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Murphy	Roosevelt	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Antolin	Anthony	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Jackson	Matthew	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Win	Kay	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Figueroa	Oscar	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Htike	Yin Win	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Mendez	Serena	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Perez	Richard	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Nono	Jessnino	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Arian	Adrian	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
DeMoss	Brandon	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Ci	Sang	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Khual	Go	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona

Davis	Cody	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Beard	Darnell	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
González	Iván	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Matus	Aaliyah	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Moreno	Juan	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Anyaeji-Daniels	Amaya	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cain	Jamell	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Akbar	Hassan	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Puiai	Cherie	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Astrain	Athena	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Wimbley	Tarrance	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Omogbemeh	Festus	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hernandez	Hector	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Thomas	Malik	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Rivera	Nilka	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Thang	Vung	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Tsinajinnie	Christy	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Lustestica	Julius	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Longoria	Estella	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Valenzuela	Marisela	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Shockey	Daniel	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Seib	Gema	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Freeman	Sacorya	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Figueroa	Destiny	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Reyes	Richard	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
V Lopez	Paulo	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Daye	Melesia	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Meza	Zuleyma	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Mayfield	Latrice	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Uriostegui Arias	Alejandro	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Ortega	Jacob	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Woodson	Dominick	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Gonzales	Cynthia	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Su	Mu	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cue	Payton	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Lopez	Angel	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hernandez	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Carter	Kenneth	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Trujillo	Aracely	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Cota	Anna	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Yarmak	Michael	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Garland	Derrick	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Hernandez	Aaron	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona
Mark	Landon	Employee	MGM McKesson Medical-Surgical Inc.	A082	Arizona

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of report (Date of earliest event reported): February 5, 2025

McKESSON CORPORATION
(Exact Name of Registrant as Specified in Charter)

Delaware	1-13252	94-3207296
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

6555 State Hwy 161
Irving, TX 75039
(Address of Principal Executive Offices, and Zip Code)

(972) 446-4800
Registrant's Telephone Number, Including Area Code

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

☐ Written communication pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communication pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communication pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common stock, $0.01 par value	MCK	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On February 5, 2025, McKesson Corporation ("Company") reported the Company's preliminary results for the quarter ended on December 31, 2024 which are attached hereto as Exhibit 99.1.

The information contained in this Form 8-K, including Exhibit 99.1, is furnished to the Securities and Exchange Commission (the "Commission"), but shall not be deemed "filed" with the Commission for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act except as shall be expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Earnings release issued by the Company dated February 5, 2025
104	Cover Page Interactive Data File - the cover page iXBRL tags are embedded within the Inline XBRL document

4M

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

MAY 2025 SCANNED

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: McKesson Medical-Surgical Inc.

Physical Address: 20710 Hempstead Road

City: Houston State: TX Zip: 77065

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: (281) 477-2100 Website: www.mckesson.com

Name of Designated Representative (DR): Matthew Poole

Licensing Company Email: McKessonLicensing@McKesson DR Email: Matt.Poole@McKesson.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2-17-2025
Date

Please note that the disciplinary actions described below do NOT pertain to operations at the location set forth in this application.

McKesson Corporation and its wholly owned subsidiaries (hereinafter "McKesson") delivers pharmaceutical and medical products and business services to retail pharmacies and institutional providers like hospitals and health systems throughout North America and globally. Over the past 185 years, McKesson has developed multiple businesses that operate pharmacies, medical supply distribution centers, wholesale drug distribution centers, 3PL facilities, repackaging facilities, and other entities subject to federal and state regulation. Currently, McKesson owns and operates over 100 facilities in the United States that are licensed, permitted, or registered with the respective state agency with jurisdiction over its business type. Due to the breadth of its operations, it is practical that we limit this summary to disciplinary actions taken against these facilities during the last five years or the time frame specified in the question. ***The information in this statement is provided to the best of our knowledge and belief and includes all public disciplinary actions. This statement does not include any fines that are deemed non-disciplinary by the issuing state (for example, it does not include non-disciplinary Citations and Fines issued by California). Please let us know if your state requires information regarding non-disciplinary fines.***

On January 7, 2020, **McKesson Corporation** entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

On January 14, 2020, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Arizona State Board of Pharmacy, regarding its Tempe, AZ distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,000 was imposed and paid on January 14, 2020.

On February 20, 2020, in response to the DEA Settlement, **McKesson Corporation** entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

On May 29, 2020, the Colorado Department of Regulatory Agencies cited **McKesson Medical-Surgical Inc.** concerning its Roseville, CA distribution center for failure to submit in a timely manner, an application to the Board detailing a change of designated representative. A fine of $1,150 was imposed and paid on July 1, 2020.

On January 27, 2021, Ohio Board of Pharmacy chose to issue a warning rather than take formal disciplinary action against **McKesson Medical-Surgical Inc.'s** Grove City, OH license.

The Board conducted an investigation regarding McKesson Specialty Care Distribution LLC's sale of 3 vials of Dangerous Drugs to an unlicensed Terminal Distributor of Dangerous Drugs on August 14, 2019. This is a non-disciplinary action.

On April 20, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $1,125 was imposed and paid on April 20, 2021.

On May 05, 2021, **McKesson Medical-Surgical Inc.** entered into a Consent Agreement with the Maine Board of Pharmacy, regarding its Roseville, CA distribution center, in relation to the late reporting of a disciplinary action that was imposed by the Colorado Board of Pharmacy, for failure to report a change of designated representative within the required timeframe. A $500 civil penalty/fine was paid on 5/7/2021.

On May 22, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a final agreement with the Illinois Department of Financial and Professional Regulation. The Illinois Consent Order applies to the McKesson distribution centers located in Aurora, Colorado, Livonia, Michigan and Washington Court House, Ohio.

- Aurora, Colorado - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2020 except for various exceptions that mirror exceptions in the DEA settlement;
- Livonia, Michigan - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

On May 27, 2021, **McKesson Corporation** entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

On June 6, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Leetsdale, PA distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on June 8, 2021.

On June 15, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $3000.00 was imposed and paid on June 15, 2021.

On June 23, 2021, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $125 was imposed and paid on June 23, 2021.

On October 1, 2021, **McKesson Corporation** ("McKesson") entered into a non-disciplinary agreement with the Connecticut Department of Consumer Protection, regarding its Memphis, TN distribution center. The agreement resolves allegations that, from January 2015 – January 2021, McKesson sold controlled substances to a practitioner that did not have an active Connecticut Controlled Substances Certificate of Registration. McKesson made no admission of liability and there were no findings of any violation of law. A monetary penalty of $4,500 was imposed.

On October 14, 2021, in response to the DEA Settlement, **McKesson Corporation** entered into a Settlement Agreement with the Ohio Board of Pharmacy (the "WCH Ohio Settlement"). The WCH Ohio Settlement applies to the McKesson distribution center located in Washington Court House, Ohio. The Ohio Settlement also resolved allegations of suspicious order reporting violations related to sales occurring between 2011 and 2017. Under the terms of terms of the WCH Ohio Settlement, there were no findings of any violation of law and McKesson made no admissions to the same. McKesson was subject to a reprimand and a fine of twenty-thousand dollars ($20,000).

On December 20, 2021, **McKesson Corporation** entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

On January 18, 2022, **McKesson Medical-Surgical Inc.** entered into a Settlement Agreement with the Ohio Board of Pharmacy, regarding its Urbancrest, OH distribution center, for shipping prescription drugs to an entity that was not properly licensed to receive them. A monetary civil penalty of $500 was imposed and paid on January 18, 2022.

On January 20, 2022, **McKesson Medical-Surgical Inc.** was fined by the California Board of Pharmacy related to the fact that its Middletown, PA distribution center failed to timely notify the state of California when their designated representative left the company. The designated representative required by the home state was always in place. The new designated representative is now fully licensed. McKesson Medical-Surgical Inc. paid $700 fine. The fine is related to a non-disciplinary action.

On March 24, 2022, **McKesson Corporation** and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and

enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and

On May 20, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On July 19, 2022, **McKesson Medical Surgical, Inc.**'s Urbancrest, Ohio facility entered into a settlement agreement with the Alabama Board of Pharmacy. The Alabama discipline was in response to discipline the facility received from the Ohio Board of Pharmacy in 2021 McKesson paid a $3,000 fine under the Alabama settlement.

On September 16, 2022, **McKesson Medical-Surgical Inc.'s** Leetsdale, PA facility entered into a consent order with the MI Dept of Licensing in connection with an Administrative Compliant from January 2022. The Administrative Complaint is a result of two settlement agreements with the Ohio BOP. Michigan states that these settlement agreements violated MCL 333.17768(2)(d). A $500.00 fine was imposed and paid.

On October 28, 2022, **McKesson Corporation**'s Aurora, IL facility received a non-disciplinary confidential letter of concern from the Colorado State Board of Pharmacy in relation to the late reporting of the 2021 Maine Board of Pharmacy discipline. No formal action or penalty was imposed.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Roseville, CA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Complaint from November 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Corporation**'s Aurora, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Complaint from September 2022. The Administrative Complaint is a result of alleged failure comply with certain licensing requirements required to maintain a license in violation of Rule 680-X-2.23(g)(3). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On December 20, 2022, **McKesson Medical-Surgical Inc.**'s Manteno, IL facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an Administrative Compliant from September 2022. The Administrative Complaint is a result of alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed

in 12/31/2023 upon compliance with the Deferral Agreement and payment of $2,500.00 costs to the Board.

On April 14, 2023, **McKesson Corporation**'s Memphis, TN facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with alleged reciprocal discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023, upon compliance with the Deferral Agreement and payment of $4,000.00 costs to the Board.

On July 10, 2023, **McKesson Medical-Surgical Inc.**'s Bethlehem, PA facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with an alleged discipline for failure to notify the Board of Designated Representative changes that occurred at the facility in violation of Rule 680-X-2.23(2)(h)(1)(ii). Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023 upon compliance with the Deferral Agreement and payment of $5,000.00 costs to the Board.

On July 22, 2023, **McKesson Corporation**'s Santa Fe Springs, CA distribution center entered into a Consent Order with the Alabama Board of Pharmacy. The Consent Order constitutes reciprocal disciplinary action that was based entirely on a February 22, 2022, Decision and Order from the California Board of Pharmacy. There were no new facts giving rise to the Alabama Consent. Your office was notified of the California Order on or about 03/25/2022. Pursuant to the terms of the Alabama Consent, McKesson agreed to pay a fine of $25,000.

On August 29, 2023, **McKesson Medical-Surgical Inc.**'s Hanover Park, IL's facility entered into a Deferral Agreement with the Alabama State Board of Pharmacy in connection with failing to provide notice of a change of ownership on a permit that the Board itself has deemed unnecessary. Pursuant to the Deferral Agreement, the alleged violation will be deferred, deemed non-disciplinary and will be dismissed in 12/31/2023, upon compliance with the Deferral Agreement and payment of $4,000 costs to the Board.

On April 12, 2024, **McKesson Corporation**'s Duluth, GA distribution center entered into a Public Consent Agreement with the Georgia State Board of Pharmacy. McKesson Corporation was disciplined for failure to maintain prescription drugs securely and assessed a fine of $10,000.

On May 29, 2024, **McKesson Medical-Surgical Inc**.'s Jacksonville, FL facility entered into a Consent Agreement with the Georgia State Board of Pharmacy due to the facility changing ownership and updating their licensure prior to receiving board approval. Under O.C.G.A § 26-4-40, the Georgia State Board of Pharmacy is authorized to deny Applicants application for licensure due to changing ownership without Board Approval. Based on the Consent Agreement, McKesson Medical-Surgical Inc shall submit a payment of One-Thousand Seven-Hundred Dollars ($1,700) for the violation. The Board agrees to grant the ownership change and licensure update once the terms and conditions of the agreement are met.

On August 29, 2024, the Ohio Board of Pharmacy issued a Final Order to **McKesson Corporation** for activities that occurred at McKesson's former distribution center previously

located in Washington Courthouse, OH for purchases of dangerous drugs from an unlicensed entity from July 2019 to April 2021. The Board imposed a monetary fine in the amount of $2,750.00.

On August 30, 2024, **McKesson** (in addition to Cardinal Health, Inc. and Cencora, Inc. (f/k/a AmerisourceBergen Corporation) (collectively, the "Distributors")) has agreed to enter into a settlement agreement with third party payor ("TPP") plaintiffs to resolve certain opioid-related claims.

On September 12, 2024, the Idaho Board of Pharmacy ("BOP") entered into a Stipulation and Consent Order with **McKesson Medical-Surgical Inc.** ("MMS") whereby the parties mutually agree to settle two separate matters from MMS' Chino, CA and Roseville, CA distribution centers in 2020 and 2021 involving a deficient Designated Representative application and failure to timely renew its license application, respectively. The parties agree that sufficient mitigating factors exist (including the COVID-19 pandemic and various stay-at-home orders) to warrant resolution of these matters via the Stipulation and Consent Order without an admission of guilt by MMS and whereby the Stipulation and Consent Order requires MMS to pay a fine to the BOP in the amount of $6,000 and to reimburse the BOP for investigative costs in the amount of $5,200.

On September 25, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of One Thousand Five Hundred Dollars ($1,500) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

On November 14, 2024, **McKesson Corporation's** Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of Five Thousand Dollars ($5,000) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: see attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Virginia

Parent Company (if any): McKesson Medical-Surgical Holdings Inc.-ultimate owner McKesson Corporation publicly traded

Corporation Name: McKesson Medical-Surgical Inc.

Mailing Address: 9954 Mayland Drive, Suite 4000

City: Richmond State: VA Zip: 23233

Telephone: 804.264.7500 Email: McKessonLicensing@McKesson.com

Contact Person Name: Steven Tarantino III

Date of SEC Registration: 7.7.1994 | SEC Registration Number: 2417015 | Stock Exchange Symbol: MCK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

McKesson Medical-Surgical Inc.

Facility Name

Steven Tarantino

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2-12-2025

Date

Board Use Only	Date Received: 3/17/25	Amount: $1000.00

McKesson Medical-Surgical Inc. • 9954 Mayland Drive, Suite 4000 • Richmond, Virginia 23233 • Tel. 800-777-4908
www.mckesson.com

McKesson Medical-Surgical Inc
FEIN: 94-2640465
Virginia Corporation Company incorporated on February 27th, 1980.

Parent Company:

McKesson Medical-Surgical Holdings Inc – 100%
9954 Mayland Drive, STE 4000., Richmond, VA 23233
FEIN: 13-3734754

Officer List:

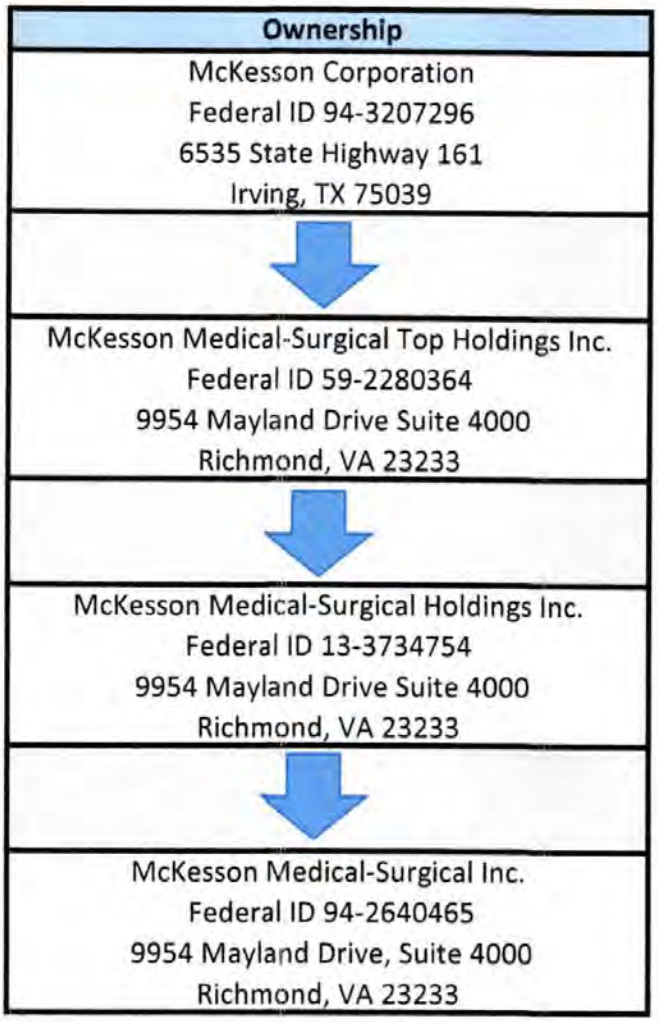
Stanton McComb, President; Director
9954 Mayland Drive, STE 4000., Richmond, VA 23233

Willard Station, Vice President & Treasurer; Director
9954 Mayland Drive, STE 4000., Richmond, VA 23233

Saralisa Brau, Secretary
6535 State Hwy 161., Irving, TX 75039

Steven Tarantino III, Vice President
6535 State Hwy 161., Irving, TX 75039

Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure or distribution is prohibited.


Ownership
McKesson Corporation
Federal ID 94-3207296
6535 State Highway 161
Irving, TX 75039
McKesson Medical-Surgical Top Holdings Inc.
Federal ID 59-2280364
9954 Mayland Drive Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Holdings Inc.
Federal ID 13-3734754
9954 Mayland Drive Suite 4000
Richmond, VA 23233
McKesson Medical-Surgical Inc.
Federal ID 94-2640465
9954 Mayland Drive, Suite 4000
Richmond, VA 23233

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That McKesson Medical-Surgical Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on February 27, 1980;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

January 16, 2025

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER: 2025011621272236

MCKESSON MEDICAL-SURGICAL INC ATTN REGULATORY AFFAIRS/MCKESSON
20710 HEMPSTEAD RD
HOUSTON TX 77065

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

MCKESSON MEDICAL-SURGICAL INC

20710 HEMPSTEAD RD
HOUSTON, TX 77065

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1001789
Expires May 19, 2025

NON-TRANSFERABLE

Commissioner

516900

License Number: 1001789 ***Current Date: 02/14/2025 05:06 PM***

Name:	**MCKESSON MEDICAL-SURGICAL INC**
License Type:	**Prescription Drug Distributor**
License Status:	**Current**
Expiry Date:	**05/19/2025**
Effective Rank Date:	**10/28/2015**
Modifier(s):	**Veterinary**
	Wholesales Distributor
	Prescription
	Non Prescript

Addresses

Mailing Address

Address

MCKESSON MEDICAL-SURGICAL INC ATTN REGULATORY AFFAIRS/MCKESSON
HOUSTON , TX
HARRIS
77065
US

Physical Loc

Address

MCKESSON MEDICAL-SURGICAL INC
20710 HEMPSTEAD RD
HOUSTON , TX
HARRIS
77065
US

Food & Drug Owner

Licensee's Role:	**Food & Drug License**
Related Party Role:	**Food & Drug Owner**

Related Party Name	License	Address
MCKESSON MEDICAL-SURGICAL INC	Owner #A030601 Status: Current Expiration Date:	RICHMOND , VA OUT OF STATE/UNKNOWN 23233

Supplier	ADDRESS_1	ADDRESS_2	CITY	STATE	ZIP
PFIZER	BANK OF AMERICA	P.O. BOX 100539	ATLANTA	GA	30384
AMGEN INC	ONE AMGEN CENTER DR		THOUSAND OAKS	CA	91320
GLAXO VACCINE	3 FRANKLIN PLAZA	1600 VINE STREET	PHILADELPHIA	PA	19102

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/21/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Aon Risk Insurance Services West, Inc. San Francisco CA Office 425 Market Street Suite 2800 San Francisco CA 94105 USA	**CONTACT NAME:** **PHONE (A/C. No. Ext):** (866) 283-7122 **FAX (A/C. No.):** (800) 363-0105 **E-MAIL ADDRESS:**
INSURED McKesson Corporation and all its subsidiaries 6555 North State Highway 161 Irving TX 75039 USA	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** **INSURER A:** Old Republic Insurance Company — 24147 **INSURER B:** **INSURER C:** **INSURER D:** **INSURER E:** **INSURER F:**

COVERAGES **CERTIFICATE NUMBER:** 570106560155 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. **Limits shown are as requested**

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR X Contractual Liability GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:			MW2Y317743	07/01/2024	07/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $10,000 $1,000,000 $2,000,000 $2,000,000
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			MWTB 317742 Self Insured for Phys Dam	07/01/2024	07/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$1,000,000
	UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION						EACH OCCURRENCE AGGREGATE	
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N [N] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			MWC31382624	07/01/2024	07/01/2025	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	$1,000,000 $1,000,000 $1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

EVIDENCE OF INSURANCE

CERTIFICATE HOLDER

MCKESSON CORPORATION
6555 State Hwy 161
Irving TX 75039 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West, Inc.

Holder Identifier :

Certificate No : 570106560155

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG McKesson Medical-Surgical Inc. MDEG License # (if applicable) _____

Physical Address 20710 Hempstead Road

City Houston State TX Zip 77065

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone (281) 477-2100 Website www.mckesson.com

Licensing Company Email Elaine.Stutman@McKesson.com or McKessonLicensing@McKesson.com

Section 2: Personal Information

First Matthew Middle Gordon Last Poole

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 20710 Hempstead Road

City Houston State TX Zip 77065

Telephone [redacted] Email Matt.Poole@McKesson.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY - MM/YY)	
See resume				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY - MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY - MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY - MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY - MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/15/20 - Present	[redacted]	Cypress	TX	[redacted]
08/18 - 05/20		Humble	TX	
04/17 - 08/18		Houston	TX	
2/16 - 03/17		Nashville	TN	
11/14 - 01/16		Nashville	TN	
From - To (MM/YY – MM/YY)	Address	City	State	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: McKesson Medical-Surgical Inc.			From - To (MM/YY – MM/YY)	
Business Address: 20710 Hempstead Road	City: Houston		State: TX	Zip: 77065
Phone: 281-468-4022	Title: Continuous Improvement Leader		Number of Employed Hours	
Description of Duties: see attached				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City: Urbancrest		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				
Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Matt Poole
Houston, TX, USA
[redacted]

Professional Summary

Experienced Continuous Improvement Leader with a strong background in distribution center operations and customer service. Proficient in strategic objectives, problem resolution, and analytical thinking. Demonstrated ability to lead projects in safety, security, regulatory compliance, and training.

Professional Experience

Continuous Improvement Leader
Mckesson, Houston, TX
July 2021 - Present

- Focused on safety and security, training, regulatory compliance, and project management.

Operations Supervisor
Mckesson
August 2019 – July 2021

- Managed outbound operations, including sorting, strapping, cooler management, and value-added services (VAS).

Branch Manager
MSD, Houston, TX
July 2019 - August 2019

- Facilitated the onboarding and training of new staff following the acquisition of Attentus Medical Sales by MSD.

Operations Manager/Transportation Manager/Account Manager/Customer Service
Attentus Medical Sales, Inc.
July 2009 - June 2017

- Oversaw inbound, outbound, and drop-ship logistics. Opened and operated a new branch in Nashville, TN, before returning to manage the Houston branch.

Education

Texas A&M University-Corpus Christi
Bachelor's Degree in Mass Communication
2009

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		x
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/06/2025
Date

I, Matthew Poole, **certify that as the MDEG Administrator for**

McKesson Medical-Surgical Inc.,

that I (initial that you have read and meet the following requirements):

1. MP Have a high school diploma or its equivalent;
2. MP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Poole
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/06/2025
Date

Board Use Only	Date Received:

First Name	Last Name	Address	City State Zip
Corry	Tynes	20710 Hempstead Road	Houston, TX 77065
Regina	Brown	20710 Hempstead Road	Houston, TX 77065
Daniel	Garces	20710 Hempstead Road	Houston, TX 77065
John	Heilmann	20710 Hempstead Road	Houston, TX 77065
Anthony	Connor	20710 Hempstead Road	Houston, TX 77065
Sylvia	Phillips	20710 Hempstead Road	Houston, TX 77065
Jackie	Hurt	20710 Hempstead Road	Houston, TX 77065
Gabriel	Garcia	20710 Hempstead Road	Houston, TX 77065
Angelica	Rios	20710 Hempstead Road	Houston, TX 77065
Roberto	Mendoza	20710 Hempstead Road	Houston, TX 77065
Sedric	Barlow	20710 Hempstead Road	Houston, TX 77065
Marcus	Kawai	20710 Hempstead Road	Houston, TX 77065
Wayne	Williams	20710 Hempstead Road	Houston, TX 77065
Monica	Valle	20710 Hempstead Road	Houston, TX 77065
Tyson	Menard	20710 Hempstead Road	Houston, TX 77065
Kevin	Womack	20710 Hempstead Road	Houston, TX 77065
Rafid	Yassin	20710 Hempstead Road	Houston, TX 77065
Mary Ann	Piert	20710 Hempstead Road	Houston, TX 77065
Daniel	Carrasco	20710 Hempstead Road	Houston, TX 77065
Bobby	Foster	20710 Hempstead Road	Houston, TX 77065
Corneisha	Hopkins	20710 Hempstead Road	Houston, TX 77065
Quinton	Wise	20710 Hempstead Road	Houston, TX 77065
Randal	Neville	20710 Hempstead Road	Houston, TX 77065
Brandon	Cablay	20710 Hempstead Road	Houston, TX 77065
Michael	Ice	20710 Hempstead Road	Houston, TX 77065
Kyle	Bishop	20710 Hempstead Road	Houston, TX 77065
Michael	Braun	20710 Hempstead Road	Houston, TX 77065
Tillie	Shepard	20710 Hempstead Road	Houston, TX 77065
Abayomi	Adeboye	20710 Hempstead Road	Houston, TX 77065
Gerald	King	20710 Hempstead Road	Houston, TX 77065
Phillip	Cavazos	20710 Hempstead Road	Houston, TX 77065
Mirian	Mejia	20710 Hempstead Road	Houston, TX 77065
Luis	Sanchez	20710 Hempstead Road	Houston, TX 77065
Guadalupe	Garcia	20710 Hempstead Road	Houston, TX 77065
Robin	DeJean	20710 Hempstead Road	Houston, TX 77065
Walter	Stinson	20710 Hempstead Road	Houston, TX 77065
Chau	Nguyen	20710 Hempstead Road	Houston, TX 77065
Kenneth	Woods	20710 Hempstead Road	Houston, TX 77065
Julio	Garcia	20710 Hempstead Road	Houston, TX 77065
Brandon	Howard	20710 Hempstead Road	Houston, TX 77065
Ryan	Mack	20710 Hempstead Road	Houston, TX 77065
Jarrell	Hartfield	20710 Hempstead Road	Houston, TX 77065
Johnathan	Johnson	20710 Hempstead Road	Houston, TX 77065
Frederick	Gilbert	20710 Hempstead Road	Houston, TX 77065
Quinton	Mayo	20710 Hempstead Road	Houston, TX 77065
Taylor	Hoffart	20710 Hempstead Road	Houston, TX 77065
Bao	Tran	20710 Hempstead Road	Houston, TX 77065
Kenny	Nguyen	20710 Hempstead Road	Houston, TX 77065
Christopher	Alexander	20710 Hempstead Road	Houston, TX 77065
Armando	Castillo	20710 Hempstead Road	Houston, TX 77065
Emerson	Duarte	20710 Hempstead Road	Houston, TX 77065
Phillip	Bailey	20710 Hempstead Road	Houston, TX 77065
Skyler	Dubose	20710 Hempstead Road	Houston, TX 77065
Raquel	Duarte	20710 Hempstead Road	Houston, TX 77065

Travis	Keyes	20710 Hempstead Road	Houston, TX 77065
Kizer	Bardos	20710 Hempstead Road	Houston, TX 77065
Belinda	Henderson	20710 Hempstead Road	Houston, TX 77065
Anthony	Davis	20710 Hempstead Road	Houston, TX 77065
Norma	Rangel	20710 Hempstead Road	Houston, TX 77065
Aung Lat	Ngaw	20710 Hempstead Road	Houston, TX 77065
Saw Blessing	Say	20710 Hempstead Road	Houston, TX 77065
Saw Eh	Wah	20710 Hempstead Road	Houston, TX 77065
Moises	Carrillo	20710 Hempstead Road	Houston, TX 77065
Naw Law Eh	Say	20710 Hempstead Road	Houston, TX 77065
Susan	George	20710 Hempstead Road	Houston, TX 77065
Valinda	Shankle	20710 Hempstead Road	Houston, TX 77065
Percy	Morris	20710 Hempstead Road	Houston, TX 77065
Ja La	Zinghang	20710 Hempstead Road	Houston, TX 77065
Derek	Petry	20710 Hempstead Road	Houston, TX 77065
Cing	Vung	20710 Hempstead Road	Houston, TX 77065
Titus	Baskin	20710 Hempstead Road	Houston, TX 77065
Ca	Phy	20710 Hempstead Road	Houston, TX 77065
Daniel	Crisp	20710 Hempstead Road	Houston, TX 77065
Sa	Thah	20710 Hempstead Road	Houston, TX 77065
Zaw Aung	Maran	20710 Hempstead Road	Houston, TX 77065
Aung	Soe	20710 Hempstead Road	Houston, TX 77065
Tang	Gun	20710 Hempstead Road	Houston, TX 77065
Tiffany	King	20710 Hempstead Road	Houston, TX 77065
Nang Awng	Nsaw	20710 Hempstead Road	Houston, TX 77065
Ja Eing	Dawshi	20710 Hempstead Road	Houston, TX 77065
Brang Seng	Lahtaw	20710 Hempstead Road	Houston, TX 77065
Daisa	Bonner	20710 Hempstead Road	Houston, TX 77065
Moises	Eastland	20710 Hempstead Road	Houston, TX 77065
Michael	Gray	20710 Hempstead Road	Houston, TX 77065
Janaw	Maran	20710 Hempstead Road	Houston, TX 77065
Iyobosa	Romero	20710 Hempstead Road	Houston, TX 77065
Consuelo	Ynigues	20710 Hempstead Road	Houston, TX 77065
Ashen	Ebert	20710 Hempstead Road	Houston, TX 77065
Gregory	Aguilar	20710 Hempstead Road	Houston, TX 77065
Russell	Holman	20710 Hempstead Road	Houston, TX 77065
Matthew	Poole	20710 Hempstead Road	Houston, TX 77065
Julio	Rios	20710 Hempstead Road	Houston, TX 77065
Hkawng	Zatau	20710 Hempstead Road	Houston, TX 77065
Naw Din	Marip	20710 Hempstead Road	Houston, TX 77065
Morris	Houston	20710 Hempstead Road	Houston, TX 77065
Javier	Flores	20710 Hempstead Road	Houston, TX 77065
Derrick	Brown	20710 Hempstead Road	Houston, TX 77065
Michael	Weasby	20710 Hempstead Road	Houston, TX 77065
Kenneth	Miller	20710 Hempstead Road	Houston, TX 77065
Khazei	Springer	20710 Hempstead Road	Houston, TX 77065
Kristi	Wilson	20710 Hempstead Road	Houston, TX 77065
Thu Ja	Lamung	20710 Hempstead Road	Houston, TX 77065
Quentin	Henderson	20710 Hempstead Road	Houston, TX 77065
Marwin	Dibdib	20710 Hempstead Road	Houston, TX 77065
Sun	Ko	20710 Hempstead Road	Houston, TX 77065
Melissa	Trader	20710 Hempstead Road	Houston, TX 77065
Vanessa Jane	Dibdib	20710 Hempstead Road	Houston, TX 77065
Elizabeth	Lutfi	20710 Hempstead Road	Houston, TX 77065
Jency	Martinez	20710 Hempstead Road	Houston, TX 77065

Ah Brang	Marip	20710 Hempstead Road	Houston, TX 77065
Nga	Reh	20710 Hempstead Road	Houston, TX 77065
Julie	Cepeda	20710 Hempstead Road	Houston, TX 77065
Liezel	Van Vleet	20710 Hempstead Road	Houston, TX 77065
Joshua	Leduc	20710 Hempstead Road	Houston, TX 77065
Jose	Delgado	20710 Hempstead Road	Houston, TX 77065
Keith	Jefferson	20710 Hempstead Road	Houston, TX 77065
Eunice	Belloso	20710 Hempstead Road	Houston, TX 77065
Devante	Franklin	20710 Hempstead Road	Houston, TX 77065
William	Sparks	20710 Hempstead Road	Houston, TX 77065
Thao	Chau	20710 Hempstead Road	Houston, TX 77065
Noel Cinh	Mangthuam	20710 Hempstead Road	Houston, TX 77065
John	Holland	20710 Hempstead Road	Houston, TX 77065
Nabo	Shi	20710 Hempstead Road	Houston, TX 77065
Christopher	Hayes	20710 Hempstead Road	Houston, TX 77065
William	Dominguez	20710 Hempstead Road	Houston, TX 77065
Lum Sing	Zahkung	20710 Hempstead Road	Houston, TX 77065
Brang	Din	20710 Hempstead Road	Houston, TX 77065
Kyimi	Aung	20710 Hempstead Road	Houston, TX 77065
Naw Bawk	Npawt	20710 Hempstead Road	Houston, TX 77065
Dumhpya	Nan Seng	20710 Hempstead Road	Houston, TX 77065
Julius	Jones Jr	20710 Hempstead Road	Houston, TX 77065
Nang Htu	Umya	20710 Hempstead Road	Houston, TX 77065
Zau	Lahpai	20710 Hempstead Road	Houston, TX 77065
Paw	Htoo	20710 Hempstead Road	Houston, TX 77065
Kyaw	Sint	20710 Hempstead Road	Houston, TX 77065
Saw	Reh	20710 Hempstead Road	Houston, TX 77065
Meh	Doe	20710 Hempstead Road	Houston, TX 77065
Long	Hang	20710 Hempstead Road	Houston, TX 77065
Kwe	Reh	20710 Hempstead Road	Houston, TX 77065
Peh	Meh	20710 Hempstead Road	Houston, TX 77065
Ben	Reh	20710 Hempstead Road	Houston, TX 77065
Rosaura	Leal	20710 Hempstead Road	Houston, TX 77065
Emerita	Baldos	20710 Hempstead Road	Houston, TX 77065
Gabriel	Pray	20710 Hempstead Road	Houston, TX 77065
Frances	Diaz Cruz	20710 Hempstead Road	Houston, TX 77065
Tin	Sun	20710 Hempstead Road	Houston, TX 77065
Tarik	Mereih	20710 Hempstead Road	Houston, TX 77065
Jonathan	Johnson	20710 Hempstead Road	Houston, TX 77065
John	Danful	20710 Hempstead Road	Houston, TX 77065
Ashlii	Beserra	20710 Hempstead Road	Houston, TX 77065
Pray	Reh	20710 Hempstead Road	Houston, TX 77065
LU	Lu	20710 Hempstead Road	Houston, TX 77065
Rodolfo	Carreon	20710 Hempstead Road	Houston, TX 77065
Keenen	Truesdale	20710 Hempstead Road	Houston, TX 77065
Yeniel	Caballol	20710 Hempstead Road	Houston, TX 77065
Jonathan	Armendariz	20710 Hempstead Road	Houston, TX 77065
Richard	Ramirez	20710 Hempstead Road	Houston, TX 77065
Kwinda	Stewart	20710 Hempstead Road	Houston, TX 77065
Moo	Saw	20710 Hempstead Road	Houston, TX 77065
Paula	Bardos	20710 Hempstead Road	Houston, TX 77065
David	Lane	20710 Hempstead Road	Houston, TX 77065
Tina	Wesley	20710 Hempstead Road	Houston, TX 77065
Na	Reh	20710 Hempstead Road	Houston, TX 77065
Anthony	Tate	20710 Hempstead Road	Houston, TX 77065

Soe	Thain	20710 Hempstead Road	Houston, TX 77065
Deon	Rodgers	20710 Hempstead Road	Houston, TX 77065
Kimberly	Shankle	20710 Hempstead Road	Houston, TX 77065
Maiquel	Nieves	20710 Hempstead Road	Houston, TX 77065
Kyle	Jayz	20710 Hempstead Road	Houston, TX 77065
Min Thurein	Kyaw	20710 Hempstead Road	Houston, TX 77065
Thomas	Bonar	20710 Hempstead Road	Houston, TX 77065
Eduard	Diaz	20710 Hempstead Road	Houston, TX 77065
Tracy	Lun	20710 Hempstead Road	Houston, TX 77065
John	Baldazo	20710 Hempstead Road	Houston, TX 77065
Aye	Soe	20710 Hempstead Road	Houston, TX 77065
Nga	Reh	20710 Hempstead Road	Houston, TX 77065
Ta	Pay	20710 Hempstead Road	Houston, TX 77065
Tyrone	Hackney	20710 Hempstead Road	Houston, TX 77065
Tiffany	Springer	20710 Hempstead Road	Houston, TX 77065
Dominique	Bowlin	20710 Hempstead Road	Houston, TX 77065
Lester	Copeland	20710 Hempstead Road	Houston, TX 77065
Bryan	Armendariz	20710 Hempstead Road	Houston, TX 77065
Adrian	Navarro	20710 Hempstead Road	Houston, TX 77065
Mauricio	Navarro	20710 Hempstead Road	Houston, TX 77065
Hsaw	Reh	20710 Hempstead Road	Houston, TX 77065
Vivian	Ruati	20710 Hempstead Road	Houston, TX 77065
Desmond	Roy	20710 Hempstead Road	Houston, TX 77065
August	Fleury	20710 Hempstead Road	Houston, TX 77065
Bethany	Hipps	20710 Hempstead Road	Houston, TX 77065
Arte	No	20710 Hempstead Road	Houston, TX 77065
Raquel	Capalad	20710 Hempstead Road	Houston, TX 77065
Tavita	Duenas	20710 Hempstead Road	Houston, TX 77065
Chari	Ebert	20710 Hempstead Road	Houston, TX 77065
Marcos Rene	Gallego Guzman	20710 Hempstead Road	Houston, TX 77065
Myo	Tun	20710 Hempstead Road	Houston, TX 77065
Logan	Sellers	20710 Hempstead Road	Houston, TX 77065
Rebecca	Moreno	20710 Hempstead Road	Houston, TX 77065
Kent	Munante	20710 Hempstead Road	Houston, TX 77065
Paw	Htoo	20710 Hempstead Road	Houston, TX 77065
Mae	Reh	20710 Hempstead Road	Houston, TX 77065
Zavalla	Jackson	20710 Hempstead Road	Houston, TX 77065
Diamond	Veal	20710 Hempstead Road	Houston, TX 77065
Tyisha	Odums	20710 Hempstead Road	Houston, TX 77065
Domingo	Alicea	20710 Hempstead Road	Houston, TX 77065
Lemuel	Dozier	20710 Hempstead Road	Houston, TX 77065
Louvanstie	Mouton	20710 Hempstead Road	Houston, TX 77065
Yahir	Rojas	20710 Hempstead Road	Houston, TX 77065
Keion	Smith	20710 Hempstead Road	Houston, TX 77065
Aaron	Sumrow	20710 Hempstead Road	Houston, TX 77065
Joseph	Jones	20710 Hempstead Road	Houston, TX 77065
Lang	Mung	20710 Hempstead Road	Houston, TX 77065
Wi	Day	20710 Hempstead Road	Houston, TX 77065
Robel	Behreh	20710 Hempstead Road	Houston, TX 77065
Htoi	Naw	20710 Hempstead Road	Houston, TX 77065
Pedro	Reinoso	20710 Hempstead Road	Houston, TX 77065
Alba	Ramirez	20710 Hempstead Road	Houston, TX 77065
Darrian	Theall	20710 Hempstead Road	Houston, TX 77065
Syedayaz	Mufti	20710 Hempstead Road	Houston, TX 77065
Nathan	Rust	20710 Hempstead Road	Houston, TX 77065

Tina	Young	20710 Hempstead Road	Houston, TX 77065

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended March 31, 2024

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from_____ to_____
Commission File Number: 1-13252



McKESSON CORPORATION
(Exact name of registrant as specified in its charter)

Delaware	**94-3207296**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

6555 State Hwy 161,
Irving, TX 75039
(Address of principal executive offices, including zip code)
(972) 446-4800
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	*(Trading Symbol)*	*(Name of each exchange on which registered)*
Common stock, $0.01 par value	MCK	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2023, was approximately $57.8 billion.

Number of shares of common stock outstanding on April 30, 2024: 129,985,514

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its calendar year 2024 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

McKESSON CORPORATION

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McKESSON CORPORATION

PART I

Item 1. Business.

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General

McKesson Corporation together with its subsidiaries (collectively, the "Company," "McKesson," "we," "our," or "us" and other similar pronouns), which traces its business roots to 1833, is a diversified healthcare services leader dedicated to advancing health outcomes for patients everywhere. Our teams partner with biopharma companies, care providers, pharmacies, manufacturers, governments, and others to deliver insights, products, and services to help make quality care more accessible and affordable.

The Company's fiscal year begins on April 1 and ends on March 31. Unless otherwise noted, all references in this document to a particular year refers to the Company's fiscal year. The Company was incorporated on July 7, 1994 in the State of Delaware.

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are available free of charge on the Company's website (www.mckesson.com under the "Investors — Financials — SEC Filings" caption) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission ("SEC"). The content on any website referred to in this Annual Report on Form 10-K ("Annual Report") is not incorporated by reference into this report, unless expressly noted otherwise. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The address of the website is www.sec.gov.

Business Segments

The Company operates its business in four reportable segments: U.S. Pharmaceutical, Prescription Technology Solutions ("RxTS"), Medical-Surgical Solutions, and International.

Our U.S. Pharmaceutical segment distributes branded, generic, specialty, biosimilar and over-the-counter ("OTC") pharmaceutical drugs, and other healthcare-related products in the United States ("U.S."). This segment provides practice management, technology, clinical support, and business solutions to community-based oncology and other specialty practices. In addition, the segment sells financial, operational, and clinical solutions to pharmacies (retail, hospital, alternate sites) and provides consulting, outsourcing, technological, and other services.

Our Prescription Technology Solutions segment helps solve medication access, affordability, and adherence challenges for patients by working across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma. RxTS serves our biopharma and life sciences partners, delivering innovative solutions that help people get the medicine they need to live healthier lives. RxTS also offers prescription price transparency, benefit insight, dispensing support services, as well as third-party logistics and wholesale distribution support designed to benefit stakeholders.

Our Medical-Surgical Solutions segment provides medical-surgical supply distribution, logistics, and other services to healthcare providers, including physician offices, surgery centers, nursing homes, hospital reference labs, and home health care agencies. We offer more than 245,000 national brand medical-surgical products as well as McKesson's own line of high-quality products through a network of distribution centers in the U.S.

Our International segment provides distribution and services to wholesale, institutional, and retail customers in Canada and Europe where we own, partner, or franchise with retail pharmacies, and support better, safer patient care by delivering vital medicines, supplies, and information technology solutions.

U.S. Pharmaceutical Segment:

Our U.S. Pharmaceutical segment provides distribution and logistics services for branded, generic, specialty, biosimilar, and OTC pharmaceutical drugs along with other healthcare-related products to customers. This business provides solutions and services to pharmacies, hospitals, oncology and other specialty practices, pharmaceutical manufacturers, biopharma partners, physicians, payors, and patients throughout the U.S. We also source generic pharmaceutical drugs through our ClarusONE Sourcing Services LLP joint venture with Walmart Inc. ("ClarusONE").

Our U.S. Pharmaceutical segment operates and serves customers through a network of 27 distribution centers in the U.S., including two strategic redistribution centers. We invest in technology and other systems at all of our distribution centers to enhance safety, reliability, and product availability. For example, we offer McKesson Connect℠, an internet-based ordering system that provides item look-up and real-time inventory availability as well as ordering, purchasing, third-party reconciliation, and account management functionality. We make extensive use of technology as an enabler to ensure customers have the right products at the right time in the right place.

To maximize distribution efficiency and effectiveness, we follow the Six Sigma methodology, which is an analytical approach that emphasizes setting high-quality objectives, collecting data, and analyzing results to a fine degree in order to improve processes, reduce costs, and enhance service accuracy and safety. We provide solutions to our customers including supply management technology, world-class marketing programs, managed care, repackaging products, and services to help them meet their business and quality goals. We continue to implement information systems to help achieve greater consistency and accuracy both internally and for our customers, as well as make investments to increase capacity and automation.

We have four primary customer pharmaceutical distribution channels: (i) retail national accounts, which include national and regional retail chains, food and drug combinations, mail order pharmacies, and mass merchandisers, (ii) community pharmacies and health (formerly described as independent, small, and medium chain retail pharmacies), (iii) institutional healthcare providers such as hospitals, health systems, integrated delivery networks, and long-term care providers, and (iv) oncology, biopharma, and other specialty partners.

Retail National Accounts: We provide business solutions that help our retail national account customers increase revenues and profitability. Solutions include:

- Central Fill℠ – Prescription refill service that enables pharmacies to more quickly refill prescriptions remotely, more accurately, and at a lower cost, while reducing inventory levels and improving customer service.
- Strategic Redistribution Centers – Two facilities totaling over 740,000 square feet that offer access to inventory for single source warehouse purchasing, including pharmaceuticals and biologics. These distribution centers also provide the foundation for a two-tiered distribution network that supports best-in-class direct store delivery.
- McKesson SynerGx® – Generic pharmaceutical purchasing program and inventory management that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping.
- Inventory Management – An integrated solution comprised of forecasting software and automated replenishment technologies that reduce inventory-carrying costs.
- ExpressRx Track™ – Pharmacy automation solution featuring state-of-the-art robotics, upgraded imaging, and expanded vial capabilities, and industry-leading speed and accuracy in a small footprint.

Community Pharmacy and Health: We strengthen the overall health of community pharmacies and elevate the role they play in people's lives. We accomplish this by providing supply chain excellence, pharmacy and patient solutions, as well as supporting independent pharmacies through industry and legislative advocacy. Our pharmacy and patient solutions include:

- Health Mart® – A national network of approximately 4,500 independently-owned pharmacies and one of the industry's most comprehensive pharmacy franchise programs. Health Mart provides franchisees support for operational excellence, managed care contracting, marketing, merchandising solutions, and clinical programs to enhance patient care.
- Health Mart Atlas® – Comprehensive managed care services that help community pharmacies save time, access competitive reimbursement rates, and improve cash flow.
- McKesson Reimbursement Advantage℠ ("MRA") – MRA is one of the industry's most comprehensive reimbursement optimization packages, comprising financial services (automated claim resubmission), analytic services, and customer care.
- McKesson Provider Pay® – Provider Pay is an automated reconciliation and payment management solution designed to maximize third-party cash flow and pursue unpaid claims.
- McKesson OneStop Generics® – Generic pharmaceutical purchasing program that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping.
- Pinpoint Community Solutions – McKesson's perpetual inventory management system targeted to independent pharmacy owners with five or fewer stores. The solution provides customers the opportunity to improve cash flow and increase efficiency with inventory visibility to help maximize operational performance.
- FrontEdge™ – Strategic planning, merchandising, and price maintenance program that helps community pharmacies maximize store profitability.
- McKesson RxOwnership Program – A confidential, no-fee resource for pharmacists and pharmacy owners interested in buying, starting, or selling an independent pharmacy, regardless of their pharmacy affiliation.

Institutional Healthcare Providers: At McKesson, we are relentless in our pursuit of opportunities to achieve operational efficiency, reduce waste, and improve the financial performance of our customers so they can achieve more of their goals today and into the future. Solutions include:

- RxO Advisory Services – A suite of supply chain management, pharmacy optimization, and 340B program advisory services driven by data and analytics.

- McKesson Plasma and Biologics – Specialty and plasma drug distributor that leads in market exclusive drug access; partner to health systems customers in navigating the complexities of limited distribution drug; and optimization of McKesson Distribution benefits.
- Outpatient and Specialty Pharmacy – A portfolio of services and solutions customized to each customer's business and clinical strategy.
- Contracting and Contract/Purchasing Optimization – Solutions across generics, specialty, branded products, biosimilars, and 340B products, for inpatient and outpatient settings.
- Supply Assurance – Solutions and strategies to enhance product availability and proactively manage inventory of critical items.
- Patient Assistance Solutions – Technologies and services that enable health systems and providers to better financially support their patients and community benefit programs.

The U.S. Pharmaceutical segment also offers solutions which enable its customers to drive greater efficiencies in their day-to-day operations, effectively managing their inventories and complying with complex government regulations. Solutions include McKesson Pharmacy Systems, MacroHelix, and Supply Logix, all of which provide innovative software technology and services that support retail pharmacies and hospitals.

Oncology, Biopharma, and Other Specialty Partners:

The U.S. Pharmaceutical segment provides a range of solutions to oncology and other specialty practices and offers community specialists (oncologists, rheumatologists, ophthalmologists, urologists, neurologists, and other specialists) an extensive set of customizable solutions and services designed to strengthen core practice operations, enhance value-based care delivery, and expand their service offering to patients. Community-based physicians in this business have broad flexibility and discretion to select the products and commitment levels that best meet their practice needs. Services in provider solutions include specialty drug distribution, group purchasing organizations ("GPO") like Onmark®, technology solutions, practice consulting services, and vaccine distribution, including our exclusive distributor relationship with the Centers for Disease Control and Prevention's ("CDC") Vaccines for Children program. Additionally, McKesson has proudly supported the U.S. efforts to fight the pandemic caused by the SARS-CoV-2 coronavirus ("COVID-19") by distributing certain COVID-19 vaccines since December 2020 at the direction of the U.S. government. This program concluded in the second quarter of fiscal 2024, at which point we began transitioning the distribution of COVID-19 vaccines commercially through our customer pharmaceutical distribution channels.

This business provides a variety of solutions, including practice operations, healthcare information technology, revenue cycle management and managed care contracting solutions, evidence-based guidelines, and quality measurements to support The U.S. Oncology Network ("USON"), one of the nation's largest networks of physician-led, integrated, community-based oncology practices dedicated to advancing high-quality, evidence-based cancer care. SCRI Oncology, LLC, an oncology research business in which we own a 51% controlling interest, is one of the nation's largest research networks and specializes in enhancing clinical trial access and availability across the country.

This segment includes Ontada®, McKesson's oncology technology and insights business providing software to support the clinical, financial, and operational needs of our oncology practice customers. Ontada also partners with oncology providers and biopharma partners to perform real-world evidence studies, retrospective research, and to provide clinical data insights, advisory solutions and education opportunities.

When we discuss specialty products or services, we consider the following factors: diseases requiring complex treatment regimens such as cancer and rheumatoid arthritis; plasma and biologics products; ongoing clinical monitoring requirements, high-cost, special handling, storage, and delivery requirements and, in some cases, exclusive distribution arrangements. Our use of the term "specialty" may not be comparable to that used by other industry participants, including our competitors.

Prescription Technology Solutions Segment:

Our Prescription Technology Solutions segment works across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma to deliver medication access solutions that support patients from first prescription fill to ongoing therapy, regardless of their insurance coverage. RxTS has connections with most electronic health record systems, over 50,000 pharmacies, approximately 950,000 providers, most pharmacy benefit managers and health plans, and has supported over 650 biopharma brands representing most therapeutic areas. Through its industry connections and ability to navigate the healthcare ecosystem, RxTS offers innovative solutions created to benefit healthcare stakeholders. Its comprehensive solution suites span across the entire patient journey, including medication access and affordability, prescription decision support, prescription price transparency, benefit insight and dispensing support services, as well as third-party logistics and wholesale distribution support, to help increase speed to therapy, reduce prescription abandonment, and support improved health outcomes for the patient. In the past year, RxTS helped patients save more than $8.8 billion on brand and specialty medications, helped to prevent an estimated 10.7 million prescriptions from being abandoned due to affordability challenges, and helped patients access their medicine more than 94 million times.

Medical-Surgical Solutions Segment:

Our Medical-Surgical Solutions segment delivers medical-supply distribution, logistics, biomedical maintenance, and other services to healthcare providers across the alternate-site spectrum. Our more than 285,000 customers include physician offices, surgery centers, post-acute care facilities, hospital reference labs, and home health agencies. We partner with manufacturers and channel partners to support our key target end-markets, including primary care, extended care, government, and other markets. We distribute medical-surgical supplies (such as gloves, needles, syringes, and wound care products), infusion pumps, laboratory equipment, and pharmaceuticals. Through a network of distribution centers in the U.S., we offer more than 245,000 products from national brand manufacturers and McKesson's own brand of high-quality products. Through the right mix of products and services, we help improve efficiencies, profitability, and compliance. We also never lose focus on helping customers improve patient and business outcomes. We develop customized plans to address the product, operational, and clinical support needs of our customers, including inventory management, reducing administrative burdens, and training and educating clinical staff. We deliver for our customers, so they can deliver and care for their patients.

International Segment:

Our International segment provides distribution and services to wholesale, institutional, and retail customers in Canada and Europe where we own, partner, or franchise with retail pharmacies. Our operations in Canada also support better, safer patient care by delivering vital medicines, supplies, and information technology solutions to customers, and through several retail health and wellness brands, across Canada.

McKesson Canada is one of the largest pharmaceutical wholesale and retail distributors in Canada. The wholesale business delivers products to retail pharmacies, hospitals, long-term care centers, clinics and institutions in Canada through a national network of distribution centers and provides logistics and distribution services for manufacturers.

Beyond wholesale pharmaceutical logistics and distribution, McKesson Canada provides automation and technology solutions to its retail and hospital customers. Additionally, McKesson Canada provides comprehensive specialty health services to Canadians and provides biopharma services to manufacturers, including a national network of specialty pharmacies, personalized patient care and support programs, and INVIVA, Canada's first and largest accredited network of private infusion clinics. McKesson Canada also owns and operates PDCI, Canada's leading market access consultancy, supporting manufacturers as they introduce new products into the Canadian market.

The Canada retail business includes approximately 2,700 banner pharmacies under the IDA®, Guardian®, The Medicine Shoppe®, Remedy'sRx®, Proxim®, and Uniprix® banners, and approximately 400 owned pharmacies under the Rexall™ brand where we provide patients with greater choice and access, integrated pharmacy care and industry-leading service levels. McKesson Canada also owns and operates Well.ca™, a leading Canadian online health and wellness retailer.

In July 2021, we announced our intention to exit our businesses in Europe. We divested the majority of our European businesses during fiscal 2022 and fiscal 2023. Our remaining operations in Europe provide distribution and services to wholesale and retail customers in Norway where we own, partner, or franchise with retail pharmacies. We continue to evaluate suitable exit alternatives for our retail and distribution businesses in Norway. Refer to Financial Note 2, "Business Acquisitions and Divestitures," to the consolidated financial statements included in this Annual Report for additional information on our European divestitures.

Investments, Restructuring, Business Combinations, and Divestitures

We invest in new and existing distribution centers to increase scale and capacity, improve efficiency through automation and technology, and enhance regulatory compliance capabilities. Additionally, we invest in data and analytics to support our growth priorities, including artificial intelligence ("AI"). We are in the early stages of exploring potential AI capabilities and related data and analytics across our enterprise to improve productivity and efficiency, as well as enhance our products and services to better support patients, employees, and customers.

We have undertaken additional strategic initiatives in recent years designed to increase operational efficiencies, focus on our core healthcare businesses, execute our business strategy, and enhance our competitive position. These initiatives are detailed in Financial Note 2, "Business Acquisitions and Divestitures," and Financial Note 3, "Restructuring, Impairment, and Related Charges, Net," to the consolidated financial statements included in this Annual Report.

Competition

We operate in highly competitive environments in North America and Norway. In recent years, the healthcare industry has been subject to increasing consolidation. In the pharmaceutical distribution environment in which our U.S. Pharmaceutical and International segments operate, we face strong competition from international, national, regional, and local full-line, short-line, and specialty distributors, service merchandisers, self-warehousing chain drug stores, manufacturers engaged in direct distribution, third-party logistics companies, and large payer organizations. We consider our largest competitors in distribution, wholesaling, and logistics to be Cencora, Inc. and Cardinal Health, Inc. Our retail businesses, which primarily operate in our International segment, face competition from various global, national, regional, and local retailers, including chain and independent pharmacies.

Our RxTS business experiences substantial competition from many companies, including other biopharma services companies, software services firms, consulting firms, shared service vendors, and internet-based companies with technology applicable to the healthcare industry. Competition in this business varies in size from large to small companies, in geographical coverage, and in scope and breadth of products and services offered.

Our Medical-Surgical Solutions segment provides medical-surgical supply distribution, logistics, and other services to healthcare providers, including physician offices, surgery centers, nursing homes, hospital reference labs, home health care agencies, and other alternative sites with competition from a wide range of national and regional medical supply and equipment distributors throughout the U.S.

In addition, we compete with other service providers and healthcare manufacturers, as well as other potential customers of our businesses, which may from time to time decide to develop, for their own internal needs, supply management capabilities that might otherwise be provided by our businesses. We believe that our scale and diversity of product and service offerings are our primary competitive advantages. In all areas, key competitive factors include price, quality of service, breadth of product lines, innovation, adoption of new and evolving technologies, and, in some cases, convenience to the customer.

Patents, Trademarks, Copyrights, and Licenses

McKesson and its subsidiaries hold patents, copyrights, trademarks, and trade secrets related to McKesson products and services. We pursue patent protection for our innovations and obtain copyright protection for our original works of authorship when such protection is advantageous. Through these efforts, we have developed a portfolio of patents and copyrights in the U.S. and worldwide. In addition, we have registered or applied to register certain trademarks and service marks in the U.S. and in foreign countries.

We believe that, in the aggregate, McKesson's confidential information, patents, copyrights, trademarks, and intellectual property licenses are important to its operations and market position, but we do not consider any of our businesses to be dependent upon any one patent, copyright, trademark, or trade secret, or any family or families of the same. We cannot guarantee that our intellectual property portfolio will be sufficient to deter misappropriation, theft, or misuse of our technology, nor that we can successfully enjoin infringers. We periodically receive notices alleging that our products or services infringe on third-party patents and other intellectual property rights. These claims may result in McKesson entering settlement agreements, paying damages, discontinuing use or sale of accused products, or ceasing other activities. While the outcome of any litigation or dispute is inherently uncertain, we do not believe that the resolution of any of these infringement notices would have a material adverse impact on our results of operations.

We hold inbound licenses for certain intellectual property that is used internally, and in some cases, utilized in McKesson's products or services. While in the future it may be necessary to seek or renew licenses relating to various aspects of our products and services, we believe, based upon past experience and industry practice, such licenses generally can be obtained on commercially reasonable terms. We believe our operations as well as our products and services are not materially dependent on any single license or other agreement with any third party.

Human Capital

Everything we do at McKesson begins with our employees, who bring our mission and purpose to life every day. As of March 31, 2024, we had approximately 51,000 employees worldwide, which includes 6,000 part-time employees. We had approximately 35,000 employees in the U.S., 13,000 employees in Canada, and 3,000 employees in Europe. Our employees in Europe primarily support our operations in Norway. We also supplement our workforce with contractors and/or consultants for certain business projects, processes, and/or operations as demand requires.

Inclusion and Belonging: As a company, we believe building a more inclusive future is everyone's responsibility. We build successful teams by fostering a culture of inclusion and belonging and ensuring we attract and retain the best talent at all levels of our organization. To help strengthen our company, we offer various learning opportunities, such as our company-wide inclusion curriculum and additional initiatives to recognize, value and leverage the diversity of our workforce, enhance the inclusiveness of our culture and candidly discuss important topics happening in the world around us. We also offer employees the opportunity to join employee resource groups ("ERGs"), which are voluntary, employee-led, company-sponsored networks that aim to make a positive impact on our employees' lives. Our ERGs focus on helping employees make authentic connections, share and affirm their identities and perspectives, showcase leadership skills and find ways to nurture and support belonging and empowerment. Our 11 ERGs provide a sense of community and insights into the perspectives and experiences across different ethnicities, genders, generations, abilities, and/or military/veteran status, as well as supporting members and allies of the LGBTQIA+ community.

At March 31, 2024, women and people of color represented the following:

Metric [1]	McKesson Overall	McKesson Leadership [2]
Women	62 %	43 %
People of Color [3][4]	49 %	28 %

(1) The data for our metrics is derived from our voluntary self-identification process as of March 31, 2024 and therefore represents our best estimate at this time.

(2) Represents our leadership at the vice president level and above.

(3) Represents U.S. employees only because the data for Canada and Europe is not available.

(4) People of Color includes the following self-identification categories: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander, or Two or More Races.

Culture and Leadership: One of McKesson's defining characteristics is our strong culture. Every day, we bring our employee value proposition to life by taking pride in fostering a sense of belonging, finding meaning in our work, and caring for each other, our customers, and all those who depend on us. More than two decades ago, our leadership team created a foundational set of values grounded in the belief that the way we do business is just as important as the business itself. Today, our I²CARE values (Integrity, Inclusion, Customer-First, Accountability, Respect, Excellence) and ILEAD leadership behaviors (Inspire, Leverage, Execute, Advance, Develop) continue to stand the test of time and remain at the core of our daily actions – from how we interact with each other and our customers, to how we make decisions, both big and small. As we work to shape the future of health and embrace the ongoing evolution of our company, we will continue to utilize our strengths to drive lasting change while remaining deeply rooted in our purpose of Advancing Health Outcomes for All®.

Investment in Employees: As an industry leader, we are committed to investing in our people, so that they, in turn, can focus on making better health possible for people everywhere. We are committed to nurturing a culture of wellbeing that empowers our employees to be at their best, including offering health and wellness benefits to advance their physical, mental, and social well-being, savings programs to help prepare them for retirement and flexible work arrangements, among other offerings, when possible. To support growth and career development, we offer employees regular training, coaching, and 360-degree assessments, and financial assistance programs for higher education opportunities.

To provide compensation that is focused on attracting and retaining talent with the skills and experience necessary for a specific role, our compensation program is built on a set of quantifiable factors defined by our guiding principles of internal equity, market competitiveness and pay for performance. We operate in several countries and our benefits vary accordingly. Our compensation philosophy is rooted in a commitment to our people by offering a fair and transparent program that regularly assesses the competitive job market based on geography and cost of labor. We use external resources to provide competitive benchmarking analyses against other companies and set pay ranges around the median of the competitive market. As part of our commitment to pay transparency, the majority of our employees can view the competitive base pay range for their roles as well as for internal and external job postings. Also, the pay range for external job postings is included on McKesson's website (www.mckesson.com under the "Careers" caption).

As we strive to become the best place to work in healthcare, we actively seek employee feedback through annual and mid-year employee opinion surveys, which assesses our employees' levels of engagement, commitment and overall satisfaction using industry benchmarks, and then design action plans to improve those metrics. We also seek feedback on our people leaders through our annual manager quality survey, which is an opportunity for employees to help their managers grow professionally and build valuable leadership skills that help to promote a positive and productive workplace.

Health and Safety: Our security and safety teams employ systems designed to continually monitor our facilities and work environment to help identify and prevent or mitigate potential risks. This includes having procedures in place and investing in equipment for both physical and electronic security. We routinely assess facilities to closely monitor adherence to established security and safety standards. If we identify a vulnerability, it is documented, and the facility prepares an action plan. Our employees receive specialized training related to their role, work setting, and equipment used in their work environment. As our processes evolve, we update relevant safety training modules, which may include new employee training programs.

Government Regulation

We operate in many highly regulated industries and are subject to oversight by various federal, state, and local governmental entities in the U.S. and elsewhere. We incur significant expense and make large capital expenditures and investments to enable us to comply with regulations and guidance promulgated by governmental entities. See "Risk Factors" in Item 1A of Part I below for information regarding material risks associated with our compliance with governmental regulations.

Controlled Substances: We are subject to the operating and security standards of the U.S. Drug Enforcement Administration ("DEA"), the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS"), various state boards of pharmacy, state health departments, and comparable agencies in the U.S. and other countries. Certain of our businesses may be required to register for permits and/or licenses with government agencies, depending upon the type of operations and location of product development, manufacture, distribution, and sale. For example, we are required to hold valid DEA and state-level registrations and licenses, meet various security and operating standards, and comply with the Controlled Substances Act and its accompanying regulations governing the sale, marketing, packaging, holding, distribution, and disposal of controlled substances. We maintain extensive controlled substance monitoring and reporting programs at considerable expense in order to help us meet those standards.

Government Contracts: Our contracts with government entities typically are subject to procurement laws that include socio-economic, employment practices, environmental protection, recordkeeping and accounting, and other requirements. These statutory and regulatory requirements complicate our business and increase our compliance burden. We are subject to audits, investigations, and oversight proceedings about our compliance with contractual and legal requirements.

Federal, state, and local governmental entities in the U.S. and elsewhere continue to strengthen their position and scrutiny of practices that may indicate fraud, waste, and abuse affecting government healthcare programs such as Medicare and Medicaid. Our relationships with pharmaceutical and medical surgical product manufacturers, healthcare providers, and other companies and individuals, as well as our provision of products and services to government entities, subject our business to statutes, regulations, and government guidance that are intended to prevent fraud and abuse. Among other things, those laws: (1) prohibit persons from soliciting, offering, receiving, or paying any remuneration in order to induce the referral of an individual for, or to induce the ordering or purchasing of, items or services that are in any way paid for by Medicare, Medicaid, or other government healthcare programs; (2) impose many restrictions upon referring physicians and providers of designated health services under Medicare and Medicaid programs; and (3) prohibit the knowing submission of a false or fraudulent claim for payment to, and knowing retention of an overpayment by, a federal healthcare program such as Medicare and Medicaid. Many of these laws are vague or indefinite and are often subject to varied and evolving interpretations by courts, regulators, and enforcing agencies and, as such, may be interpreted or applied by a prosecutorial, regulatory, or judicial authority in a manner that could require us to make changes in our operations at added expense.

Healthcare Program Regulation: In the U.S., the Patient Protection and Affordable Care Act ("ACA") significantly expanded health insurance coverage to uninsured Americans and changed the way healthcare is financed by both governmental and private payors. The implementation of the Inflation Reduction Act of 2022 (the "IRA") has begun to change benefit design and how Medicare pays for drugs, which are all intended to reduce the price of drugs. Three central features of the IRA have authorized the government to negotiate drug prices for certain Parts B and D drugs over time, establish an inflation rebate program, and cap patient cost sharing under Medicare Part D.

Provincial governments in Canada that provide partial funding for the purchase of pharmaceuticals and independently regulate the sale and reimbursement of drugs have sought to reduce the costs of publicly funded health programs. For example, provincial governments have taken steps to reduce consumer prices for generic pharmaceuticals and, in some provinces, change professional allowances paid to pharmacists by generic drug manufacturers.

McKesson continues to advocate for policies that would improve drug cost transparency under a patient's drug plan to better inform prescribing decisions, and also address access to care, affordability, and treatment regimen adherence, all designed to improve clinical outcomes and reduce the health spending burden.

FDA Regulation and Supply Chain Integrity: In the U.S., the FDA is the principal federal authority that regulates the safety, efficacy, quality, testing, premarket approval, manufacture, labeling, storage, distribution, and post-market surveillance of healthcare products, such as drugs and medical devices, foods, and cosmetics.

Certain federal and state laws regulate the pharmaceutical drug supply chain in order to prevent the distribution of counterfeit, stolen, contaminated, or otherwise harmful prescription drugs in interstate commerce. At the federal level, the Drug Supply Chain Security Act ("DSCSA") requires standardized, unit-level traceability of pharmaceutical products along the entire drug supply chain and requires all trading partners to cooperate in an electronic, interoperable prescription drug traceability system. In August 2023, the FDA established a one-year stabilization period to certain DSCSA requirements that allows trading partners to implement, troubleshoot, and mature their electronic interoperable systems until the stabilization period ends on November 27, 2024. The FDA has also issued a proposed rule that would establish national standards for the licensure of wholesale drug distributors and third-party logistic providers and other requirements applicable to these entities. These federal and state regulatory requirements increase our compliance burden and our distribution costs.

Cybersecurity, Data Security, and Privacy: We are subject to many cybersecurity, privacy, and data protection laws that change frequently and have requirements that vary from jurisdiction to jurisdiction. Our efforts to comply with these laws complicates our operations and adds to our costs. We are subject to significant compliance obligations under privacy laws such as the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the General Data Protection Regulation ("GDPR") in the European Union, the Personal Information Protection and Electronic Documents Act ("PIPEDA") in Canada, and an expanding list of comprehensive state privacy laws in the U.S. Some privacy laws prohibit the transfer of personal information to certain other jurisdictions or otherwise limit our use of data. Many of these laws also require us to provide access or other data rights (modification, deletion, portability, etc.) to consumers' and patients' individual personal data records within specified periods of time. Cybersecurity laws such as the federal Cyber Incident Reporting for Critical Infrastructure Act of 2022, proposed Federal Acquisition Regulations, and recent amendments to SEC reporting requirements may require us to provide notifications of certain cybersecurity incidents before our investigations are complete and within short timeframes. Regulations and guidance targeting critical infrastructure entities, including McKesson, continue to be a focus of regulators. We are subject to privacy and data protection compliance audits or investigations by various government agencies. The introduction of new technologies, such as AI, may result in additional regulation.

Environmental Regulation: We are subject to many environmental and hazardous materials regulations, including those relating to radiation-emitting equipment operated at U.S. Oncology Network practices. Additionally, our operations are subject to regulations under various federal, state, local and foreign laws concerning the environment, including laws addressing the discharge of pollutants into the air and water, the management and disposal of hazardous substances and wastes, and the cleanup of contaminated sites.

We sold our chemical distribution operations in 1987 and retained responsibility for certain environmental obligations. Agreements with the U.S. Environmental Protection Agency and certain states have required and may require environmental assessments and cleanups at several closed sites. These matters are described further in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report.

Climate Change Regulation: Governments in the U.S. and abroad have adopted or are considering new or expanded policies and laws to address climate change. Such policies and laws may require or necessitate reductions of greenhouse gas ("GHG") emissions, mandates that companies implement processes and controls to monitor and disclose climate-related matters, additional taxes or offset charges on specified energy sources, and other requirements. Compliance with climate-related policies and laws may be further complicated by disparate regulatory approaches in various jurisdictions. Methodologies for reporting climate-related information may change and previously reported information may be retroactively adjusted, if required. New or expanded climate-related policies and laws could impose costs on us, including capital expenditures to develop data gathering and reporting systems, costly third-party attestations, and additional GHG reduction measures. Until the timing and extent of climate-related policies and laws are clarified, including due to legal challenges, we cannot predict their potential effect on our capital expenditures, results of operations, or competitive position.

Other Information about the Business

Customers: During fiscal 2024, sales to our ten largest customers, including group purchasing organizations ("GPOs") accounted for approximately 69% of our total consolidated revenues. Sales to our largest customer, CVS Health Corporation ("CVS"), accounted for approximately 28% of our total consolidated revenues in fiscal 2024. In fiscal 2023, we extended our pharmaceutical distribution partnership with CVS to June 2027. Our ten largest customers comprised approximately 43%, and CVS was approximately 24%, of our total trade accounts receivable at March 31, 2024. We also have agreements with GPOs, each of which functions as a purchasing agent on behalf of member hospitals, pharmacies, and other healthcare providers, as well as with government entities and agencies. The accounts receivable balances are with individual members of the GPOs, and therefore no significant concentration of credit risk exists. Substantially all of these revenues and accounts receivable are included in our U.S. Pharmaceutical segment.

Suppliers: We obtain pharmaceutical and other products from manufacturers and our largest supplier accounted for 12% of our total purchases in fiscal 2024. The loss of a supplier could adversely affect our business if alternate sources of supply are unavailable. We believe that our relationships with our suppliers are generally sound. The ten largest suppliers in fiscal 2024 accounted for approximately 67% of our total purchases.

Some of our distribution arrangements with manufacturers provide us consideration based on a percentage of our purchases. In addition, we have certain distribution arrangements with pharmaceutical manufacturers that include an inflation-based consideration component whereby we benefit when the manufacturers increase their prices as we sell our existing inventory at the new higher prices. For these manufacturers, a reduction in the frequency and magnitude of price increases, as well as restrictions in the amount of inventory available to us, could have an adverse impact on our gross profit margin.

Research and Development: Research and development expenses were $77 million, $89 million, and $70 million for the years ended March 31, 2024, 2023, and 2022, respectively.

Financial Information About Foreign and Domestic Operations: Certain financial information relating to foreign and domestic operations is discussed in Financial Note 20, "Segments of Business," to the consolidated financial statements included in this Annual Report as well as in "Foreign Operations" in Item 7 of Part II of this Annual Report. See "Risk Factors" in Item 1A of Part I below for information regarding risks associated with our foreign operations.

Forward-Looking Statements

This Annual Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II of this report and the "Risk Factors" in Item 1A of Part I of this report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 ("Securities Act") and Section 21E of the Exchange Act. Forward-looking statements may be identified by their use of terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "projects," "plans," "estimates," "targets," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans, assumptions, expectations, or intentions may also include forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated, or implied. Although it is not possible to predict or identify all such risks and uncertainties, they include, but are not limited to, the factors discussed in Item 1A of Part I of this report under "Risk Factors" and in our publicly available SEC filings and press releases. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date such statements were first made. Except to the extent required by federal securities laws, we undertake no obligation to publicly release the result of any revisions to any forward-looking statements to reflect events or circumstances after the date the statements are made, or to reflect the occurrence of unanticipated events.

Available Information

We routinely post on our company website, and via our social media channels, information that may be material to investors, including details and updates to information disclosed elsewhere, which may include business developments, earnings and financial performance, sustainability matters, and materials for presentations to investors and financial analysts. Investors are encouraged to monitor our website www.mckesson.com. Interested parties can sign up on our website, including our Investor Relations site, to receive automated e-mail alerts, such as via RSS newsfeed, when we post certain information. Interested parties can also follow our social media feed @McKesson on X, formerly known as Twitter. The content on any website or social media channel is not incorporated by reference into this report, unless expressly noted otherwise.

Item 1A. Risk Factors.

INDEX TO RISK FACTORS

Section	Page
Litigation and Regulatory Risks	14
Company and Operational Risks	16
Industry and Economic Risks	21
General Risks	24

The discussion below identifies certain representative risks that might cause our actual business results to materially differ from our estimates. It is not practical to identify or describe all risks and uncertainties that might materially impact our business operations, reputation, financial position, or results of operations. Our business could be materially affected by risks that we have not yet identified or that we currently consider to be immaterial. This is not a complete discussion of all potential risks and uncertainties.

Litigation and Regulatory Risks

We experience costly and disruptive legal disputes.

We are routinely named as a defendant in litigation or regulatory proceedings and other legal disputes, which may include asserted class action litigation, such as those described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report. Regulatory proceedings involve allegations such as false claims, healthcare fraud and abuse, and antitrust violations. Civil litigation proceedings involve commercial, employment, environmental, intellectual property, tort, and other claims. Despite valid defenses that we assert, legal disputes are often costly, time-consuming, distracting to management, and disruptive to normal business operations. The uncertainty and expense associated with unresolved legal disputes might harm our business and reputation even if the matter ultimately is favorably resolved. The outcome of legal disputes is difficult to predict, and outcomes may occur that we believe are not justified by the evidence or existing law. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Accordingly, legal disputes might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We experience losses not covered by insurance or indemnification.

Our business exposes us to risks that are inherent in the distribution, manufacturing, dispensing, and administration of pharmaceuticals and medical-surgical supplies, the provision of ancillary services, the conduct of our payer businesses, practice support services, and the provision of products that assist clinical decision-making and relate to patient medical histories and treatment plans. For example, pharmacy operations are exposed to risks such as improper filling of prescriptions, mislabeling of prescriptions, inadequacy of warnings, unintentional distribution of counterfeit drugs, and expiration of drugs. Although we seek to maintain adequate insurance coverage, such as property insurance for inventory and professional and general liability insurance, coverages on acceptable terms might be unavailable, or coverages might not cover our losses. We generally seek to limit our contractual exposure, but limitations of liability or indemnity provisions in our contracts may not be enforceable or adequately protect us from liability. Uninsured or non-indemnified losses might have a materially adverse impact on our business operations and our financial position or results of operations.

We experience costly legal disputes, government actions, and adverse publicity regarding our role in distributing controlled substances such as opioids.

The Company is a defendant in many litigation matters alleging claims related to the distribution of controlled substances (opioids), as described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements in this Annual Report. We are sometimes named as a defendant in similar, new cases. The plaintiffs in those cases include governmental entities (such as states, provinces, counties, and municipalities) as well as businesses, groups, and individuals. The cases allege violations of controlled substance laws and other laws, and they make common law claims such as negligence and public nuisance. Many of these cases raise novel theories of liability and can have unexpected outcomes that we believe are not justified by evidence or existing law. Legal proceedings such as these often involve significant expense, management time and distraction, and risk of loss that can be difficult to predict or quantify. It is not uncommon for claims to be resolved over many years. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Although the Company has valid defenses and is vigorously defending itself, some proceedings have been and others may be resolved by negotiated outcome. For example, we are subject to consent decrees issued by state courts that govern our distribution of controlled substances. Not all proceedings, however, are resolved by settlement. Our reputation has been and may continue to be impacted by publicity regarding opioids litigation and related allegations. An adverse outcome of any such legal proceedings might have a materially adverse impact on our business operations and our financial position or results of operations.

We experience increased costs to distribute controlled substances such as opioids.

Legislative, regulatory, or industry measures related to the distribution of controlled substances such as prescription opioids could affect our business in ways that we may not be able to predict. For example, some states have passed legislation that could require us to pay taxes or assessments on the distribution of opioid medications in those states and other states have considered similar legislation. Liabilities for taxes or assessments or other costs of compliance under any such laws might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We are subject to extensive, complex, and challenging healthcare, environmental, and other laws.

As described in "Government Regulation" in Item 1 of Part I above, our industry is highly regulated, and further regulation of our distribution businesses, technology products, and services could impose increased costs, negatively impact our profit margins and the profit margins of our customers, delay the introduction or implementation of our new products, or otherwise negatively impact our business and expose the Company to litigation and regulatory investigations. We incur cleanup costs under environmental laws and may incur additional costs under environmental laws. Additionally, we are subject to various routine and ad hoc inspections and requests for information by government agencies to determine compliance with various statutes and regulations. Any noncompliance by us with applicable laws or the failure to maintain, renew, or obtain necessary permits and licenses could lead to enforcement actions or litigation and might have a materially adverse impact on our business operations and our financial position or results of operations.

We are subject to extensive and frequently changing laws relating to healthcare fraud, waste, and abuse.

As described in "Government Regulation" in Item 1 of Part I above, federal, state, and local governmental entities in the U.S. and elsewhere continue to strengthen their position and scrutiny over practices that may indicate fraud, waste, and abuse affecting government healthcare programs such as Medicare and Medicaid. Those laws may be interpreted or applied in a manner that could require us to make changes in our operations at added expense. Failures to comply with those laws, including the federal Anti-Kickback Statute, might expose us to federal or state government investigations or qui tam actions, and to liability for damages and civil and criminal penalties. Such failures might result in the loss of licenses or our ability to participate in Medicare, Medicaid, or other federal and state healthcare programs, or pursue government contracts. These sanctions might have a materially adverse impact on our business operations and our financial position or results of operations.

4N

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Nuvaila US, LLC

Physical Address: 8950 Global Way SW, Suite 200

City: Etna State: OH Zip: 43062

Mailing Address (if different from physical address): Same as physical address

City: _____ State: _____ Zip: _____

Telephone: 380-218-3860 Website: N/A

Name of Designated Representative (DR): Timmy Lee Pence II

Licensing Company Email: ORxPharmLic@optum.com DR Email: tim.pence@optum.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies ☐ Practitioners ■ Hospitals ■ Wholesalers ☐ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ☐ [a]Medical devices, equipment, supplies, gases ☐ Others:	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: Virtual Wholesaler

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - New Facility - No Pharmaceutical Products have been sold, dispensed, or distributed within the last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): N/A

Corporation Name: UnitedHealth Group Incorporated

Mailing Address: 1 Health Drive

City: Eden Prairie State: MN Zip: 55344

Telephone: (952) 936-1300 Email: kelly.orourke@uhg.com

Contact Person Name: Kelly O'Rourke

Date of SEC Registration: 10/17/1984 | SEC Registration Number: CIK 0000731766 | Stock Exchange Symbol: UNH

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Nuvaila US, LLC

Facility Name

Karen Bohmer

Print Name of Authorized Person Submitting Application

Karen R Bohmer

Original signature of Authorized Person (copies or stamps not accepted)

4/16/25

Date

Board Use Only	Date Received: 4/21/25	Amount: $1600 - CK 15880202

nuvaila

Nuvaila US, LLC
8950 Global Way SW, Suite 200
Etna, OH 43062

List top four corporation shareholders and their percent ownership

- List the top four corporation shareholders and their percent ownership.

Below are the Top 4 Shareholders for UnitedHealth Group Incorporated as of its most recent SEC filings.

1. **Vanguard Group Inc.** - 9.31%
2. **BlackRock Inc.** - 7.87%
3. **State Street Corp.** - 4.98%
4. **FMR LLC** - 3.29%

nuvaila

Officer List

Entity			
Nuvaila US, LLC 8950 Global Way SW Suite 200 Etna OH 43062 Tax ID: 93-2785584			
Officers of Entity	**Title**	**% of Ownership**	**Business Address**
James G. Millar	Manager, CEO & President	0%	1 Optum Circle, Suite 100 Eden Prairie MN 55344
Marilyn V. Hirsch	Treasurer	0%	1 Optum Circle, Suite 100 Eden Prairie MN 55344
Karen E. Bohmer	Secretary	0%	1 Optum Circle, Suite 100 Eden Prairie MN 55344
Heather A. Lang	Assistant Secretary	0%	1 Optum Circle, Suite 100 Eden Prairie MN 55344

nuvaila


UnitedHealth Group Incorporated
Delaware
NYSE Symbol : UNH
41-1321939
100%
United Healthcare Services, Inc.
Minnesota
41-1289245
100%
Optum, Inc.
Delaware
30-0580620
100%
Nuvaila US, LLC
Delaware
93-2785584

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "OPTUM PACKAGING SERVICES, LLC", CHANGING ITS NAME FROM "OPTUM PACKAGING SERVICES, LLC" TO "NUVAILA US, LLC", FILED IN THIS OFFICE ON THE THIRTIETH DAY OF AUGUST, A.D. 2024, AT 5:43 O`CLOCK P.M.

Jeffrey W. Bullock, Secretary of State

7588081 8100
SR# 20243571122

Authentication: 204291911
Date: 09-03-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "NUVAILA US, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

7588081 8300

SR# 20250470678

Authentication: 202901919

Date: 02-10-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show NUVAILA US, LLC, a Delaware Limited Liability Company, Registration Number 5089581, was registered in the State of Ohio on August 1, 2023, is currently authorized to transact business in this state.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 12th day of February, A.D. 2025.

Ohio Secretary of State

Validation Number: 202504301642

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "UNITEDHEALTH GROUP INCORPORATED" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FIFTH DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203082424

Date: 03-05-25

5777355 8300

SR# 20250926134

You may verify this certificate online at corp.delaware.gov/authver.shtml

Ohio Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

Nuvaila US, LLC

8950 Global Way SW Suite 200

Etna, OH 43062

License Number: 0132000177

License Type: Wholesaler - Category 3

Sub-Category: VW – Virtual Wholesaler

Expiration Date: June 30, 2025

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
TIMMY PENCE	

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

Ohio Board of Pharmacy

VERIFICATION OF LICENSURE

BUSINESS NAME:	Nuvaila US, LLC
LOCATION:	8950 Global Way SW Suite 200 Etna, OH 43062
LICENSE NUMBER:	0132000177
TYPE OF LICENSE:	Wholesaler - Category 3
ORIGINAL LICENSURE DATE:	January 13, 2025
EXPIRATION DATE:	June 30, 2025
CURRENT LICENSE STATUS:	Active
CURRENT LICENSE SUB STATUS:	N/A
BOARD ACTION:	No (If Board Action is "Yes", you may find more information at elicense.ohio.gov)
DATE OF VERIFICATION:	1/22/2025

Grant Miller
Licensing Administrator
Ohio Board of Pharmacy

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

nuvaila

Nuvaila US, LLC
8950 Global Way SW, Suite 200
Etna, OH 43062

List containing each employee, agent, personal representative, lender or holder of indebtedness of the applicant

- **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**

Please see applicable portion Nuvaila US, LLC

Nuvaila US, LLC 's Current Employees

Brian McMahon – Site Director, Operations
Brian_McMahon@optum.com

Timmy Lee Pence II – Manager, Quality Assurance, Designated Representative
Tim.Pence@optum.com

nuvaila

April 16, 2025

To: Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, # 206
Reno, NV 89521

Re: Nuvaila US, LLC
8950 Global Way SW, Suite 200
Etna OH 43062

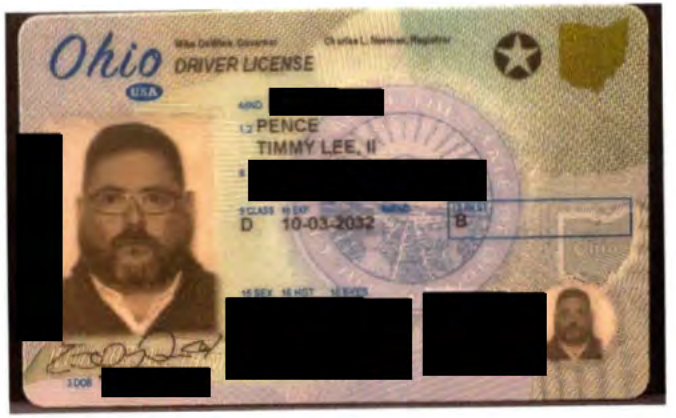
Please accept this letter as formal notice that Timmy Lee Pence II, in his capacity as Designated Representative of the above-mentioned Wholesaler, is an authorized person to speak on behalf of Nuvaila US, LLC regarding the application as well as any Nevada Board of Pharmacy Board Meetings.

If you should have any questions or concerns, or require additional information, please contact Tara Mihans, Pharmacy Licensing Manager via telephone at 612-474-7302 or email Tara.Mihans@optum.com.

Thank you,

Karen Bohmer

Karen Bohmer, Secretary
Nuvaila US, LLC


Ohio
DRIVER LICENSE
USA
PENCE
TIMMY LEE, II
D
10-03-2032
B

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Form 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2024

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission file number: 1-10864

UNITEDHEALTH GROUP

UnitedHealth Group Incorporated

(Exact name of registrant as specified in its charter)

Delaware	41-1321939
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1 Health Drive			655 New York Avenue NW		
Eden Prairie,	Minnesota	55344	Washington,	DC	20001
(Address of principal executive offices)		(Zip Code)	(Address of principal executive offices)		(Zip Code)

(800) 328-5979

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $.01 par value	UNH	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐
Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒
Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐
Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐	Non-accelerated filer	☐
Smaller reporting company	☐			Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐
Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒
If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐
Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐
Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒
The aggregate market value of voting stock held by non-affiliates of the registrant as of June 30, 2024 was $468,433,146,650 (based on the last reported sale price of $509.26 per share on June 30, 2024 as reported on the New York Stock Exchange), excluding only shares of voting stock held beneficially by directors, executive officers and subsidiaries of the registrant.
As of January 31, 2025, there were 914,712,333 shares of the registrant's Common Stock, $.01 par value per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

The information required by Part III of this report, to the extent not set forth herein, is incorporated by reference from the registrant's definitive proxy statement relating to its 2025 Annual Meeting of Shareholders. Such proxy statement will be filed with the Securities and Exchange Commission within 120 days after the end of the fiscal year to which this report relates.

UNITEDHEALTH GROUP

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PART I

ITEM 1. BUSINESS

OUR BUSINESSES

Overview

The terms "we," "our," "us," "its," "UnitedHealth Group," or the "Company" used in this report refer to UnitedHealth Group Incorporated and its subsidiaries.

UnitedHealth Group Incorporated is a health care and well-being company with a mission to help people live healthier lives and help make the health system work better for everyone. Our two distinct, yet complementary businesses — Optum and UnitedHealthcare — are working to help build a modern, high-performing health system through improved access, affordability, outcomes and experiences for the individuals and organizations we are privileged to serve.

The ability to analyze complex data and apply deep health care expertise and insights allows us to serve patients, consumers, care providers, businesses, communities and governments with more innovative products and complete, end-to-end offerings for many of the biggest challenges facing health care today.

Optum seeks to create a higher-performing, value-oriented and more connected approach to health care. Bringing together clinical expertise, technology and data to make care simpler, more effective and more affordable, we seek to advance whole-person health, creating a seamless consumer experience and supporting clinicians with insights to deliver personalized, evidence-based care. Optum serves the broad health care marketplace, including patients and consumers, payers, care providers, employers, governments and life sciences companies, through its Optum Health, Optum Insight and Optum Rx businesses. These businesses improve overall health system performance by optimizing health care quality and delivery, reducing costs and improving patient, consumer and provider experience, leveraging distinctive capabilities in data and analytics, pharmacy care services, health care operations, population health and health financial services.

UnitedHealthcare offers a full range of health benefits, designed to simplify the health care experience and make it more affordable for consumers to access high-quality care. UnitedHealthcare Employer & Individual serves consumers and employers, ranging from sole proprietorships to large, multi-site and national employers and public sector employers. UnitedHealthcare Medicare & Retirement delivers health and well-being benefits to seniors and other Medicare eligible consumers. UnitedHealthcare Community & State serves consumers who are economically disadvantaged, the medically underserved and those without the benefit of employer sponsored health benefits coverage.

We have four reportable segments:

- Optum Health;
- Optum Insight;
- Optum Rx; and
- UnitedHealthcare, which includes UnitedHealthcare Employer & Individual, UnitedHealthcare Medicare & Retirement and UnitedHealthcare Community & State.

Optum

Optum is an information and technology-enabled health services business serving the broad health care marketplace, including:

- Those who need care: patients who need the right care, information, resources, products and engagement to improve their health, achieve their health goals and receive an improved patient experience that is personalized, comprehensive and delivered in all care settings, including in-home and virtually.
- Those who provide care: physicians, hospitals, pharmacies and others seeking to improve the health system and reduce the administrative burden, allowing for providers to focus time on patients leading to the best possible patient care and experiences while achieving better health outcomes at lower costs. Improved health outcomes are achieved by utilizing our clinical expertise, data and analytics to better understand, treat and prevent consumers' health conditions and ensure they receive the best evidence-based care.
- Those who pay for care: consumers; employers; health plans; and state, federal and municipal agencies devoted to ensuring the people they sponsor receive high-quality care, administered and delivered efficiently and effectively, all while driving health equity so that every individual, family and community has access to the care they need.
- Those who innovate for care: global life sciences organizations dedicated to developing more effective approaches to care, enabling technologies and medicines to improve care delivery and health outcomes.

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Optum operates three business segments which combine distinctive capabilities in value-based care, population health, health care operations, data and analytics and pharmacy care services:

- Optum Health delivers patient-centered care, care management, wellness and consumer engagement, and health financial services;
- Optum Insight offers data, analytics, research, consulting, technology and managed services solutions; and
- Optum Rx provides diversified pharmacy care services.

Optum Health

Optum Health provides comprehensive and patient-centered care, addressing the physical, mental, social, and financial well-being of 100 million consumers and serves more than 100 health payer partners. We engage people in the most appropriate care settings, including clinical sites, in-home and virtual. Optum Health delivers primary, specialty and surgical care; helps patients and providers navigate and address complex, chronic and behavioral health needs; offers post-acute care planning services; and serves consumers and care providers through advanced, on-demand digital health technologies, such as telehealth and remote patient monitoring, and innovative health care financial services. Optum Health works directly with patients, consumers, care delivery systems, providers, employers, payers, and public-sector entities to provide high quality, accessible and equitable care with improved health outcomes and reduced total cost of care. Optum Health enables care providers to transition from traditional fee-for-service payment models to performance-based delivery and payment models designed to improve patient health outcomes and experience through value-based care.

Optum Health offerings include fully accountable value-based arrangements, where Optum Health assumes responsibility for health care costs in exchange for a monthly premium. Offerings also include administrative fee arrangements, where Optum Health manages or administers products and services in exchange for a monthly fee, and fee-for-service arrangements, where Optum Health delivers health-related products and medical services for patients at a contracted fee.

Optum Financial, including Optum Bank, serves consumers through more than 27 million consumer accounts with $24 billion in assets under management as of December 31, 2024. Organizations across the health system rely on Optum Financial to manage and improve payment flows through its highly automated, scalable, end-to-end digital payment and financing systems and integrated card solutions. For financial services offerings, Optum Financial charges fees and earns investment income on managed funds.

Optum Health sells its products primarily through its direct sales force, strategic collaborations and external producers in three key areas: employers, including large, mid-sized and small employers; payers including health plans, third-party administrators (TPAs), underwriter/stop-loss carriers and individual product intermediaries; and public entities, including the U.S. Departments of Health and Human Services (HHS), Veterans Affairs, Defense, and other federal, state and local health care agencies.

Optum Insight

Optum Insight connects the health care system with services, analytics and platforms that make clinical, administrative and financial processes simpler and more efficient for all participants in the health care system. Hospital systems, physicians, health plans, public entities, life sciences companies and other organizations comprising the health care industry depend on Optum Insight to help them improve performance and reduce costs through administrative efficiency and payment simplification, advance care quality through evidence-based standards built directly into clinical workflows, meet compliance mandates and modernize their core operating systems to meet the changing needs of the health system.

Health Systems. Serves hospitals, physicians and other care providers to improve operating performance, better coordinate care and reduce administrative costs through technology and services to improve population health management, patient engagement, revenue cycle management and strategic growth plans.

Health Plans. Serves health plans by improving financial performance and enhancing outcomes through proactive analytics, a comprehensive payment integrity portfolio and technology-enabled and staff-supported risk and quality services. Optum Insight helps health plans navigate a dynamic environment defined by shifts in employer vs. public-sector coverage, the demand for affordable benefit plans and the need to leverage new technology to reduce complexity.

State Governments. Provides advanced technology and analytics services to modernize the administration of critical safety net programs, such as Medicaid, while improving cost predictability.

Life Sciences Companies. Combines data and analytics expertise with comprehensive technologies and health care knowledge to help life sciences companies, including those in pharmaceuticals and medical technology, adopt a more comprehensive approach to advancing therapeutic discoveries and improving clinical outcomes.

Many of Optum Insight's software and information products and professional services are delivered over extended periods, often several years. Optum Insight maintains an order backlog to track unearned revenues under these long-term arrangements. The backlog consists of estimated revenue from signed contracts, other legally binding agreements and anticipated contract renewals based on historical experience with Optum Insight's customers. Optum Insight's aggregate backlog as of December 31, 2024 was approximately $32.8 billion, of which $19.8 billion is expected to be realized within the next 12 months. The aggregate backlog includes $12.5 billion related to affiliated agreements. Optum Insight's aggregate backlog as of December 31, 2023, was $32.1 billion, including $11.9 billion related to affiliated agreements.

Optum Insight's products and services are sold primarily through a direct sales force. Optum Insight's products are also supported and distributed through an array of alliances and business partnerships with other technology vendors, who integrate and interface Optum Insight's products with their applications.

Optum Rx

Optum Rx provides a full spectrum of pharmacy care services through its network of more than 65,000 retail pharmacies, through home delivery, specialty and community health pharmacies, the provision of in-home and community-based infusion services and through rare disease and gene therapy support services. It also offers direct-to-consumer solutions.

Optum Rx manages a broad range of prescription drug spend, including widely available retail drugs as well as limited and ultra-limited distribution drugs in oncology, HIV, pain management and ophthalmology. Optum Rx serves the growing pharmacy needs of people with behavioral health and substance use disorders. In 2024, Optum Rx managed $178 billion in pharmaceutical spending, including $74 billion in specialty pharmaceutical spending.

Optum Rx serves health benefits providers, large national employer plans, unions and trusts, purchasing coalitions and public-sector entities. Optum Rx sells its services through direct sales, health insurance brokers and other health care consultants.

Optum Rx offers multiple clinical programs, digital tools and services to help clients manage overall pharmacy and health care costs in a clinically appropriate manner which are designed to deliver improved consumer experiences, better health outcomes and a lower total cost of care. Optum Rx provides various utilization management, medication management, quality assurance, adherence and counseling programs to complement each client's plan design and clinical strategies. Optum Rx is accelerating the integration of medical, pharmacy and behavioral care and treating the whole patient by embedding our pharmacists as key members of the patient care team.

UnitedHealthcare

Through its health benefits offerings, UnitedHealthcare is enabling better health, creating a better health care experience for its customers and helping to control rising health care costs. UnitedHealthcare's market position is built on:

- strong local-market relationships;
- the breadth of product offerings, based upon extensive expertise in distinct market segments in health care;
- service and advanced technology, including digital consumer engagement;
- competitive medical and operating cost positions;
- effective clinical engagement; and
- innovation for customers and consumers.

UnitedHealthcare arranges for discounted access to care through its extensive networks and uses Optum's capabilities to help coordinate and provide patient care, improve affordability of medical care, analyze cost trends, manage pharmacy care services, work with care providers more effectively and create a simpler and more satisfying consumer and physician experience.

UnitedHealthcare is subject to extensive government regulation. See further discussion of our regulatory environment below under "Government Regulation" and in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

UnitedHealthcare Employer & Individual

Domestically, UnitedHealthcare Employer & Individual offers a comprehensive array of consumer-oriented health benefit plans and services for large national employers, public sector employers, mid-sized employers, small businesses, and individuals. As of December 31, 2024, UnitedHealthcare Employer & Individual provides access to medical services for 29.7 million people.

Through its risk-based product offerings, UnitedHealthcare Employer & Individual assumes the risk of both medical and administrative costs for its customers in return for a monthly premium which is typically a fixed rate per individual served for a one-year period. Through its administrative and other management services arrangements to customers who elect to self-fund the health care costs of their employees and employees' dependents, UnitedHealthcare Employer & Individual receives a fixed

monthly service fee per individual served. These customers retain the risk of financing medical benefits for their employees and employees' dependents, while UnitedHealthcare Employer & Individual provides services such as coordination and facilitation of medical and related services to customers, consumers and health care professionals, administration of transaction processing and access to a contracted network of physicians, hospitals and other health care professionals, including dental and vision professionals. UnitedHealthcare Employer & Individual is focused on providing informed benefit solutions that create customized plan designs and clinical programs for employers that contribute to well-being and reduce the total cost of care along with providing simpler consumer experiences in response to market dynamics.

UnitedHealthcare Employer & Individual typically distributes its products through a variety of channels, dependent upon the specific product, including: through consultants or direct sales, in collaboration with brokers and agents, through wholesale agents or agencies who contract with health insurance carriers to distribute individual or group benefits, through professional employer organizations and associations and through both multi-carrier and its own proprietary private exchange marketplaces.

UnitedHealthcare Employer & Individual's major product families include consumer engagement products, such as high-deductible consumer driven benefit plans and a variety of innovative consumer centric products; traditional products; clinical and pharmacy products; and specialty benefits, such as vision, dental, accident protection, critical illness, disability and hospital indemnity offerings.

UnitedHealthcare Medicare & Retirement

UnitedHealthcare Medicare & Retirement provides health and well-being services to seniors and other Medicare eligible consumers, addressing their unique needs. UnitedHealthcare Medicare & Retirement has distinct benefit designs, pricing, underwriting, clinical program management and marketing capabilities dedicated to health products and services in this market.

UnitedHealthcare Medicare & Retirement offers a selection of products allowing people choice in obtaining the health coverage and services they need as their circumstances change. These offerings include care management and health system navigator services, clinical management programs, nurse health line services, 24-hour access to health care information, access to discounted health services from a network of care providers and administrative services.

UnitedHealthcare Medicare & Retirement has extensive distribution capabilities and experience, including direct marketing to consumers on behalf of its key clients, a membership organization, and state and U.S. government agencies. Products are also offered through agents, employer groups and digital channels.

Major product categories include:

Medicare Advantage. Provides health care coverage for seniors and other eligible Medicare beneficiaries through the Medicare Advantage program administered by the Centers for Medicare & Medicaid Services (CMS), including Medicare Advantage HMO plans, Preferred Provider Organization (PPO) plans, Point-of-Service plans, Private-Fee-for-Service plans and Special Needs Plans (SNPs). Under the Medicare Advantage program, UnitedHealthcare Medicare & Retirement provides health benefits coverage in exchange for a fixed monthly premium per member from CMS plus, in some cases, monthly consumer premiums. Premium amounts received from CMS vary based on the geographic areas in which individuals reside; demographic factors such as age, gender and institutionalized status; and the health status of the individual. UnitedHealthcare Medicare & Retirement served 7.8 million people through its Medicare Advantage products as of December 31, 2024.

We have continued to enhance our offerings, focusing on more digital and physical care resources in the home, expanding our concierge navigation services and enabling the home as a safe and effective setting for care. For example, through our HouseCalls program, nurse practitioners performed 2.9 million clinical preventive home care visits in 2024 to address unmet care opportunities and close gaps in care.

Medicare Part D. Provides Medicare Part D benefits to beneficiaries through its Medicare Advantage and stand-alone Medicare Part D plans. The stand-alone Medicare Part D plans address a large spectrum of people's needs and preferences for their prescription drug coverage, including low-cost prescription options. As of December 31, 2024, UnitedHealthcare enrolled 10.1 million people in the Medicare Part D programs, including 3.1 million individuals in stand-alone Medicare Part D plans, with the remainder in Medicare Advantage plans incorporating Medicare Part D coverage.

Medicare Supplement. Provides a full range of supplemental products at diverse price points. These products cover various levels of coinsurance and deductible gaps to which seniors are exposed in the traditional Medicare program. UnitedHealthcare Medicare & Retirement served 4.3 million seniors nationwide through various Medicare Supplement products as of December 31, 2024.

Premium revenues from CMS represented 40% of UnitedHealth Group's total consolidated revenues for the year ended December 31, 2024, most of which were generated by UnitedHealthcare Medicare & Retirement.

UnitedHealthcare Community & State

UnitedHealthcare Community & State is dedicated to serving state programs caring for the economically disadvantaged, the medically underserved and those without the benefit of employer-funded health care coverage, typically in exchange for a monthly premium per member from the state program. UnitedHealthcare Community & State's primary customers oversee Medicaid plans, including Temporary Assistance to Needy Families; Children's Health Insurance Programs (CHIP); Dual SNPs (DSNPs); Long-Term Services and Supports (LTSS); Aged, Blind and Disabled; and other federal, state and community health care programs. As of December 31, 2024, UnitedHealthcare Community & State participated in programs in 33 states and the District of Columbia, and served more than 7.4 million people; including 1.2 million people through Medicaid expansion programs in 20 states under the Patient Protection and Affordable Care Act (ACA).

States using managed care services for Medicaid beneficiaries select health plans by using a formal bid process or by awarding individual contracts. These health plans and care programs are designed to address the complex needs of the populations they serve, including the chronically ill, people with disabilities and people with a higher risk of medical, behavioral and social conditions. UnitedHealthcare Community & State administers benefits for the unique needs of children, pregnant women, adults, seniors and those who are institutionalized or are nursing home eligible. These individuals often live in medically underserved areas and are less likely to have a consistent relationship with the medical community or a care provider. They also often face significant social and economic challenges.

GOVERNMENT REGULATION

Our businesses are subject to comprehensive U.S. federal and state and international laws and regulations. We are regulated by agencies which generally have discretion to issue regulations and interpret and enforce laws and rules. U.S. federal and state and international governments continue to consider and enact various legislative and regulatory proposals which could materially impact certain aspects of the health care system. New laws, regulations and rules, or changes in the interpretation of existing laws, regulations and rules, including as a result of changes in the political environment, could adversely affect our businesses.

See Part I, Item 1A, "Risk Factors" for a discussion of the risks related to our compliance with U.S. federal and state and international laws and regulations.

U.S. Federal Laws and Regulation

When we contract with the federal government, we are subject to federal laws and regulations relating to the award, administration and performance of U.S. government contracts. CMS regulates our UnitedHealthcare businesses and certain aspects of our Optum businesses. Payments by CMS to our businesses are subject to regulations, including those governing fee-for-service and the submission of information relating to the health status of enrollees for purposes of determining the amounts of certain payments to us. CMS also has the right to audit our performance to determine our compliance with CMS contracts and regulations and the quality of care we provide to Medicare beneficiaries. Our commercial business is further subject to CMS audits related to medical loss ratios (MLRs) and risk adjustment data.

UnitedHealthcare Community & State has Medicaid and CHIP contracts, which are subject to federal regulations regarding services to be provided to Medicaid enrollees, payment for those services and other aspects of these programs. There are many regulations affecting Medicare and Medicaid compliance, and the regulatory environment with respect to these programs is complex.

Our businesses are also subject to laws and regulations relating to consumer protection, anti-fraud and abuse, anti-kickbacks, false claims, prohibited referrals, inappropriate reduction or limitation of health care services, anti-money laundering and securities and antitrust compliance.

Privacy, Security and Data Standards Regulation. Certain of our operations are subject to regulation under the administrative simplification provisions of the Health Insurance Portability and Accountability Act of 1996, as amended (HIPAA), which apply to both the group and individual health insurance markets, including self-funded employee benefit plans. Federal regulations related to HIPAA contain minimum standards for electronic transactions and code sets and for the privacy and security of protected health information.

Our businesses must comply with the Health Information Technology for Economic and Clinical Health Act (HITECH), which regulates matters relating to privacy, security and data standards. HITECH imposes requirements on uses and disclosures of health information; includes contracting requirements for HIPAA business associate agreements; extends parts of HIPAA privacy and security provisions to business associates; adds federal data breach notification requirements for covered entities and business associates and reporting requirements to HHS and the Federal Trade Commission (FTC) and, in some cases, to the local media; strengthens enforcement and imposes higher financial penalties for HIPAA violations and, in certain cases, imposes criminal penalties for individuals, including employees. In the conduct of our business, depending on the circumstances, we may act as either a covered entity or a business associate.

Optum operates three business segments which combine distinctive capabilities in value-based care, population health, health care operations, data and analytics and pharmacy care services:

- Optum Health delivers patient-centered care, care management, wellness and consumer engagement, and health financial services;
- Optum Insight offers data, analytics, research, consulting, technology and managed services solutions; and
- Optum Rx provides diversified pharmacy care services.

Optum Health

Optum Health provides comprehensive and patient-centered care, addressing the physical, mental, social, and financial well-being of 100 million consumers and serves more than 100 health payer partners. We engage people in the most appropriate care settings, including clinical sites, in-home and virtual. Optum Health delivers primary, specialty and surgical care; helps patients and providers navigate and address complex, chronic and behavioral health needs; offers post-acute care planning services; and serves consumers and care providers through advanced, on-demand digital health technologies, such as telehealth and remote patient monitoring, and innovative health care financial services. Optum Health works directly with patients, consumers, care delivery systems, providers, employers, payers, and public-sector entities to provide high quality, accessible and equitable care with improved health outcomes and reduced total cost of care. Optum Health enables care providers to transition from traditional fee-for-service payment models to performance-based delivery and payment models designed to improve patient health outcomes and experience through value-based care.

Optum Health offerings include fully accountable value-based arrangements, where Optum Health assumes responsibility for health care costs in exchange for a monthly premium. Offerings also include administrative fee arrangements, where Optum Health manages or administers products and services in exchange for a monthly fee, and fee-for-service arrangements, where Optum Health delivers health-related products and medical services for patients at a contracted fee.

Optum Financial, including Optum Bank, serves consumers through more than 27 million consumer accounts with $24 billion in assets under management as of December 31, 2024. Organizations across the health system rely on Optum Financial to manage and improve payment flows through its highly automated, scalable, end-to-end digital payment and financing systems and integrated card solutions. For financial services offerings, Optum Financial charges fees and earns investment income on managed funds.

Optum Health sells its products primarily through its direct sales force, strategic collaborations and external producers in three key areas: employers, including large, mid-sized and small employers; payers including health plans, third-party administrators (TPAs), underwriter/stop-loss carriers and individual product intermediaries; and public entities, including the U.S. Departments of Health and Human Services (HHS), Veterans Affairs, Defense, and other federal, state and local health care agencies.

Optum Insight

Optum Insight connects the health care system with services, analytics and platforms that make clinical, administrative and financial processes simpler and more efficient for all participants in the health care system. Hospital systems, physicians, health plans, public entities, life sciences companies and other organizations comprising the health care industry depend on Optum Insight to help them improve performance and reduce costs through administrative efficiency and payment simplification, advance care quality through evidence-based standards built directly into clinical workflows, meet compliance mandates and modernize their core operating systems to meet the changing needs of the health system.

Health Systems. Serves hospitals, physicians and other care providers to improve operating performance, better coordinate care and reduce administrative costs through technology and services to improve population health management, patient engagement, revenue cycle management and strategic growth plans.

Health Plans. Serves health plans by improving financial performance and enhancing outcomes through proactive analytics, a comprehensive payment integrity portfolio and technology-enabled and staff-supported risk and quality services. Optum Insight helps health plans navigate a dynamic environment defined by shifts in employer vs. public-sector coverage, the demand for affordable benefit plans and the need to leverage new technology to reduce complexity.

State Governments. Provides advanced technology and analytics services to modernize the administration of critical safety net programs, such as Medicaid, while improving cost predictability.

Life Sciences Companies. Combines data and analytics expertise with comprehensive technologies and health care knowledge to help life sciences companies, including those in pharmaceuticals and medical technology, adopt a more comprehensive approach to advancing therapeutic discoveries and improving clinical outcomes.

Many of Optum Insight's software and information products and professional services are delivered over extended periods, often several years. Optum Insight maintains an order backlog to track unearned revenues under these long-term arrangements. The backlog consists of estimated revenue from signed contracts, other legally binding agreements and anticipated contract renewals based on historical experience with Optum Insight's customers. Optum Insight's aggregate backlog as of December 31, 2024 was approximately $32.8 billion, of which $19.8 billion is expected to be realized within the next 12 months. The aggregate backlog includes $12.5 billion related to affiliated agreements. Optum Insight's aggregate backlog as of December 31, 2023, was $32.1 billion, including $11.9 billion related to affiliated agreements.

Optum Insight's products and services are sold primarily through a direct sales force. Optum Insight's products are also supported and distributed through an array of alliances and business partnerships with other technology vendors, who integrate and interface Optum Insight's products with their applications.

Optum Rx

Optum Rx provides a full spectrum of pharmacy care services through its network of more than 65,000 retail pharmacies, through home delivery, specialty and community health pharmacies, the provision of in-home and community-based infusion services and through rare disease and gene therapy support services. It also offers direct-to-consumer solutions.

Optum Rx manages a broad range of prescription drug spend, including widely available retail drugs as well as limited and ultra-limited distribution drugs in oncology, HIV, pain management and ophthalmology. Optum Rx serves the growing pharmacy needs of people with behavioral health and substance use disorders. In 2024, Optum Rx managed $178 billion in pharmaceutical spending, including $74 billion in specialty pharmaceutical spending.

Optum Rx serves health benefits providers, large national employer plans, unions and trusts, purchasing coalitions and public-sector entities. Optum Rx sells its services through direct sales, health insurance brokers and other health care consultants.

Optum Rx offers multiple clinical programs, digital tools and services to help clients manage overall pharmacy and health care costs in a clinically appropriate manner which are designed to deliver improved consumer experiences, better health outcomes and a lower total cost of care. Optum Rx provides various utilization management, medication management, quality assurance, adherence and counseling programs to complement each client's plan design and clinical strategies. Optum Rx is accelerating the integration of medical, pharmacy and behavioral care and treating the whole patient by embedding our pharmacists as key members of the patient care team.

UnitedHealthcare

Through its health benefits offerings, UnitedHealthcare is enabling better health, creating a better health care experience for its customers and helping to control rising health care costs. UnitedHealthcare's market position is built on:

- strong local-market relationships;
- the breadth of product offerings, based upon extensive expertise in distinct market segments in health care;
- service and advanced technology, including digital consumer engagement;
- competitive medical and operating cost positions;
- effective clinical engagement; and
- innovation for customers and consumers.

UnitedHealthcare arranges for discounted access to care through its extensive networks and uses Optum's capabilities to help coordinate and provide patient care, improve affordability of medical care, analyze cost trends, manage pharmacy care services, work with care providers more effectively and create a simpler and more satisfying consumer and physician experience.

UnitedHealthcare is subject to extensive government regulation. See further discussion of our regulatory environment below under "Government Regulation" and in Part II, Item 7, "Management's Discussion and Analysis of Financial Condition and Results of Operations."

UnitedHealthcare Employer & Individual

Domestically, UnitedHealthcare Employer & Individual offers a comprehensive array of consumer-oriented health benefit plans and services for large national employers, public sector employers, mid-sized employers, small businesses, and individuals. As of December 31, 2024, UnitedHealthcare Employer & Individual provides access to medical services for 29.7 million people.

Through its risk-based product offerings, UnitedHealthcare Employer & Individual assumes the risk of both medical and administrative costs for its customers in return for a monthly premium which is typically a fixed rate per individual served for a one-year period. Through its administrative and other management services arrangements to customers who elect to self-fund the health care costs of their employees and employees' dependents, UnitedHealthcare Employer & Individual receives a fixed

monthly service fee per individual served. These customers retain the risk of financing medical benefits for their employees and employees' dependents, while UnitedHealthcare Employer & Individual provides services such as coordination and facilitation of medical and related services to customers, consumers and health care professionals, administration of transaction processing and access to a contracted network of physicians, hospitals and other health care professionals, including dental and vision professionals. UnitedHealthcare Employer & Individual is focused on providing informed benefit solutions that create customized plan designs and clinical programs for employers that contribute to well-being and reduce the total cost of care along with providing simpler consumer experiences in response to market dynamics.

UnitedHealthcare Employer & Individual typically distributes its products through a variety of channels, dependent upon the specific product, including: through consultants or direct sales, in collaboration with brokers and agents, through wholesale agents or agencies who contract with health insurance carriers to distribute individual or group benefits, through professional employer organizations and associations and through both multi-carrier and its own proprietary private exchange marketplaces.

UnitedHealthcare Employer & Individual's major product families include consumer engagement products, such as high-deductible consumer driven benefit plans and a variety of innovative consumer centric products; traditional products; clinical and pharmacy products; and specialty benefits, such as vision, dental, accident protection, critical illness, disability and hospital indemnity offerings.

UnitedHealthcare Medicare & Retirement

UnitedHealthcare Medicare & Retirement provides health and well-being services to seniors and other Medicare eligible consumers, addressing their unique needs. UnitedHealthcare Medicare & Retirement has distinct benefit designs, pricing, underwriting, clinical program management and marketing capabilities dedicated to health products and services in this market.

UnitedHealthcare Medicare & Retirement offers a selection of products allowing people choice in obtaining the health coverage and services they need as their circumstances change. These offerings include care management and health system navigator services, clinical management programs, nurse health line services, 24-hour access to health care information, access to discounted health services from a network of care providers and administrative services.

UnitedHealthcare Medicare & Retirement has extensive distribution capabilities and experience, including direct marketing to consumers on behalf of its key clients, a membership organization, and state and U.S. government agencies. Products are also offered through agents, employer groups and digital channels.

Major product categories include:

Medicare Advantage. Provides health care coverage for seniors and other eligible Medicare beneficiaries through the Medicare Advantage program administered by the Centers for Medicare & Medicaid Services (CMS), including Medicare Advantage HMO plans, Preferred Provider Organization (PPO) plans, Point-of-Service plans, Private-Fee-for-Service plans and Special Needs Plans (SNPs). Under the Medicare Advantage program, UnitedHealthcare Medicare & Retirement provides health benefits coverage in exchange for a fixed monthly premium per member from CMS plus, in some cases, monthly consumer premiums. Premium amounts received from CMS vary based on the geographic areas in which individuals reside; demographic factors such as age, gender and institutionalized status; and the health status of the individual. UnitedHealthcare Medicare & Retirement served 7.8 million people through its Medicare Advantage products as of December 31, 2024.

We have continued to enhance our offerings, focusing on more digital and physical care resources in the home, expanding our concierge navigation services and enabling the home as a safe and effective setting for care. For example, through our HouseCalls program, nurse practitioners performed 2.9 million clinical preventive home care visits in 2024 to address unmet care opportunities and close gaps in care.

Medicare Part D. Provides Medicare Part D benefits to beneficiaries through its Medicare Advantage and stand-alone Medicare Part D plans. The stand-alone Medicare Part D plans address a large spectrum of people's needs and preferences for their prescription drug coverage, including low-cost prescription options. As of December 31, 2024, UnitedHealthcare enrolled 10.1 million people in the Medicare Part D programs, including 3.1 million individuals in stand-alone Medicare Part D plans, with the remainder in Medicare Advantage plans incorporating Medicare Part D coverage.

Medicare Supplement. Provides a full range of supplemental products at diverse price points. These products cover various levels of coinsurance and deductible gaps to which seniors are exposed in the traditional Medicare program. UnitedHealthcare Medicare & Retirement served 4.3 million seniors nationwide through various Medicare Supplement products as of December 31, 2024.

Premium revenues from CMS represented 40% of UnitedHealth Group's total consolidated revenues for the year ended December 31, 2024, most of which were generated by UnitedHealthcare Medicare & Retirement.

The use and disclosure of individually identifiable health data by our businesses are also regulated in some instances by other federal laws, including the Gramm-Leach-Bliley Act (GLBA) or state statutes implementing GLBA. These federal laws and state statutes generally require insurers to provide customers with notice regarding how their non-public personal health and financial information is used and the opportunity to "opt out" of certain disclosures before the insurer shares such information with a third party, and generally prescribe safeguards for the protection of personal information. Neither the GLBA nor HIPAA privacy regulations preempt more stringent state laws and regulations, which may apply to us, as discussed below. Federal consumer protection laws may also apply in some instances to privacy and security practices related to personally identifiable information.

ERISA. The Employee Retirement Income Security Act of 1974, as amended (ERISA), regulates how our services are provided to or through certain types of employer-sponsored health benefit plans. ERISA is a set of laws and regulations subject to interpretation by the U.S. Department of Labor (DOL) as well as the federal courts. ERISA sets forth standards on how our business units may do business with employers who sponsor employee health benefit plans, particularly those who maintain self-funded plans. Regulations established by the DOL subject us to additional requirements for administration of benefits, claims payment and member appeals under health care plans governed by ERISA.

State Laws and Regulation

Health Care Regulation. Our insurance and HMO subsidiaries must be licensed by the jurisdictions in which they conduct business. All of the states in which our subsidiaries offer insurance and HMO products regulate those products and operations. The states require periodic financial reports and establish minimum capital or restricted cash reserve requirements. The National Association of Insurance Commissioners (NAIC) has adopted model regulations, which require expanded governance practices and risk and solvency assessment reporting. Most states have adopted these or similar measures to expand the scope of regulations relating to corporate governance and internal control activities of HMOs and insurance companies. We are required to maintain a risk management framework and file a confidential self-assessment report with state insurance regulators. We file reports annually with Connecticut, our lead regulator, and with New York, as required by the state's regulation.

Our health plans and insurance companies are regulated under state insurance holding company regulations. Such regulations generally require registration with applicable state departments of insurance and the filing of reports describing capital structure, ownership, financial condition, certain affiliated transactions and general business operations. Most state insurance holding company laws and regulations require prior regulatory approval of acquisitions and material affiliated transfers of assets, as well as transactions between the regulated companies and their parent holding companies or affiliates. These laws may restrict the ability of our regulated subsidiaries to pay dividends to our holding companies.

Some of our business activity is subject to other health care-related regulations and requirements, including PPO, Managed Care Organization (MCO), utilization review (UR), TPA, pharmacy care services, durable medical equipment or care provider-related regulations and licensure requirements. These regulations differ from state to state and may contain network, contracting, product and rate, licensing and financial and reporting requirements. Health care-related laws and regulations set specific standards for delivery of services, appeals, grievances and payment of claims, adequacy of health care professional networks, fraud prevention, protection of consumer health information, pricing and underwriting practices and covered benefits and services. State health care anti-fraud and abuse prohibitions encompass a wide range of activities, including kickbacks for referral of members, billing for unnecessary medical services and improper marketing. Certain of our businesses are subject to state general agent, broker and sales distribution laws and regulations. UnitedHealthcare Community & State and certain of our Optum businesses are subject to regulation by state Medicaid agencies which oversee the provision of benefits to our Medicaid and CHIP beneficiaries and to our beneficiaries dually eligible for Medicare and Medicaid. We also contract with state governmental entities and are subject to state laws and regulations relating to the award, administration and performance of state government contracts.

State Privacy and Security Regulations. A number of states have adopted laws and regulations which may affect our privacy and security practices, such as state laws governing the use, disclosure and protection of social security numbers and protected health information or which are designed to implement GLBA or protect credit card account data. State and local authorities increasingly focus on the importance of protecting individuals from identity theft, with a significant number of states enacting laws requiring businesses to meet minimum cyber-security standards and notify individuals of security breaches involving personal information. State consumer protection laws may also apply to privacy and security practices related to personally identifiable information, including information related to consumers and care providers. Different approaches to state privacy and insurance regulation and varying enforcement philosophies may materially and adversely affect our ability to standardize our products and services across state lines. See Part I, Item 1A, "Risk Factors" for a discussion of the risks related to compliance with state privacy and security regulations.

Corporate Practice of Medicine and Fee-Splitting Laws. Certain of our businesses function as direct medical service providers and, as such, are subject to additional laws and regulations. Some states have corporate practice of medicine laws prohibiting specific types of entities from practicing medicine or employing physicians to practice medicine. Moreover, some states prohibit certain entities from engaging in fee-splitting practices, which involve sharing in the fees or revenues of a professional practice. These prohibitions may be statutory or regulatory, or may be imposed through judicial or regulatory interpretation. The laws, regulations and interpretations in certain states have been subject to limited judicial and regulatory interpretation and are subject to change.

Pharmacy and Pharmacy Benefits Management (PBM) Regulations

Optum Rx's businesses include home delivery, specialty and compounding pharmacies, as well as clinic-based pharmacies which must be licensed as pharmacies in the states in which they are located. Certain of our pharmacies must also register with the U.S. Drug Enforcement Administration (DEA) and individual state controlled substance authorities to dispense controlled substances. In addition to adhering to the laws and regulations in the states where our pharmacies are located, we also are required to comply with laws and regulations in some non-resident states where we deliver pharmaceuticals, including those requiring us to register with the board of pharmacy in the non-resident state. These non-resident states generally expect our pharmacies to follow the laws of the state in which the pharmacies are located, but some non-resident states also require us to comply with their laws where pharmaceuticals are delivered. Additionally, certain of our pharmacies which participate in programs for Medicare and state Medicaid providers are required to comply with applicable Medicare and Medicaid provider rules and regulations. Other laws and regulations affecting our pharmacies include federal and state statutes and regulations governing the labeling, packaging, advertising and adulteration of prescription drugs and dispensing of controlled substances. See Part I, Item 1A, "Risk Factors" for a discussion of the risks related to our pharmacy care services businesses.

Federal and state legislation regulating PBM activities affects both our ability to limit access to a pharmacy provider network or remove network providers. Additionally, many states limit our ability to manage and establish maximum allowable costs for generic prescription drugs. With respect to formulary services, a number of government entities, including CMS, HHS and state departments of insurance, regulate the administration of prescription drug benefits offered through federal or state exchanges. Many states also regulate the scope of prescription drug coverage, as well as the delivery channels to receive such prescriptions, for insurers, MCOs and Medicaid managed care plans. These regulations could limit or preclude (i) certain plan designs, (ii) limited networks, (iii) use of particular care providers or distribution channels, (iv) copayment differentials among providers and (v) formulary tiering practices.

Legislation seeking to regulate PBM activities introduced or enacted at the federal or state level could impact our business practices with others in the pharmacy supply chain, including pharmaceutical manufacturers and network providers. In addition, organizations like the NAIC periodically issue model regulations while credentialing organizations, like the National Committee for Quality Assurance (NCQA) and the Utilization Review Accreditation Commission (URAC), may establish standards impacting PBM pharmacy activities. Although these model regulations and standards do not have the force of law, they may influence states to adopt their recommendations and impact the services we deliver to our clients.

Consumer Protection Laws

Certain of our businesses participate in direct-to-consumer activities and are subject to regulations applicable to online communications and other general consumer protection laws and regulations such as the Federal Tort Claims Act, the Federal Postal Service Act and the FTC's Telemarketing Sales Rule. Most states also have similar consumer protection laws.

Certain laws, such as the Telephone Consumer Protection Act, give the FTC, the Federal Communications Commission (FCC) and state attorneys general the ability to regulate, and bring enforcement actions relating to, telemarketing practices and certain automated outbound contacts such as phone calls, texts or emails. Under certain circumstances, these laws may provide consumers with a private right of action. Violations of these laws could result in substantial statutory penalties and other sanctions.

Banking Regulation

Optum Bank is subject to regulation by federal banking regulators, including the Federal Deposit Insurance Corporation (FDIC), which performs annual examinations to ensure the bank is operating in accordance with federal safety and soundness requirements, and the Consumer Financial Protection Bureau, which may perform periodic examinations to ensure the bank is in compliance with applicable consumer protection statutes, regulations and agency guidelines. Optum Bank is also subject to supervision and regulation by the Utah State Department of Financial Institutions, which carries out annual examinations to ensure the bank is operating in accordance with state safety and soundness requirements and performs periodic examinations of the bank's compliance with applicable state banking statutes, regulations and agency guidelines. In the event of unfavorable examination results from any of these agencies, the bank could become subject to increased operational expenses and capital requirements, enhanced governmental oversight and monetary penalties.

Non-U.S. Regulation

Certain of our businesses operate internationally and are subject to regulation in the jurisdictions in which they are organized or conduct business. These regulatory regimes vary from jurisdiction to jurisdiction. In addition, our non-U.S. businesses and operations are subject to U.S. laws regulating the conduct and activities of U.S.-based businesses operating outside the United States, such as the Foreign Corrupt Practices Act (FCPA), which prohibits offering, promising, providing or authorizing others to give anything of value to a foreign government official to obtain or retain business or otherwise secure a business advantage.

COMPETITION

As a diversified health care company, we operate in highly competitive markets across the full expanse of health care benefits and services. Our competitors include organizations ranging from startups to highly sophisticated Fortune 50 global enterprises, for-profit and non-profit companies, and private and government-sponsored entities. New entrants to our markets and business combinations among our competitors and suppliers also contribute to a dynamic and competitive environment. We compete fundamentally on the quality and value we provide to those we serve which can include elements such as product and service innovation; use of technology; consumer and provider engagement and satisfaction; and sales, marketing and pricing. See Part I, Item 1A, "Risk Factors" for additional discussion of our risks related to competition.

INTELLECTUAL PROPERTY RIGHTS

We have obtained trademark registration for the UnitedHealth Group, Optum and UnitedHealthcare names and logos. We own registrations for certain of our other trademarks in the United States and abroad. We hold a portfolio of patents and have patent applications pending from time to time. We are not substantially dependent on any single patent or group of related patents.

Unless otherwise noted, trademarks appearing in this report are trademarks owned by us. We disclaim any proprietary interest in the marks and names of others.

HUMAN CAPITAL RESOURCES

Our nearly 400,000 employees, as of December 31, 2024, including more than 140,000 clinical professionals, are guided by our mission to help people live healthier lives and help make the health system work better for everyone. Our mission and cultural values of integrity, compassion, inclusion, relationships, innovation, performance and quality align with our long-term business strategy to increase access to care, make care more affordable, enhance the care experience, improve health outcomes and advance health equity. Our mission and values attract individuals who are determined to make a difference – individuals whose talent, innovation, engagement and empowerment are critical in our ability to achieve our mission.

We are committed to developing our people and culture by creating an inclusive environment where people of diverse talents, backgrounds, experiences and perspectives make us better. Our approach is data-driven and leader-led and uses enterprise and business scorecards to ensure our leaders are accountable for a consistent focus on hiring, developing, advancing and retaining diverse talent. We have embedded inclusion and diversity throughout our culture, including in our talent acquisition and talent management practices; leadership development; careers; learning and skills; and systems and processes. We strive to maintain a skilled, sustainable and diverse talent pipeline by building strong strategic partnerships and outreach through early career programs, internships and apprenticeships. We support career coaching, mentorship and accelerated leadership development programs to ensure mobility and advancement for our diverse talent. To foster an engaged workforce and an inclusive culture, we invest in a broad array of skills-based learning and culture development programs. We rely on a shared leadership framework, which clearly and objectively defines our expectations, enables an environment where everyone has the opportunity to learn and grow, and helps us identify, develop and deploy talent to help achieve our mission.

We prioritize pay equity by objectively and regularly evaluating and reviewing our compensation practices by performance, age, experience, gender, ethnicity and race. Receiving on-going feedback from our team members is another way to strengthen and reinforce a culture of inclusion. Our Employee Experience Index measures an employee's sense of commitment and belonging to our company and is a metric in the Stewardship section of our annual incentive plan. Our Sustainability Report, which can be accessed on our website at www.unitedhealthgroup.com, provides further information about our people and culture.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

The following sets forth certain information regarding our executive officers as of February 27, 2025, including the business experience of each executive officer during the past five years:

Name	Age	Position
Andrew Witty	60	Chief Executive Officer
John Rex	63	President and Chief Financial Officer
Heather Cianfrocco	51	Chief Executive Officer, Optum
Erin McSweeney	60	Executive Vice President and Chief People Officer
Timothy Noel	53	Chief Executive Officer, UnitedHealthcare
Thomas Roos	52	Senior Vice President and Chief Accounting Officer
Christopher Zaetta	53	Executive Vice President and Chief Legal Officer and Corporate Secretary

Our Board of Directors elects executive officers annually. Our executive officers serve until their successors are duly elected and qualified, or until their earlier death, resignation, removal or disqualification.

Andrew Witty has served as Chief Executive Officer and a member of the Board of Directors of UnitedHealth Group since February 2021. Previously, Andrew served as Chief Executive Officer of Optum from July 2018 to April 2021, President of UnitedHealth Group from November 2019 to February 2021 and as a UnitedHealth Group director from August 2017 to March 2018. Prior to joining UnitedHealth Group, he was Chief Executive Officer and a board member of GlaxoSmithKline, a global pharmaceutical company, from 2008 to 2017.

John Rex has served as President and Chief Financial Officer of UnitedHealth Group since April 2024. Previously, John served as Chief Financial Officer of UnitedHealth Group since June 2016. From March 2012 to June 2016, he served as Executive Vice President and Chief Financial Officer of Optum. Prior to joining Optum in 2012, John was a Managing Director at JP Morgan, a global financial services firm.

Heather Cianfrocco has served as Chief Executive Officer of Optum since April 2024. Previously, Heather served as Optum's President and held numerous leadership roles since joining UnitedHealth Group from 2008 until April 2024, including serving as Chief Executive Officer of Optum Rx, Chief Executive Officer for Optum's Health Services and Chief Executive Officer of UnitedHealthcare Community & State.

Erin McSweeney has served as Executive Vice President and Chief People Officer of UnitedHealth Group since March 2022. From February 2021 to March 2022, Erin served as chief of staff to UnitedHealth Group's Office of the Chief Executive. From January 2017 to February 2021, she served as Executive Vice President and Chief Human Resources Officer at Optum. Prior to joining UnitedHealth Group, Erin was Executive Vice President and Chief Human Resources Officer for EMC Corporation, an international technology company.

Tim Noel has served as Chief Executive Officer of UnitedHealthcare since January 2025. Previously, Tim served as Chief Executive Officer of UnitedHealthcare's Medicare & Retirement business and held numerous leadership roles since joining UnitedHealth Group from 2007 until January 2025, including serving as Chief Financial Officer and Senior Vice President of federal products for Medicare & Retirement.

Tom Roos has served as Senior Vice President and Chief Accounting Officer of UnitedHealth Group since August 2015. Prior to joining UnitedHealth Group, Tom was a Partner at Deloitte & Touche LLP, an independent registered public accounting firm.

Chris Zaetta has served as Executive Vice President, Chief Legal Officer and Corporate Secretary of UnitedHealth Group since May 2024. Previously, Chris served as Chief Legal Officer of Optum from September 2020 until May 2024. Prior to joining Optum in 2020, Chris was Vice President at Johnson & Johnson, a pharmaceutical company. Chris also held several leadership roles at UnitedHealth Group from May 2011 to September 2019, including Head of Litigation and General Counsel of the organization's government businesses.

ADDITIONAL INFORMATION

Our executive offices are located at 1 Health Drive, Eden Prairie, Minnesota 55344 and 655 New York Avenue, Washington, DC 20001; our telephone number is (800) 328-5979. You can access our website at www.unitedhealthgroup.com to learn more about our company. We make periodic and current reports and amendments available, free of charge, on our website, as soon as reasonably practicable after we file or furnish these reports to the Securities and Exchange Commission (SEC). Information on or linked to our website is neither part of nor incorporated by reference into this Annual Report on Form 10-K or any other SEC filings.

ITEM 1A. RISK FACTORS

CAUTIONARY STATEMENTS

The statements, estimates, projections or outlook contained in this Annual Report on Form 10-K include forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 (PSLRA). When used in this Annual Report on Form 10-K and in future filings by us with the SEC, in our news releases, presentations to securities analysts or investors, and in oral statements made by or with the approval of one of our executive officers, the words "believe," "expect," "intend," "estimate," "anticipate," "forecast," "outlook," "plan," "project," "should" or similar words or phrases are intended to identify such forward-looking statements. These statements are intended to take advantage of the "safe harbor" provisions of the PSLRA. These forward-looking statements involve risks and uncertainties which may cause our actual results to differ materially from the expectations expressed or implied in the forward-looking statements. Any forward-looking statement in this report speaks only as of the date of this report and, except as required by law, we undertake no obligation to update any forward-looking statement to reflect events or circumstances, including unanticipated events, after the date of this report.

The following discussion contains cautionary statements regarding our business, which investors and others should consider. We do not undertake to address in future filings with the SEC or other communications regarding our business or results of operations how any of these factors may have caused our results to differ from discussions or information contained in our previous filings or communications. In addition, any of the matters discussed below may have affected past, as well as current, forward-looking statements about future results. Any or all forward-looking statements in this Annual Report on Form 10-K and in any other SEC filings or public statements we make may turn out to be wrong. Our forward-looking statements can be affected by inaccurate assumptions we might make or by known or unknown risks and uncertainties. Many factors discussed below will be important in determining our future results. By their nature, forward-looking statements are not guarantees of future performance or results and are subject to risks, uncertainties and assumptions which are difficult to predict or quantify.

Risks Related to Our Business and Our Industry

If we fail to estimate, price for and manage our medical costs or design benefits in an effective manner, the profitability of our risk-based products and services could decline and could materially and adversely affect our results of operations, financial position and cash flows.

Through our risk-based benefit products, we assume the risk of both medical and administrative costs for our customers in return for monthly premiums. The profitability of our products depends in large part on our ability to predict and effectively price for and manage medical costs. Our Optum Health business also enters into fully accountable value-based arrangements with payers. Premium revenues from risk-based products constitute nearly 80% of our total consolidated revenues. Estimates of benefit expense payments involve extensive judgement and are subject to considerable inherent variability. Relatively small differences between predicted and actual medical costs, or utilization rates as a percentage of revenues, have resulted and in the future may result in significant changes in our financial results. If we fail to predict accurately, or effectively price for or manage, the costs of providing care under risk-based arrangements, our results of operations could be materially and adversely affected.

We manage medical costs through underwriting criteria, product design, negotiation of competitive provider contracts and care management programs. Total medical costs are affected by the number of individual services rendered, the cost of each service and the type of service rendered. Although we base the premiums we charge on our estimates of future medical costs over the fixed contract period, many factors may cause, and have previously caused, actual costs to exceed those estimated and reflected in premiums or bids. These factors may include medical cost inflation, increased use of services, business mix, unexpected differences among new customer populations, increased cost of individual services, costs to deliver care, large-scale medical emergencies, the potential effects of climate change, pandemics, the introduction of new or costly drugs or increases in drug prices, treatments and technology, new treatment guidelines, newly mandated benefits or other regulatory changes and insured population characteristics. Cost increases in excess of our forecasts typically cannot be recovered in the fixed premium period through higher premiums. For Optum Health's fully accountable value-based care, any inability to provide higher-quality outcomes and better experiences at lower costs or to integrate our care delivery models could impact our results of operations, financial positions and cash flows.

In addition, the financial results we report for any particular period include estimates of costs incurred for which claims are still outstanding. These estimates involve an extensive degree of judgment. If these estimates prove inaccurate, our results of operations could be materially and adversely affected.

If we fail to maintain properly the integrity or availability of our data or successfully consolidate, integrate, upgrade or expand our existing information systems, or if our technology products do not operate as intended, our business could be materially and adversely affected.

Our business depends on the integrity and timeliness of the data we use to serve our members, customers and health care professionals and to operate our business. If the data we rely upon to run our businesses is found to be inaccurate or unreliable or if we fail to effectively maintain or protect the integrity of our data and information systems, including systems powered by or incorporating artificial intelligence and machine learning (AI/ML), we could experience failures in our health, wellness and information technology products; lose existing customers; have difficulty attracting new customers; experience problems in determining medical cost estimates and establishing appropriate pricing; have difficulty preventing, detecting and controlling fraud; have disputes with customers, physicians and other health care professionals; become subject to regulatory sanctions, penalties, investigations or audits; incur increases in operating expenses; or suffer other adverse consequences.

The volume of health care data generated, and the uses of data, including electronic health records, are rapidly expanding. We depend on the integrity of the data in our information systems to implement new and innovative services, automate and deploy new technologies to simplify administrative processes and clinical decision making, price our products and services adequately, provide effective service to our customers and consumers in an efficient and uninterrupted fashion, provide timely payments to care providers, and accurately report our results of operations. In addition, increasing connectivity among technologies and recent trends toward greater consumer engagement in health care require new and enhanced technologies, including more sophisticated applications for mobile devices and new tools and products that leverage AI/ML to improve the customer experience. We anticipate that fast-evolving AI/ML technologies, including generative AI, will play an increasingly important role in our information systems and customer-facing technology products. Our ability to protect and enhance existing systems and develop new systems to keep pace with changes in information processing technology (including AI/ML), regulatory standards and changing customer preferences will require an ongoing commitment of significant development and operational resources. If these commitments fail to provide the anticipated benefits, if we are unable to successfully anticipate future technology developments, or if the cost to keep pace with the technological changes exceeds our estimates, we could be exposed to reputational harm and experience adverse effects on our business.

We may not successfully implement our initiatives to consolidate the number of systems we operate, upgrade and expand our information systems' capabilities, integrate and enhance our systems and develop new systems to keep pace with recent regulations and changes in information processing technology. Failure to protect, consolidate and integrate our systems successfully could result in higher than expected costs.

Some of our businesses sell and install software products which may contain unexpected design defects or may encounter unexpected complications during installation or when used with other technologies utilized by the customer. A failure of our technology products to operate as intended and in a seamless fashion with other products could materially and adversely affect our results of operations, financial position and cash flows.

Uncertain and rapidly evolving U.S. federal and state, non-U.S. and international laws and regulations related to health data and health information technologies, including those powered by or incorporating AI/ML, may alter the competitive landscape or impose new compliance requirements and could materially and adversely affect the configuration of our information systems and platforms, and our ability to compete in our markets.

If we or third parties we rely on sustain cyberattacks or other privacy or data security incidents resulting in disruption to our operations or the disclosure of protected personal information or proprietary or confidential information, we could suffer a loss of revenue and increased costs, negative operational effects, exposure to significant liability, reputational harm and other serious negative consequences.

We routinely process, store and transmit large amounts of data in our operations, including protected personal information subject to privacy, security or data breach notification laws, as well as proprietary or confidential information relating to our business or third parties. Some of the data we process, store and transmit may be outside of the United States due to our information technology systems and international business operations. We are regularly the target of attempted cyberattacks and other security threats and have previously been, and may in the future be, subject to compromises of the information technology systems we use, information we hold, or information held on our behalf by third parties. For example, we previously reported our Change Healthcare business, which we had recently acquired, was subject to a cyberattack in 2024, in which the data involved contained protected health information or personally identifiable information.

While we have programs in place to detect, contain and respond to data security incidents and provide employee awareness training regarding phishing, malware and other cyber threats to protect against cybersecurity risks and incidents, we expect that we will continue to experience these incidents, some of which may negatively affect our business. Further, because the techniques used to obtain unauthorized access, disable or degrade service, or sabotage systems change frequently and are increasing in sophistication, in part due to use of evolving AI/ML technologies (including generative AI), and because our businesses are changing as well, we may be unable to anticipate these techniques and threats, timely detect data security

incidents or implement adequate preventive measures. Threat actors and hackers have previously been, and may in the future be, able to negatively affect our operations by penetrating our security controls and causing system and operational disruptions or shutdowns, accessing, misappropriating or otherwise compromising protected personal information or proprietary or confidential information or that of third parties, and developing and deploying viruses, ransomware and other malware that can attack our systems, exploit any security vulnerabilities, and disrupt or shutdown our systems and operations. In addition, hardware, software, or applications we develop or procure from third parties may contain defects or other problems which could unexpectedly compromise our information security controls. Our systems may also be vulnerable to financial fraud schemes, misplaced or lost data, error, malicious social engineering, or other events which could negatively affect the data or financial accounts, proprietary or confidential information relating to our business or third parties, or our operations. There have previously been and may be in the future heightened vulnerabilities due to recently-acquired or non-integrated businesses. We rely in some circumstances on third-party vendors to process, store and transmit large amounts of data for our business. The operations of these vendors are subject to similar risks, but are outside our direct oversight and control.

The costs to eliminate or address the foregoing security threats and vulnerabilities before or after a cybersecurity incident could be material. We have business continuation and resiliency plans which we maintain, update and test regularly in an effort to contain and remediate potential disruptions or cybersecurity events. If our remediation efforts are not successful, we may experience operational interruptions, delays, or cessation of service and loss of existing or potential customers. In addition, compromises of our security measures or the unauthorized dissemination of sensitive personal information, proprietary information or confidential information about us, our customers or other third parties, previously and in the future, could expose us or them to the risk of financial or medical identity theft, negative operational impacts, and loss or misuse of this information, result in litigation and liability, including regulatory penalties, for us, damage our brand and reputation, or otherwise harm our business.

If we fail to develop and maintain satisfactory relationships with health care payers, physicians, hospitals and other service providers, our business could be materially and adversely affected.

We depend substantially on our continued ability to contract with health care payers (as a service provider to those payers), as well as physicians, hospitals, pharmaceutical benefit service providers, pharmaceutical manufacturers and other care and service providers at competitive prices. If we fail to develop and maintain satisfactory relationships with health care providers, whether in-network or out-of-network, our failure to do so could materially and adversely affect our business, results of operations, financial position and cash flows. In addition, some of our activities related to network design, provider participation in networks and provider payments could result in disputes, which may be costly and attract negative publicity.

In any particular market, physicians and health care providers could refuse to contract with us, demand higher payments, or take other actions which could result in higher medical costs, less desirable products for customers or difficulty meeting regulatory or accreditation requirements. In some markets, certain health care providers, particularly hospitals, physician and hospital organizations or multi-specialty physician groups, may have significant market positions which could diminish our bargaining power. In addition, Accountable Care Organizations (ACOs); physician group management services organizations (which aggregate physician practices for administrative efficiency); and other organizational structures adopted by physicians, hospitals and other care providers may change the way in which these providers do business with us and may change the competitive landscape. Such organizations or groups of physicians may compete directly with us, which could adversely affect our business, and our results of operations, financial position and cash flows by impacting our relationships with these providers or affecting the way we price our products and estimate our costs, which might require us to incur costs to change our operations in an effort to mitigate these impacts. In addition, if these providers refuse to contract with us, use their market position to negotiate favorable contracts or place us at a competitive disadvantage, our ability to market products or to be profitable in those areas could be materially and adversely affected.

Our health care benefits businesses have risk-based arrangements with some physicians, hospitals and other health care providers. These arrangements limit our exposure to the risk of increasing medical costs, but expose us to risk related to the adequacy of the financial and medical care resources of the health care providers. To the extent a risk-based health care provider organization faces financial difficulties or otherwise is unable to perform its obligations under the arrangement, we may be held responsible for unpaid health care claims which should have been the responsibility of the health care provider and for which we have already paid the provider. Further, payment or other disputes between a primary care provider and specialists with whom the primary care provider contracts could result in a disruption in the provision of services to our members or a reduction in the services available to our members. Health care providers with which we contract may not properly manage the costs of services, maintain financial solvency or avoid disputes with other providers. They may also fail to provide us with the information we need to effectively conduct our businesses, such as information enabling us to estimate costs of care. Any of these events could have a material adverse effect on the provision of services to our members and our operations.

Some providers that render services to our members do not have contracts with us. In some instances, those providers may dispute the payment for these services and may institute litigation or arbitration relying on state and federal laws that define the compensation that must be paid to out-of-network providers in some circumstances.

The success of some of our businesses depends on maintaining satisfactory relationships with employed, affiliated, and independently contracted physicians and joint venture partners. The physicians who practice medicine or contract with our affiliated physician organizations could terminate their provider contracts or otherwise become unable or unwilling to continue practicing medicine or contracting with us. We face and will likely continue to face heightened competition to acquire or manage physician practices or to employ or contract with individual physicians. Our revenues could be materially and adversely affected if we are unable to maintain or expand satisfactory relationships with physicians, to acquire, recruit or, in some instances, employ physicians, or to retain enrollees following physician departures. In addition, our affiliated physician organizations contract with competitors of UnitedHealthcare. Our businesses could suffer if our affiliated physician organizations fail to maintain relationships with or fail to adequately price their contracts with these third-party payer competitors.

Further, physicians, hospitals, pharmaceutical benefit service providers, pharmaceutical manufacturers and certain health care providers are customers of our Optum businesses. Physicians also provide medical services at facilities owned by our Optum businesses. Given the importance of health care providers and other constituents to our businesses, failure to maintain satisfactory relationships with them could materially and adversely affect our results of operations, financial position and cash flows.

If we fail to compete effectively to maintain or increase our market share, including maintaining or increasing enrollments in businesses providing health benefits, our results of operations, financial position and cash flows could be materially and adversely affected.

Our businesses face significant competition in all of the markets in which we operate. In many geographies or product segments, our competitors have and may continue to have certain competitive advantages. Our competitive position may also be adversely affected by significant merger and acquisition activity in the industries in which we operate, among both our competitors and suppliers. Consolidation among competitors may make it more difficult for us to retain or increase our customer base, maintain or improve the terms on which we do business with our suppliers, or maintain or increase our profitability.

In addition, our success in the health care marketplace and future growth depends on our ability to develop and deliver innovative and potentially disruptive products and services to satisfy evolving market demands. If we do not continue to innovate and provide products and services which are useful and relevant to health care payers, consumers and our customers, we may not remain competitive and risk losing market share to existing competitors and disruptive new market entrants. We may face risks from new technologies and market entrants which could affect our existing relationship with health plan enrollees in the affected markets. We could sustain competitive disadvantages and loss of market share if we fail to continue developing innovative care models, including by accelerating the transition of care to value-based models that achieve higher quality outcomes and better experiences at lower costs and expand access to virtual and in-home care. If health care payers or providers are unwilling or unable to enter into value-based agreements with us, we may be unable to successfully establish or maintain the contractual or employment relationships necessary to achieve the quality and cost objectives we have for value-based contracting. Additionally, our competitive position could be adversely affected by any failure to develop and apply innovative technologies and other effective data and analytics capabilities or to provide services to our clients focused on these technologies and capabilities.

Our business, results of operations, financial position and cash flows also could be materially and adversely affected if we do not compete effectively in our markets, if our reputation suffers harm, if we set rates too high or too low in highly competitive markets, if we do not design and price our products properly and competitively, if we are unable to innovate and deliver products and services demonstrating value to our customers, if we do not provide a satisfactory level of services, if membership or demand for other services does not increase as we expect or declines, or if we lose accounts with more profitable products while retaining or increasing membership in accounts with less profitable products.

We are routinely subject to various private party and governmental legal actions and investigations, which could damage our reputation and, if resolved unfavorably, could result in substantial penalties or monetary damages and materially and adversely affect our results of operations, financial position and cash flows.

We are routinely made party to a variety of private party and governmental legal actions and investigations related to, among other matters, the design, management and delivery of our product and service offerings. Any failure by us to adhere to the laws and regulations applicable to our businesses could subject us to civil and criminal penalties.

Legal actions to which we are a party have included and in the future could include matters related to health care benefits coverage and payment of claims (including disputes with enrollees, customers and contracted and non-contracted physicians, hospitals and other health care professionals), tort claims (including claims related to the delivery of health care services, such as medical malpractice by personnel at our affiliates' facilities, or by health care practitioners who are employed by us, have contractual relationships with us, or serve as providers to our managed care networks, including as a result of a failure to adhere to applicable clinical, quality and/or patient safety standards), antitrust claims (including as a result of changes in the

enforcement of antitrust laws), whistleblower claims (including claims under the False Claims Act or similar statutes), matters related to our use of or alleged failure to adequately safeguard personal information or other proprietary data, claims related to alleged failure of our technology products to operate properly or fairly, contract and labor disputes, tax claims and claims related to disclosure of certain business practices. In addition, some of our pharmacy services operations are subject to clinical quality, patient safety and other risks inherent in the dispensing, packaging and distribution of drugs, including claims related to purported dispensing and other operational errors. We may also be party to certain class action lawsuits brought by health care professional groups and consumers. We operate in jurisdictions outside of the United States where contractual rights, tax positions and applicable regulations may be subject to interpretation or uncertainty to a greater degree than in the United States, and therefore subject to dispute by customers, government authorities or others.

We are largely self-insured with regard to litigation risks, including claims of medical malpractice against our affiliated physicians and us. Although we record liabilities for our estimates of the probable costs resulting from self-insured matters, it is possible the level of actual losses will significantly exceed the liabilities recorded. Additionally, physicians and other healthcare providers have become subject to an increasing number of legal actions alleging medical malpractice and general professional liabilities. Even in states that have imposed caps on damages for such actions, litigants are seeking recoveries under theories of liability that might not be subject to the caps on damages. These actions involve significant defense costs and could result in substantial monetary damages or damage to our reputation.

We cannot predict the outcome of significant legal actions in which we are involved. Even in situations where we engage external insurers, our coverage may be disputed or may not be sufficient to cover the entirety of certain claims. We incur expenses to resolve these matters and current and future legal actions could further increase our cost of doing business, require us to potentially change the way we conduct our business, and materially and adversely affect our results of operations, financial position and cash flows. Moreover, certain legal actions could result in adverse publicity which could damage our reputation and materially and adversely affect our ability to retain our current business or grow our market share in some markets and businesses.

Our business could suffer, and our results of operations, financial position and cash flows could be materially and adversely affected, if we fail to successfully manage our strategic alliances, or to complete, manage or integrate acquisitions and other significant strategic transactions or relationships.

As part of our business strategy, we frequently engage in discussions with third parties regarding possible investments, acquisitions, divestitures, strategic alliances, joint ventures and outsourcing transactions and often enter into agreements relating to such transactions. If we fail to meet the needs of our alliance or joint venture partners, including by developing additional products and services, providing high levels of service, pricing our products and services competitively or responding effectively to applicable federal and state regulatory changes, our alliances and joint ventures could be damaged or terminated, which in turn could adversely impact our reputation, business and results of operations. Further, governmental actions, such as actions by the FTC or DOJ, may affect our ability to complete strategic transactions, which could adversely affect our future growth. If we fail to identify and successfully complete transactions to meet our strategic objectives, including as a result of antitrust regulatory enforcement actions, such as those that have been brought against us in the past, we may be required to expend resources to develop products and technology internally, be placed at a competitive disadvantage or be adversely affected by negative market perceptions, any of which may have a material adverse effect on our results of operations, financial position or cash flows.

Successful acquisitions also require us to effectively integrate the acquired business into our existing operations, including our internal control environment and culture, or otherwise leveraging its operations which may present risks different from those presented by organic growth and may be difficult for us to manage. For example, we have experienced and in the future may encounter more acute information technology system vulnerabilities or different litigation risk profiles in recently acquired business than we have historically managed. We may be unable to address such vulnerabilities, inadequacies, differences, or failures soon after acquiring a business, which could undermine integration activities, delay launch of acquired products, and increase infrastructure risk. In addition, even with appropriate diligence, pre-acquisition practices of an acquired business have exposed us in the past and may expose us in the future to legal challenges and investigations that could subject us to criminal fines or reputational harm. Even if we are ultimately successful in resolving these matters, defending such claims may be costly and result in negative publicity. If we cannot successfully integrate our acquired businesses and realize contemplated revenue growth opportunities, cost savings and other synergies, our business, prospects, results of operations, financial position and cash flows could be materially and adversely affected.

We are subject to risks associated with public health crises arising from large-scale medical emergencies, pandemics, natural disasters and other extreme events, which have had and could have an adverse effect on our business, results of operations, financial condition and financial performance.

Large-scale medical emergencies, pandemics, natural disasters, public health crises and other extreme events could have a material adverse effect on our business operations, cash flows, financial conditions and results of operations. For example, disruptions in public and private infrastructure resulting from such events could increase our operating costs and impair our ability to provide services to our clients and customers. In addition, as a result of these events, the premiums and fees we charge may not be sufficient to cover our medical and administrative costs, deferred medical care could be sought in future periods at potentially higher acuity levels, we could experience reduced demand for our services, and our clinical and non-clinical workforce could be affected and sustain a reduced capacity to handle demand for care. Public health crises arising from natural disasters, such as wildfires, hurricanes, and snowstorms, or effects of climate change could impact our business operations and result in increased medical care costs. Government enactment of emergency powers in response to public health crises could disrupt our business operations, including by restricting availability of, or our ability to deliver, pharmaceuticals or other supplies, and could increase the risk of shortages of necessary items.

Our sales performance will suffer if we do not adequately attract, retain and provide support to a network of independent producers and consultants.

Our products and services are sold in part through nonexclusive producers and consultants for whose services and allegiance we must compete. Our sales could be materially and adversely affected if we are unable to attract, retain and support independent producers and consultants or if our sales strategy is not appropriately aligned across distribution channels. Our relationships with producers could be impaired by changes in our business practices and the terms of our relationships, including commission levels.

Our businesses are subject to risks associated with unfavorable economic conditions.

Unfavorable economic conditions may have a range of impacts on the demand for our products and services. Such conditions also have caused and in future periods could continue to cause employers to stop offering certain health care coverage as an employee benefit or elect to offer particular coverage on a voluntary, employee-funded basis to reduce their operating costs. In addition, unfavorable economic conditions could adversely impact our ability to increase premiums or result in the cancellation by certain customers of our products and services. These conditions could lead to a decrease in people served and in the premium and fee revenues we generate.

A prolonged unfavorable economic environment could constrain state and federal budgets and result in reduced reimbursements or payments in our federal and state government health care coverage programs, including Medicare, Medicaid and CHIP. A reduction in state Medicaid reimbursement rates could be implemented retroactively to apply to payments already negotiated or received from the government. In addition, state and federal budgetary pressures could cause the affected governments to impose new or a higher level of taxes or assessments for our commercial programs, such as premium taxes on health insurance and surcharges or fees on select fee-for-service and capitated medical claims. Any of these developments or actions could materially and adversely affect our results of operations, financial position and cash flows.

A prolonged unfavorable economic environment could also adversely impact the financial position of hospitals and other care providers which could negatively affect our contracted rates with these parties and increase our medical costs or materially and adversely affect their ability to purchase our service offerings. Further, unfavorable economic conditions could have a material adverse effect on our financial results by impacting the customers of our Optum businesses, including health plans, hospitals, care providers, employers and others.

Our failure to attract, develop, retain, and manage the succession of key employees and executives could adversely affect our business, results of operations and future performance.

We depend on our ability to attract, develop and retain qualified employees and executives, including those with diverse talents, backgrounds, experiences and perspectives, to operate and expand our business. While we have development and succession plans in place for our key employees and executives, these plans do not guarantee that the services of our key employees and executives will continue to be available to us. If we are unable to attract, develop, retain and effectively manage the development and succession plans for key employees and executives, our business, results of operations and future performance could be adversely affected. Experienced and highly skilled employees and executives in the health care and technology industries are in high demand and the market for their services is competitive. We may have difficulty in replacing key executives because of the limited number of qualified individuals in these industries with the breadth of skills and experience required to operate and successfully expand our business. Adverse changes to our corporate culture could harm our business operations and our ability to retain key employees and executives.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Surmodics, Inc.

Physical Address: 9700 West 76th Street, Suite 123

City: Eden Prairie State: MN Zip: 55344

Mailing Address (if different from physical address): 9924 West 74th Street

City: Eden Prairie State: MN Zip: 55344

Telephone: 952-500-7000 Website: www.surmodics.com

Name of Designated Representative (DR): Shawn Fuller

Licensing Company Email: sfuller@surmodics.com DR Email: sfuller@surmodics.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:
N/A

Shawnlee Jacobs
Original Signature (electronic, copies or stamps not accepted)

12 MARCH 2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Resonetics
Address: 3761 95th Avenue NE, Suite 100 City: Blaine State: MN Zip: 55014

Name: Sigma-Aldrich dba MilliporeSigma
Address: 3050 Spruce Street City: St. Louis State: MO Zip: 63103

Name: VWR International, Inc., Radnor
Address: 100 Matsonford Rd, Suite 200 City: Radnor State: PA Zip: 19087

Name: Fisher Scientific Company, LLC
Address: 4500 Turnberry Dr. City: Hanover Park State: IL Zip: 60133

Section 4: Publicly Traded Corporation

State of Incorporation: MN
Parent Company (if any): N/A
Corporation Name: Surmodics, Inc.
Mailing Address: 9924 West 74th Street
City: Eden Prairie State: MN Zip: 55344
Telephone: 952-500-7090 Email: sfuller@surmodics.com
Contact Person Name: Shawn Fuller

Date of SEC Registration: 3/4/1998 | SEC Registration Number: 0-23837 | Stock Exchange Symbol: SRDX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: Exempt, Publicly Traded		
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Surmodics, Inc.
Facility Name

Shawn Fuller
Print Name of Authorized Person Submitting Application

Shawn K Fuller
Original signature of Authorized Person (copies or stamps not accepted)

12 MARCH 2025
Date

Board Use Only	Date Received: 3/19/25	Amount: $1,000 Ck 1000002032

Surmodics, Inc.

Ownership:
Surmodics, Inc. is a publicly-traded company (NASDAQ: SRDX)

List of Officers

Gary R. Maharaj, President and Chief Executive Officer
Business Address: 9924 West 74th Street, Eden Prairie, MN 55344

Tim J. Arens, Sr. VP – Finance and CFO
Business Address: 9924 West 74th Street, Eden Prairie, MN 55344

Teri L.W. Sides, Sr. VP & President – Vascular Interventions
Business Address: 9924 West 74th Street, Eden Prairie, MN 55344

Joseph J. Stich, Sr. VP – Human Resources and President – In Vitro Diagnostics
Business Address: 9924 West 74th Street, Eden Prairie, MN 55344

Gordon S. Weber, Sr. VP – Legal, General Counsel & Secretary
Business Address: 9924 West 74th Street, Eden Prairie, MN 55344

Charlie W. Olson, Sr. VP & President – Medical Device Coatings
Business Address: 9924 West 74th Street, Eden Prairie, MN 55344

Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Surmodics, Inc.
Date Filed:	06/27/1979
File Number:	3L-831
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 11/18/2024

Steve Simon
Secretary of State
State of Minnesota

MINNESOTA
BOARD OF PHARMACY

Minnesota Board of Pharmacy
335 Randolph Ave., Suite 230
St. Paul, MN 55102
pharmacy.board@state.mn.us
Protecting the Public Since 1885

October 16, 2024

Jonathan A. Keller
Faegre Drinker Biddle & Reath, LLP.
600 Campus Drive
Florham Park, New Jersey 07932

Re: Surmodics MD Operations, LLC

Dear Mr. Keller and To Whom it May Concern,

The Minnesota Board of Pharmacy does not license or register companies that exclusively manufacture, distribute, supply, or sell medical devices or supplies. If a company that handles medical devices or supplies also manufactures or distributes drugs, it must be licensed as a drug manufacturer or drug wholesaler. Exception if the drug is coated on or embedded in the device (e.g. drug-coated stents) and the resultant product is approved by the FDA as a device, the company does not have to be licensed as a manufacturer or wholesale distributor.

Based upon information provided to the Board and as of the date of this letter, it is the Board's understanding Surmodics, Inc., a Minnesota corporation located at 9700 W 76th Street, Eden Prairie, Minnesota, 55344, does not meet the definition of either a drug manufacturer or drug wholesaler set forth in Minnesota Statutes, Chapter 151. Accordingly, the Board would not issue to it a drug manufacturer's or drug wholesaler's license.

Sincerely,

Brian A. Park, J.D.
Associate Director for Enforcement
Minnesota Board of Pharmacy

Cc: Jill Phillips, Executive Director
Minnesota Board of Pharmacy

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 03/28/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Midwest, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com
INSURED Surmodics, Inc. 9924 West 74th Street Eden Prairie, MN 553443523	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Federal Insurance Company — 20281 INSURER B: Chubb Indemnity Insurance Company — 12777 INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** W38443015 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY [ ] PRO-JECT [ ] LOC OTHER:	Y		36036806	10/01/2024	10/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $ $ $ $ $	1,000,000 1,000,000 10,000 1,000,000 2,000,000 0
A	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY [ ] SCHEDULED AUTOS X HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			73599996	10/01/2024	10/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $	1,000,000
A	X UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED RETENTION $			78181721	10/01/2024	10/01/2025	EACH OCCURRENCE AGGREGATE	$ $	15,000,000 15,000,000
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? Y/N [No] (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		71756338	10/01/2024	10/01/2025	X PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $	1,000,000 1,000,000 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Re: 9700 West 76th Street, Eden Prairie MN 55344

Nevada Board of Pharmacy is included as an Additional Insured as respects to General Liability as required by written contract.

CERTIFICATE HOLDER

Nevada Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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SR ID: 27515470 BATCH: 3896690

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Surmodics, Inc. MDEG License # (if applicable): N/A

Physical Address: 9700 West 76th Street, Suite 123

City: Eden Prairie State: MN Zip: 55344

Mailing Address (if different from physical address): 9924 West 74th Street

City: Eden Prairie State: MN Zip: 55344

Telephone: 952-500-7000 Website: www.surmodics.com

Licensing Company Email: sfuller@surmodics.com

Section 2: Personal Information

First: Shawn Middle: Kathleen Last: Fuller

Alias(es, nicknames, name changes, etc.): Shawn Kathleen Fahey, Shawn Kathleen Tipton

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Minneapolis State: MN Zip: [redacted]

Telephone: 952-500-7090 Email: sfuller@surmodics.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
WG ENLOE HIGH SCHOOL		08/1980 - 5/1984	
Address	**City**	**State**	**Zip**
128 CLARENDON CRESCENT	RALEIGH	NC	27610
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Wingate College		8/29/1984-5/14/1988	
Address	**City**	**State**	**Zip**
211 East Wilson Street	Wingate	NC	28174
Diploma/Degree obtained, if any			
Bachelor of Science in Biology			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
~~01/2015-01/2025~~	[redacted]	Minneapolis	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Surmodics, Inc			01/21-Present
Business Address	**City**	**State**	**Zip**
9700 West 76th Street, Suite 123	Eden Praire	MN	55418
Phone	**Title**	**Number of Employed Hours**	
952-500-7090	VP, Quality and Regulatory	8,000	
Description of Duties			
Management of the Quality & Regulatory Department. Define the regulatory and clinical strategy for company through the product lifecycle in line with client expectations and project timelines. Provide support in the oversight of clinical studies.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Shawnie Fuller — 12 MARCH 2025

Original Signature (electronic, copies or stamps not accepted) — Date

I, Shawn Fuller, **certify that as the MDEG Administrator for**

Surmodics, Inc.,

that I (initial that you have read and meet the following requirements):

1. SKF Have a high school diploma or its equivalent;
2. SKF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SKF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SKF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shawn Fuller

Print Name (First, Last)

Shawn Fuller

Original Signature (electronic, copies or stamps not accepted)

02/12/2025

Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Surmodics, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 9700 West 76th Street, Suite 123

City: Eden Prairie State: MN Zip: 55344

Mailing Address (if different from physical address): 9924 West 74th Street

City: Eden Prairie State: MN Zip: 55344

Telephone: 952-500-7000 Website: www.surmodics.com

Licensing Company Email: sfuller@surmodics.com

Section 2: Personal Information

First: Shawn Middle: Kathleen Last: Fuller

Alias(es, nicknames, name changes, etc.): Shawn Kathleen Fahey, Shawn Kathleen Tipton

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Minneapolis State: MN Zip: [redacted]

Telephone: 952-500-7090 Email: sfuller@surmodics.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
W.G. Enloe			1980-1984	
Address		City	State	Zip
128 Claredon Crescent		Raleigh	NC	27610
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Wingate College			8/29/1984-5/14/1988	
Address		City	State	Zip
211 East Wilson Street		Wingate	NC	28174
Diploma/Degree obtained, if any				
Bachelor of Science in Biology				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2015-01/2025	[redacted]	Minneapolis	MN	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Surmodics, Inc			01/21-Present	
Business Address		**City**	**State**	**Zip**
9700 West 76th Street, Suite 123		Eden Praire	MN	55418
Phone	**Title**		**Number of Employed Hours**	
952-500-7090	VP, Quality and Regulatory		8,000	
Description of Duties				
Management of the Quality & Regulatory Department. Define the regulatory and clinical strategy for company through the product lifecycle in line with client expectations and project timelines. Provide support in the oversight of clinical studies.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Shawn Fuller, **certify that as the designated representative for**

Surmodics, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SLF I am at least 21 years of age;
3. SLF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SLF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SLF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SLF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SLF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Shawn Fuller

Print Name (First, Last)

Shawn L Fuller

Original Signature (electronic, copies or stamps not accepted)

27Feb2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shawn Fuller

Print Name (First, Last)

Shawn Fuller — 27 Feb 2025

Original Signature (electronic, copies or stamps not accepted) — Date

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Please have this section completed in the presence of a Notary Public.

State of Minnesota, ss. County of Hennepin

I, SHAWN FULLER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Shawn Fuller — 27 Feb 2025

Original Signature — **Date**

Subscribed and Sworn to before me this 27 day of February.

Dawn Nygren

Notary Public Signature

DAWN FARAH NYGREN
Notary Public - Minnesota
My Commission Expires Jan 31, 2029

(Seal)

Supplemental Information: Section 9

SRDX Response: List of full time employees for the warehouse

- Keith Rix
- Randy O'Brien
- Janice Arnst

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended September 30, 2023

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____

Commission File Number 0-23837

Surmodics, Inc.

(Exact name of Registrant as specified in its Charter)

Minnesota	41-1356149
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
9924 West 74th Street Eden Prairie, Minnesota	55344
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: (952) 500-7000

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.05 par value	SRDX	Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. YES ☐ NO ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. YES ☐ NO ☒

Indicate by check mark whether the Registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. YES ☒ NO ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). YES ☒ NO ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☐	Accelerated filer	☒		
Non-accelerated filer	☐	Smaller reporting company	☐	Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). YES ☐ NO ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant as of March 31, 2023 was approximately $310 million (based on the closing price of the Registrant's Common Stock on such date).

The number of shares of Registrant's Common Stock outstanding as of November 17, 2023 was 14,156,000.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's Proxy Statement for the Registrant's 2024 Annual Meeting of Shareholders are incorporated by reference into Part III.



Surmodics, Inc.

Annual Report on

Form 10-K

for the fiscal year ended

September 30, 2023

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Forward-looking Statements

Certain statements contained in this Form 10-K, or in other reports of the Company and other written and oral statements made from time to time by the Company, do not relate strictly to historical or current facts. As such, they are considered "forward-looking statements" that provide current expectations or forecasts of future events. These forward-looking statements are made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. These statements include, but are not limited to, the expected results of clinical studies, future clinical studies, and their potential timing; our strategies for growth, including our ability to sign new license agreements, conduct clinical evaluations, complete process and manufacturing validations, and bring new products to market; planned limited market evaluations or commercial launches for our products; the development of future products and their anticipated attributes; regulatory submissions and approvals; our intent to pursue certain regulatory actions, including to expand the field of use for our thrombectomy products; the potential impact of U.S. Food and Drug Administration ("FDA") communications; our initiations for product evaluation activities; expected timing of the commercialization in the U.S. of our SurVeil™ drug-coated balloon ("DCB"); revenue potential related to sales and commercialization of the *SurVeil* DCB; opportunities for the clinical development and future commercialization of our other DCB products; potential partnership opportunities for our DCB products; future revenue growth, our longer-term valuation-creation strategy, and our future potential; plans for future clinical investment in new products; potential future disease rates; future opportunities and goals related to new product offerings; future gross margins and operating expenses; estimated future amortization expense; expectations regarding operating expenses and interest expense; recognition of unrecognized compensation costs; anticipated patent expirations and their potential impacts on our royalties and license fee revenue; potential future customer actions; research and development plans and expenses, including the estimated cost associated with the TRANSCEND clinical trial; expectations regarding clinical follow up and completion of the TRANSCEND trial; anticipated cash requirements; future cash flow and sources of funding, and their ability together with existing cash, cash equivalents, and investments to provide liquidity sufficient to meet our cash needs and fund our operations and planned capital expenditures for the next twelve months; the availability of funds under our debt arrangements; future property and equipment investment levels; expectations regarding declaring or paying dividends; plans regarding our securities investments and the potential impact of interest rate fluctuations; expectations regarding the maturity of debt; the impact of potential lawsuits or claims; where our manufacturing activities will take place for various categories of products; the impact of potential change in raw material prices, sources of raw materials and our ability to manufacture raw materials ourselves; the impact of Abbott and Medtronic, as well as other significant customers; our ability to recognize the expected benefits of our acquisitions; our strategic transformation to become a provider of vascular intervention medical device products; future income tax expense (benefit), including from the Coronavirus Aid, Relief and Economic Security Act (the "CARES Act"); the future impact of off-balance sheet arrangements and contractual obligations; and the impact of the adoption of new accounting pronouncements. Without limiting the foregoing, words or phrases such as "anticipate," "believe," "could," "estimate," "expect," "forecast," "intend," "may," "plan," "possible," "project," "will" and similar terminology, generally identify forward-looking statements. Forward-looking statements may also represent challenging goals for us. These statements, which represent our expectations or beliefs concerning various future events, are based on current expectations that involve a number of risks and uncertainties that could cause actual results to differ materially from those of such forward-looking statements. We caution that undue reliance should not be placed on such forward-looking statements, which speak only as of the date made. Some of the factors which could cause results to differ from those expressed in any forward-looking statement are set forth under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K. We disclaim any intent or obligation to update publicly these forward-looking statements, whether because of new information, future events or otherwise.

Although it is not possible to create a comprehensive list of all factors that may cause actual results to differ from our forward-looking statements, such factors include, among others:

1. ongoing operating losses, interest expense, and failure to generate cash flows from operations, which could impact expected expenditures and investments in growth initiatives;
2. our reliance on a small number of significant customers, including our largest customers, Abbott and Medtronic, which causes our financial results and stock price to be subject to factors affecting those significant customers and their products, the timing of market introduction of their or competing products, product safety or efficacy concerns and intellectual property litigation impacting such customers, which could adversely affect our growth strategy and the revenue we derive;
3. our ability to successfully manufacture at commercial volumes our *SurVeil* DCB, and our ability to successfully develop, obtain regulatory approval for, commercialize, and manufacture at commercial volumes our other DCB products, including our reliance on clinical research organizations to manage the TRANSCEND clinical trial and uncertainty related to the impacts of any clinical research relative to drug-coated balloons, including our other DCB products and other catheter and balloon-based products;
4. general economic conditions that are beyond our control, such as the impact of recession, inflation, rising interest rates, customer mergers and acquisitions, business investment, changes in consumer confidence, and medical epidemics or pandemics such as the COVID-19 pandemic, which negatively impacted our business and results of operations;
5. our ability to successfully and profitably commercialize our vascular intervention products, including our Pounce™ Venous Thrombectomy System, through our direct salesforce, or otherwise;

6. our ability to comply with the covenants in our credit facility;
7. the difficulties and uncertainties associated with the lengthy and costly new product development and foreign and domestic regulatory approval processes, such as delays, difficulties or failures in achieving acceptable clinical results or obtaining foreign or FDA marketing clearances or approvals, which may result in lost market opportunities, failure to bring new products to market or postpone or preclude product commercialization by licensees or ourselves;
8. whether operating expenses that we incur related to the development and commercialization of new technologies and products are effective;
9. our ability to successfully perform product development activities, the related research and development expense impact, and governmental and regulatory compliance activities, with which we do not have extensive experience;
10. impairment of goodwill and intangible assets or the establishment of reserves against other assets on our balance sheet; and
11. other factors described under "Risk Factors" in Part I, Item 1A of this Annual Report on Form 10-K, which you are encouraged to read carefully.

Many of these factors are outside our control and knowledge and could result in increased volatility in period-to-period results. Investors are advised not to place undue reliance upon our forward-looking statements and to consult any further disclosures by us on this subject in our filings with the SEC.

PART I

ITEM 1. BUSINESS.

OVERVIEW

Surmodics, Inc. (referred to as "Surmodics," the "Company," "we," "us," "our" and other like terms) is a leading provider of performance coating technologies for intravascular medical devices and chemical and biological components for in vitro diagnostic ("IVD") immunoassay tests and microarrays. Surmodics also develops and commercializes highly differentiated vascular intervention medical devices that are designed to address unmet clinical needs and engineered to the most demanding requirements. This key growth strategy leverages the combination of the Company's expertise in proprietary surface modification and drug-delivery coating technologies, along with its device design, development and manufacturing capabilities. The Company's mission is to improve the detection and treatment of disease. Surmodics is headquartered in Eden Prairie, Minnesota.

SURMODICS' REPORTABLE SEGMENTS:

MEDICAL DEVICE	IN VITRO DIAGNOSTICS ("IVD")
Manufacture and licensing of **performance coatings**, including **surface modification coating technologies** to improve access, deliverability and predictable deployment of medical devices and **drug-delivery coating technologies** to provide site-specific drug-delivery from the surface of a medical device, with end markets that include neurovascular, peripheral, coronary, and structural heart, among others. Manufacture of **vascular intervention medical devices**, including drug-coated balloons, mechanical thrombectomy devices, and radial access balloon catheters and guide sheaths.	Manufacture of **chemical and biological components** used in **in vitro diagnostic immunoassay and molecular tests** within the diagnostic and biomedical research markets. Component products include protein stabilizers, substrates, surface coatings and antigens.

SURMODICS' PRIMARY REVENUE SOURCES:

PRODUCT SALES	ROYALTIES & LICENSE FEES	RESEARCH & DEVELOPMENT
• **IVD chemical and biological components**, including protein stabilizers, substrates, surface coatings and antigens to the diagnostic and biomedical research markets (IVD segment) • **Performance coating reagents**, the chemicals used in performance coatings by licensees (Medical Device segment) • **Vascular intervention medical devices** and related products to original equipment manufacturer suppliers and distributors, as well as directly to healthcare providers (Medical Device segment)	• **Performance coating royalties and license fees** from licensing of our proprietary performance coating technologies to medical device manufacturers (Medical Device segment) • **SurVeil™ DCB license fees** associated with upfront and milestone payments received pursuant to our Development and Distribution Agreement with Abbott Vascular, Inc. (Medical Device segment)	• Contract coating services and commercial development feasibility services (Medical Device segment) • Commercial development services (IVD segment)

Revenue fluctuates from quarter to quarter depending on, among other factors: our customers' success in selling products incorporating our technologies; our and our customers' success in selling our vascular intervention products; the occurrence of milestone events under our development contracts; the timing of introductions of licensed products by our customers and proprietary products by us and our distributors; the timing of introductions of products that compete with our products and our customers' products; the number and activity level associated with customer development projects; the number and terms of new license agreements that are finalized; and the value of reagent chemicals, medical device and diagnostic products sold to our customers.

The information below provides an overview of the principal products, services and markets for each of our two reportable segments. The discussion of other aspects of our business, including patents and proprietary rights, significant customers, manufacturing, government regulation, and our human capital, applies to our business in general, and we describe material segment information within these sections where relevant.

MEDICAL DEVICE SEGMENT

Our Medical Device segment consists of two interrelated product platforms:

- **Vascular Intervention Medical Devices.** We develop and manufacture our own proprietary vascular intervention medical device products, which leverages the combination of our expertise in proprietary surface modification and drug-delivery coating technologies, along with our device design, development and manufacturing capabilities. We believe our strategy of developing our own medical device products has increased, and will continue to increase, our relevance in the medical device industry. This strategy is key to our future growth and profitability, providing us with the opportunity to capture more revenue and operating margin with vascular intervention medical device products than we would by licensing our device-enabling technologies.

- **Performance Coatings**. Surmodics is an established market leader in proprietary surface modification coating technologies that impart lubricity, pro-healing and biocompatibility characteristics, as well as drug-delivery capabilities (together, "performance coatings" or "performance coating technologies") to medical devices and delivery systems. We develop and commercialize our performance coatings through license agreements with medical device manufacturers for use in their medical devices.

OVERVIEW: VASCULAR INTERVENTION MEDICAL DEVICES — MEDICAL DEVICE SEGMENT

Our strategy is to develop a portfolio of highly differentiated medical devices for vascular interventional treatment. We invest in the development and commercialization of devices that serve large, under-penetrated markets; address unmet clinical needs; improve clinical outcomes for patients; and reduce procedure costs. Our portfolio and pipeline of vascular intervention medical device products includes the following primary platforms:

- **Drug-coated balloons** ("DCBs") which combine a pharmaceutical drug with a medical device to treat narrowing of the blood vessels supplying the peripheral vasculature (most commonly in the legs), known as peripheral artery disease ("PAD");
- **Mechanical thrombectomy devices** to remove clots from arteries and veins in the peripheral vasculature; and
- **Radial access devices** to enable treatment of arterial lesions in the lower extremities via radial (wrist) access, and which can also be used in alternative access sites, including femoral and pedal access.

In addition to these primary platforms, our device manufacturing operations include:

- **Specialty catheters.** We have successfully developed, received U.S. and European Union ("E.U.") regulatory approvals, and executed commercialization partnerships for several specialty catheter products. We have partnered with Medtronic plc ("Medtronic") to distribute our *Telemark* microcatheter in the U.S. and Europe for coronary applications. We have partnered with Cook Medical to distribute our 0.014" and 0.018" low-profile percutaneous transluminal angioplasty ("PTA") balloon catheters in the U.S. and Europe.

  In addition, we leverage our proprietary balloon catheter technology to deliver contract-manufactured balloon catheter products to original equipment manufacturers ("OEMs") on a limited scale.

We commercialize our medical device products using two strategies:

- **Direct sales.** We have a direct salesforce, which was established in fiscal 2022, that sells our mechanical thrombectomy and radial access devices directly to healthcare providers.
- **Strategic partnerships.** For certain of our products, including our DCB products, our clinical development and commercialization strategy utilizes distribution partnerships with large, strategic medical device companies. The exclusive distribution partner for our *SurVeil* DCB is Abbott Vascular, Inc.

For all of our products under development, as further described under the caption "Government Regulation" below, the expected timing and potential success of regulatory approval and commercialization for the products pending regulatory approval can vary greatly given the significant uncertainty inherent in the product development and regulatory approval processes.

Vascular Intervention Medical Devices – Drug Coated Balloons ("DCBs") **MEDICAL DEVICE SEGMENT**

We have leveraged our performance coating technologies to successfully develop multiple DCB devices for use in vascular interventions for the treatment of PAD. DCBs are used by physicians to expand the diameter (lumen) of a narrowed vessel, thus improving or restoring blood flow. The drug coating helps to prevent the vessel from narrowing again (restenosis) after treatment. PAD is a serious and under-diagnosed circulatory condition caused by build-up of plaque, most commonly in the legs. Over 8 million Americans are affected by PAD, which increases risk of coronary artery disease, heart attack and stroke. PAD can impair the ability to walk and, if left untreated, can lead to gangrene and limb amputation.

The following is a brief description of each of these devices and their stage of clinical development, with additional information about each device provided further below.

- ***SurVeil* DCB** is a paclitaxel-coated DCB to treat PAD in the upper leg (superficial femoral artery). Our *SurVeil* DCB utilizes a proprietary paclitaxel drug-excipient formulation for a durable balloon coating and is manufactured using an innovative process to improve coating uniformity.

  In June 2023, the *SurVeil* DCB received U.S. Food and Drug Administration ("FDA" or the "Agency") premarket approval ("PMA") and may now be marketed and sold in the U.S. by our exclusive distribution partner, Abbott Vascular, Inc. ("Abbott"). Abbott has exclusive worldwide commercialization rights for the *SurVeil* DCB under a Development and Distribution Agreement that we entered into in fiscal 2018 (the "Abbott Agreement"), as further discussed below. Abbott has discretion as to when to begin commercialization in the U.S., which is expected to occur in the first half of calendar 2024.

- **Sundance™ DCB** is a sirolimus-coated DCB used for the treatment of below-the-knee PAD, including critical limb ischemia ("CLI"). Our SWING first-in-human, 35-patient, 36-month clinical study was designed to evaluate the safety and performance of our *Sundance* DCB when used to treat occlusive disease of the infra-popliteal arteries. SWING study data at 24 months demonstrated an excellent safety profile and promising signals of potential performance. We continue to evaluate our strategy for further clinical investment in the *Sundance* DCB based on the experience we have gained from the PMA application process for the *SurVeil* DCB.

Our DCB products are required to go through clinical studies in order for us to obtain regulatory approval or clearance to market the product in the U.S. Each clinical study includes one or more primary endpoints, which measure the effectiveness and/or safety of a device based on the product's ability to achieve one or more pre-specified outcomes. Primary endpoints are selected based on the proposed intended use of the medical device. A pivotal trial is a definitive study designed to gather evidence to evaluate the safety and effectiveness of a product prior to its marketing.

***SurVeil* DCB.** Our *SurVeil* DCB product is a paclitaxel-coated DCB to treat PAD in the upper leg (superficial femoral artery). The *SurVeil* DCB is a next-generation device that utilizes best-in-class technology for the treatment of PAD, including a proprietary paclitaxel drug-excipient formulation for a durable balloon coating manufactured using an innovative process to improve coating uniformity. The design of the *SurVeil* DCB is intended to provide more uniform drug distribution, better efficiency of drug transfer, and fewer downstream particulates and downstream embolization.

Our *SurVeil* DCB product has the necessary regulatory approval for commercialization in the U.S. (PMA from the FDA was received in June 2023), as well as the necessary regulatory approval for commercialization in the E.U. (Conformité Européenne Mark, or CE Mark, received in fiscal 2020). The timing of commercialization is at the discretion of Abbott, subject to the terms of the Abbott Agreement, and U.S. commercialization is expected to occur in the first half of calendar 2024.

TRANSCEND Pivotal Clinical Trial. The TRANSCEND pivotal clinical trial has been used to support the regulatory approval for the *SurVeil* DCB in the U.S. by providing the data necessary to evaluate the safety and effectiveness of our *SurVeil* DCB compared with the Medtronic IN.PACT® Admiral® DCB in treating PAD in the upper leg (superficial femoral artery). The trial enrolled 446 subjects at 65 global sites. The trial's primary efficacy endpoint is primary patency, defined as a composite of freedom from restenosis and clinically-driven target lesion revascularization through 12 months post-index procedure. TRANSCEND enrollment was completed in fiscal 2019, and all randomized subjects will be followed through 60 months post-index procedure.

- In January 2021, we announced the TRANSCEND 12-month pivotal clinical trial met both the primary safety and primary efficacy endpoints, and the *SurVeil* DCB was found to be non-inferior in those endpoints to the Medtronic IN.PACT® Admiral® DCB, while delivering a substantially lower drug dose.

- TRANSCEND 36-month data demonstrated comparable, sustained clinical outcomes between the *SurVeil* DCB and IN.PACT® Admiral® DCB cohorts through 36 months, including rates of clinically driven target lesion revascularization, major limb amputation, thrombosis at the target lesion, and major adverse events.

Abbott Agreement. In fiscal 2018, we entered into the Abbott Agreement, which provided Abbott with exclusive worldwide commercialization rights for the *SurVeil* DCB.

- Pursuant to the terms of the Abbott Agreement, the Company has received upfront and milestone payments totaling $87.8 million as of September 30, 2023. These payments are recognized as *SurVeil* DCB license fee revenue as costs are incurred over the five-year TRANSCEND pivotal clinical trial. There are no additional potential milestone payments available under the Abbott Agreement.
- Under the Abbott Agreement, Abbott has the right to purchase commercial units of the *SurVeil* DCB from Surmodics. Upon shipment of *SurVeil* DCB units to Abbott, we will recognize product revenue, which will include (i) an agreed-upon transfer price and (ii) a share of net profits resulting from product sales by Abbott to third parties.
- Surmodics is responsible for conducting all necessary clinical trials and other activities required to obtain and maintain U.S. and E.U. regulatory clearances for the *SurVeil* DCB, including completion of the ongoing TRANSCEND pivotal clinical trial. Expenses related to these activities are paid by Surmodics. Abbott and Surmodics participate on a joint development committee charged with providing guidance on the Company's clinical and regulatory activities related to the *SurVeil* DCB product.

***Sundance* DCB**. Our sirolimus-coated *Sundance* DCB is used for the treatment of below-the-knee PAD, including CLI. CLI is estimated to impact between 2.1 million and 3.8 million Americans, a number that could grow to between 2.4 million and 4.7 million by 2030. Rates of amputation and death are significant for CLI patients, and there are currently no DCB devices approved to treat the condition in the U.S.

Sirolimus has potent anti-inflammatory and anti-proliferative effects to inhibit cell division, without creating vascular toxicity, and has a proven history of safety and efficacy in vascular anatomy. We leveraged our expertise in performance coatings in the innovative design of our *Sundance* DCB, which in pre-clinical benchtop and animal testing has shown clear advantages over competitive technologies, including superior drug coating durability, higher levels of drug transfer, and a unique ability to achieve sustained therapeutic levels in the tissue.

Below is a summary of our clinical and regulatory progress related to the *Sundance* DCB.

- In October 2019, the FDA designated the *Sundance* DCB as a "Breakthrough Device" under the FDA's Breakthrough Devices Program, which is designed to streamline the market clearance/approval process for products that have the potential to provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions.
- Our SWING first-in-human, 35-patient, 36-month clinical study was designed to evaluate the safety and performance of our *Sundance* DCB when used to treat occlusive disease of the infra-popliteal arteries. Enrollment and six-month follow up visits were completed in fiscal 2021. The clinical report for the SWING study was completed in fiscal 2022, which demonstrated promising early safety data and performance insights. SWING study data demonstrated an excellent safety profile at 24 months, with no major amputations and low rates of major adverse events. There were no clinically driven target lesion revascularizations in study participants between six- and 24-months post procedure. SWING study data also showed promising signals of potential performance of the device, with target lesion primary patency maintained in 80% of per protocol patients at 12 months and in 71% of per protocol patients at 24 months.

We continue to evaluate our strategy for further clinical investment in the *Sundance* DCB based on the experience we have gained from the PMA application process for the *SurVeil* DCB.

Vascular Intervention Medical Devices – Mechanical Thrombectomy **MEDICAL DEVICE SEGMENT**

We have successfully developed, internally and through acquisitions, multiple FDA 510(k)-cleared mechanical thrombectomy devices for the non-surgical removal of thrombi and emboli (clots) from the peripheral vasculature. We believe that the ease of use, intuitive design and efficient performance of our thrombectomy products make these devices viable first-line treatment options for interventionalists. These devices include:

- **Pounce™ Arterial Thrombectomy System** is designed for the removal of clots from arteries in the peripheral vasculature, which is known as peripheral arterial occlusion ("PAO") and is associated with PAD. During fiscal 2022, we established a direct salesforce and commenced commercial sales of our *Pounce* Arterial Thrombectomy System to hospitals and clinics.
- ***Pounce* Venous Thrombectomy System** is designed for the removal of clots from veins in the peripheral vasculature generally associated with venous thromboembolism ("VTE"). We conducted limited market evaluations in fiscal 2023 to obtain physician feedback across a variety of cases and clinical conditions. Completion of limited market evaluations of the *Pounce* Venous Thrombectomy System and transition to commercial launch are targeted for fiscal 2024.

Our thrombectomy devices represent a core offering within our vascular intervention product strategy, providing the opportunity for:

- Rapid growth in large, under-penetrated markets; and
- Improved clinical outcomes and reduced healthcare costs, with single session treatment for removal of difficult clots, no capital equipment, and the potential to reduce the need for thrombolytic drugs.

PAO, the blocking of arteries by clots or plaque, is a peripheral vascular condition commonly associated with CLI. Often, these arterial clots require surgical intervention and have proven difficult to remove with currently available medical device technologies. Depending on the age and magnitude of the occlusion and the viability of the threatened limb, existing treatments for this condition may include catheter-directed thrombolysis, surgical embolectomy, and/or percutaneous mechanical thrombectomy. In cases in which the occlusion has caused irreversible damage to the limb, acute limb ischemia can result in the amputation of a lower extremity.

VTE, a blood clot in the veins, is an under-diagnosed and serious, yet treatable, medical condition that can cause disability and death. VTE includes deep vein thrombosis ("DVT"), which occurs when a blood clot forms in a deep vein, usually in the lower leg, thigh, or pelvis, and pulmonary embolism ("PE"), which occurs when a clot breaks loose and travels through the bloodstream to the lungs. VTE affects approximately 1.2 million U.S. patients each year, of which approximately 800,000 are affected by DVT. The current standard of care for treating VTE is conservative medical management with anticoagulant drugs designed to prevent further blood clotting. While anticoagulation remains the most widespread therapy for DVT, interventional treatment has demonstrated the potential for better outcomes in select patients.

We believe our proprietary *Pounce* arterial and venous thrombectomy devices provide physicians with the opportunity to treat PAD and VTE in a more effective, cost-efficient manner than currently available treatments. The devices offer innovative designs that may reduce the need for the use of thrombolytic drugs. Thrombolytic drugs are often associated with complications, which can include bleeding complications, longer hospital stays and higher cost of treatment. Our *Pounce* arterial and venous thrombectomy devices are designed to reduce procedure time, efficiently remove large volumes of clot, and eliminate the need for additional external capital equipment, thereby providing an easy-to-use, on-the-table, single-session solution for clinicians.

***Pounce* Arterial Thrombectomy System.** Our *Pounce* Arterial Thrombectomy System, which received FDA 510(k) clearance in fiscal 2020, is a mechanical thrombectomy device intended for the non-surgical removal of thrombi and emboli from the peripheral arterial vasculature. Commercial sales began in the first quarter of fiscal 2022.

In fiscal 2023, we received FDA 510(k) clearance for the low-profile (LP) model of the *Pounce* Arterial Thrombectomy System, which will allow for clot removal in below-the-knee peripheral arteries (2 mm to 4 mm in diameter), expanding the addressable market for the *Pounce* arterial platform. Limited market evaluations of the *Pounce* LP device and transition to commercial launch are targeted for fiscal 2024.

The *Pounce* Arterial Thrombectomy device consists of three components: a 5 Fr basket delivery catheter, a basket wire, and a funnel assembly. After the basket wire is delivered distal to the location of the thrombus, two nitinol self-expanding baskets are deployed to collect and entrain the clot into a funnel-shaped nitinol wire mesh. With the clot entrained, the funnel assembly is then collapsed into a 7 Fr procedure guide sheath through which the clot is withdrawn and removed from the body. Physician feedback indicates the *Pounce* Arterial Thrombectomy System is capable of achieving positive outcomes with minimal blood loss and with minimal use of thrombolytics. The device offers an intuitive, grab-and-go design to simplify setup and reduce the physician's learning curve.

***Pounce* Venous Thrombectomy System.** Our *Pounce* Venous Thrombectomy System, which received FDA 510(k) clearance in fiscal 2021, is a mechanical thrombectomy catheter for use in venous vascular beds that is specifically designed to remove large, mixed-morphology blood clots commonly found with VTE. The *Pounce* Venous Thrombectomy System has also received CE Mark approval, which is a prerequisite for commercialization in the E.U. The device's dual-action technology features a constant spring tension basket, which provides optimal wall apposition over a range of vessel diameters, to engage and collect the clot, while the motor-driven Archimedes screw macerates and removes the collected clot. As with our *Pounce* arterial device, the *Pounce* Venous Thrombectomy System is intuitive and approachable to facilitate widespread adoption, with a low learning curve for the physician.

We acquired the venous thrombectomy device technology with our fiscal 2021 acquisition of Vetex Medical Limited ("Vetex"), which was privately held and is based in Galway, Ireland. We acquired Vetex with an upfront cash payment of $39.9 million and deferred, guaranteed consideration of $3.5 million to be paid in two equal installments in the fourth quarter of fiscal 2024 and 2027.

Limited market evaluations for the *Pounce* Venous Thrombectomy System were conducted in fiscal 2023, and are expected to continue in fiscal 2024, to obtain physician feedback across a variety of cases and clinical conditions. Completion of limited market evaluations of the *Pounce* Venous Thrombectomy System and transition to commercial launch are targeted for fiscal 2024.

The FDA requires specific indications for devices to be marketed for treatment of certain aspects of VTE, such as DVT and PE. The *Pounce* Venous Thrombectomy System is indicated for mechanical de-clotting and controlled and selected infusion of physician specified fluids, including thrombolytics, in the peripheral vasculature. The device currently is not indicated for the treatment of DVT or PE. We intend to pursue development and regulatory actions that would expand the field of use for our thrombectomy products, which may include specific indications, and which may include DVT and PE.

Vascular Intervention Medical Devices – Radial Access **MEDICAL DEVICE SEGMENT**

We have successfully developed and received FDA 510(k) regulatory clearance for our Sublime™ portfolio of devices designed for vascular intervention via radial (wrist) access that can also be used via alternative access sites, including femoral (thigh) and pedal (foot) access. Our *Sublime* devices are used to access and treat narrowed arteries both above and below the knee, commonly associated with PAD. During fiscal 2022, we established a direct salesforce and commenced commercial sales of our *Sublime* device portfolio to hospitals and clinics. These radial access devices include:

- ***Sublime* guide sheath** to provide the conduit for peripheral intervention with an access point at the wrist that enables treatment all the way to the pedal loop of the foot;
- ***Sublime* .014 RX PTA dilatation catheter** for treatment of lesions in arteries below the knee all the way to the patient's foot and around the pedal loop;
- ***Sublime* .018 RX PTA dilatation catheter** for treatment of lesions in arteries above and below the knee; and
- ***Sublime microcatheter***, peripheral microcatheters with multiple configurations (compatible with .014, .018 and .035 guidewires) for access to arterial lesions above and below the knee. Limited market evaluations of the *Sublime* microcatheter began in the third quarter of fiscal 2023 and are expected to continue in fiscal 2024.

Our *Sublime* device portfolio is unique in that each of these devices are purpose built for above and below the knee peripheral interventions that can employ a transradial approach *and* alternative access sites, including conventional femoral access and pedal access. Our *Sublime* guide sheath performance is enhanced by our recent generation hydrophilic coating. We believe that radial access procedures offer significant benefits by improving patient comfort, reducing recovery and ambulation times, and potentially lowering access site complications. Our *Sublime* device portfolio meets an unmet clinical need by providing longer, lower-profile devices that are robust enough to deliver treatment from the wrist all the way to the pedal loop in the foot.

We believe the *Sublime* device portfolio is uniquely positioned to lead the market for dedicated devices that facilitate a radial-to-peripheral approach. Below are a few of the unique advantages of our *Sublime* devices.

- Our *Sublime* guide sheath is the only 5F guide sheath available in a length up to 150cm, making it an ideal device for operators who seek a smaller profile sheath to help minimize radial artery spasm or to treat smaller patients when performing peripheral interventions via radial access. Physician feedback has indicated our *Sublime* guide sheath offers a low-profile design for patient comfort, superior trackability through tortuous anatomy, and resistance to kinking when compared to alternative devices.
- Our *Sublime* .014 RX PTA dilatation catheter is the longest catheter of its kind in the U.S. market, at 250 cm. Physician feedback has indicated both our *Sublime* .014 and .018 catheters provide superb deliverability and the ability to cross challenging lesions.

OVERVIEW: PERFORMANCE COATINGS — MEDICAL DEVICE SEGMENT

Surmodics' industry-leading performance coatings are used in a minimally invasive procedure every minute of every day. Surmodics' surface-enhancing performance coatings add differentiated value to more than 150 medical, biotechnology and pharmaceutical product families worldwide. Our customers use Surmodics' performance coatings to enable, optimize and differentiate their device products. These performance coatings include:

- **Hydrophilic coatings** enable vascular device performance and maneuverability by reducing friction by imparting the necessary lubricity (smoothness or slipperiness) for minimally invasive, intravascular procedures. Surmodics' low-particulate, hydrophilic coatings have a proven track record, meeting demanding regulatory requirements in the following clinical segments: neurovascular, peripheral, coronary, and structural heart devices.
- **Drug-delivery coatings** enable a device to achieve the desired biological effect through the precisely controlled transfer of a pharmaceutical drug to targeted tissues. Surmodics possesses expertise across a range of compounds to meet a variety of clinical needs.
- **Hemocompatible coatings** improve the safety and function of devices by reducing the risk of thrombus (clot) formation actively (heparin) or passively (non-heparin).

Surmodics generates royalties and license fee revenue by licensing our performance coating technologies to medical device manufacturers, product revenue from sales to licensees of the chemical reagents used in coatings, and R&D revenue from commercial development feasibility services and contract coating services.

Our performance coatings are differentiated by their flexibility, durability and ease of use. In terms of flexibility, coatings can be applied to many kinds of surfaces and can immobilize a variety of chemical, pharmaceutical and biological agents. Additionally, the surface modification process can be tailored to provide customers with the ability to improve their devices' performance by choosing the specific coating properties desired for particular applications. Our performance coating technologies can also be combined to deliver multiple surface-enhancing characteristics on the same device.

The continuing trend toward minimally invasive surgical procedures, which often employ catheter-based delivery technologies, has increased the demand for hydrophilic (i.e., lubricious or slippery) coatings and other coating technologies, including drug-delivery coatings. For example, stents, particularly drug-eluting stents, have significantly reduced the need for repeat intravascular procedures or more invasive cardiac bypass surgery. Transcatheter heart valve repair, or replacement via a minimally invasive catheter-based system, has enabled the treatment of patients suffering from heart valve disease who are too ill to undergo open-heart surgery.

Hydrophilic Coatings. Our proprietary PhotoLink™ coating technology ("*PhotoLink* Technology") is a versatile, easily applied, coating technology that modifies medical device surfaces by creating covalent bonds between device surfaces and a variety of chemical agents. *PhotoLink* Technology can impart many performance-enhancing characteristics, such as advanced lubricity (slipperiness or smoothness) and hemocompatibility (preventing blood clot formation), when bound onto surfaces of medical devices or other biological materials without materially changing the dimensions or other physical properties of devices.

PhotoLink Technology reagents can be applied to a range of substrates. The coating formulations are easily applied to the material surface by a variety of methods including, but not limited to, dipping, spraying, roll-coating and ink-jetting. We continue to expand our proprietary reagent portfolio for use by our customers. These reagents enable our customers to develop novel surface features for their devices, satisfying the expanding healthcare industry requirements. We are also continually working to expand the list of materials that are compatible with our surface modification and device drug-delivery reagents. Additionally, we develop coating processes and coating equipment to meet the device quality, manufacturing throughput, and cost requirements of our customers.

The *PhotoLink* Technology coating process is relatively simple to use and is easily integrated into the customer's manufacturing operations. In addition, the process does not subject the coated products to harsh chemical or temperature conditions, produces no hazardous byproducts, and does not require lengthy processing or curing time. Further, coatings incorporating the *PhotoLink* Technology are generally compatible with accepted sterilization processes, so the surface attributes are not lost when the medical device is sterilized.

Our Serene™ hydrophilic coating platform, which uses our *Photolink* Technology, improves lubricity and durability, while significantly reducing particulates generation. This *PhotoLink* Technology-enabled coating has demonstrated excellent lubricity on a wide range of substrates and has been used on FDA-cleared coronary, peripheral and structural heart devices.

In October 2023, we announced the commercial launch of our most advanced hydrophilic medical device coating technology, Preside™ hydrophilic coatings. *Preside* hydrophilic coatings complement our existing *Serene* hydrophilic coatings by providing customers with a unique low-friction and low-particulate generation coating to further enhance distal access for neuro-vascular applications, as well as improved crossing for challenging coronary lesions or chronic total occlusions. *Preside* hydrophilic coatings are specifically formulated to meet the challenge of achieving the right balance of enhanced lubricity (reduction in friction) and excellent coating durability (resulting in low particulates) for the next generation of neurovascular, coronary and peripheral vascular devices. Our *Preside* and *Serene* hydrophilic coatings both allow customers to leverage their existing coating process to apply these innovative surface treatments.

Drug-delivery Coatings. Our device drug-delivery coating technologies allow therapeutic drugs to be incorporated within our proprietary polymer matrices to provide controlled, site-specific release of the drug into the surrounding environment. The drug release can be tuned to elute quickly (within minutes to a few days) or slowly (from several months to over a year), illustrating the wide range of release profiles that can be achieved with our coating systems. On a wide range of devices, drug-eluting coatings can help improve device performance, increase patient safety, and enable innovative new treatments. DCBs are a typical example of short-term use drug-delivery devices. An example of longer-term drug-delivery devices is drug-eluting stents. We work with companies in the medical device and biotechnology industries to develop specialized coatings that allow for the controlled release of drugs from device surfaces. We see at least three primary areas with strong future potential:

(1) improving the function of a device which itself is necessary to treat the medical condition;

(2) enabling site-specific drug delivery while limiting systemic exposure; and

(3) enhancing the biocompatibility of a medical device to ensure that it continues to function over a long period of time.

Performance Coatings – Licensing Arrangements — MEDICAL DEVICE SEGMENT

We commercialize our performance coating technologies primarily through licensing arrangements with medical device manufacturers. We believe this approach allows us to focus our resources on further developing new technologies and expanding our licensing activities. Many of our technologies have been designed to allow manufacturers to implement them easily into their own manufacturing processes so customers can control production and quality internally without the need to send their products to a contract manufacturer. We generate the largest proportion of our revenue through licensing arrangements. Revenue from these licensing arrangements typically includes royalties based on a percentage of licensees' product sales, with a contractual minimum, and license fees upon achievement of regulatory and commercialization milestones. Royalties and license fee revenue from our performance coatings represented 25%, 31% and 29% of our total revenue in fiscal 2023, 2022 and 2021, respectively. In fiscal 2023, 2022 and 2021, we saw double-digit year-over-year growth in revenue associated with our *Serene* hydrophilic coating technology driven by customer product launches and resulting market share increases associated with the customer device applications that incorporate the *Serene* coating technology.

The licensing process for our performance coating technologies begins with the customer specifying a desired product feature to be created, such as lubricity or drug delivery. Because each device and coating application is unique, we routinely conduct a feasibility study to qualify each new potential product application, often generating commercial development revenue. Feasibility studies can range in duration from several months to a year. After we complete a feasibility study, our customers cannot market their product until they receive regulatory approval. As further described under the caption "Government Regulation," the regulatory approval process varies in each country and ranges from several months to four or more years. At any time prior to a customer's commercial launch, a license agreement may be executed granting the licensee rights to use our technology. We often support our customers by providing coating assistance for parts required in animal tests and human clinical trials. Typically, we complete a technology transfer to most customers which enables those customers to apply the coating at their own facilities. We also generate revenue from reagent chemical product sales to licensees for use in their coating processes, as well as from providing contract coating services.

License agreement terms are generally for a specified number of years or our patent's life, whichever is longer, although a license generally may be terminated by the licensee for any reason with advance written notice. In cases where the royalty obligation extends beyond the life of the applicable patent, it is because the license also includes rights to our know-how or other proprietary rights. Under these circumstances, the royalty obligation typically continues at a reduced royalty rate for a specified number of years, generally tied to the date on which the licensee's medical device product was first sold.

Our license agreements may include certain license fees and/or milestone payments. Substantially all our licensed performance coating technology applications are nonexclusive, allowing us to license each technology to multiple customers. Moreover, even exclusive performance coating technology licenses generally are limited to a specific "field of use," allowing us the opportunity to further license technology to other customers. The royalty rate on a substantial number of the coatings agreements has traditionally been in the range of two to three percent, but there are certain contracts with lower or higher rates. In certain agreements, our royalty is based on an agreed-upon amount per unit. License fees, milestone payments, and royalty rates are based on various factors, including the licensed product's or technology's stage of development, the perceived value of our technology to the customer's product, the size of the potential market, and whether the arrangement is exclusive or nonexclusive. Our agreements often incorporate a minimum royalty to be paid by the licensee. Royalty payments generally commence one quarter after the customer's actual product sales occur because of the delay in reporting sales by our licensees. We estimate and recognize sales-based royalties revenue from our performance coating licensees in the same quarter that the underlying customer product sale occurs.

We have over 150 licensed product classes (customer products utilizing Surmodics technology) already in the market generating royalties and greater than 100 customer product classes incorporating our technology in various stages of pre-commercialization.

Under our performance coating technology license agreements, the responsibility for securing regulatory approval for and ultimately commercializing these products rests with our customers. Our reliance on our customers in this regard and the potential risks to our operations as a result are discussed in "Risk Factors" in Part I, Item IA of this Annual Report on Form 10-K. Moreover, we are often contractually obligated to keep the details concerning our customers' R&D efforts (including the timing of expected regulatory filings, approvals and market introductions) confidential.

Our licensing agreements generally require us to keep our customers' identities confidential, unless they approve of such disclosure. Licensed customers that allow the use of their name include: Abbott Laboratories and Abbott Vascular, Inc., Boston Scientific Corporation ("Boston Scientific"), Cook Medical, Cordis Corporation, Covidien PLC (a subsidiary of Medtronic), Edwards Lifesciences Corporation, Evalve, Inc. (a subsidiary of Abbott), ev3 Inc. (a subsidiary of Medtronic), Medtronic, OrbusNeich Medical, Inc., and Spectranetics Corporation (a subsidiary of Koninklijke Philips N.V.).

Performance Coatings – R&D Services for Customers — MEDICAL DEVICE SEGMENT

For our medical device performance coating customers, we have distinct, specifically-dedicated R&D facilities and personnel to support delivery of R&D services. We work with our customers to integrate the best possible surface modification and device drug-delivery technologies with their products, not only to meet their performance requirements, but also to perform services quickly so that the product may reach the market ahead of the competition. To quickly solve problems that might arise during the development and optimization process, we offer extensive capabilities in analytical chemistry and surface characterization within our R&D organization. Our state-of-the-art instrumentation and extensive experience allow us to test the purity of coating reagents, to monitor the drug elution rate from coatings, to measure coating thickness and smoothness, and to map the distribution of chemicals throughout coatings. We believe our capabilities in this area exceed those of our competitors. Our R&D staff support our business development staff and business units in performing feasibility studies, as well as providing technical assistance to existing and potential customers. These services, which generate R&D and other revenue, include optimizing the relevant technologies for specific customer applications; supporting clinical trials; training customers; and integrating our technologies and know-how into customer manufacturing operations.

Competition — MEDICAL DEVICE SEGMENT

We are developing and commercializing differentiated vascular intervention medical devices that integrate our performance coatings, catheter, balloon and other proprietary technologies. This high degree of differentiation is strategically designed to capture market share in a highly competitive, dynamic industry. Our vascular intervention products compete with the global leaders in the vascular medical device market. We believe our vascular intervention products will be competitive on the basis of their safety and efficacy as a result of the innovative design and differentiated coating and device design technology. We believe these innovations will enable our vascular intervention products to demonstrate improvements in patient outcomes through reduced invasiveness compared to other devices used for comparable procedures.

We believe that the intense competition within the medical device market creates opportunities for our performance coating technologies as medical device manufacturers seek to differentiate their products through new enhancements or to remain competitive with enhancements offered by other manufacturers. Because a significant portion of our revenue depends on royalties and license fees derived from our customers' medical device product sales incorporating our performance coating technologies, we are also affected by competition within the markets for such devices. As we typically license our performance coating technologies on a non-exclusive basis, we benefit by offering our technologies to multiple competing manufacturers of a device. However, competition in the medical device market could also have an adverse effect on us. While we seek to license our coatings products to established manufacturers, in certain cases, our performance coating licensees may compete directly with larger, dominant manufacturers with extensive product lines and greater sales, marketing and distribution capabilities.

We also are unable to control other factors that may impact commercialization of our vascular intervention products and licensees with medical devices that utilize our performance coatings, such as regulatory approval, marketing and sales efforts of our customers and licensees, and competitive pricing pressures within the particular market. Many of our existing and potential competitors have greater financial, technical and marketing resources than we have.

The ability of performance coating technologies to improve the performance of medical devices and drugs and to enable new product categories has resulted in increased competition in these markets. Some of our competitors offer device drug-delivery technologies, while others specialize in lubricious or hemocompatible coating technology. Some of these companies target cardiovascular, peripheral or other medical device applications. In addition, because of the many product possibilities afforded by performance coatings, many of the large medical device manufacturers have developed, or are engaged in efforts to develop, internal competency in the area of performance coatings, including drug-delivery technologies.

We differentiate ourselves from our performance coatings competitors by providing what we believe is a high value-added approach. We have a proven track record of our customers successfully navigating the regulatory approval process with devices utilizing our enabling technology. We believe that the primary factors customers consider in choosing a particular technology include performance (e.g., flexibility, ability to fine tune drug elution profiles, biocompatibility), ease of manufacturing, time-to-market, intellectual property protection, ability to produce multiple products from a single process, compliance with manufacturing regulations, ability to manufacture clinical and commercial products, customer service, and total cost of goods (including manufacturing process labor). We believe our technologies deliver exceptional performance in these areas, allowing us to compete favorably with respect to these factors. With respect to our licensed performance coating technologies, we believe that the cost and time required to obtain the necessary regulatory approvals significantly reduces the likelihood of a customer changing the manufacturing process it uses once a device or drug has been approved for sale.

R&D Strategy — MEDICAL DEVICE SEGMENT

Our significant R&D investments over the past several years reflect our ongoing commitment to strengthen our proprietary product pipeline and broaden our capacity for medical device R&D activities. In fiscal 2023, 2022 and 2021, consolidated R&D expense as a percentage of consolidated revenue was 35%, 51% and 45%, respectively. In fiscal 2023, R&D expense was largely associated with our investments in vascular intervention product development; costs associated with the *SurVeil* DCB; and regulatory infrastructure, facilities and personnel. R&D expenses primarily consist of research, development, clinical and regulatory activities related to the design, development and commercialization of our products, as well as costs associated with our R&D services revenue.

We intend to continue our development efforts to expand our proprietary medical device offerings, including advancing our performance coating technologies to better meet these needs across multiple medical markets and to capture more of the final product value. We anticipate R&D expenses will continue to be significant in fiscal 2024 and beyond, primarily related to medical device product development, including continued investment in our thrombectomy and radial access platforms.

To strengthen our licensing business model, R&D personnel and facilities for our *Pounce* thrombectomy and *Sublime* radial access vascular intervention products are fully segregated from those for our performance coatings to preserve confidential information of our coatings customers (licensees). In our Medical Device segment, we conduct manufacturing and R&D in multiple facilities. Two of those separate facilities are located in Eden Prairie, Minnesota. We also utilize external contract manufacturers for certain device products.

We have robust procedures to ensure that we protect our coatings customers' (licensees) intellectual property and avoid conflicts of interest. R&D personnel have specific roles and are part of distinct teams, clearly segregated between (i) performance coating technologies R&D, including customer development to support our licensing partnership model; and (ii) internal R&D activities to further advance our vascular intervention product portfolio. Our procedures include strict restrictions for physical access to customers' products and records and limitations on computer file access based on an R&D team member's role.

IN VITRO DIAGNOSTICS SEGMENT

Surmodics' In Vitro Diagnostics ("IVD") segment provides leading in vitro diagnostic companies with the critical components for developing sensitive, reproducible immunoassays to enable our customers' diagnostic tests to detect the absence or presence of disease. We develop, manufacture, and sell chemical and biological components for in vitro diagnostic immunoassay tests and molecular diagnostic tests for the diagnostic and biomedical research markets.

Our portfolio of IVD chemical and biological component products includes:

- **Protein Stabilizers.** We offer a full line of stabilization products for the IVD market. These products increase sensitivity and specificity and reduce false positive and false negative results, while extending the diagnostic test's shelf life, thereby producing more consistent assay results. Our stabilization products are ready-to-use, eliminating the in-house manufacturing preparation time and cost of producing stabilization and blocking reagents.

- **Substrates.** We provide colorimetric and chemiluminescent substrates to the IVD market under our BioFX® trademark. A substrate is the diagnostic test kit component that detects and signals that a reaction has taken place so that a result can be recorded. Colorimetric substrates signal a positive diagnostic result through a color change. Chemiluminescent substrates signal a positive diagnostic result by emitting light. We believe that our substrates offer a high level of stability, sensitivity and consistency.

- **Surface Coatings for Molecular Diagnostic Applications.** We offer custom coatings for molecular diagnostic applications, including DNA, RNA and protein microarrays. Our TRIDIA™ surface coatings bind molecules to a variety of surfaces and geometries and may be customized for selectivity using passivating polymers and reactive groups. This proprietary technology immobilizes DNA and protein to adhere to testing surfaces. We offer other surface coatings that improve flow characteristics through membranes and microfluidic channels on diagnostic devices, including point-of-care components.

- **Antigens and Antibodies.** We are the exclusive distributor in the U.S., Canada and Puerto Rico (and non-exclusive distributor in Japan) of the BBI Solutions' DIARECT™ line of antigens and antibodies ("DIARECT"). DIARECT produces the majority of these antigens and antibodies using recombinant technology.

Our IVD products address the following customer needs:

- **Immunoassay Diagnostics.** Surmodics develops, manufactures and sells high-performing, consistent-quality and stable immunoassay component products to enable our customers' diagnostic tests to detect the absence or presence of disease. An immunoassay is a biochemical test that measures the presence or concentration of a target molecule, or analyte, in a biological fluid or sample. Analyte levels are correlated to the patient's disease state or medical condition to diagnose the presence, absence or severity of disease. Analytes can range from large molecules such as proteins to small molecules such as hormones. Immunoassays are developed and produced using multiple components. The component's selection and optimization confer the quality and performance of the assay in terms of sensitivity and specificity. IVD companies select these critical biochemical and reagent components to meet the assay's diagnostic specifications.

- **Molecular Diagnostics – DNA and Protein Immobilization.** Surmodics has developed various surface chemistries for both DNA and protein immobilization. Our TRIDIA™ product optimizes DNA, RNA, protein, and cell attachment for molecular diagnostic and immunoassay applications, reducing non-specific background and improving sensitivity. Surmodics' versatile coatings bind molecules to a variety of surfaces and geometries and may be customized for selectivity using passivating polymers and reactive groups. Both DNA and protein microarrays are useful tools for the pharmaceutical, diagnostic and research industries. During a DNA gene analysis, typically thousands of different probes need to be placed in a pattern on a surface, called a DNA microarray. These microarrays are used by the pharmaceutical industry to screen for new drugs; by genome mappers to sequence human, animal or plant genomes; or by diagnostic companies to search a patient sample for disease-causing bacteria or viruses. However, DNA does not readily adhere to most surfaces. Protein microarrays are used as diagnostic and research tools to determine the presence and/or quantity of proteins in a biological sample. The most common type of protein microarray is the antibody microarray, where antibodies are spotted onto a surface and used as capture molecules for protein detection.

Customer R&D. The sales cycle for our IVD products generally begins when an IVD company initiates the process to develop a new, or improve a current, diagnostic test. During product development, these companies seek to source the test's critical components with reagents that it produces internally or with reagents from a supplier, such as Surmodics.

As IVD tests are developed and various reagents are tested, companies will generally seek to optimize the sensitivity (false negative reductions), specificity (false positive reductions), speed (time from sample to results), convenience (ideally as few steps as possible), and cost effectiveness. Upon regulatory approval or clearance, the customer's diagnostic test can be sold in the marketplace. It may take several years after approval or clearance for the test to achieve peak market share and optimize Surmodics' revenue.

New Product R&D. Our R&D efforts to grow our IVD business segment include identifying and addressing unmet needs that exist in the global IVD marketplace. Our pipeline of IVD products includes components for immunoassay and molecular diagnostic applications, such as new protein stabilizers, detection technologies, accessory reagents and surface coatings that have the potential to add greater sensitivity, specificity, speed, convenience, and lower cost for IVD test manufacturers.

Competition. The diagnostics market is highly fragmented. In the product lines in which we compete, we face an array of competitors ranging from large manufacturers with multiple business lines to small manufacturers that offer a limited selection of products. Some of our competitors have substantially more capital resources, marketing experience, R&D resources and production facilities than we do. We believe that our products compete on performance, stability (shelf life), sensitivity (lower levels detected, faster results), consistency and price. We believe that our continued competitive success will depend on our ability to gain market share, develop or acquire new proprietary products, obtain patent or other protection for our products, and successfully market our products directly or through partners.

OTHER FACTORS IMPACTING OUR OPERATIONS

Patents and Proprietary Rights

OTHER FACTORS IMPACTING OUR OPERATIONS

Patents and other forms of proprietary rights are an essential part of Surmodics' business. We aggressively pursue patent protection covering the proprietary technologies that we consider strategically important to our business. In addition to seeking patent protection in the U.S., we also generally file patent applications in European countries and, on a selective basis, other foreign countries. We strategically manage our patent portfolio in a manner designed to ensure that we have valid and enforceable patent rights protecting our technological innovations. As of September 30, 2023, Surmodics owned or had exclusive rights to 161 issued U.S. patents and 303 issued international patents. As of the same date, we also owned or had exclusive rights to 37 U.S. pending patent applications and 62 foreign pending patent applications.

We have licensed our *PhotoLink* Technology on a non-exclusive basis to a number of our customers for use in a variety of medical device surface applications, including those described above. In particular, we have 35 issued U.S. patents, four pending U.S. patent applications, 79 issued international patents, and 18 pending international patent applications protecting various aspects of these technologies, including compositions, methods of manufacture and methods of coating devices. The expiration dates for these patents and anticipated expiration dates of the patent applications range from fiscal 2025 to 2042. These patents and patent applications represent distinct families, with each family generally covering a successive generation of the technology, including improvements that enhance coating performance, manufacturability, or other important features desired by our customers. For additional details, refer to the caption "Performance Coatings – Licensing Arrangements" within this section of this Annual Report on Form 10-K.

We also rely upon trade secrets, trademarks and other un-patented proprietary technologies. We seek to maintain the confidentiality of such information by requiring employees, consultants and other parties to sign confidentiality agreements and by limiting access by parties outside the Company to such information. There can be no assurance, however, that these measures will prevent the unauthorized disclosure or use of this information, or that others will not be able to independently develop such information. Additionally, there can be no assurance that any agreements regarding confidentiality and non-disclosure will not be breached, or, in the event of any breach, that adequate remedies would be available to us.

Significant Customers

OTHER FACTORS IMPACTING OUR OPERATIONS

Revenue from Abbott and Medtronic represented approximately 27% and 10%, respectively, of our consolidated revenue for fiscal 2023. Revenue from these customers was generated from multiple products and fields of use, including revenue from the Abbott Agreement, substantially all of which were recognized in our Medical Device segment. No other customer accounted for more than 8% of our consolidated revenue in fiscal 2023.

With respect to our Medical Device segment, revenue from Abbott and Medtronic represented approximately 35% and 12%, respectively, of our Medical Device segment revenue for fiscal 2023, and revenue from one additional customer represented approximately 9% of our Medical Device segment revenue for fiscal 2023. No other customer accounted for greater than 4% of Medical Device segment revenue for fiscal 2023.

With respect to our IVD segment, revenue from two customers represented approximately 21% and 12%, respectively, of our IVD segment revenue for fiscal 2023. No other customer accounted for greater than 8% of IVD segment revenue for fiscal 2023.

Manufacturing — OTHER FACTORS IMPACTING OUR OPERATIONS

We manufacture the reagent chemicals used in our performance coatings and our IVD products in one of our Eden Prairie, Minnesota facilities. In certain limited circumstances, we also provide contract manufacturing services for our customers, including, for example, coating their medical devices that are intended for pre-clinical and clinical development (including human clinical trials), and products that are sold for commercial use by our customers. We manufacture PTA balloon catheters and microcatheters in our Ballinasloe, Ireland facility, which offers a suite of capabilities, including balloon forming, extrusion, coating, braiding and assembly of finished products. We manufacture our vascular intervention products in our Ireland and U.S. facilities, and we also utilize contract manufacturers for our vascular intervention products. At our Ballinasloe, Ireland manufacturing facility, we perform a limited volume of contract manufacturing of medical devices for our customers.

We attempt to maintain multiple sources of supply for the key raw materials used to manufacture our products. We do, however, purchase some raw materials from single sources, but we believe that additional sources of supply are readily available. Further, to the extent additional sources of supply are not readily available, we believe that we could manufacture such raw materials.

We follow quality management procedures in accordance with applicable regulations and guidance for the development and manufacture of materials and device, biotechnology or combination products that support clinical trials and commercialization. In order to meet our customers' needs in this area, all of our manufacturing facilities in Eden Prairie, Minnesota and Ballinasloe, Ireland are certified to ISO 13485 and registered with the U.S. FDA as "Contract Manufacturers." In addition, one of our manufacturing facilities and our warehouse facility in Eden Prairie, Minnesota are certified to ISO 9001.

Government Regulation — OTHER FACTORS IMPACTING OUR OPERATIONS

Medical device and in vitro diagnostic products are required to undergo regulatory review processes that are governed by the FDA and other international regulatory authorities. The process of regulatory review and approval is often prolonged, expensive and uncertain. New medical devices can only be marketed in the U.S. after a pre-market notification for 510(k) clearance or a PMA by the FDA. These processes can take anywhere from several months (e.g., for medical device products seeking regulatory approval under the 510(k) clearance process) to several years (e.g., for medical device products seeking regulatory approval under the PMA application process). In the E.U., regulatory approval is signified by the CE Mark, which is generally granted by one of several competent authorities and is based on the submission of a design dossier, a manufacturer validation assessment, a third-party assessment, and review of the design dossier by a "Notified Body." In 2017, the E.U. authorized a new medical device regulation. The new regulation, which imposes significant additional pre-market and post-market requirements, became effective for devices submitted for CE Mark after May 2021. Medical devices granted CE Mark prior to May 2021 may continue to be sold until December 2027 for class III and class IIb devices and until December 2028 for class IIa and class I devices, or until the CE Mark expires, whichever comes first, providing there are no significant changes to the design or intended use of the device.

For our customers' products that incorporate our performance coating and IVD technologies, the burden of securing regulatory approval typically rests with the customer, as the medical device manufacturer. For our vascular intervention products, the burden of securing regulatory approval rests on us, unless we contract with other organizations to pursue such approval.

In support of our customers' and our own regulatory filings, we maintain various confidential Device Master Files with the FDA and provide technical information to other regulatory agencies outside the U.S. regarding the nature, chemical structure and biocompatibility of our reagents. Our licensees generally do not have direct access to these files. However, they may, with our permission, reference these files in their various regulatory submissions to these agencies. This approach allows regulatory agencies to understand the details of our technologies without our having to share this highly confidential information with our customers.

U.S. legislation allows companies, prior to obtaining FDA clearance or approval to market a medical product in the U.S., to manufacture medical products in the U.S. and export them for sale in international markets. This generally allows us to realize earned royalties sooner and may result in opportunities to market our vascular intervention products in other countries. However, sales of medical products outside the U.S. are subject to international requirements that vary from country to country. The time required to obtain approval for sale internationally may be longer or shorter than that required by the FDA.

Human Capital

OTHER FACTORS IMPACTING OUR OPERATIONS

As of September 30, 2023, we had 376 employees, of which 101 were employed outside the U.S., primarily in manufacturing functions. We are not a party to any collective bargaining agreements.

Our success depends upon our ability to retain and attract highly qualified management and technical personnel. Talent management is critical to our ability to execute on our long-term growth strategy. Through our history of technological innovation, we appreciate the importance of retention, growth and development of our employees. We are committed to an inclusive culture which values equality, opportunity, and respect. In support of our inclusive culture, we believe we offer competitive compensation and benefits, including an annual pay gap assessment; provide respectful workplace training to strengthen employee understanding; and strive to recruit a diverse talent pool across all levels of the organization. We are focused on the engagement and empowerment of our employees through demonstration of our foundational values, which we refer to as the five Cs: we have *courage* to face challenges with determination, honesty and resourcefulness; *candor* to speak openly and respectfully; *collaboration* that recognizes teamwork as the key to success; *camaraderie* that is genuine and supportive; and *commitment* to our cause.

SEC FILINGS

We file annual reports, quarterly reports, proxy statements, and other documents with the SEC under the Securities Exchange Act of 1934, as amended (the "Exchange Act"). The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public may obtain any documents that we file with the SEC at http://www.sec.gov.

We make available, free of charge, copies of our annual report on Form 10-K, proxy statement, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act on our website, www.surmodics.com, as soon as reasonably practicable after filing such material electronically or otherwise furnishing it to the SEC. We are not including the information on our website as a part of, or incorporating it by reference into, our Form 10-K.

INFORMATION ABOUT OUR EXECUTIVE OFFICERS

As of November 17, 2023, the names, ages and positions of the Company's executive officers were as follows:

Name	Age	Position
Gary R. Maharaj	60	President and Chief Executive Officer
Timothy J. Arens	56	Senior Vice President of Finance and Information Technology and Chief Financial Officer
Charles W. Olson	59	Senior Vice President and President, Medical Device Coatings
Teryl L.W. Sides	54	Senior Vice President and President, Vascular Interventions
Joseph J. Stich	58	Senior Vice President Human Resources and President, In Vitro Diagnostics
Gordon S. Weber	60	Senior Vice President of Legal, General Counsel and Secretary

Gary R. Maharaj joined the Company in December 2010 as President and Chief Executive Officer and was also appointed to the Surmodics Board of Directors at such time. Prior to joining Surmodics, Mr. Maharaj served as President and Chief Executive Officer of Arizant Inc., a provider of patient temperature management systems in hospital operating rooms, from 2006 to 2010. Previously, Mr. Maharaj served in several senior-level management positions for Augustine Medical, Inc. (predecessor to Arizant Inc.) from 1996 to 2006, including Vice President of Marketing, and Vice President of Research and Development. During his over 35 years in the medical device industry, Mr. Maharaj has also served in various management and research positions for the orthopedic implant and rehabilitation divisions of Smith & Nephew, PLC.

Timothy J. Arens joined the Company in February 2007 as Director, Business Development and became Senior Director of Financial Planning and Analysis and General Manager, In Vitro Diagnostics in October 2010. He was promoted to Vice President of Finance and Interim Chief Financial Officer in August 2011 and in February 2013 became Vice President Corporate Development and Strategy. In May 2018, Mr. Arens was named interim Vice President of Finance and Chief Financial Officer for a second time and in February 2019 he was named Vice President of Finance and Chief Financial Officer. In April 2020, he was promoted to Senior Vice President of Finance and Information Technology and Chief Financial Officer. Prior to joining Surmodics, Mr. Arens was employed at St. Jude Medical, Inc., a medical technology company, from 2003 to 2007, in positions of increasing responsibility related to business development and strategic planning functions.

Charles W. Olson joined the Company in July 2001 as Market Development Manager, was promoted in December 2002 to Director, Business Development, named General Manager of the Hydrophilic Technologies business unit in April 2004, and promoted to Vice President and General Manager, Hydrophilic Technologies in October 2004. In April 2005, the position of Vice President, Sales was added to his responsibilities. In November 2008, Mr. Olson was named Vice President of our Cardiovascular business unit, in October 2010, he was named Senior Vice President and General Manager, Medical Device, and in August 2016 he was named Senior Vice President of Commercial and Business Development, Medical Devices. In May 2022, Mr. Olson was named Senior Vice President and President, Medical Device Coatings. Prior to joining Surmodics, Mr. Olson was employed as General Manager at Minnesota Extrusion from 1998 to 2001 and at Lake Region Manufacturing in project management and technical sales from 1993 to 1998.

Teryl L.W. Sides joined the Company in November 2018 as Senior Vice President and Chief Marketing Officer. In April 2020, Ms. Sides was promoted to Senior Vice President of Product Development and Chief Marketing Officer. In May 2022, Ms. Sides was named Senior Vice President and President, Vascular Interventions. Before joining Surmodics, Ms. Sides served as Founder and Chief Executive Officer of Projectory, a consulting firm that provides strategic marketing services to medical technology clients, ranging from start-ups to global businesses, from 2011 to 2018. Prior to joining Projectory, Ms. Sides was the Vice President of Marketing and Product Development for Arizant, Inc. from 1998 to 2011.

Joseph J. Stich joined the Company in March 2010 as Vice President of Corporate Development and Strategy. In August 2011, Mr. Stich became Vice President, Business Operations and General Manager In Vitro Diagnostics. In September 2013, Mr. Stich's role was adjusted to Vice President and General Manager, In Vitro Diagnostics. In April 2020, Mr. Stich was promoted to Senior Vice President of Human Resources and General Manager, In Vitro Diagnostics. In May 2022, Mr. Stich was named Senior Vice President Human Resources and President, In Vitro Diagnostics. Prior to joining Surmodics, Mr. Stich was Vice President of Corporate Development for Abraxis BioScience, LLC, a biotechnology company focused on oncology therapeutics, from 2009 to 2010. Prior to joining Abraxis, he was a Vice President for MGI Pharma, Inc., a biopharmaceutical company, from 2005 to 2009. Mr. Stich's prior experience also includes serving as President/COO of Pharmaceutical Corp. of America (a subsidiary of Publicis Healthcare Specialty Group), and positions of increasing responsibility in sales and marketing at Sanofi-Aventis Pharmaceuticals.

Gordon S. Weber joined the Company in May 2020 as Senior Vice President of Legal, General Counsel and Secretary. Prior to joining Surmodics, Mr. Weber served as the Founder and President of Sapere Aude, LLC, a consulting firm, from 2018 to 2020. From 2017 to 2018, Mr. Weber served as Vice President, General Counsel and Secretary of CHF Solutions, Inc., which manufactures and markets ultrafiltration systems for patients suffering from fluid overload. Mr. Weber served as Vice President, General Counsel and Secretary of Vascular Solutions, Inc., a medical device company focused on products treating coronary and peripheral vascular disease, from 2013 until the company was acquired by Teleflex Incorporated in 2017. Mr. Weber practiced law for 13 years with Faegre & Benson LLP (now Faegre Drinker Biddle & Reath LLP), where he was Partner. Mr. Weber began his career with the accounting firm now known as KPMG and has served as Corporate Controller for Osmonics, Inc., an NYSE-listed manufacturer of fluid filtration equipment.

The executive officers of the Company are elected by and serve at the discretion of the Board of Directors. None of our executive officers are related to any other executive officer or any of our directors.

4P

Initial

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: McKesson Corporation dba McKesson Drug Company

Physical Address: 8200 Bluegrass Blvd

City: Jeffersonville State: OH Zip: 43128

Mailing Address (if different from physical address): 8200 Bluegrass Blvd

City: Jeffersonville State: OH Zip: 43128

Telephone: 800-521-0727 Website: www.mckesson.com

Name of Designated Representative (DR): Pavel Duzhiy

Licensing Company Email: mckessonlicensing@mckesson.c DR Email: Pavel.Duzhiy@mckesson.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Health and Beauty Aids	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Clinics		■ Others: Full Line Drug Wholesaler

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: NORTHSTAR RX LLC
Address: 4835 CRUMPLER ROAD City: MEMPHIS State: TN Zip: 38141

Name: AUROBINDO PHARMA USA INC
Address: 279 PRINCETON HIGHSTOWN R City: EAST WINDSOR State: NJ Zip: 08520

Name: ELI LILLY AND COMPANY
Address: LILLY CORPORATE CENTER City: INDIANAPOLIS State: IN Zip: 46225

Name: MAJOR PHARMACEUTICALS
Address: 341 MASON ROAD City: LA VERGNE State: TN Zip: 37086

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware
Parent Company (if any): N/A
Corporation Name: McKesson Corporation
Mailing Address: 6535 State HWY 161
City: Irving State: TX Zip: 75039
Telephone: 972-446-4800 Email: mckessonlicensing@mckesson.com
Contact Person Name: Saralisa Brau

Date of SEC Registration: 1995 | SEC Registration Number: 033-86536 | Stock Exchange Symbol: MCK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A
Parent Company (if any):
Corporation/Organization Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [3]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [3]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

McKesson Corporation dba McKesson Drug Company

Facility Name

Saralisa Brau

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

1/15/25

Date

Board Use Only	Date Received: 3/7/25	Amount: $1000 - cc ✓

NABP ACCREDITED
DRUG DISTRIBUTOR

McKesson Corporation
dba McKesson Drug Company

located at

8200 Bluegrass Blvd, Jeffersonville, OH 43128

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/18/2023 - 12/17/2026
Period of Accreditation

0528

McKesson Corporation dba McKesson Drug Company
Owner: McKesson Corporation – 100% Ownership
McKesson Corporation is a publicly traded company
FEIN: 94-3207296

Incorporated 07/07/1994 in the state of Delaware

Officers:

Brian Tyler, Chief Executive Officer
Britt Vitalone, Executive Vice-President and Chief Financial Officer
Akinjide Falaki, Senior Vice-President and Treasurer
Saralisa Brau, Corporate Secretary

Directors:

Richard Carmona
Dominic Caruso
Lynne Doughtie
W. Roy Dunbar
Deborah Dunsire
Julie Gerberding
James Hinton
Donald Knauss
Bradley Lerman
Maria Martinez
Kevin Ozan
Brian Tyler
Kathleen Wilson-Thompson

Top Shareholders:

The Vanguard Group – 9.5%
Blackrock, Inc – 9.03%

Confidentiality Notice: This document, including any attachments, is for the sole use of its intended recipients and may contain confidential, proprietary and/or privileged information of McKesson Corporation or its affiliates. Any unauthorized review, use, disclosure or distribution is prohibited.

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "MCKESSON CORPORATION" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTEENTH DAY OF JULY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "MCKESSON CORPORATION" WAS INCORPORATED ON THE SEVENTH DAY OF JULY, A.D. 1994.

Jeffrey W. Bullock, Secretary of State

2417015 8300

SR# 20243148854

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203933631

Date: 07-16-24

STATE OF OHIO
BOARD OF PHARMACY

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until June 30, 2025.

McKesson Corporation

McKesson Drug Company

8200 Bluegrass Blvd

Jeffersonville, OH 43128-3500

License Number: 0132000107

Wholesaler - Category 3

Expiration Date: June 30, 2025

CLASS: Wholesaler - Category 3
BUSINESS TYPE: FS – Full Service

Responsible Person – Print, sign and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person
TODD SPAULDING	Todd Spaulding

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request on your Ohio eLicense Dashboard - https://elicense.ohio.gov/oh_homepage.

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0623834	01-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	12-31-2024

MCKESSON CORPORATION
DBA MCKESSON DRUG CO.
8200 BLUEGRASS BLVD
JEFFERSONVILLE, OH 43128

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0623834	01-31-2026	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
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MCKESSON CORPORATION
DBA MCKESSON DRUG CO.
8200 BLUEGRASS BLVD
JEFFERSONVILLE, OH 43128

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY) 06/21/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Aon Risk Insurance Services West, Inc. San Francisco CA Office 425 Market Street Suite 2800 San Francisco CA 94105 USA	CONTACT NAME: PHONE (A/C. No. Ext): (866) 283-7122 FAX (A/C. No.): (800) 363-0105 E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Old Republic Insurance Company	24147
INSURER B:		
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
McKesson Corporation and
all its subsidiaries
6555 North State Highway 161
Irving TX 75039 USA

COVERAGES **CERTIFICATE NUMBER:** 570106560155 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS. Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			MWZY317743	07/01/2024	07/01/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
	X Contractual Liability						MED EXP (Any one person)	$10,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$1,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$2,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$2,000,000
A	AUTOMOBILE LIABILITY			MWTB 317742 Self Insured for Phys Dam	07/01/2024	07/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N / A		MWC31382624	07/01/2024	07/01/2025	X PER STATUTE OTH-ER	
							E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE-EA EMPLOYEE	$1,000,000
							E.L. DISEASE-POLICY LIMIT	$1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
EVIDENCE OF INSURANCE

CERTIFICATE HOLDER

MCKESSON CORPORATION
6555 State Hwy 161
Irving TX 75039 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West Inc.

Holder Identifier :

Certificate No : 570106560155

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG McKesson Corporation dba McKesson Drug Company MDEG License # (if applicable) N/A
Physical Address 8200 Bluegrass Blvd
City Jeffersonville State OH Zip 43128
Mailing Address (if different from physical address) 8200 Bluegrass Blvd
City Jeffersonville State OH Zip 43128
Telephone 800-521-0727 Website www.mckesson.com
Licensing Company Email mckessonlicensing@mckesson.com

Section 2: Personal Information

First Pavel Middle Orestovich Last Duzhiy
Alias(es, nicknames, name changes, etc.) N/A
Date of Bir [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address 8200 Bluegrass Blvd
City Jeffersonville State OH Zip 43128
Telephone [redacted] Email Pavel.Duzhiy@mckesson.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Portland State University		graduated 2014	
Address	**City**	**State**	**Zip**
1825 SW Broadway	Portland	OR	97201
Diploma/Degree obtained, if any			
Bachelor of Science; Business Administration, Supply Chain and Logistics Management			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2024-Present	[redacted]	Centerville	OH	[redacted]
02/2024-01/2025		Puyallup	WA	
02/2023-02/2024		Edgewood	WA	
03/2022-03/2023		Spanaway	WA	
08/2021-03/2022		Puyallup	WA	
01/2019-07/2021		Saint Charles	MO	
06/2017-12/2018		Aurora	IL	
03/2014-05/2017		Aloha	OR	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
McKesson Corporation			07/16/2014 - Current
Business Address	**City**	**State**	**Zip**
6555 State HWY 161	Irving	TX	75039
Phone	**Title**	**Number of Employed Hours**	
972-446-4800	Assistant Director of Operations	~20000	
Description of Duties			
Responsible for managing day to day activities including, but not limited to, receiving, warehouse, wholesale distribution, and recording keeping of prescription drugs.			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03.21.2025
Date

I, Pavel Duzhiy, **certify that as the MDEG Administrator for**

McKesson Corporation dba McKesson Drug Company,

that I (initial that you have read and meet the following requirements):

1. PD Have a high school diploma or its equivalent;
2. PD Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. PD Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. PD Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pavel Duzhiy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05.21.2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (04/22/2021)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler McKesson Corporation dba McKesson Drug Company

Physical Address 8200 Bluegrass Blvd

City Jeffersonville State OH Zip 43128

Mailing Address (if different from physical address) 8200 Bluegrass Blvd

City Jeffersonville State OH Zip 43128

Telephone 800-521-0727 Website www.mckesson.com

Licensing Company Email mckessonlicensing@mckesson.com

Section 2: Personal Information

First Pavel Middle Orestovich Last Duzhiy

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Centerville State OH Zip [redacted]

Telephone [redacted] Email pavel.duzhiy@mckesson.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/Reserves ☐ Navy/Reserves ☐ Airforce/Reserves ☐ Marine Corps/Reserves ☐ Coast Guard/Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Applicant's initials PD

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Portland State University			graduated 2014
Address	**City**	**State**	**Zip**
1825 SW Broadway	Portland	OR	97201
Diploma/Degree obtained, if any			
Bachelor of Science: Business Administration, Supply and Logistic Management			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/2024 - Present	[redacted]	Centerville	OH	[redacted]
02/2024-01/2025		Puyallup	WA	
02/2023-02/2024		Edgewood	WA	
03/2022-03/2023		Spanaway	WA	
08/2021-03/2022		Puyallup	WA	
01/2019-072021		Saint Charles	MO	
06/2017-12/2018		Aurora	IL	
03/2014-05/2018		Aloha	OR	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
McKesson Corporation			07/16/2014-Current	
Business Address		**City**	**State**	**Zip**
6555 State HWY 161		Irving	TX	75039
Phone	**Title**		**Number of Employed Hours**	
972-446-4800	Assistant Director of Operations		~20000	
Description of Duties				
Responsible for managing day to day activities including, but not limited to, receiving, warehouse, wholesale distribution, and record keeping of prescription drugs.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Applicant's initials RD

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

03.03.2025
Date

Applicant's initials PD

I, Pavel Duzhiy, **certify that as the designated representative for**

McKesson Corporation dba McKesson Drug Company,

that I am qualified as follows and will comply with the following:

1. I am at least 21 years of age;
3. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. I will serve in this representative capacity for only one pharmacy or wholesaler at a time

Pavel Duzhiy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03.03.2025

Date

Applicant's Initials PD

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pavel Duzhiy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03.03.2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Pavel Duzhiy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03.03.2025

Date

Subscribed and Sworn to before me this 03 day of March 2025.

Notary Public Signature

Commission Exp: 0821-2024

Zachery Hicks

NOTARY PUBLIC STATE OF (Seal)

Applicant's initials PP

List of Employees

Cynthia Krueger	Brendon Lyons	Cody Moore	James Potts	Jeremy Brown
Edward Kinsey	Broghan Cooper	Sahslly Morillo Paredes	Jason Booth	Bryson Lytle
Lee Cherry	Patrick Summers	Yvemichelle Laveus	Bonnie Hopper	Sean Lawwell
Kathern Potts	Christian Grove	Brian Ledbetter	Caleb Campbell	Christina Stone
Tiffany Long	Ivan Cruz	Michele Swayne	Terran Yoakem	Anna Sellers
Caleb Embree	Dawn Barnhart	Paris Nelson	Luke Turner	Bryan Southworth
Melissa McCoy	Sarah Hogle	Chacy Smith	Brian Chapman	Christina Morris
Kevin Kleather	Ashley Woods	Kendall Stevens	Calesha Walton	Chad Sever
Ola Afolayan	Anthony Beverly	Troy Montgomery	Tara Luikart	Michael Cade
Triveon Kidd	Heather Parr	Jamie Treadway	Suzette Duron-Ackley	Shawnn Bussey
Hannah Newland	Patricia Arreguin	Dakota Weikle	Crystal Crites	Brian Smith
Haylee Dudley	Hannah Howard	Andy Pastore	Troy Hamilton	Livia Sheppard
Teresa Mcgraw	Sara Cordell	Cynthia Pastore	Sara Beedy	Walter Stump
Shaylee Wright	Robert Newkirk	Jennifer Cade	Aaron Harris	Jay Bloomer
Arthur Mack	Angela Smith	Kandis Huff	Marah Knisley	Kathryn Wilson
Yvemirtha Laveus	Carrie Parks	Kariann Smart	Timothy Fugate	William Backenstoe
Lona Alexander	Regina Thacker	John Allen	Teresa Evans	Jon Kellough
Christina Russell	Brandon Hall	Mary Hafer	Chloe Bender	Yolonda Higgins
Christopher Kokensparger	Jacob Coulter	William Tripp	Jaylen Murta	Nicole Badgley
Austin Bond	Hayden Pendergraft	Robert Humphries	Addelynne Cockerill	Carleigh Cupp
Sarah Kirsch	Stephanie Clyburn	Sarah Curtis	Michele Huff	Chris Clark
Nathan Carroll	Albert Roehrich	Sean Gausman	C. Warning	Denise Shadburn
Marinda Shoemaker	Brayden May	Nicholas Yoe	Bruno Battistin	Kelly Johnson
Ashlyn Burns	Christina Sturgeon	Rebecca May	Tammy Griffith	Linda Justice
Thei Casteel	Jennifer Rodriguez	Ma Joana Greenwood	Lisa Brown	Richard Fraley
Gabriel Vilchez	Bertha Loor Andrade	Melanie Jones	Susan Perdue	Sarah Copley
Nathan Barnhart	Brandon Ulloa	Amantha Davis	Micah Creamer	Jonathan Cruz Lopez
Sherri Baldwin	Katie Buford	Emilee Vail	Kimberly Roberts	Renee Stanley
Jozlin Quarles	Elizibeth Howell	Tanner Bain	John Krupla	Amber Sykes
Alcibiades Martinez	Traci Johnson	Teresa Stroud	Kristi Brickles	Joshua Warnock
Anastasia Bennett	Karla Merz	Shawn Arrington	Gregory Stump	Heidi Southworth
Thomas Kent	Linzy Turley	Billie Jo Leslie	Shannon Lemmings	Marcelina Stoffer
Aaliyah Niciu	Stephany Matheny	Crystal Brown	Cindy Bakenhester	Matthew Perigo
Mikayla Burke	Zachary Johnson	Jesse Miller	April Uhl	Chemica Miles
Corbyn Guisinger	Natasha Cain	Rodney List	Justin Jester	Jay Smalley
Brooklyn Dudley	Chad Hice	Bruce Jones	Taylor Klontz	Homer Holsted
Twila Jones	Jeanie Todd	Douglas Krieger	Amanda Teeters	Heidi Walker
Samantha Reed	Summer Ruth	Mathew Sturgeon	Shannon Gilkerson	Kathy Kellough
Tina Williams	Seth Collins	Katie Hatfield	Bethany Woolever	John Robb
Claudia González	Jane McLister	Chris Justice	Brad Vansickle	Kyle Bevan
Tiffany Miller	Amy Walton	Alexander Gonzalez	Tanya Cook	Adam Buckner
Davon McCullough	Marjorie Brown	Travis Streitenberger	Amika Stubbs	Syron Johnson
Blaine Rowlett	Jessica Leaverton	Madison Davis	Nancy Brown	Mark Grooms
Maliki Wagner	Jalen Johnson	Tyler Belcher	Robert Cook	Justin Hardeman
Juan Calderón	Melissa Born	Jennifer Pendergraft	Courtney Daugherty	William Turner
Destiny Thomas	Anna Johnson	Justin Brown	Shelby Burns	John McNamara
Cassandra Wilt	Ryan Robison	Kali Hatfield	Joseph Yoho	Kevin Umbarger
Dennis Bryan III	Mardy Smith	Alisha Brown	Amy Whitworth	Pavel Duzhiy
Maria Vanessa Cuadros Moreira	Nathan Molloy	Kathy Clark	Henry Post	Michael Southward
Eli Combs	Simon Contreras	Kristy Rowland	Sean Larkins	
Lindsey Highley	Sarah Kelley	Melissa Wysong	Mykel Hamilton	
Charlene Smith	Michael Johnson	Jennifer Bryant	Darrin Sparks	
Jordan Cordell	Darren Abel	Amber Harmon	Zane Brown	

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549
FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended March 31, 2024

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from_____to_____

Commission File Number: 1-13252

McKESSON

McKESSON CORPORATION

(Exact name of registrant as specified in its charter)

Delaware	**94-3207296**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

6555 State Hwy 161,
Irving, TX 75039

(Address of principal executive offices, including zip code)

(972) 446-4800

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

(Title of each class)	*(Trading Symbol)*	*(Name of each exchange on which registered)*
Common stock, $0.01 par value	MCK	New York Stock Exchange
1.500% Notes due 2025	MCK25	New York Stock Exchange
1.625% Notes due 2026	MCK26	New York Stock Exchange
3.125% Notes due 2029	MCK29	New York Stock Exchange

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer	☒	Accelerated filer	☐
Non-accelerated filer	☐	Smaller reporting company	☐
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant, computed by reference to the closing price as of the last business day of the registrant's most recently completed second fiscal quarter, September 30, 2023, was approximately $57.8 billion.

Number of shares of common stock outstanding on April 30, 2024: 129,985,514

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Proxy Statement for its calendar year 2024 Annual Meeting of Shareholders are incorporated by reference into Part III of this Annual Report on Form 10-K.

McKESSON CORPORATION

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McKESSON CORPORATION

PART I

Item 1. Business.

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General

McKesson Corporation together with its subsidiaries (collectively, the "Company," "McKesson," "we," "our," or "us" and other similar pronouns), which traces its business roots to 1833, is a diversified healthcare services leader dedicated to advancing health outcomes for patients everywhere. Our teams partner with biopharma companies, care providers, pharmacies, manufacturers, governments, and others to deliver insights, products, and services to help make quality care more accessible and affordable.

The Company's fiscal year begins on April 1 and ends on March 31. Unless otherwise noted, all references in this document to a particular year refers to the Company's fiscal year. The Company was incorporated on July 7, 1994 in the State of Delaware.

Our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (the "Exchange Act"), are available free of charge on the Company's website (www.mckesson.com under the "Investors — Financials — SEC Filings" caption) as soon as reasonably practicable after such material is electronically filed with, or furnished to, the Securities and Exchange Commission ("SEC"). The content on any website referred to in this Annual Report on Form 10-K ("Annual Report") is not incorporated by reference into this report, unless expressly noted otherwise. The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The address of the website is www.sec.gov.

Business Segments

The Company operates its business in four reportable segments: U.S. Pharmaceutical, Prescription Technology Solutions ("RxTS"), Medical-Surgical Solutions, and International.

Our U.S. Pharmaceutical segment distributes branded, generic, specialty, biosimilar and over-the-counter ("OTC") pharmaceutical drugs, and other healthcare-related products in the United States ("U.S."). This segment provides practice management, technology, clinical support, and business solutions to community-based oncology and other specialty practices. In addition, the segment sells financial, operational, and clinical solutions to pharmacies (retail, hospital, alternate sites) and provides consulting, outsourcing, technological, and other services.

Our Prescription Technology Solutions segment helps solve medication access, affordability, and adherence challenges for patients by working across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma. RxTS serves our biopharma and life sciences partners, delivering innovative solutions that help people get the medicine they need to live healthier lives. RxTS also offers prescription price transparency, benefit insight, dispensing support services, as well as third-party logistics and wholesale distribution support designed to benefit stakeholders.

Our Medical-Surgical Solutions segment provides medical-surgical supply distribution, logistics, and other services to healthcare providers, including physician offices, surgery centers, nursing homes, hospital reference labs, and home health care agencies. We offer more than 245,000 national brand medical-surgical products as well as McKesson's own line of high-quality products through a network of distribution centers in the U.S.

Our International segment provides distribution and services to wholesale, institutional, and retail customers in Canada and Europe where we own, partner, or franchise with retail pharmacies, and support better, safer patient care by delivering vital medicines, supplies, and information technology solutions.

U.S. Pharmaceutical Segment:

Our U.S. Pharmaceutical segment provides distribution and logistics services for branded, generic, specialty, biosimilar, and OTC pharmaceutical drugs along with other healthcare-related products to customers. This business provides solutions and services to pharmacies, hospitals, oncology and other specialty practices, pharmaceutical manufacturers, biopharma partners, physicians, payors, and patients throughout the U.S. We also source generic pharmaceutical drugs through our ClarusONE Sourcing Services LLP joint venture with Walmart Inc. ("ClarusONE").

Our U.S. Pharmaceutical segment operates and serves customers through a network of 27 distribution centers in the U.S., including two strategic redistribution centers. We invest in technology and other systems at all of our distribution centers to enhance safety, reliability, and product availability. For example, we offer McKesson Connect℠, an internet-based ordering system that provides item look-up and real-time inventory availability as well as ordering, purchasing, third-party reconciliation, and account management functionality. We make extensive use of technology as an enabler to ensure customers have the right products at the right time in the right place.

To maximize distribution efficiency and effectiveness, we follow the Six Sigma methodology, which is an analytical approach that emphasizes setting high-quality objectives, collecting data, and analyzing results to a fine degree in order to improve processes, reduce costs, and enhance service accuracy and safety. We provide solutions to our customers including supply management technology, world-class marketing programs, managed care, repackaging products, and services to help them meet their business and quality goals. We continue to implement information systems to help achieve greater consistency and accuracy both internally and for our customers, as well as make investments to increase capacity and automation.

We have four primary customer pharmaceutical distribution channels: (i) retail national accounts, which include national and regional retail chains, food and drug combinations, mail order pharmacies, and mass merchandisers, (ii) community pharmacies and health (formerly described as independent, small, and medium chain retail pharmacies), (iii) institutional healthcare providers such as hospitals, health systems, integrated delivery networks, and long-term care providers, and (iv) oncology, biopharma, and other specialty partners.

Retail National Accounts: We provide business solutions that help our retail national account customers increase revenues and profitability. Solutions include:

- Central Fill℠ – Prescription refill service that enables pharmacies to more quickly refill prescriptions remotely, more accurately, and at a lower cost, while reducing inventory levels and improving customer service.
- Strategic Redistribution Centers – Two facilities totaling over 740,000 square feet that offer access to inventory for single source warehouse purchasing, including pharmaceuticals and biologics. These distribution centers also provide the foundation for a two-tiered distribution network that supports best-in-class direct store delivery.
- McKesson SynerGx® – Generic pharmaceutical purchasing program and inventory management that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping.
- Inventory Management – An integrated solution comprised of forecasting software and automated replenishment technologies that reduce inventory-carrying costs.
- ExpressRx Track™ – Pharmacy automation solution featuring state-of-the-art robotics, upgraded imaging, and expanded vial capabilities, and industry-leading speed and accuracy in a small footprint.

Community Pharmacy and Health: We strengthen the overall health of community pharmacies and elevate the role they play in people's lives. We accomplish this by providing supply chain excellence, pharmacy and patient solutions, as well as supporting independent pharmacies through industry and legislative advocacy. Our pharmacy and patient solutions include:

- Health Mart® – A national network of approximately 4,500 independently-owned pharmacies and one of the industry's most comprehensive pharmacy franchise programs. Health Mart provides franchisees support for operational excellence, managed care contracting, marketing, merchandising solutions, and clinical programs to enhance patient care.
- Health Mart Atlas® – Comprehensive managed care services that help community pharmacies save time, access competitive reimbursement rates, and improve cash flow.
- McKesson Reimbursement Advantage℠ ("MRA") – MRA is one of the industry's most comprehensive reimbursement optimization packages, comprising financial services (automated claim resubmission), analytic services, and customer care.
- McKesson Provider Pay® – Provider Pay is an automated reconciliation and payment management solution designed to maximize third-party cash flow and pursue unpaid claims.
- McKesson OneStop Generics® – Generic pharmaceutical purchasing program that helps pharmacies maximize their cost savings with a broad selection of generic drugs, competitive pricing, and one-stop shopping.
- Pinpoint Community Solutions – McKesson's perpetual inventory management system targeted to independent pharmacy owners with five or fewer stores. The solution provides customers the opportunity to improve cash flow and increase efficiency with inventory visibility to help maximize operational performance.
- FrontEdge™ – Strategic planning, merchandising, and price maintenance program that helps community pharmacies maximize store profitability.
- McKesson RxOwnership Program – A confidential, no-fee resource for pharmacists and pharmacy owners interested in buying, starting, or selling an independent pharmacy, regardless of their pharmacy affiliation.

Institutional Healthcare Providers: At McKesson, we are relentless in our pursuit of opportunities to achieve operational efficiency, reduce waste, and improve the financial performance of our customers so they can achieve more of their goals today and into the future. Solutions include:

- RxO Advisory Services – A suite of supply chain management, pharmacy optimization, and 340B program advisory services driven by data and analytics.

- McKesson Plasma and Biologics – Specialty and plasma drug distributor that leads in market exclusive drug access; partner to health systems customers in navigating the complexities of limited distribution drug; and optimization of McKesson Distribution benefits.
- Outpatient and Specialty Pharmacy – A portfolio of services and solutions customized to each customer's business and clinical strategy.
- Contracting and Contract/Purchasing Optimization – Solutions across generics, specialty, branded products, biosimilars, and 340B products, for inpatient and outpatient settings.
- Supply Assurance – Solutions and strategies to enhance product availability and proactively manage inventory of critical items.
- Patient Assistance Solutions – Technologies and services that enable health systems and providers to better financially support their patients and community benefit programs.

The U.S. Pharmaceutical segment also offers solutions which enable its customers to drive greater efficiencies in their day-to-day operations, effectively managing their inventories and complying with complex government regulations. Solutions include McKesson Pharmacy Systems, MacroHelix, and Supply Logix, all of which provide innovative software technology and services that support retail pharmacies and hospitals.

Oncology, Biopharma, and Other Specialty Partners:

The U.S. Pharmaceutical segment provides a range of solutions to oncology and other specialty practices and offers community specialists (oncologists, rheumatologists, ophthalmologists, urologists, neurologists, and other specialists) an extensive set of customizable solutions and services designed to strengthen core practice operations, enhance value-based care delivery, and expand their service offering to patients. Community-based physicians in this business have broad flexibility and discretion to select the products and commitment levels that best meet their practice needs. Services in provider solutions include specialty drug distribution, group purchasing organizations ("GPO") like Onmark®, technology solutions, practice consulting services, and vaccine distribution, including our exclusive distributor relationship with the Centers for Disease Control and Prevention's ("CDC") Vaccines for Children program. Additionally, McKesson has proudly supported the U.S. efforts to fight the pandemic caused by the SARS-CoV-2 coronavirus ("COVID-19") by distributing certain COVID-19 vaccines since December 2020 at the direction of the U.S. government. This program concluded in the second quarter of fiscal 2024, at which point we began transitioning the distribution of COVID-19 vaccines commercially through our customer pharmaceutical distribution channels.

This business provides a variety of solutions, including practice operations, healthcare information technology, revenue cycle management and managed care contracting solutions, evidence-based guidelines, and quality measurements to support The U.S. Oncology Network ("USON"), one of the nation's largest networks of physician-led, integrated, community-based oncology practices dedicated to advancing high-quality, evidence-based cancer care. SCRI Oncology, LLC, an oncology research business in which we own a 51% controlling interest, is one of the nation's largest research networks and specializes in enhancing clinical trial access and availability across the country.

This segment includes Ontada®, McKesson's oncology technology and insights business providing software to support the clinical, financial, and operational needs of our oncology practice customers. Ontada also partners with oncology providers and biopharma partners to perform real-world evidence studies, retrospective research, and to provide clinical data insights, advisory solutions and education opportunities.

When we discuss specialty products or services, we consider the following factors: diseases requiring complex treatment regimens such as cancer and rheumatoid arthritis; plasma and biologics products; ongoing clinical monitoring requirements, high-cost, special handling, storage, and delivery requirements and, in some cases, exclusive distribution arrangements. Our use of the term "specialty" may not be comparable to that used by other industry participants, including our competitors.

Prescription Technology Solutions Segment:

Our Prescription Technology Solutions segment works across healthcare to connect patients, pharmacies, providers, pharmacy benefit managers, health plans, and biopharma to deliver medication access solutions that support patients from first prescription fill to ongoing therapy, regardless of their insurance coverage. RxTS has connections with most electronic health record systems, over 50,000 pharmacies, approximately 950,000 providers, most pharmacy benefit managers and health plans, and has supported over 650 biopharma brands representing most therapeutic areas. Through its industry connections and ability to navigate the healthcare ecosystem, RxTS offers innovative solutions created to benefit healthcare stakeholders. Its comprehensive solution suites span across the entire patient journey, including medication access and affordability, prescription decision support, prescription price transparency, benefit insight and dispensing support services, as well as third-party logistics and wholesale distribution support, to help increase speed to therapy, reduce prescription abandonment, and support improved health outcomes for the patient. In the past year, RxTS helped patients save more than $8.8 billion on brand and specialty medications, helped to prevent an estimated 10.7 million prescriptions from being abandoned due to affordability challenges, and helped patients access their medicine more than 94 million times.

Medical-Surgical Solutions Segment:

Our Medical-Surgical Solutions segment delivers medical-supply distribution, logistics, biomedical maintenance, and other services to healthcare providers across the alternate-site spectrum. Our more than 285,000 customers include physician offices, surgery centers, post-acute care facilities, hospital reference labs, and home health agencies. We partner with manufacturers and channel partners to support our key target end-markets, including primary care, extended care, government, and other markets. We distribute medical-surgical supplies (such as gloves, needles, syringes, and wound care products), infusion pumps, laboratory equipment, and pharmaceuticals. Through a network of distribution centers in the U.S., we offer more than 245,000 products from national brand manufacturers and McKesson's own brand of high-quality products. Through the right mix of products and services, we help improve efficiencies, profitability, and compliance. We also never lose focus on helping customers improve patient and business outcomes. We develop customized plans to address the product, operational, and clinical support needs of our customers, including inventory management, reducing administrative burdens, and training and educating clinical staff. We deliver for our customers, so they can deliver and care for their patients.

International Segment:

Our International segment provides distribution and services to wholesale, institutional, and retail customers in Canada and Europe where we own, partner, or franchise with retail pharmacies. Our operations in Canada also support better, safer patient care by delivering vital medicines, supplies, and information technology solutions to customers, and through several retail health and wellness brands, across Canada.

McKesson Canada is one of the largest pharmaceutical wholesale and retail distributors in Canada. The wholesale business delivers products to retail pharmacies, hospitals, long-term care centers, clinics and institutions in Canada through a national network of distribution centers and provides logistics and distribution services for manufacturers.

Beyond wholesale pharmaceutical logistics and distribution, McKesson Canada provides automation and technology solutions to its retail and hospital customers. Additionally, McKesson Canada provides comprehensive specialty health services to Canadians and provides biopharma services to manufacturers, including a national network of specialty pharmacies, personalized patient care and support programs, and INVIVA, Canada's first and largest accredited network of private infusion clinics. McKesson Canada also owns and operates PDCI, Canada's leading market access consultancy, supporting manufacturers as they introduce new products into the Canadian market.

The Canada retail business includes approximately 2,700 banner pharmacies under the IDA®, Guardian®, The Medicine Shoppe®, Remedy'sRx®, Proxim®, and Uniprix® banners, and approximately 400 owned pharmacies under the Rexall™ brand where we provide patients with greater choice and access, integrated pharmacy care and industry-leading service levels. McKesson Canada also owns and operates Well.ca™, a leading Canadian online health and wellness retailer.

In July 2021, we announced our intention to exit our businesses in Europe. We divested the majority of our European businesses during fiscal 2022 and fiscal 2023. Our remaining operations in Europe provide distribution and services to wholesale and retail customers in Norway where we own, partner, or franchise with retail pharmacies. We continue to evaluate suitable exit alternatives for our retail and distribution businesses in Norway. Refer to Financial Note 2, "Business Acquisitions and Divestitures," to the consolidated financial statements included in this Annual Report for additional information on our European divestitures.

Investments, Restructuring, Business Combinations, and Divestitures

We invest in new and existing distribution centers to increase scale and capacity, improve efficiency through automation and technology, and enhance regulatory compliance capabilities. Additionally, we invest in data and analytics to support our growth priorities, including artificial intelligence ("AI"). We are in the early stages of exploring potential AI capabilities and related data and analytics across our enterprise to improve productivity and efficiency, as well as enhance our products and services to better support patients, employees, and customers.

We have undertaken additional strategic initiatives in recent years designed to increase operational efficiencies, focus on our core healthcare businesses, execute our business strategy, and enhance our competitive position. These initiatives are detailed in Financial Note 2, "Business Acquisitions and Divestitures," and Financial Note 3, "Restructuring, Impairment, and Related Charges, Net," to the consolidated financial statements included in this Annual Report.

Competition

We operate in highly competitive environments in North America and Norway. In recent years, the healthcare industry has been subject to increasing consolidation. In the pharmaceutical distribution environment in which our U.S. Pharmaceutical and International segments operate, we face strong competition from international, national, regional, and local full-line, short-line, and specialty distributors, service merchandisers, self-warehousing chain drug stores, manufacturers engaged in direct distribution, third-party logistics companies, and large payer organizations. We consider our largest competitors in distribution, wholesaling, and logistics to be Cencora, Inc. and Cardinal Health, Inc. Our retail businesses, which primarily operate in our International segment, face competition from various global, national, regional, and local retailers, including chain and independent pharmacies.

Our RxTS business experiences substantial competition from many companies, including other biopharma services companies, software services firms, consulting firms, shared service vendors, and internet-based companies with technology applicable to the healthcare industry. Competition in this business varies in size from large to small companies, in geographical coverage, and in scope and breadth of products and services offered.

Our Medical-Surgical Solutions segment provides medical-surgical supply distribution, logistics, and other services to healthcare providers, including physician offices, surgery centers, nursing homes, hospital reference labs, home health care agencies, and other alternative sites with competition from a wide range of national and regional medical supply and equipment distributors throughout the U.S.

In addition, we compete with other service providers and healthcare manufacturers, as well as other potential customers of our businesses, which may from time to time decide to develop, for their own internal needs, supply management capabilities that might otherwise be provided by our businesses. We believe that our scale and diversity of product and service offerings are our primary competitive advantages. In all areas, key competitive factors include price, quality of service, breadth of product lines, innovation, adoption of new and evolving technologies, and, in some cases, convenience to the customer.

Patents, Trademarks, Copyrights, and Licenses

McKesson and its subsidiaries hold patents, copyrights, trademarks, and trade secrets related to McKesson products and services. We pursue patent protection for our innovations and obtain copyright protection for our original works of authorship when such protection is advantageous. Through these efforts, we have developed a portfolio of patents and copyrights in the U.S. and worldwide. In addition, we have registered or applied to register certain trademarks and service marks in the U.S. and in foreign countries.

We believe that, in the aggregate, McKesson's confidential information, patents, copyrights, trademarks, and intellectual property licenses are important to its operations and market position, but we do not consider any of our businesses to be dependent upon any one patent, copyright, trademark, or trade secret, or any family or families of the same. We cannot guarantee that our intellectual property portfolio will be sufficient to deter misappropriation, theft, or misuse of our technology, nor that we can successfully enjoin infringers. We periodically receive notices alleging that our products or services infringe on third-party patents and other intellectual property rights. These claims may result in McKesson entering settlement agreements, paying damages, discontinuing use or sale of accused products, or ceasing other activities. While the outcome of any litigation or dispute is inherently uncertain, we do not believe that the resolution of any of these infringement notices would have a material adverse impact on our results of operations.

We hold inbound licenses for certain intellectual property that is used internally, and in some cases, utilized in McKesson's products or services. While in the future it may be necessary to seek or renew licenses relating to various aspects of our products and services, we believe, based upon past experience and industry practice, such licenses generally can be obtained on commercially reasonable terms. We believe our operations as well as our products and services are not materially dependent on any single license or other agreement with any third party.

Human Capital

Everything we do at McKesson begins with our employees, who bring our mission and purpose to life every day. As of March 31, 2024, we had approximately 51,000 employees worldwide, which includes 6,000 part-time employees. We had approximately 35,000 employees in the U.S., 13,000 employees in Canada, and 3,000 employees in Europe. Our employees in Europe primarily support our operations in Norway. We also supplement our work-force with contractors and/or consultants for certain business projects, processes, and/or operations as demand requires.

Inclusion and Belonging: As a company, we believe building a more inclusive future is everyone's responsibility. We build successful teams by fostering a culture of inclusion and belonging and ensuring we attract and retain the best talent at all levels of our organization. To help strengthen our company, we offer various learning opportunities, such as our company-wide inclusion curriculum and additional initiatives to recognize, value and leverage the diversity of our workforce, enhance the inclusiveness of our culture and candidly discuss important topics happening in the world around us. We also offer employees the opportunity to join employee resource groups ("ERGs"), which are voluntary, employee-led, company-sponsored networks that aim to make a positive impact on our employees' lives. Our ERGs focus on helping employees make authentic connections, share and affirm their identities and perspectives, showcase leadership skills and find ways to nurture and support belonging and empowerment. Our 11 ERGs provide a sense of community and insights into the perspectives and experiences across different ethnicities, genders, generations, abilities, and/or military/veteran status, as well as supporting members and allies of the LGBTQIA+ community.

At March 31, 2024, women and people of color represented the following:

	McKesson Overall	McKesson Leadership [2]
Metric [1]		
Women	62 %	43 %
People of Color [3][4]	49 %	28 %

(1) The data for our metrics is derived from our voluntary self-identification process as of March 31, 2024 and therefore represents our best estimate at this time.

(2) Represents our leadership at the vice president level and above.

(3) Represents U.S. employees only because the data for Canada and Europe is not available.

(4) People of Color includes the following self-identification categories: American Indian or Alaska Native, Asian, Black or African American, Hispanic or Latino, Native Hawaiian or Other Pacific Islander, or Two or More Races.

Culture and Leadership: One of McKesson's defining characteristics is our strong culture. Every day, we bring our employee value proposition to life by taking pride in fostering a sense of belonging, finding meaning in our work, and caring for each other, our customers, and all those who depend on us. More than two decades ago, our leadership team created a foundational set of values grounded in the belief that the way we do business is just as important as the business itself. Today, our I²CARE values (Integrity, Inclusion, Customer-First, Accountability, Respect, Excellence) and ILEAD leadership behaviors (Inspire, Leverage, Execute, Advance, Develop) continue to stand the test of time and remain at the core of our daily actions – from how we interact with each other and our customers, to how we make decisions, both big and small. As we work to shape the future of health and embrace the ongoing evolution of our company, we will continue to utilize our strengths to drive lasting change while remaining deeply rooted in our purpose of Advancing Health Outcomes for All®.

Investment in Employees: As an industry leader, we are committed to investing in our people, so that they, in turn, can focus on making better health possible for people everywhere. We are committed to nurturing a culture of wellbeing that empowers our employees to be at their best, including offering health and wellness benefits to advance their physical, mental, and social well-being, savings programs to help prepare them for retirement and flexible work arrangements, among other offerings, when possible. To support growth and career development, we offer employees regular training, coaching, and 360-degree assessments, and financial assistance programs for higher education opportunities.

To provide compensation that is focused on attracting and retaining talent with the skills and experience necessary for a specific role, our compensation program is built on a set of quantifiable factors defined by our guiding principles of internal equity, market competitiveness and pay for performance. We operate in several countries and our benefits vary accordingly. Our compensation philosophy is rooted in a commitment to our people by offering a fair and transparent program that regularly assesses the competitive job market based on geography and cost of labor. We use external resources to provide competitive benchmarking analyses against other companies and set pay ranges around the median of the competitive market. As part of our commitment to pay transparency, the majority of our employees can view the competitive base pay range for their roles as well as for internal and external job postings. Also, the pay range for external job postings is included on McKesson's website (www.mckesson.com under the "Careers" caption).

As we strive to become the best place to work in healthcare, we actively seek employee feedback through annual and mid-year employee opinion surveys, which assesses our employees' levels of engagement, commitment and overall satisfaction using industry benchmarks, and then design action plans to improve those metrics. We also seek feedback on our people leaders through our annual manager quality survey, which is an opportunity for employees to help their managers grow professionally and build valuable leadership skills that help to promote a positive and productive workplace.

Health and Safety: Our security and safety teams employ systems designed to continually monitor our facilities and work environment to help identify and prevent or mitigate potential risks. This includes having procedures in place and investing in equipment for both physical and electronic security. We routinely assess facilities to closely monitor adherence to established security and safety standards. If we identify a vulnerability, it is documented, and the facility prepares an action plan. Our employees receive specialized training related to their role, work setting, and equipment used in their work environment. As our processes evolve, we update relevant safety training modules, which may include new employee training programs.

Government Regulation

We operate in many highly regulated industries and are subject to oversight by various federal, state, and local governmental entities in the U.S. and elsewhere. We incur significant expense and make large capital expenditures and investments to enable us to comply with regulations and guidance promulgated by governmental entities. See "Risk Factors" in Item 1A of Part I below for information regarding material risks associated with our compliance with governmental regulations.

Controlled Substances: We are subject to the operating and security standards of the U.S. Drug Enforcement Administration ("DEA"), the U.S. Food and Drug Administration ("FDA"), the U.S. Department of Health and Human Services ("HHS"), the Centers for Medicare & Medicaid Services ("CMS"), various state boards of pharmacy, state health departments, and comparable agencies in the U.S. and other countries. Certain of our businesses may be required to register for permits and/or licenses with government agencies, depending upon the type of operations and location of product development, manufacture, distribution, and sale. For example, we are required to hold valid DEA and state-level registrations and licenses, meet various security and operating standards, and comply with the Controlled Substances Act and its accompanying regulations governing the sale, marketing, packaging, holding, distribution, and disposal of controlled substances. We maintain extensive controlled substance monitoring and reporting programs at considerable expense in order to help us meet those standards.

Government Contracts: Our contracts with government entities typically are subject to procurement laws that include socio-economic, employment practices, environmental protection, recordkeeping and accounting, and other requirements. These statutory and regulatory requirements complicate our business and increase our compliance burden. We are subject to audits, investigations, and oversight proceedings about our compliance with contractual and legal requirements.

Federal, state, and local governmental entities in the U.S. and elsewhere continue to strengthen their position and scrutiny of practices that may indicate fraud, waste, and abuse affecting government healthcare programs such as Medicare and Medicaid. Our relationships with pharmaceutical and medical surgical product manufacturers, healthcare providers, and other companies and individuals, as well as our provision of products and services to government entities, subject our business to statutes, regulations, and government guidance that are intended to prevent fraud and abuse. Among other things, those laws: (1) prohibit persons from soliciting, offering, receiving, or paying any remuneration in order to induce the referral of an individual for, or to induce the ordering or purchasing of, items or services that are in any way paid for by Medicare, Medicaid, or other government healthcare programs; (2) impose many restrictions upon referring physicians and providers of designated health services under Medicare and Medicaid programs; and (3) prohibit the knowing submission of a false or fraudulent claim for payment to, and knowing retention of an overpayment by, a federal healthcare program such as Medicare and Medicaid. Many of these laws are vague or indefinite and are often subject to varied and evolving interpretations by courts, regulators, and enforcing agencies and, as such, may be interpreted or applied by a prosecutorial, regulatory, or judicial authority in a manner that could require us to make changes in our operations at added expense.

Healthcare Program Regulation: In the U.S., the Patient Protection and Affordable Care Act ("ACA") significantly expanded health insurance coverage to uninsured Americans and changed the way healthcare is financed by both governmental and private payors. The implementation of the Inflation Reduction Act of 2022 (the "IRA") has begun to change benefit design and how Medicare pays for drugs, which are all intended to reduce the price of drugs. Three central features of the IRA have authorized the government to negotiate drug prices for certain Parts B and D drugs over time, establish an inflation rebate program, and cap patient cost sharing under Medicare Part D.

Provincial governments in Canada that provide partial funding for the purchase of pharmaceuticals and independently regulate the sale and reimbursement of drugs have sought to reduce the costs of publicly funded health programs. For example, provincial governments have taken steps to reduce consumer prices for generic pharmaceuticals and, in some provinces, change professional allowances paid to pharmacists by generic drug manufacturers.

McKesson continues to advocate for policies that would improve drug cost transparency under a patient's drug plan to better inform prescribing decisions, and also address access to care, affordability, and treatment regimen adherence, all designed to improve clinical outcomes and reduce the health spending burden.

FDA Regulation and Supply Chain Integrity: In the U.S., the FDA is the principal federal authority that regulates the safety, efficacy, quality, testing, premarket approval, manufacture, labeling, storage, distribution, and post-market surveillance of healthcare products, such as drugs and medical devices, foods, and cosmetics.

Certain federal and state laws regulate the pharmaceutical drug supply chain in order to prevent the distribution of counterfeit, stolen, contaminated, or otherwise harmful prescription drugs in interstate commerce. At the federal level, the Drug Supply Chain Security Act ("DSCSA") requires standardized, unit-level traceability of pharmaceutical products along the entire drug supply chain and requires all trading partners to cooperate in an electronic, interoperable prescription drug traceability system. In August 2023, the FDA established a one-year stabilization period to certain DSCSA requirements that allows trading partners to implement, troubleshoot, and mature their electronic interoperable systems until the stabilization period ends on November 27, 2024. The FDA has also issued a proposed rule that would establish national standards for the licensure of wholesale drug distributors and third-party logistic providers and other requirements applicable to these entities. These federal and state regulatory requirements increase our compliance burden and our distribution costs.

Cybersecurity, Data Security, and Privacy: We are subject to many cybersecurity, privacy, and data protection laws that change frequently and have requirements that vary from jurisdiction to jurisdiction. Our efforts to comply with these laws complicates our operations and adds to our costs. We are subject to significant compliance obligations under privacy laws such as the Health Insurance Portability and Accountability Act of 1996 ("HIPAA"), the General Data Protection Regulation ("GDPR") in the European Union, the Personal Information Protection and Electronic Documents Act ("PIPEDA") in Canada, and an expanding list of comprehensive state privacy laws in the U.S. Some privacy laws prohibit the transfer of personal information to certain other jurisdictions or otherwise limit our use of data. Many of these laws also require us to provide access or other data rights (modification, deletion, portability, etc.) to consumers' and patients' individual personal data records within specified periods of time. Cybersecurity laws such as the federal Cyber Incident Reporting for Critical Infrastructure Act of 2022, proposed Federal Acquisition Regulations, and recent amendments to SEC reporting requirements may require us to provide notifications of certain cybersecurity incidents before our investigations are complete and within short timeframes. Regulations and guidance targeting critical infrastructure entities, including McKesson, continue to be a focus of regulators. We are subject to privacy and data protection compliance audits or investigations by various government agencies. The introduction of new technologies, such as AI, may result in additional regulation.

Environmental Regulation: We are subject to many environmental and hazardous materials regulations, including those relating to radiation-emitting equipment operated at U.S. Oncology Network practices. Additionally, our operations are subject to regulations under various federal, state, local and foreign laws concerning the environment, including laws addressing the discharge of pollutants into the air and water, the management and disposal of hazardous substances and wastes, and the cleanup of contaminated sites.

We sold our chemical distribution operations in 1987 and retained responsibility for certain environmental obligations. Agreements with the U.S. Environmental Protection Agency and certain states have required and may require environmental assessments and cleanups at several closed sites. These matters are described further in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report.

Climate Change Regulation: Governments in the U.S. and abroad have adopted or are considering new or expanded policies and laws to address climate change. Such policies and laws may require or necessitate reductions of greenhouse gas ("GHG") emissions, mandates that companies implement processes and controls to monitor and disclose climate-related matters, additional taxes or offset charges on specified energy sources, and other requirements. Compliance with climate-related policies and laws may be further complicated by disparate regulatory approaches in various jurisdictions. Methodologies for reporting climate-related information may change and previously reported information may be retroactively adjusted, if required. New or expanded climate-related policies and laws could impose costs on us, including capital expenditures to develop data gathering and reporting systems, costly third-party attestations, and additional GHG reduction measures. Until the timing and extent of climate-related policies and laws are clarified, including due to legal challenges, we cannot predict their potential effect on our capital expenditures, results of operations, or competitive position.

Other Information about the Business

Customers: During fiscal 2024, sales to our ten largest customers, including group purchasing organizations ("GPOs") accounted for approximately 69% of our total consolidated revenues. Sales to our largest customer, CVS Health Corporation ("CVS"), accounted for approximately 28% of our total consolidated revenues in fiscal 2024. In fiscal 2023, we extended our pharmaceutical distribution partnership with CVS to June 2027. Our ten largest customers comprised approximately 43%, and CVS was approximately 24%, of our total trade accounts receivable at March 31, 2024. We also have agreements with GPOs, each of which functions as a purchasing agent on behalf of member hospitals, pharmacies, and other healthcare providers, as well as with government entities and agencies. The accounts receivable balances are with individual members of the GPOs, and therefore no significant concentration of credit risk exists. Substantially all of these revenues and accounts receivable are included in our U.S. Pharmaceutical segment.

Suppliers: We obtain pharmaceutical and other products from manufacturers and our largest supplier accounted for 12% of our total purchases in fiscal 2024. The loss of a supplier could adversely affect our business if alternate sources of supply are unavailable. We believe that our relationships with our suppliers are generally sound. The ten largest suppliers in fiscal 2024 accounted for approximately 67% of our total purchases.

Some of our distribution arrangements with manufacturers provide us consideration based on a percentage of our purchases. In addition, we have certain distribution arrangements with pharmaceutical manufacturers that include an inflation-based consideration component whereby we benefit when the manufacturers increase their prices as we sell our existing inventory at the new higher prices. For these manufacturers, a reduction in the frequency and magnitude of price increases, as well as restrictions in the amount of inventory available to us, could have an adverse impact on our gross profit margin.

Research and Development: Research and development expenses were $77 million, $89 million, and $70 million for the years ended March 31, 2024, 2023, and 2022, respectively.

Financial Information About Foreign and Domestic Operations: Certain financial information relating to foreign and domestic operations is discussed in Financial Note 20, "Segments of Business," to the consolidated financial statements included in this Annual Report as well as in "Foreign Operations" in Item 7 of Part II of this Annual Report. See "Risk Factors" in Item 1A of Part I below for information regarding risks associated with our foreign operations.

Forward-Looking Statements

This Annual Report, including "Management's Discussion and Analysis of Financial Condition and Results of Operations" in Item 7 of Part II of this report and the "Risk Factors" in Item 1A of Part I of this report, contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933 ("Securities Act") and Section 21E of the Exchange Act. Forward-looking statements may be identified by their use of terminology such as "believes," "expects," "anticipates," "may," "will," "should," "seeks," "approximately," "intends," "projects," "plans," "estimates," "targets," or the negative of these words or other comparable terminology. The discussion of financial trends, strategy, plans, assumptions, expectations, or intentions may also include forward-looking statements. Forward-looking statements involve risks and uncertainties that could cause actual results to differ materially from those projected, anticipated, or implied. Although it is not possible to predict or identify all such risks and uncertainties, they include, but are not limited to, the factors discussed in Item 1A of Part I of this report under "Risk Factors" and in our publicly available SEC filings and press releases. Readers are cautioned not to place undue reliance on forward-looking statements, which speak only as of the date such statements were first made. Except to the extent required by federal securities laws, we undertake no obligation to publicly release the result of any revisions to any forward-looking statements to reflect events or circumstances after the date the statements are made, or to reflect the occurrence of unanticipated events.

Available Information

We routinely post on our company website, and via our social media channels, information that may be material to investors, including details and updates to information disclosed elsewhere, which may include business developments, earnings and financial performance, sustainability matters, and materials for presentations to investors and financial analysts. Investors are encouraged to monitor our website www.mckesson.com. Interested parties can sign up on our website, including our Investor Relations site, to receive automated e-mail alerts, such as via RSS newsfeed, when we post certain information. Interested parties can also follow our social media feed @McKesson on X, formerly known as Twitter. The content on any website or social media channel is not incorporated by reference into this report, unless expressly noted otherwise.

Item 1A. Risk Factors.

INDEX TO RISK FACTORS

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Litigation and Regulatory Risks	14
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General Risks	24

The discussion below identifies certain representative risks that might cause our actual business results to materially differ from our estimates. It is not practical to identify or describe all risks and uncertainties that might materially impact our business operations, reputation, financial position, or results of operations. Our business could be materially affected by risks that we have not yet identified or that we currently consider to be immaterial. This is not a complete discussion of all potential risks and uncertainties.

Litigation and Regulatory Risks

We experience costly and disruptive legal disputes.

We are routinely named as a defendant in litigation or regulatory proceedings and other legal disputes, which may include asserted class action litigation, such as those described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements included in this Annual Report. Regulatory proceedings involve allegations such as false claims, healthcare fraud and abuse, and antitrust violations. Civil litigation proceedings involve commercial, employment, environmental, intellectual property, tort, and other claims. Despite valid defenses that we assert, legal disputes are often costly, time-consuming, distracting to management, and disruptive to normal business operations. The uncertainty and expense associated with unresolved legal disputes might harm our business and reputation even if the matter ultimately is favorably resolved. The outcome of legal disputes is difficult to predict, and outcomes may occur that we believe are not justified by the evidence or existing law. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Accordingly, legal disputes might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We experience losses not covered by insurance or indemnification.

Our business exposes us to risks that are inherent in the distribution, manufacturing, dispensing, and administration of pharmaceuticals and medical-surgical supplies, the provision of ancillary services, the conduct of our payer businesses, practice support services, and the provision of products that assist clinical decision-making and relate to patient medical histories and treatment plans. For example, pharmacy operations are exposed to risks such as improper filling of prescriptions, mislabeling of prescriptions, inadequacy of warnings, unintentional distribution of counterfeit drugs, and expiration of drugs. Although we seek to maintain adequate insurance coverage, such as property insurance for inventory and professional and general liability insurance, coverages on acceptable terms might be unavailable, or coverages might not cover our losses. We generally seek to limit our contractual exposure, but limitations of liability or indemnity provisions in our contracts may not be enforceable or adequately protect us from liability. Uninsured or non-indemnified losses might have a materially adverse impact on our business operations and our financial position or results of operations.

We experience costly legal disputes, government actions, and adverse publicity regarding our role in distributing controlled substances such as opioids.

The Company is a defendant in many litigation matters alleging claims related to the distribution of controlled substances (opioids), as described in Financial Note 17, "Commitments and Contingent Liabilities," to the consolidated financial statements in this Annual Report. We are sometimes named as a defendant in similar, new cases. The plaintiffs in those cases include governmental entities (such as states, provinces, counties, and municipalities) as well as businesses, groups, and individuals. The cases allege violations of controlled substance laws and other laws, and they make common law claims such as negligence and public nuisance. Many of these cases raise novel theories of liability and can have unexpected outcomes that we believe are not justified by evidence or existing law. Legal proceedings such as these often involve significant expense, management time and distraction, and risk of loss that can be difficult to predict or quantify. It is not uncommon for claims to be resolved over many years. Outcomes include monetary damages, penalties and fines, and injunctive or other relief that requires us to change our business operations and incur significant expense. Although the Company has valid defenses and is vigorously defending itself, some proceedings have been and others may be resolved by negotiated outcome. For example, we are subject to consent decrees issued by state courts that govern our distribution of controlled substances. Not all proceedings, however, are resolved by settlement. Our reputation has been and may continue to be impacted by publicity regarding opioids litigation and related allegations. An adverse outcome of any such legal proceedings might have a materially adverse impact on our business operations and our financial position or results of operations.

We experience increased costs to distribute controlled substances such as opioids.

Legislative, regulatory, or industry measures related to the distribution of controlled substances such as prescription opioids could affect our business in ways that we may not be able to predict. For example, some states have passed legislation that could require us to pay taxes or assessments on the distribution of opioid medications in those states and other states have considered similar legislation. Liabilities for taxes or assessments or other costs of compliance under any such laws might have a materially adverse impact on our reputation, our business operations, and our financial position or results of operations.

We are subject to extensive, complex, and challenging healthcare, environmental, and other laws.

As described in "Government Regulation" in Item 1 of Part I above, our industry is highly regulated, and further regulation of our distribution businesses, technology products, and services could impose increased costs, negatively impact our profit margins and the profit margins of our customers, delay the introduction or implementation of our new products, or otherwise negatively impact our business and expose the Company to litigation and regulatory investigations. We incur cleanup costs under environmental laws and may incur additional costs under environmental laws. Additionally, we are subject to various routine and ad hoc inspections and requests for information by government agencies to determine compliance with various statutes and regulations. Any noncompliance by us with applicable laws or the failure to maintain, renew, or obtain necessary permits and licenses could lead to enforcement actions or litigation and might have a materially adverse impact on our business operations and our financial position or results of operations.

We are subject to extensive and frequently changing laws relating to healthcare fraud, waste, and abuse.

As described in "Government Regulation" in Item 1 of Part I above, federal, state, and local governmental entities in the U.S. and elsewhere continue to strengthen their position and scrutiny over practices that may indicate fraud, waste, and abuse affecting government healthcare programs such as Medicare and Medicaid. Those laws may be interpreted or applied in a manner that could require us to make changes in our operations at added expense. Failures to comply with those laws, including the federal Anti-Kickback Statute, might expose us to federal or state government investigations or qui tam actions, and to liability for damages and civil and criminal penalties. Such failures might result in the loss of licenses or our ability to participate in Medicare, Medicaid, or other federal and state healthcare programs, or pursue government contracts. These sanctions might have a materially adverse impact on our business operations and our financial position or results of operations.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
08/29/2019	08/29/2019	CO	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CO Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On August 29, 2019, McKesson Corporation received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

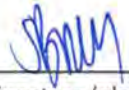
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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/17/2018	12/17/2018	VA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		VA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On December 17, 2018, in response to the DEA Settlement, McKesson Corporation entered into a consent agreement with the Virginia Board of Pharmacy (the "Virginia Consent"). The Virginia Consent applies to the McKesson distribution center located in Livonia, Michigan. The Livonia facility's right to distribute controlled substances into Virginia was suspended until 1/17/2019. The suspension period imposed by Virginia aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.



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1/15/25

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/14/2019	01/14/2019	CT	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CT Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On January 14, 2019, McKesson Corporation entered into a settlement for a payment of $10,000 on behalf of a now-closed facility in Connecticut. This settlement arose from the failure of employees of McKesson's contracted local delivery carrier to secure their vehicles when making deliveries within Connecticut. Importantly, there were never any reports of theft or loss based on this failure and McKesson's contract with the local delivery carrier specifically required security measures, including the securing of vehicles.

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/27/2019	02/27/2019	WI	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		WI Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On February 27, 2019, in response to the DEA Settlement, McKesson Corporation entered into a consent agreement with the Wisconsin Pharmacy Examining Board (the "Wisconsin Consent"). Under the terms of the consent, the Livonia, Michigan facility was fined and the facility's right to distribute controlled substances into Wisconsin was suspended from 1/17/17 to 1/17/19. The Washington Court House, Ohio facility was fined and the facility's ability to distribute controlled substances into Wisconsin has been suspended effective 1/17/19 to 1/17/2021. The suspension period imposed by Wisconsin aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/10/2019	05/10/2019	NM	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		NM Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On May 10, 2019, in response to the DEA Settlement, McKesson Corporation entered into the stipulated agreement with the New Mexico Board of Pharmacy (the "New Mexico Agreement"). The New Mexico Agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's ability to distribute controlled substances into New Mexico has been suspended until February 16, 2021. The suspension period imposed by New Mexico aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

Original Signature (electronic, copies or stamps not accepted)

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Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/21/2019	05/21/2019	AL	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		AL Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On May 21, 2019, in response to the DEA Settlement, McKesson Corporation entered into a consent order with the Alabama Board of Pharmacy (the "Alabama Consent"). The Alabama Consent applies to the McKesson distribution centers located in Washington Court House, Ohio and Livonia, Michigan. Under the terms of the Alabama Consent, each facility was subject to a fine of fifteen thousand dollars ($15,000).

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Date

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Date of Event/Arrest	Disposition Date	State	City	County
06/10/2019	06/10/2019	VA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		VA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On June 10, 2019, in response to the DEA Settlement, McKesson Corporation entered into a consent agreement with the Virginia Board of Pharmacy (the "WCH Virginia Consent"). The WCH Virginia Consent applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Virginia has been suspended from June 10, 2019 to February 16, 2021. The WCH Virginia Consent originates from McKesson's report to Virginia of settlements that McKesson entered into with the DEA and Louisiana Board of Pharmacy.

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Date of Event/Arrest	Disposition Date	State	City	County
06/29/2019	06/29/2019	CA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On June 29, 2019, in response to the DEA Settlement, the California Board of Pharmacy approved a Stipulated Settlement and Disciplinary Order for Public Reproval with McKesson Corporation (the "California Settlement"). The California Settlement is effective on August 28, 2019 and applies to both the Washington Court House, Ohio and Livonia, MI distribution centers. Subject to the terms of the settlement, McKesson was issued a public letter of Reproval, agreed to pay $4,000 in investigative fees.

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Date of Event/Arrest	Disposition Date	State	City	County
08/29/2019	08/29/2019	CO	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CO Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On August 29, 2019, McKesson Corporation received a Letter of Admonition from the Colorado State Board of Pharmacy due to the delinquent notification of a change in the Designated Representative at its distribution center located at in O'Fallon, MO ("McKesson St. Louis").

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Date of Event/Arrest	Disposition Date	State	City	County
08/29/2019	08/29/2019	CO	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CO Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On August 29, 2019, McKesson Corporation entered into a Stipulation and Final Agency Order with the Colorado State Board of Pharmacy regarding the delinquent notification of a change in the Designated Representative at its distribution center located in Aurora, IL ("McKesson Chicagoland"). The terms of the settlement included a fine in the amount of $1,150.00.

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/07/2020	01/07/2020	IA	N/A	N/A
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		IA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On January 7, 2020, McKesson Corporation entered into a Consent Agreement and Final Order with the Iowa Board of Pharmacy regarding pseudoephedrine products that had not been included in the McKesson's Clear Lake, IA facility's annual controlled substance inventory and butalbital products that continued to be treated as legend drugs after such products became schedule III products in the state on June 26, 2019 (the "2020 Clear Lake Consent").

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/20/2020	02/20/2020	IN	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		IN Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On February 20, 2020, in response to the DEA Settlement, McKesson Corporation entered into a final agreement with the Indiana Board of Pharmacy. The agreement applies to the McKesson distribution center located in Washington Court House, Ohio. The facility's right to distribute controlled substances into Indiana has been placed on indefinite probation until the facility's DEA Registration is fully re-instated on or about February 16, 2021. The suspension period imposed by Indiana aligns with the federal DEA suspensions and with those imposed by other states that have taken reciprocal action based on the DEA Settlement.

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/22/2021	05/22/2021	IL	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		IL Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On May 22, 2021, in response to the DEA Settlement, McKesson Corporation entered into a final agreement with the Illinois Department of Financial and Professional Regulation. The Illinois Consent Order applies to the McKesson distribution centers located in Aurora, Colorado, Livonia, Michigan and Washington Court House, Ohio.

- Aurora, Colorado - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2020 except for various exceptions that mirror exceptions in the DEA settlement;
- Livonia, Michigan - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/17/2019 except for various exceptions that mirror exceptions in the DEA settlement; and
- Washington Court House, Ohio - the facility's Illinois controlled substance was restricted. The facility was prohibited from distributing controlled substances into the state until 1/18/2021 except for various exceptions that mirror exceptions in the DEA settlement.

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/27/2021	05/27/2021	ME	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		ME Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On May 27, 2021, McKesson Corporation entered into a consent agreement with the Maine Board of Pharmacy regarding its Aurora, IL distribution center failing to report the Colorado disciplinary action to the Maine Board of Pharmacy within 10 days as required. The Colorado disciplinary action is now reported to the Maine Board of Pharmacy. The terms of the consent agreement included a fine in the amount of $500.00.

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1/15/25
Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/20/2021	12/20/2021	IL	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		IL Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On December 20, 2021, McKesson Corporation entered into a Consent Order with the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation (the "IDFPR") based on reciprocal state action from the 2020 Clear Lake Consent. The Illinois Consent applied to McKesson's Clear Lake, IA distribution center. Under the terms of the Illinois Consent Order, the facility was subject to a public reprimand by the IDFPR.

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/24/2022	03/24/2022	CA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On March 24, 2022, McKesson Corporation and the California Board of Pharmacy (the "Board") entered into a settlement agreement which resolved allegations against McKesson relating to the sale of controlled substances in 2017 and 2018 to an outpatient hospital pharmacy that the pharmacy discovered were being stolen by a pharmacy employee. Pursuant to the settlement agreement, the Board publicly reproved McKesson's Santa Fe Springs distribution center permit, and McKesson agreed to pay the board's costs related to the investigation and enforcement of the matter. As set forth in the settlement agreement, McKesson denies any allegation that it violated California laws regarding the distribution of controlled substances and there are no findings of any violation of state or federal laws.

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
07/22/2023	07/22/2023	AL	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		AL Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
McKesson Corporation				

Provide explanation below:

On July 22, 2023, McKesson Corporation's Santa Fe Springs, CA distribution center entered into a Consent Order with the Alabama Board of Pharmacy. The Consent Order constitutes reciprocal disciplinary action that was based entirely on a February 22, 2022, Decision and Order from the California Board of Pharmacy. There were no new facts giving rise to the Alabama Consent. Your office was notified of the California Order on or about 03/25/2022. Pursuant to the terms of the Alabama Consent, McKesson agreed to pay a fine of $25,000.

SBM

Original Signature (electronic, copies or stamps not accepted)

1/15/25

Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
04/12/2024	04/12/2024	GA	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		GA Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
Please see attached/below				

Provide explanation below:

On April 12, 2024, McKesson Corporation's Duluth, GA distribution center entered into a Public Consent Agreement with the Georgia State Board of Pharmacy. McKesson Corporation was disciplined for failure to maintain prescription drugs securely and assessed a fine of $10,000.

SBM

Original Signature (electronic, copies or stamps not accepted)

1/15/25

Date

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This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
08/29/2024	08/29/2024	OH	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		OH Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Please see attached/below		Please see attached/below		
Name of Business/Industry/Entity				
Please see attached/below				

Provide explanation below:

On August 29, 2024, the Ohio Board of Pharmacy issued a Final Order to McKesson Corporation for activities that occurred at McKesson's former distribution center previously located in Washington Courthouse, OH for purchases of dangerous drugs from an unlicensed entity from July 2019 to April 2021. The Board imposed a monetary fine in the amount of $2,750.00.

SBM

Original Signature (electronic, copies or stamps not accepted)

1/15/25

Date

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This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
09/25/2024	09/25/2024	CT	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CT Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
Please see attached/below				

Provide explanation below:

On September 25, 2024, McKesson Corporation's Montgomery, NY facility entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of One Thousand Five Hundred Dollars ($1,500) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/14/2024	11/14/2024	CT	N/A	N/A
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
		CT Board of Pharmacy		
Reason/Charge				
Please see attached/below				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Please see attached/below			Please see attached/below	
Name of Business/Industry/Entity				
Please see attached/below				

Provide explanation below:

On November 14, 2024, McKesson Corporation entered into a Settlement Agreement with the Connecticut Department of Consumer Protection Drug Control Division. Pursuant the terms of the Agreement, the Department of Consumer Protection alleged that McKesson's contracted courier failing to maintain prescription drugs securely in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies. The Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection. Per the Settlement Agreement, McKesson Corporation shall submit a payment of Five Thousand Dollars ($5,000) to the Department of Consumer Protection and shall be issued a Letter of Reprimand.

Original Signature (electronic, copies or stamps not accepted)

1/15/25
Date

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: **MCKESSON DRUG COMPANY**
Permit Number: 0219-000374
Case Number: 184655

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Scott Miller, authorized representative, McKesson Drug Company, as evidenced by their signatures hereto, in lieu of proceeding to an informal conference, enter into the following Consent Order affecting McKesson Drug Company's permit to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On January 19, 2000, the Board issued Permit Number 0219-000374 to McKesson Drug Company ("McKesson") to operate as a non-resident wholesale distributor in the Commonwealth of Virginia. Said permit is scheduled to expire on February 28, 2019. At all times relevant hereto, said permit was in full force and effect.

2. McKesson violated Virginia Code § 54.1-3316(8) in that on January 17, 2017, by settlement with the United States Drug Enforcement Administration ("DEA"), McKesson's authority to distribute controlled substances from its Livonia, Michigan, distribution center, DEA Certificate of Registration PM0030849, was suspended for a period of two years. Not included in this suspension was McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia, Michigan, distribution center, which are authorized under DEA registration number PM0030849. Also not included in this suspension was McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances

from McKesson's Livonia, Michigan distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

3. McKesson violated Virginia Code § 54.1-3316(10) in that on October 17, 2017, by Consent Agreement, the Louisiana Board of Pharmacy suspended McKesson's Louisiana Controlled Dangerous Substance License for McKesson's Livonia, Michigan, distribution center from June 29, 2017 to January 17, 2019. Additionally, on March 14, 2018, by Consent Agreement, the Iowa Board of Pharmacy suspended McKesson's Controlled Substances Act Registration for McKesson's Livonia, Michigan, distribution center from March 14, 2018 to January 17, 2019. Actions by the Louisiana Board of Pharmacy and the Iowa Board of Pharmacy did not include the suspension of McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia, Michigan distribution center, which are authorized under DEA registration number PM0030849. These Actions also did not affect McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Livonia, Michigan distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

CONSENT

McKesson Drug Company, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. McKesson has been advised to seek advice of counsel prior to signing this document and is represented by Roger Morris, Esq.;

2. McKesson is fully aware that without its consent, no legal action can be taken against it or its permit except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. McKesson acknowledges that it has the following rights, among others: the right to an informal fact-finding conference before the Board; and the right to representation by counsel;

4. McKesson waives its right to an informal conference;

5. McKesson admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6. McKesson consents to the entry of the following Order affecting its right to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

1. McKesson Drug Company shall not distribute Schedule II-V controlled substances from its Livonia, Michigan, distribution center into the Commonwealth of Virginia from the date of entry of this Order until January 17, 2019. This restriction shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia, Michigan, distribution center, which are authorized under the DEA registration number PM0030849. This restriction also shall not apply to or limit McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Livonia, Michigan distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

2. McKesson Drug Company shall comply with all laws and regulations governing the practice of a non-resident wholesale distributor in the Commonwealth of Virginia.

3. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of a non-resident wholesale distributor shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

ENTERED: 12/7/18

SEEN AND AGREED TO:

Ammie McAsey
~~Scott Miller~~, representative for Ammie McAsey
McKesson Drug Company

COMMONWEALTH OF VIRGINIA STATE OF TEXAS
COUNTY/CITY OF DALLAS, TO WIT:

Subscribed and sworn to before me, a notary public in and for the Commonwealth of Virginia at large, on this 30TH day of NOVEMBER, 2018.

NICOLE VALLEY
Notary Public, State of Texas
My Commission Expires
September 29, 2019

Nicole Valley
Notary Public

My commission expires: SEPTEMBER 29, 2019

Registration No.: 130386666-0

CERTIFIED TRUE COPY
BY:
VIRGINIA BOARD OF PHARMACY

STATE OF CONNECTICUT

BEFORE THE COMMISSIONER OF CONSUMER PROTECTION

In the Matter of	Case Nos.	2017-964
		2017-1876
McKesson Corporation		2018-143
		2018-731

Settlement Agreement Concerning

Wholesaler / Distributor of Drugs License of McKesson Corporation

This Settlement Agreement Concerning Wholesaler / Distributor of Drugs License of McKesson Corporation ("Settlement Agreement") is entered into by the duly authorized representative for McKesson Corporation ("Licensee") and the Commissioner of the Department of Consumer Protection ("Commissioner") in accordance with Sections 4-177(c), 21a-8 and 21a-70 of the Connecticut General Statutes.

PARAGRAPH ONE: Licensee is the holder of Connecticut Wholesaler / Distributor of Drugs License No. CSW 369 for a distribution center located at 280 Dividend Road, Rocky Hill, Connecticut.

PARAGRAPH TWO: The Department of Consumer Protection's Drug Control Division ("Department") has conducted an investigation and alleges the following violations committed from in or around May 2016 to January 2018:

1. Licensee is subject to an enforcement action, in particular suspension, revocation, probation or refusal to renew their registration for a violation of provisions of federal or state statutes or regulations concerning drugs in accordance with Section 21a-70(d)(5) of the Connecticut General Statutes;
2. Licensee, through its contracted carrier, failed to operate in compliance with applicable federal state and local statutes, regulations and ordinances, including any applicable laws concerning controlled substances, drug product salvaging or reprocessing in violation of Section 21a-70(e) of the Connecticut General Statutes;

3. Licensee, through its contracted carrier, failed to provide adequate control against the diversion, theft, and loss of drugs in violation of Section 21a-70(d)(4) of the Connecticut General Statutes and Sections 21a-262-4(c) and 21a-262-2(b) of the Regulations of Connecticut State Agencies; and
4. Licensee, through its contracted carrier, failed to maintain all equipment used for storage of controlled substances securely locked except for the actual time required to remove or replace needed items in violation of Sections 21a-262-4(c) and 21a-262-2(c) of the Regulations of Connecticut State Agencies.

PARAGRAPH THREE: In lieu of a hearing and without making any admission of guilt, Licensee has:

1. Provided the Department with its policies and procedures for training their delivery drivers and securing their delivery vehicles and the drugs contained therein; and
2. Participated in a Department training on May 9, 2018 regarding policies and procedures, best practices and Connecticut laws for Licensee's delivery drivers and securing delivery vehicles and the drugs contained therein.

PARAGRAPH FOUR: In lieu of a hearing and without making any admission of guilt, Licensee agrees to:

1. Maintain all records generated pursuant to the terms of this Settlement Agreement and have said records readily available for inspection by the Department, understanding that due to the closure of Licensee's distribution center in September 2018 that all records have been transferred to a New York distribution center; and

2. Pay a civil penalty of Ten Thousand Dollars ($10,000.00). This civil penalty shall be made payable to "Treasurer, State of Connecticut" and be deposited into the Consumer Protection Enforcement Fund (Account #35125) in accordance with Connecticut General Statutes, Section 21a-8a.

PARAGRAPH FIVE: Licensee agrees to waive:

1. any right to seek judicial review or otherwise challenge or contest the validity of this Settlement Agreement;
2. any requirement that this Settlement Agreement contain findings of fact and conclusions of law; and
3. any right to a hearing or other procedural requirements of the Uniform Administrative Procedure Act, Connecticut General Statutes, Section 4-166 et seq.

PARAGRAPH SIX: This Settlement Agreement is a revocable offer of settlement that may be modified by mutual agreement or withdrawn by the Department at any time prior to its being executed and shall not become binding unless and until it is accepted and approved by the Commissioner of the Department.

[SIGNATURE PAGE TO FOLLOW]

[SIGNATURE PAGE FOR SETTLEMENT AGREEMENT CONCERNING

WHOLESALE / DISTRIBUTOR OF DRUGS LICENSE OF McKESSON CORPORATION

Case Nos. 2017-964; 2017-1876; 2018-143; 2018-731]

FOR THE LICENSEE

Dated: 11/8/18

By: David Morrissey

Name: David Morrissey

Title: VP & M

FOR THE DEPARTMENT OF CONSUMER PROTECTION

Dated: 12/27/2018

By:

Bryan Cafferelli
Staff Attorney

The above Settlement Agreement concerning Licensee is accepted and approved by Michelle Seagull on this 4th day of January, 2019.

Michelle Seagull
Commissioner of Consumer Protection

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST MCKESSON DRUG COMPANY, RESPONDENT.	:	FINAL DECISION AND ORDER 000083

Division of Legal Services and Compliance Case No. 17 PHM 014

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

McKesson Drug Company
38220 Plymouth Road
Livonia, MI 48150

Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board ("Board"). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

1. Respondent, McKesson Drug Company, is licensed in the state of Wisconsin as a wholesale distributor of prescription drugs, having license number 2228-45, first issued on May 29, 2009, and current through May 31, 2020 (This wholesale distribution license, through its owner, McKesson Drug Company, is hereinafter referred to as "Respondent"). Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services ("Department") is 38220 Plymouth Road, Livonia, Michigan 48150.

2. At all times relevant to this proceeding, Respondent was a wholesale distributor of prescription drugs, located in Livonia, Michigan.

3. In 2008, McKesson Corporation ("McKesson") entered into a Settlement and Release Agreement and an Administrative Memorandum of Agreement with the United States Department of Justice, Drug Enforcement Administration ("DEA") ("the 2008 Agreement"). The 2008 Agreement arose out of, among other things, allegations regarding McKesson's failure to report suspicious orders of controlled substances, as required by 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As part of the 2008 Agreement, McKesson paid a $13.25 million civil penalty and created a Controlled Substance Monitoring Program ("CSMP").

4. On January 17, 2017, Respondent self-reported to the Board that McKesson entered into a Settlement Agreement and Release and an Administrative Memorandum of Agreement with the DEA ("the 2017 Agreement"), based on allegations that McKesson, including Respondent, had failed to adequately monitor and or report suspicious orders of controlled substances.

5. In the 2017 Agreement, the DEA alleged the following:

   a. McKesson failed to properly monitor its sales of controlled substances, including:

      i. failure to follow the procedures and polices set forth in the CSMP;
      ii. failure to conduct adequate due diligence of its customers;
      iii. failure to keep complete and accurate records in the CSMP files maintained for many of its customers;
      iv. bypassing suspicious order reporting procedures set forth in the CSMP; and
      v. failure to report suspicious orders—including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency.

   b. Certain McKesson distribution centers distributed controlled substances to pharmacies even though those distribution centers should have known that the pharmacists practicing at those pharmacies had failed to fulfill their corresponding responsibility to ensure that the controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes.

   c. McKesson violated the 2008 Agreement and federal law.

6. The DEA's allegations were limited to certain of McKesson's distribution centers, including Respondent.

7. The DEA's allegations were also against the following distribution centers licensed in Wisconsin: Aurora, Illinois (License No. 2230-45, Current, Active from June 3, 2009 to May 31, 2020); West Sacramento, California (License No. 1366-45, Current, Active from February 13, 2002 to May 31, 2020); LaCrosse, Wisconsin (License No. 868-45, Not Current, Active from November 12, 1996 to May 31, 2018); LaVista, Nebraska (License No. 2572-45, Not Current, Active from November 11, 2013 to May 31, 2018). The DEA took no action against these facilities and these distribution centers are not subject to this Final Decision and Order.

8. Pursuant to the 2017 Agreement, McKesson acknowledged that, at various times from January 1, 2009, through January 17, 2017, it did not identify or report to the DEA certain orders placed by certain pharmacies which McKesson should have detected as suspicious in a manner fully consistent with the requirements set forth in the 2008 Agreement.

9. The 2017 Agreement required McKesson to pay a settlement payment of $150 million and provided for a time-limited suspension of the DEA Certification of Registrations of four (4) of McKesson's distribution centers, including Respondent.

10. The suspension included an exception that permits, but does not require, Respondent, during the period of suspension, to continue to distribute controlled substances to federal customers that purchase controlled substances from Respondent under McKesson's exclusive contract with the United States Department of Veteran Affairs. The suspensions also do not apply or limit McKesson's authority to distribute, or operations involving, List 1 Chemical products from any of its distribution centers.

11. Respondent neither admits nor denies wrong-doing. In resolution of this matter, and to avoid the expense and uncertainty of litigation, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

1. The Wisconsin Pharmacy Examining Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1), and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, Respondent, license no. 2228-45, engaged in unprofessional conduct as defined by Wis. Admin. Code § Phar 10.03(17), by having been subject to disciplinary action by another licensing authority.

3. As a result of the above violations, Respondent, license no. 2228-45, is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)1.

4. Pursuant to Wis. Stat. § 450.10(2), in addition to a limitation or suspension, the Board may, for violations of Wis. Stat. § 450.10(1), assess a forfeiture of not more than $1,000.00 for each separate offense, with each day of violation constituting a separate offense.

ORDER

1. The attached Stipulation is accepted.

2. Except as provided in paragraph 3 of this Order, the ability to distribute controlled substances under the license to practice as a wholesale distributor of prescription drugs in the state of Wisconsin issued to Respondent, license no. 2228-45, is SUSPENDED for a period of two (2) years, effective from January 17, 2017, to January 17, 2019, or for the same effective dates as the suspension of the DEA Certificate of Registration for this distribution center under the 2017 Agreement. The suspension will terminate

automatically on either January 17, 2019, or upon the date the suspension of the DEA Certificate of Registration for this facility terminates. In the event that Respondent's DEA Certificate of Registration will remain suspended beyond January 17, 2019, Respondent shall notify the Board prior to January 17, 2019, of the continued suspension of its DEA Certificate of Registration and the date that the suspension of its DEA Certification of Registration will terminate.

3. This suspension shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Certificate of Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the United States Department of Veterans Affairs.

4. The license to practice as a wholesale distributor of prescription drugs in the state of Wisconsin, issued to Respondent, license no. 2228-45, is further LIMITED to require Respondent to fully comply with Administrative Memorandum of Agreement and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice, Drug Enforcement Administration and effective on January 17, 2017.

5. Within one-hundred and twenty (120) days from the date of this Order, Respondent, license no. 2228-45, shall pay a FORFEITURE in the amount of fifty thousand dollars ($50,000.00).

6. Within one-hundred and twenty (120) days from the date of this Order, Respondent, license no. 2228-45, shall pay costs in the amount of $1,959.00.

7. Any payments, requests, petitions, reports, and other information required by this Order may be mailed, faxed, or emailed to:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 267-3817; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

You may also submit this information online via DSPS' Monitoring Case Management System, here:

https://app.wi.gov/DSPSMonitoring

8. In the event that Respondent violates any term of this Order, Respondent's license, license no. 2228-45, to practice as a wholesale distributor in the state of Wisconsin may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of this Order. The Board may, in addition

and/or in the alternative, refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.

9. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

by: _____ 2/25/2013
A Member of the Board Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
MCKESSON DRUG COMPANY, RESPONDENT.	:	STIPULATION
	:	0006083

Division of Legal Services and Compliance Case No. 17 PHM 014

Respondent McKesson Drug Company, license no. 2228-45, and the Division of Legal Services and Compliance, Department of Safety and Professional Services stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Respondent;
- the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
- the right to testify on Respondent's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation. Respondent is represented by Attorneys Roger N. Morris and Susan Brichler Trujillo.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board ("Board"). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent or Respondent's attorney, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

Ammie McAsey
McKesson Drug Company, Respondent
38220 Plymouth Road
Livonia, MI 48150
License no. 2228-45

1-16-2019
Date

Roger N. Morris, Attorney for Respondent
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004

1-18-19
Date

Susan Brichler Trujillo, Attorney for Respondent
Quarles & Brady LLP
One Renaissance Square
Two North Central Avenue
Phoenix, AZ 85004

1/22/2019
Date

Zachary J. Peters, Attorney
Wisconsin Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

1/23/19
Date

BEFORE THE BOARD OF PHARMACY
OF THE STATE OF NEW MEXICO

IN THE MATTER OF:

Case No. 2018-047

McKESSON CORPORATION,
CS 19948,

Respondent.

STIPULATED AGREEMENT

The New Mexico Board of Pharmacy ("Board") received self-reports from McKesson Corporation ("Respondent") which stated that Respondent entered into a settlement agreement with the U.S. Department of Justice ("DOJ") on or about January 17, 2017 (the "Settlement Agreement"). The Settlement Agreement suspended the registration for the Respondent's Washington Court House Ohio location for two (2) years, effective from February 16, 2019 to February 16, 2021. The Respondent also self-reported disciplinary actions imposed by other state boards.

In lieu of instituting formal proceedings against Respondent, and in accordance with the New Mexico Controlled Substances Act, NMSA 1978 Sections 30-31-1 to -41, the New Mexico Uniform Licensing Act ("ULA"), NMSA 1978 Sections 61-1-1 to -34, and the New Mexico Pharmacy Act, NMSA 1978 Sections 61-11-1 to -29, the Board and the Respondent have agreed to resolve this matter as outlined in this Stipulated Agreement.

Findings of Fact

1. Respondent was issued a controlled substance registration and is authorized to distribute and operate in New Mexico under CS 19948. The Respondent's permit is active and will expire on January 31, 2020.

2. The Respondent is located in Washington Court House Ohio and distributes prescription drugs, including controlled drug substances into New Mexico.
3. On or about January 17, 2017, the Respondent entered into a Settlement Agreement with the DOJ based on the DOJ's allegations that McKesson failed to properly monitor its sales of controlled substances; failed to conduct adequate due diligence and keep accurate records of its sales; failed to maintain effective controls against diversion of particular controlled substances into channels other than legitimate medical, scientific and industrial channels; and failed to report suspicious orders of controlled substances to the U.S. Drug Enforcement Administration ("DEA").
4. Twelve (12) McKesson distribution centers were referenced in the Settlement Agreement, including the distribution center located in Washington Court House, Ohio.
5. Under the terms of the Settlement Agreement, the DEA registrations issued to the Aurora, Livonia, and Washington Court House distribution centers were suspended for certain periods of time on a staggered basis. Specifically, the DEA registration issued to the Respondent Washington Court House distribution center is suspended from February 16, 2019 to February 16, 2021, with the exceptions that the Respondent may possess and distribute controlled substances to federal customers which purchase controlled substances from the Respondent under the exclusive contract with the U.S. Department of Veteran's Affairs ("VA"). In addition, the suspension does not apply to or limit Respondent's authority to distribute or operations involving, List 1 Chemical products at or from Respondent's Washington Court House distribution center.
6. The Board was also notified that the following state boards of pharmacy took action that mirrors the restrictions imposed by the Settlement Agreement: Idaho Board of Pharmacy,

Louisiana Board of Pharmacy, New Hampshire Board of Pharmacy, Iowa Board of Pharmacy, Maryland Board of Pharmacy, Utah Board of Pharmacy, Oregon Board of Pharmacy and the Wisconsin Board of Pharmacy.

7. Respondent admits that the Board has jurisdiction over the Respondent and the subject matter herein.
8. Respondent acknowledges that if the allegations in the Findings of Fact were proven in a contested hearing, it would constitute grounds for disciplinary action, including suspension or revocation, of Respondent's controlled substance registration.
9. Respondent enters into this Agreement voluntarily and waives Respondent's right to have these matters heard in the manner described in the ULA, including the right to a full evidentiary hearing, and the right to appeal any decision of the board following such hearing.
10. Respondent also waives any and all time limitations set forth in the ULA, including all rights to have this matter heard within the time frame established in the ULA.
11. Respondent waives Respondent's right to assert a claim of bias or move to excuse any Board member based on the Board member's consideration of this agreement.
12. Upon execution of this Agreement, Respondent releases the Board from any and all claims potentially arising out of the Board's decision to take the actions described herein.
13. Respondent's waiver of these rights is made knowingly, intentionally, and voluntarily.
14. Respondent affirmatively states that Respondent has read this entire document and understands Respondent's responsibilities and duties in reference to this Agreement. Respondent agrees and stipulates to all of the terms of this agreement. Respondent knowingly, intentionally and voluntarily enters into and executes this Agreement and

affirms that no promises or representations have been made other than the terms and conditions expressly stated herein.

It is hereby **ORDERED** that:

A. The Respondent, McKesson Corporation, CS#19948, shall be prohibited from distributing controlled substances into New Mexico effective from the date of this order to February 16, 2021. If the effective suspension dates in the Settlement Agreement referenced herein for the Washington Court House distribution center are changed, the Respondent shall immediately notify the Board of such change and the change will automatically be incorporated into this Stipulated Agreement without the need for further Board action or approval;

B. The above prohibition does not apply to or limit the Respondent's authority to distribute, or operations involving, List I Chemical Products at or from the Respondent that are authorized under the Respondent's DEA registration and the Settlement Agreement. The Respondent is also permitted, at its option, to possess and distribute controlled substances to federal customers that purchase controlled substances from the Respondent under an exclusive contract with the VA;

C. The Respondent shall comply with all laws and regulations governing the operation of a wholesale distributor in New Mexico, which includes federal and State laws governing the proper handling and distribution of controlled dangerous substances; and

D. Failure to abide by these terms shall be grounds for summary suspension of Respondent's controlled substance registration.

E. This agreement will be included in Respondent's licensing file and is a public record open to inspection by the public.

F. This agreement constitutes disciplinary action against the Respondent by the Board and is reportable to the Healthcare Integrity and Protection Data Bank.

G. This agreement is effective as of the date it is signed by the Board Chair or his designee.

SO ORDERED on this 10th day of ~~April~~ May, 2019.

McKesson Corporation
CS 19948

Richard Mazzoni, R.Ph. - Chairman
New Mexico Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that a copy the foregoing document sent via United States Postal Service certified, return receipt mail, on ~~April~~ May 10, 2019 to:

McKesson Corporation
c/o Roger Morris, R. Ph, J.D.
Quarles & Brady
Renaissance One
Two North Central Avenue
Phoenix, AZ85005-2391

Certified Return Receipt Mail
Article No.: 7012 0470 0001 4488 5791

KRISTINA M. BENAVIDEZ
FOR THE NEW MEXICO BOARD OF PHARMACY

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 192010	)	**CASE NO: 17-L-0007**
	)	
and	)	
	)	
MCKESSON DRUG COMPANY	)	
	)	
Wholesale Distributor Permit No. 191852	)	
	)	
and	)	
	)	
MCKESSON DRUG CO.	)	
	)	
Wholesale Distributor Permit No. 192158	)	
	)	
and	)	
	)	
MCKESSON CORPORATION	)	
	)	
Wholesale Distributor Permit No. 193420	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against McKesson Corporation d/b/a McKesson Drug Company, McKesson Drug Company, McKesson Drug Co. and McKesson Corporation (hereinafter referred to collectively as "McKesson") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement"), alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties through counsel have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The parties stipulate that McKesson denies the allegations of the Statement. The Board finds that McKesson permit numbers 192158, 191852, and 193420 violated the applicable provisions based upon the conduct set out in each and every Count of the Statement. The charges against permit number 192010 shall be dismissed with prejudice.

2. McKesson shall pay to the Board an administrative fine in the amount of Fifteen Thousand dollars ($15,000.00) as to each applicable permit (192158, 191852 and 193420) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and McKesson shall not attempt to discharge the same in any bankruptcy proceeding.

3. That McKesson expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. McKesson further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, McKesson hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That McKesson agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That McKesson acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. McKesson acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and on the advice of its attorney.

DONE this the _____day of _____, 2018.

McKesson Corporation d/b/a McKesson Drug Company

By: _____
Its: Corporate Secretary

McKesson Drug Company

By: _____
Its: McKesson Corporate Secretary

McKesson Drug Co.

By: _____
Its: McKesson Corporate Secretary

McKesson Corporation

By: _____
Its: Corporate Secretary

_____
Roger N. Morris, Attorney for McKesson Corporation d/b/a/ McKesson Drug Company, McKesson Drug Company, McKesson Drug Co. and McKesson Corporation

DONE this the 24th day of May 2018.

ALABAMA STATE BOARD OF PHARMACY

By: _____
David Darby, R.Ph., President
Kendall Ingram

By: _____
James S. Ward
Its Attorney

OF COUNSEL:
WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 580
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON CORPORATION d/b/a MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 192010	)	**CASE NO: 17-L-0007**
	)	
and	)	
	)	
MCKESSON DRUG COMPANY	)	
	)	
Wholesale Distributor Permit No. 191852	)	
	)	
and	)	
	)	
MCKESSON DRUG CO.	)	
	)	
Wholesale Distributor Permit No. 192158	)	
	)	
and	)	
	)	
MCKESSON CORPORATION	)	
	)	
Wholesale Distributor Permit No. 193420	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **McKesson Corporation d/b/a McKesson Drug Company**
3400 Fraser Street
Aurora, Colorado 80011

McKesson Drug Company
300 Kenskill Avenue
Washington, Ohio 43160

McKesson Drug Co.
38220 Plymouth Road
Livonia, MI 48150

McKesson Corporation
1515 Kendrick Lane
Lakeland, Florida 33805

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on June 21st, 2018 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate McKesson Corporation d/b/a McKesson Drug Company, McKesson Drug Company, McKesson Drug Co., and McKesson Corporation (hereinafter referred to collectively as "McKesson") as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that McKesson has been guilty of the following, to-wit:

1. Board Rule 680-X-2.23 is entitled Drug Manufacturers, Wholesale Distributors.

2. Board Rule 680-X-2.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors include:

(a) Compliance with licensing requirements under previously granted license, if any.

(b) Compliance with the requirements to maintain records required to

be maintained.

(c) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

3. Board Rule 680-X-2.23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health.

4. Board Rule 680-X-2.23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation.

5. Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law.

COUNT ONE

As to Permit No. 191258, based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures

and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT TWO

As to Permit No. 193420, based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT THREE

As to Permit No. 192010, based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars

($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

COUNT FOUR

As to Permit No. 191852, based upon the (a) Settlement Agreement and Release by and between the United States of America acting through the United States Department of Justice and the Drug Enforcement Administration (USA) and McKesson Corporation (McKesson) entered in or about December 2016, and/or January 2017, including but not limited to the Covered Conduct (III), Acceptance of Responsibility (IV) and/or the payment by McKesson on One Hundred Fifty Million Dollars ($150,000,000.00) the (b) Administrative Memorandum of Agreement by and between the United States Department of Justice, Drug Enforcement Administration (DEA) and McKesson Corporation as required as a term of the Settlement referenced above, these documents being attached hereto and made a part hereof as Exhibits "A" and "B".

The Board alleges that each and every instance of the deficiencies or failures and/or the failure to comply with the applicable statutes or Rules as set out in the above is a separate and distinct violation.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-

examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 16th day of February, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT A

SETTLEMENT AGREEMENT AND RELEASE

I. PARTIES

This Settlement Agreement and Release ("Settlement Agreement" or "Agreement") is entered into between the United States of America, acting through the United States Department of Justice ("DOJ"),[1] and on behalf of the Drug Enforcement Administration ("DEA") (collectively referred to herein as the "United States"), and McKesson Corporation ("McKesson").

II. RECITALS

A. McKesson is a corporation organized and existing under the laws of the State of Delaware. McKesson's corporate headquarters and principal place of business is located at One Post Street, San Francisco, California.

B. McKesson is a wholesale distributor of pharmaceuticals, including controlled substances and non-controlled prescription medications. McKesson distributes pharmaceuticals through a network of distribution centers located throughout the United States, including distribution centers located in the following areas: Aurora, Colorado; Aurora, Illinois; Delran, New Jersey; La Crosse, Wisconsin; Lakeland, Florida; Livonia, Michigan; Methuen, Massachusetts; Santa Fe Springs, California; Washington Courthouse, Ohio; and West Sacramento, California. McKesson formerly distributed pharmaceuticals through a distribution center located in Landover, Maryland, which closed in January 2012 (the "Landover Distribution Center"), and in La Vista, Nebraska, which closed in October 2016. A list of all McKesson U.S. Pharmaceutical distribution

[1] The Department of Justice is represented by the following 12 U.S. Attorney's Offices: Central District of California; Eastern District of California; District of Colorado; Middle District of Florida; Eastern District of Kentucky; Northern District of Illinois; District of Massachusetts; Eastern District of Michigan; District of Nebraska; District of New Jersey; Northern District of West Virginia; and Western District of Wisconsin.

centers that hold a DEA Certificate of Registration as of the Effective Date of this Agreement is attached hereto as Appendix A. Collectively, the distribution centers listed in Appendix A and the Landover Distribution Center are referred to herein as the "McKesson Distribution Centers."

C. At times relevant to this Agreement, the McKesson Distribution Centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* (the "CSA" or the "Act"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

D. The DEA is the DOJ component agency primarily responsible for administering the CSA and the regulations promulgated thereunder, and is vested with the responsibility of investigating CSA violations.

E. The Attorney General, through the United States Attorneys, has primary authority to bring civil actions to enforce the CSA and the regulations promulgated thereunder. *See* 21 U.S.C. § 871 and 28 C.F.R. § 0.55(c).

F. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation. *See* 21 C.F.R. § 1301.74(b).

G. The CSA authorizes the imposition of a civil penalty of up to $10,000 for each violation of 21 C.F.R. § 1301.74(b). *See* 21 U.S.C. §§ 842(a)(5) and (c)(1)(B).

III. COVERED CONDUCT

The United States contends that it has certain civil claims against McKesson under 21 U.S.C. §§ 821, 823, 827, and 842(a)(5) for engaging in the following conduct (the "Covered Conduct") from January 1, 2009, through the Effective Date as that term is defined in Section

VI(F) (the "Covered Time Period"):

A. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific, and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations at McKesson Distribution Centers, including the following specific centers:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
La Crosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;
Washington Courthouse, Ohio; and
West Sacramento, California.

B. In 2008, McKesson entered into a settlement agreement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to herein as the "2008 Agreements") arising out of, among other things, McKesson's failure to report suspicious orders of controlled substances to the DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP") in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to the DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to the DEA, in accordance with McKesson's obligations under the 2008 Agreements, the CSA, and 21 C.F.R. § 1301.74(b).

C. McKesson failed to follow the procedures and policies set forth in the McKesson

CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP.

D. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of suspicious orders of controlled substances made by its customers during the Covered Time Period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. §1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements.

E. McKesson failed to report suspicious orders for controlled substances in accordance with the standards identified and outlined by the DEA in three letters from the DEA's Deputy Assistant Administrator, Office of Diversion Control sent to every registered manufacturer and distributor, including McKesson, on September 27, 2006, February 7, 2007, and December 27, 2007.

F. Certain McKesson Distribution Centers distributed controlled substances to pharmacies even though those Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

IV. ACCEPTANCE OF RESPONSIBILITY

A. On or about September 27, 2006, February 7, 2007, and December 27, 2007, DEA's

Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum. The Compliance Addendum is an attachment to the Administrative Memorandum of Agreement (the "2017 MOA") entered into by McKesson and DEA contemporaneously with this Agreement. The Compliance Addendum and the 2017 MOA are attached hereto as Appendix B.

B. On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided, among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its CSMP. McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to

prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

V. TERMS AND CONDITIONS

In consideration of the mutual promises, covenants, and obligations set forth in this Settlement Agreement, the United States and McKesson agree as follows:

A. McKesson shall pay the United States the sum of One Hundred Fifty Million Dollars ($150,000,000.00) (the "Settlement Amount") within five (5) business days of the Effective Date of this Settlement Agreement, by electronic funds transfer ("EFT") pursuant to written instructions to be provided by the United States.

B. In consideration of the fulfillment of the payment of the Settlement Amount, the United States agrees to:

1. Fully and finally release McKesson and all McKesson facilities, including McKesson subsidiary entities, affiliates, and registrants, (collectively, the "Released Parties") from any and all civil penalty claims under 21 U.S.C. § 842 that the United States could have asserted, or may assert in the future, against McKesson related to the Covered Conduct; and

2. Refrain from filing any action for civil penalty claims under 21 U.S.C. § 842 by any U.S. Attorney's Office and/or DOJ based on the Covered Conduct.

C. Nothing in this Settlement Agreement shall prohibit or limit any other agency within DOJ or any other law enforcement, administrative, or regulatory agency of the United States from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that has initiated or initiates an investigation, action, or proceeding involving the Covered Conduct, but will not otherwise initiate or refer any civil action to any U.S. Attorney's Office or to any

component of DOJ, based on the Covered Conduct.

D. McKesson fully and finally releases the United States, its agencies, employees, servants, and agents from any claims (including for attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States, its agencies, employees, servants, and agents, related to the Covered Conduct and the investigation and prosecution thereof by the United States.

E. Notwithstanding any term of this Settlement Agreement, specifically reserved and excluded from the scope and terms of this Settlement Agreement, and the releases set forth herein, as to any entity or person (including McKesson) are the following:

1. Any potential criminal liability;

2. Any civil, criminal, or administrative liability arising under Title 26, United States Code (the Internal Revenue Code);

3. Any civil or administrative liability to the United States for any conduct other than the Covered Conduct, as described in paragraph III(A)-(F); and

4. Any liability based upon any obligation created by or arising under this Settlement Agreement.

F. Contemporaneously with the execution of this Settlement Agreement, McKesson will enter into the 2017 MOA, which will resolve administrative claims that DEA has or may have against McKesson related to the Covered Conduct. *See* Appendix B. McKesson acknowledges that it is required to comply with the controlled substance record keeping and reporting requirements of the CSA. McKesson represents that it has taken, is taking, and will be taking further good faith actions to detect and prevent diversion. *See* Compliance Addendum attached hereto in Appendix B.

G. Nothing in this Settlement Agreement shall prevent, preclude, limit, or prejudice the right of the United States to enforce the CSA by commencing a civil or administrative action against McKesson for violations of the CSA, and regulations promulgated thereunder, unrelated to the Covered Conduct as described in Section III of this Settlement Agreement or which occur after the Effective Date of this Settlement Agreement.

H. McKesson agrees that any and all costs it has, will, or may incur in connection with this matter – including payment of the Settlement Amount under this Settlement Agreement, attorney's fees, costs of investigation, negotiation, future compliance efforts, and remedial action - shall be unallowable costs (as defined in the Federal Acquisition Regulation, 48 C.F.R. § 31.205-47; and in Titles XVIII and XIX of the Social Security Act, 42 U.S.C. §§ 1395-1395kkk-1 and 1396-1396w-5; and the regulations and official program directives promulgated thereunder) for government contracting accounting and for purposes of any government reimbursement program.

I. McKesson warrants that it has reviewed its financial situation and that it currently is solvent within the meaning of 11 U.S.C. §§ 547(b)(3) and 548(a)(1)(B)(ii)(I), and will remain solvent following its payment to the United States of the Settlement Amount. Furthermore, the Parties warrant that, in evaluating whether to execute this Settlement Agreement, they (a) intended that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to McKesson, within the meaning of 11 U.S.C. § 547(c)(1); and (b) concluded that the mutual promises, covenants, and obligations set forth herein do, in fact, constitute such a contemporaneous exchange. In addition, the Parties warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value which is not meant to hinder or delay payment to, or to

defraud any entity to which McKesson was or became indebted on or after the date of this transfer, all within the meaning of 11 U.S.C. § 548(a)(1).

J. If, within 91 days of the Effective Date of this Settlement Agreement or of any payment made hereunder, McKesson commences, or a third-party commences, any case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors, (i) seeking to have any order for relief of McKesson's debts, or seeking to adjudicate McKesson as bankrupt or insolvent; or (ii) seeking appointment of a receiver, trustee, custodian, or other similar official for McKesson or for all or any substantial part of McKesson's assets, McKesson agrees as follows:

1. McKesson's obligations under this Settlement Agreement may not be avoided pursuant to 11 U.S.C. §§ 547 or 548, and McKesson will not argue or otherwise take the position in any such case, proceeding, or action that: (i) McKesson's obligations under this Settlement Agreement may be avoided under 11 U.S.C. §§ 547 or 548; (ii) McKesson was insolvent at the time this Settlement Agreement was entered into, or became insolvent as a result of the payment made to the United States hereunder; or (iii) the mutual promises, covenants, and obligations set forth in this Settlement Agreement do not constitute a contemporaneous exchange for new value given to McKesson;

2. If McKesson's obligations under this Settlement Agreement are avoided for any reason, including, but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code, the United States, at its sole option, may rescind the releases in this Settlement Agreement, and bring any civil claims that would otherwise be covered by the release provided in Paragraph 2, above. McKesson agrees that (i) any such claims, actions, or proceedings brought by the United States are not subject to an "automatic stay" pursuant to 11 U.S.C. § 362(a) as a result of the action, case, or proceeding described in the first clause of this Paragraph, and that McKesson will not argue or otherwise contend that the United States' claims, actions, or proceedings are subject to an automatic stay; (ii) that McKesson will not plead, argue, or otherwise raise any defenses under the theories of statute of limitations, laches, estoppel, or similar theories, to any such civil or administrative claims, actions, or proceeding which are brought

by the United States within 90 calendar days of written notification to McKesson that the releases herein have been rescinded pursuant to this Paragraph, except to the extent such defenses were available on the Effective Date of the Settlement Agreement; and (iii) the United States may pursue any and all claims it had as of July 1, 2014, in the case, action, or proceeding referenced in the first clause of this Paragraph, as well as in any other case, action, or proceeding; and

3. McKesson acknowledges that its agreements in this Paragraph are provided in exchange for valuable consideration provided by and through this Settlement Agreement.

K. Each Party to this Settlement Agreement will bear its own legal expenses and other costs incurred in connection with this matter, including those for the preparation and performance of this Settlement Agreement.

L. This Settlement Agreement is intended to be for the benefit of the Parties only.

M. McKesson represents that this Settlement Agreement is freely and voluntarily entered into, without any degree of duress or compulsion whatsoever. McKesson also acknowledges that it was represented by legal counsel of its choosing throughout the negotiation and execution of this Settlement Agreement.

N. McKesson consents to the disclosure of this Settlement Agreement, information about this Settlement Agreement, and the settlement memorialized herein by the United States to the public.

O. Nothing in this Settlement Agreement constitutes an agreement by the United States concerning characterization of the Settlement Amount for purposes of Title 26 of the United States Code (Internal Revenue Code).

VI. GENERAL PROVISIONS

A. Governing Law: This Settlement Agreement is governed by the laws of the United States of America. The Parties agree that the exclusive jurisdiction and venue for any dispute arising between and among the Parties regarding this Settlement Agreement and its terms shall be the United States District Court for the Northern District of West Virginia.

B. Headings: The section and paragraph headings in this Settlement Agreement are inserted solely for the convenience of the Parties and shall not be construed to be part of or in any way affect the substantive provisions of this Settlement Agreement.

C. Merger Clause: This Settlement Agreement, including Attachments, constitutes the complete agreement and understanding by and between the United States and McKesson with respect to the settlement of claims against McKesson arising out of the Covered Conduct and no promises, agreements, or understandings, written or oral, not contained herein shall be of any force or effect. This Settlement Agreement may be amended at any time by mutual consent of the parties hereto, with any such amendment to be invalid, unless in writing, signed by an authorized agent of McKesson and an authorized representative of the United States.

D. Counterparts: This Settlement Agreement may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Settlement Agreement.

E. Binding: This Settlement Agreement is binding on McKesson and its successors, transferees, and assigns.

F. Effective Date: This Settlement Agreement shall be effective when the last signatory to this Settlement Agreement executes the Agreement.

G. Drafting: For purposes of construing this Settlement Agreement, this Agreement shall be deemed to have been drafted by all Parties to this Agreement and shall not, therefore, be construed against any Party for that reason in any subsequent dispute.

H. Authority to Sign: Each person who signs this Settlement Agreement in a representative capacity warrants that he or she is fully authorized to do so. The government signatories represent that they are signing this Settlement Agreement in their official capacities.

IN WITNESS WHEREOF, the United States and McKesson have duly executed this Settlement Agreement with the intent to be bound by the terms, conditions, and representations herein.

THE UNITED STATES OF AMERICA

Dated: 12/30/2016

William J. Ihlenfeld, II
U.S. Attorney
Northern District of West Virginia

Dated: 1/17/17

Robert C. Troyer
Acting U.S. Attorney
District of Colorado

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

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_____
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_____
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Eastern District of Michigan

Dated: _____

_____
Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

Zachary T. Fardon
U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: 01-05-17

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: _____

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: _____

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U.S. Attorney
Northern District of Illinois

Dated: _____

John W. Vaudreuil
U.S. Attorney
Western District of Wisconsin

Dated: _____

Barbara L. McQuade
U.S. Attorney
Eastern District of Michigan

Dated: 1-6-17

Kerry B. Harvey
U.S. Attorney
Eastern District of Kentucky

THE UNITED STATES OF AMERICA

Dated: 1/4/17

Deborah R. Gilg
U.S. Attorney
District of Nebraska

Dated: _____

Phillip A. Talbert
U.S. Attorney
Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: _____

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

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Dated: 1/4/11

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Eastern District of California

Dated: _____

Carmen M. Ortiz
U.S. Attorney
District of Massachusetts

Dated: 1/4/17

Paul J. Fishman
U.S. Attorney
District of New Jersey

THE UNITED STATES OF AMERICA

Dated: 1-5-17

A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

Dated: _____

_____
A. Lee Bentley, III
U.S. Attorney
Middle District of Florida

Dated: 1/5/17

_____
Eileen M. Decker
U.S. Attorney
Central District of California

Dated: _____

_____
Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

THE UNITED STATES OF AMERICA

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U.S. Attorney
Middle District of Florida

Dated: _____

Eileen M. Decker
U.S. Attorney
Central District of California

Dated: 1/5/17

Wendy H. Goggin
Chief Counsel
U.S. Drug Enforcement Administration

McKESSON CORPORATION

Dated: 1/5/17

Lori A. Schechter
Executive Vice President, General Counsel and
Chief Compliance Officer for
McKesson Corporation

Dated: 1/5/17

Geoffrey E. Hobart
Covington & Burling LLP
Counsel for McKesson Corporation

EXHIBIT B

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2 Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5 Term of Agreement The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination

II Terms and Conditions

1 Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/dearepports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/dearepports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, *Detroit Field Division*, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II 1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, e.g., administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II 1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants, and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement

III. Miscellaneous

1 Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2 Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5 Execution of Agreement. This Agreement shall become effective (i.e., final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
6535 State Highway 161
Irving, TX 75039-2402

Asaistant General Counsel, US Pharmaceuticul
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

7 Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8 Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9 Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

COMMONWEALTH of VIRGINIA

David E. Brown, D.C.
Director

Department of Health Professions
Perimeter Center
9960 Mayland Drive, Suite 300
Henrico, Virginia 23233-1463
Board of Pharmacy
804/367-4456
804-527-4472 (fax)

www.dhp.virginia.gov
TEL (804) 367- 4400
FAX (804) 527- 4475

June 10, 2019

Certified Article Number
9414 7266 9904 2125 4156 58
SENDER'S RECORD
Return receipt requested

Scott Miller, Pharmacist-in-Charge
Mckesson Drug Company
3000 Kenskill Avenue
Washington Court House, OH 43160

RE: Case Number 194092

Dear Mr. Miller:

Enclosed is a certified true copy of the Consent Order entered by the Virginia Board of Pharmacy ("Board"), which resolves this matter.

This Order will be forwarded to Rose Dematteo, Compliance Case Manager for the Board of Pharmacy. Ms. Dematteo will monitor your compliance with the terms of the Order on behalf of the Board. Please direct all questions, documents, and correspondence related to your compliance with your Order to Ms. Dematteo at (804) 367-4456 or directly to her by mail at the Board of Pharmacy, Perimeter Center, 9960 Mayland Drive, Suite 300, Henrico, Virginia 23233-1463.

Should you have any questions or concerns regarding this matter, please contact our office at (804)367-4456.

Sincerely,

Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

cc: Anne Joseph, Deputy Director, Administrative Proceedings Division
Rose Dematteo, Compliance Case Manager
Susan Brooks, Operations Manager, Administrative Proceedings Division
Nicholas H. Meza, Attorney
David E. Brown, D.C., Director, Department of Health Professions
Barbara Allison-Bryan, M.D., Chief Deputy Director, Department of Health Professions

JUN 0 7 2019
DHP

BEFORE THE VIRGINIA BOARD OF PHARMACY

IN RE: **MCKESSON DRUG COMPANY**
Permit Number: **0219-000202**
Case Number: **194092**

CONSENT ORDER

JURISDICTION AND PROCEDURAL HISTORY

The Virginia Board of Pharmacy ("Board") and Scott Miller, authorized representative, McKesson Drug Company, as evidenced by their signatures hereto, in lieu of proceeding to an informal conference, enter into the following Consent Order affecting McKesson Drug Company's permit to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

FINDINGS OF FACT AND CONCLUSIONS OF LAW

1. On 2/25/1997, the Board issued Permit Number 0219-000202 to McKesson Drug Company ("McKesson") to operate as a non-resident wholesale distributor in the Commonwealth of Virginia. Said permit is scheduled to expire on 2/29/2020. At all times relevant hereto, said permit was in full force and effect.

2. McKesson violated Virginia Code § 54.1-3316(8) in that on January 17, 2017, by settlement with the United States Drug Enforcement Administration ("DEA"), McKesson's authority to distribute controlled substances from its Washington Court House, Ohio, distribution center, DEA Certificate of Registration RM0220688, was suspended for a period of two years from February 16, 2019 to February 16, 2021. Not included in this suspension was McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Washington Court House, Ohio, distribution center, which are authorized under DEA registration number RM0220688. Also not included in this suspension was McKesson's authority to, at its option, continue to possess and

distribute controlled substances to federal customers that purchase controlled substances from McKesson's Washington Court House, Ohio, distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

3. McKesson violated Virginia Code § 54.1-3316(10) in that on October 17, 2017, by Consent Agreement, the Louisiana Board of Pharmacy suspended McKesson's Louisiana Controlled Dangerous Substance License for McKesson's Washington Court House, Ohio, distribution center from January 18, 2019 to January 18, 2021. The action by the Louisiana Board of Pharmacy did not include the suspension of McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Washington Court House, Ohio, distribution center, which are authorized under DEA registration number RM0220688. These Actions also did not affect McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Washington Court House, Ohio, distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

CONSENT

McKesson Drug Company, by affixing the signature of a representative hereon to this Order, agrees to the following:

1. McKesson has been advised to seek advice of counsel prior to signing this document and is represented by Roger Morris, Esq.;

2. McKesson is fully aware that without its consent, no legal action can be taken against it or its permit except pursuant to the Virginia Administrative Process Act, Virginia Code § 2.2-4000 *et seq.*;

3. McKesson acknowledges that it has the following rights, among others: the right to an informal fact-finding conference before the Board; and the right to representation by counsel;

4. McKesson waives its right to an informal conference;

5. McKesson admits to the Findings of Fact and Conclusions of Law contained herein and waives its right to contest such Findings of Fact and Conclusions of Law and any sanction imposed hereunder in any future judicial or administrative proceeding in which the Board is a party;

6. McKesson consents to the entry of the following Order affecting its right to operate as a non-resident wholesale distributor in the Commonwealth of Virginia.

ORDER

Based on the foregoing Findings of Fact and Conclusions of Law, the Virginia Board of Pharmacy hereby ORDERS as follows:

1. McKesson Drug Company shall not distribute Schedule II-V controlled substances from its Washington Court House, Ohio, distribution center into the Commonwealth of Virginia from the date of entry of this Order until February 16, 2021. This restriction shall not apply to or limit McKesson's authority to distribute, or operations involving, List 1 Chemical products at or from the Washington Court House, Ohio, distribution center, which are authorized under the DEA registration number RM0220688. This restriction also shall not apply to or limit McKesson's authority to, at its option, continue to possess and distribute controlled substances to federal customers that purchase controlled substances from McKesson's Washington Court House, Ohio, distribution center under McKesson's exclusive contract with the U.S. Department of Veteran's Affairs.

2. McKesson Drug Company shall comply with all laws and regulations governing the practice of a non-resident wholesale distributor in the Commonwealth of Virginia.

3. Any violation of the foregoing terms and conditions of this Order or any statute or regulation governing the practice of a non-resident wholesale distributor shall constitute grounds for further disciplinary action.

Pursuant to Virginia Code §§ 2.2-4023 and 54.1-2400.2, the signed original of this Order shall remain in the custody of the Department of Health Professions as a public record, and shall be made available for public inspection and copying upon request.

FOR THE BOARD

Caroline D. Juran, RPh, DPh
Executive Director
Virginia Board of Pharmacy

ENTERED: 6/10/19

SEEN AND AGREED TO:

Todd Spaulding
~~Scott Miller~~, representative for
McKesson Drug Company

~~COMMONWEALTH OF VIRGINIA~~
COUNTY/CITY OF Fayette Co Ohio, TO WIT:

Subscribed and sworn to before me, a notary public in and for the Commonwealth of Virginia at large, on this 31st day of May, 2019.

Notary Public

My commission expires: Dec 6 2020

Registration No.:

NOTARY PUBLIC STATE OF OHIO
SANDRA L. HELSEL
Notary Public, State of Ohio
My Commission Expires
December 6, 2020

CERTIFIED TRUE COPY
BY:
VIRGINIA BOARD OF PHARMACY

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION** 3000 Kenskill Ave. Washington Court House, OH 43160 **Out of State Distributor License No. OSD 3275** and **MCKESSON DRUG CO.** 38220 Plymouth Rd. Livonia, MI 48150 **Out of State Distributor License No. OSD 4086** Respondents.	Case No. 6413 OAH No. 2019010083

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on August 28, 2019.

It is so ORDERED on July 29, 2019.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By

Greg Lippe
Board Vice President (Acting President)

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
KEVIN W. BELL
Deputy Attorney General
State Bar No. 192063
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7511
Facsimile: (916) 327-8643
E-mail: Kevin.Bell@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION** **3000 Kenskill Ave.** **Washington Court House, OH 43160** **Out of State Distributor License No. OSD 3275** **And** **MCKESSON DRUG CO.** **38220 Plymouth Rd.** **Livonia, MI 48150** **Out of State Distributor License No. OSD 4086** Respondents.	Case No. 6413 OAH No. 2019010083 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Interim Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Xavier Becerra, Attorney General of the State of California, by Kevin W. Bell, Deputy Attorney General.

2. Respondent John Hammergren[1], McKesson Corporation and McKesson Drug Co. (Respondents) are represented in this proceeding by attorney Alissa Brice Castaneda, whose address is: Renaissance One, Two North Central Avenue, Phoenix, AZ 85004-2391.

JURISDICTION

3. On or about August 11, 2000, the Board issued Out of State Distributor License No. OSD 3275 to John Hammergren, McKesson Corporation, and Out of State Distributor License No. OSD 4086 to John Hammergren, McKesson Drug Co. The Out of State Distributor Licenses were in full force and effect at all times relevant to the charges brought in Accusation No. 6413 and will expire on August 1, 2020, unless renewed.

4. First Amended Accusation No. 6413 was filed before the Board and is currently pending against Respondents. The Accusation and all other statutorily required documents were properly served on Respondents on May 15, 2019. Respondents timely filed his Notice of Defense contesting the Accusation. A copy of First Amended Accusation No. 6413 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in First Amended Accusation No. 6413. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the Accusation; the right to be represented by counsel at their own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

[1] The Board has recently discovered that John Hammergren, CEO of both Respondents McKesson Corporation and McKesson Drug Company, disassociated with Respondents on April 1, 2019. Because Respondents have not provided the identity of the new CEO, John Hammergren remains as the CEO of record.

7. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

CULPABILITY

8. Respondents understand and agree that the charges and allegations in First Amended Accusation No. 6413, if proven at a hearing, constitute cause for imposing discipline upon their Out of State Distributor Licenses.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondents hereby give up their right to contest the charges in the First Amended Accusation.

10. Respondents agree that their Out of State Distributor Licenses are subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondents understand and agree that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondents or their counsel. By signing the stipulation, Respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including Portable Document Format (PDF) and facsimile signatures thereto, shall have the same force and effect as the originals.

///

///

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. This Stipulated Settlement and Disciplinary Order is dispositive of any and all known and extant violations of California law that the Board of Pharmacy has asserted or could have asserted against Respondents relating to the 2017 DEA Settlement and underlying facts. It is the complete, final, and exclusive embodiment of claims related to First Amended Accusation No. 6413, including any past or future nondisciplinary or disciplinary actions taken by other Federal or state entities related to the 2017 DEA Settlement referenced in the First Amended Accusation and underlying facts.

15. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Out of State Distributor License No. OSD 3275 issued to John Hammergren, McKesson Corporation, and Out of State Distributor License No. OSD 4086 issued to John Hammergren, McKesson Drug Co. shall be publicly REPROVED by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6413, attached as exhibit A.

Cost Recovery. Respondents shall pay $4,000.00 to the Board, jointly and severally, for its costs associated with the investigation and enforcement of this matter. Respondents shall be permitted to pay these costs in a payment plan approved by the Board. If Respondents fail to pay the Board costs as ordered, Respondents shall not be allowed to renew their Out of State Distributor Licenses until Respondents pay costs in full.

Community Service. Respondents shall provide $1.5 million (wholesale value) worth of Naloxone, jointly and severally, to be distributed at no charge to California entities such as First Responders or to similar non-profit entities.

Respondents must submit to the Board within 120 days of the effective date of the Order a proposal for the distribution of the Naloxone. The proposal must specify the entities within California that will receive the Naloxone, the manner and timing in which the entities will receive the Naloxone, and the quantities of Naloxone distributed to each entity. Respondents will determine at their sole discretion the manner and timing in which the entities will receive the Naloxone, and the quantities of Naloxone distributed to each entity.

Respondents shall submit to the Board a report every six months detailing the progress in distributing the Naloxone, which shall include the names of the entities to which the Naloxone has been distributed and the quantities of Naloxone distributed. The first report shall be due 180 days after Respondents' proposal has been submitted to the Board.

This community service requirement shall be completed within 4 years of the effective date of the Order.

Failure to abide by any term of this Disciplinary Order shall constitute grounds for discipline against Respondents, up to and including Revocation.

ACCEPTANCE

Respondents have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with their attorney, Alissa Brice Castaneda. Respondents understand the stipulation and the effect it will have on the Out-of State Distributor License No. OSD 3275, and Out of State Distributor License No. OSD 4086. Respondents enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: May 23, 2019

for MCKESSON CORPORATION
and MCKESSON DRUG CO.
Respondents

I have read and fully discussed with Respondent John Hammergren, McKesson Corporation/McKesson Drug Co. the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 5/21/19 Alissa Brice Castaneda

Alissa Brice Castaneda
Attorney for Respondents

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 5/21/19

Respectfully submitted,

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General

KEVIN W. BELL
Deputy Attorney General
Attorneys for Complainant

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McKessonSettlement5-18.docx

XAVIER BECERRA
Attorney General of California
KENT D. HARRIS
Supervising Deputy Attorney General
KEVIN W. BELL
Deputy Attorney General
State Bar No. 192063
1300 I Street, Suite 125
P.O. Box 944255
Sacramento, CA 94244-2550
Telephone: (916) 210-7511
Facsimile: (916) 327-8643
E-mail: Kevin.Bell@doj.ca.gov
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION** **3000 Kenskill Ave.** **Washington Court House, OH 43160** **Out of State Distributor License** **No. OSD 3275** **And** MCKESSON DRUG CO. **38220 Plymouth Rd.** **Livonia, MI 48150** **Out of State Distributor License** **No. OSD 4086** Respondents.	Case No. 6413 OAH No. 2019010083 **FIRST AMENDED ACCUSATION**

Complainant alleges:

PARTIES

1. Ann Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Interim Executive Officer of the Board of Pharmacy, Department of Consumer Affairs (Board).

2. On or about August 11, 2000, the Board issued Out of State Distributor License Number OSD 3275 to McKesson Corporation, John Hammergren, CEO[1]. The License will expire on August 1, 2019 unless otherwise renewed.

3. On or about July 1, 2002, the Board issued Out of State Distributor License Number OSD 4086 to McKesson Corporation to do business as McKesson Drug Co., John Hammergren, CEO. The License will expire on July 1, 2019, unless otherwise renewed.

REGULATORY AND STATUTORY AUTHORITY

4. This Accusation is brought before the Board under the authority of the following laws. All section references are to the Business and Professions Code unless otherwise indicated.

5. Section 141 of the Code states:

> (a) For any licensee holding a license issued by a board under the jurisdiction of the department, a disciplinary action taken by another state, by any agency of the federal government, or by another country for any act substantially related to the practice regulated by the California license, may be a ground for disciplinary action by the respective state licensing board. A certified copy of the record of the disciplinary action taken against the licensee by another state, an agency of the federal government, or another country shall be conclusive evidence of the events related therein.
>
> (b) Nothing in this section shall preclude a board from applying a specific statutory provision in the licensing act administered by that board that provides for discipline based upon a disciplinary action taken against the licensee by another state, an agency of the federal government, or another country.

6. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board . . .whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.

[1] The Board has recently discovered that John Hammergren, CEO of both Respondents McKesson Corporation and McKesson Drug Company, disassociated with Respondents on April 1, 2019. Because Respondents have not provided the identity of the new CEO, John Hammergren remains as the CEO of record.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

7. Section 4300.1 of the Code states:

The expiration, cancellation, forfeiture, or suspension of a board-issued license by operation of law or by order or decision of the board or a court of law, the placement of a license on a retired status, or the voluntary surrender of a license by a licensee shall not deprive the board of jurisdiction to commence or proceed with any investigation of, or action or disciplinary proceeding against, the licensee or to render a decision suspending or revoking the license.

8. Section 4301 of the Code states in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . . .

(n) The revocation, suspension, or other discipline by another state of a license to practice pharmacy, operate a pharmacy, or do any other act for which a license is required by this chapter that would be grounds for revocation, suspension, or other discipline under this chapter. Any disciplinary action taken by the board pursuant to this section shall be coterminous with action taken by another state, except that the term of any discipline taken by the board may exceed that of another state, consistent with the board's enforcement guidelines. The evidence of discipline by another state is conclusive proof of unprofessional conduct.

(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

. . . ."

COST RECOVERY

9. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct)

10. Respondents McKesson Corporation and McKesson Drug Co are subject to disciplinary action under section 4301(o) for violating or attempting to violate, directly or

indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency. The circumstances are as follows:

11. On or about May 2, 2008, Respondents entered into an Administrative Memorandum of Agreement (2008 MOA) with the United States Drug Enforcement Administration (DEA). The MOA provided, amongst other things, that Respondents maintain a compliance program designed to detect and prevent the diversion of controlled substances, and inform the DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b).

12. On or about January 17, 2017, Respondents entered into a Settlement Agreement with the United States Department of Justice and the DEA. In the Settlement Agreement, Respondents acknowledged that, at various times during the period covered by the Settlement Agreement, it did not identify or report to the DEA certain orders placed by certain pharmacies which should have been detected as suspicious in a manner fully consistent with the requirements set forth on the 2008 MOA, and based on the guidance contained in letters sent by the DEA about the requirements of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a part of the Settlement Agreement, Respondents agreed to pay $150 million to the United States, and the DEA suspended the DEA registration of Respondent McKesson Corporation (OSD3275) from January 18, 2019 to January 18, 2021, and suspended Respondent McKesson Drug Co. (OSD4086) from January 17, 2017 to January 17, 2019.

SECOND CAUSE FOR DISCIPLINE

(Discipline by an Agency of the Federal Government and/or Another State)

13. Respondents McKesson Corporation and McKesson Drug Co are subject to disciplinary action under sections 141 and 4301 (n) for a disciplinary action taken by any agency of the federal government and by another state for any act substantially related to the practice regulated by the California license, as set forth in paragraph 12 above and incorporated by reference. In addition to the disciplinary action taken by the federal government, other state regulatory agencies disciplined Respondents for violations of state laws or regulations as a result

the disciplinary action taken by the federal government. Those states include, but are not limited to the following: the Idaho Board of Pharmacy, Case Nos. BOP 17-054 and BOP 17-055; and the State of Oregon, Board of Pharmacy, Case No. 2017-0291.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoke or Suspend Out of State Distributor License Number OSD 3275, issued to Respondent McKesson Corporation, John Hammergren, CEO;

2. Revoke or Suspend Out of State Distributor License Number OSD 4086, issued to Respondent McKesson Drug Co., John Hammergren, CEO;

3. Ordering Respondents to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

4. Taking such other and further action as deemed necessary and proper.

DATED: May 15, 2019

Anne Sodergren

Anne Sodergren
Interim Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

SA2018101253
McKessonFirstAmACC.docx

August 23, 2019

VIA E-MAIL ONLY - dora_pharmacyboard@state.co.us

Yukon Morford
Colorado State Board of Pharmacy
Colorado Department of Regulatory Agencies
Division of Professions and Occupations
1560 Broadway
Suite 1350
Denver Colorado, CO 80202

RE: License Number: WHO.7035
Case Number: 2019-3776

Dear Mr. Morford:

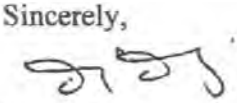
This letter is McKesson Corporation's ("McKesson") response to the Colorado State Board of Pharmacy's ("Board") Complaint (Case Number 2019-3776), dated June 3rd, 2019[1]. The Complaint alleges that McKesson's O'Fallon, Missouri distribution center (License Number: WHO.7035) failed to provide timely notice of a change in the Designated Representative in violation of Colo. Code Regs. 719-1:15.01.14(c). I acknowledge the untimely notification and sincerely apologize for the oversight. As explained below, procedures were in place to properly notify the Board of the change.

I assumed the duties of Designated Representative of the O'Fallon distribution center in place of Tom Hughes on April 1, 2019. Upon the change, our internal licensing team prepared all required notices to state boards and regulatory authorities, including Colorado. These notices and forms were sent to me for my final review. Upon my review and signature, the notices were mailed to the respective boards. Unfortunately, this was not the case with Colorado. There was an internal misunderstanding of where and how to submit the registration and fingerprints cards and that led to the untimely notification. Upon discovery we immediately took steps to correct the problem and submitted the application that same day.

Again, I acknowledge the untimely notification and sincerely apologize for this oversight. I understand the notification requirements under the law and I take my responsibility as Designated Representative seriously. McKesson has appropriate procedures in place to ensure compliance with applicable laws and regulations; the failure to provide timely notice to the Board in this instance was due to human error.

I look forward to working with the Board to promptly resolve this matter. If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,



Travis Flieg

[1] Please note that the Board's letter, which was sent to McKesson via email on July 24, 2019, was dated June 3, 2019.

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

August 29, 2019

McKesson Pharmaceutical
Attn: Designated Representative
1 Commerce Dr
O Fallon, MO 63366-4413

Re: License Number: WHO.0007035
Case Number: 2019-3776

Dear: Designated Representative,

The Colorado Board of Pharmacy ("Board") reviewed the available material concerning the above referenced case. After thorough review, the Board found probable cause to believe you violated the Pharmacy Practice Act and issues this Letter of Admonition in accordance with 12-42.5-124(6)(a).

51 days transpired between the 4/1/19 date the previous designated representative of Respondent Wholesaler ceased that position and the 5/22/19 date Respondent Wholesaler submitted an application and fee detailing a change in its designated representative. Pursuant to Board Rule 15.01.11(b), changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof. The Board did not receive the required notification.

By this letter, the Board takes the formal disciplinary action of admonishing you for the conduct specified above, and warns you that repetition of such practice may lead to imposition of more severe disciplinary action. This letter is an open public record and a reportable action to individuals or entities requesting disciplinary information. The Board strongly encourages you to review and understand the Pharmacy Practice Act requirements and obligations for the practice of pharmacy in Colorado.

In accordance with 12-42.5-124(6)(b), the Board advises you that you have the right to make a written request that the Board initiate formal disciplinary proceedings in order to adjudicate the conduct or acts upon which this letter is based. You must make your written request within twenty (20) days after receipt of this letter and address your request to Dmitry Kunin, Program Director, at the address listed below. If you make a timely request, the Board will deem this letter of admonition vacated and may proceed with disciplinary and/or injunctive proceedings in accordance with 12-42.5-124(c), C.R.S., and applicable rules.

A Letter of Admonition, when accepted, becomes a permanent, public portion of your record. It is not, however, a restriction on your practice as a professional pharmacist.

If you have further questions or concerns, please visit our website at https://www.colorado.gov/dora/dpo or you can contact our office at dora_pharmacyboard@state.co.us or by calling (303) 894-7800.

Sincerely,

FOR THE COLORADO STATE BOARD OF PHARMACY

Dmitry Kunin
Program Director

Please complete a short survey at https://www.surveymonkey.com/r/B5JR27T regarding aspects of the service you received. Your anonymous response will be used to evaluate the service experience and to identify areas where improvements may be appropriate.

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **LETTER OF ADMONITION** upon all parties herein by depositing copies of same in the United States mail, certified, postage prepaid, at Denver, Colorado this 29th day of August 2019, addressed as follows:

McKesson Pharmaceutical
Attn: Designated Representative
1 Commerce Dr
O Fallon, MO 63366-4413
tom.hughes@mckesson.com

Linda Stanko

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

October 17, 2019

McKesson Corporation
1995 McKesson Street, Suite 101
Aurora, IL 60502-7703

Sent via email: mckessonlicensing@MCKesson.com

RE: Case No. 2019-5119 - Stipulation and Final Agency Order

Dear Pharmacy Manager:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the terms and conditions of the above listed Stipulation and Final Agency Order effective October 4, 2019.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released you from the terms and conditions of the October 4, 2019, Stipulation and Final Agency Order and restored your Registration No. WHO.0007154 to unencumbered status.

Although this disciplinary action will remain a public document, our records show that the requirements of your Order are complete. Please retain this letter for your records.

Your cooperation during the pendency of this matter is sincerely appreciated.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Dmitry Kunin
Program Director

cc: File

August 9, 2019

VIA E-MAIL ONLY - dora_pharmacyboard@state.co.us

Lana Hyatte
Program Specialist
Colorado State Board of Pharmacy
Colorado Department of Regulatory Agencies
Division of Professions and Occupations
1560 Broadway
Suite 1350
Denver Colorado, CO 80202

RE: License Number: WHO.7154
Case Number: 2019-5119

Dear Ms. Hyatte:

This letter is McKesson Corporation's ("McKesson") response to the Colorado State Board of Pharmacy's ("Board") July 24, 2019[1] Complaint (Case Number: 2019-5119). The Complaint alleges that McKesson's Chicagoland, Illinois distribution center (License Number: WHO.7154) failed to provide timely notice of a change in the Designated Representative in violation of Colo. Code Regs. 719-1:15.01.14(c). I acknowledge the untimely notification and sincerely apologize for the oversight. As explained below, procedures were in place to properly notify the Board of the change. However, there was an internal misunderstanding of the need to submit background check results with the notice of change that led to the untimely notification.

I assumed the duties of Designated Representative of the Chicagoland distribution center in place of Robert Perrich on May 1, 2019. Upon the change, our internal licensing team prepared all required notices to state boards and regulatory authorities, including Colorado. These notices and forms were sent to me for my final review. Upon my review and signature, the notices were mailed to the respective boards. Unfortunately, this was not the case with Colorado. Our internal licensing team was under the impression that we needed to receive the fingerprint results from IdentoGo before we could submit the Change of Designated Representative application to the Board.

On July 7, 2019, I received a phone call from the Colorado Bureau of Investigations to let me know they had received the fingerprint cards but the results had not yet been "pulled" by the Board. It was not until then that I realized our licensing team had not sent the Change of

[1] Please note, the Board's letter, which was sent to McKesson via email on July 24, 2019, is erroneously dated as June 3, 2019.

Designated Representative application to the Board. Upon discovery we immediately took steps to correct the problem and submitted the application that same day.

Again, I acknowledge the untimely notification and sincerely apologize for this oversight. I understand the notification requirements under the law and I take my responsibility as Designated Representative seriously. McKesson has appropriate procedures in place to ensure compliance with applicable laws and regulations. Our failure to provide timely notice to the Board in this instance was due to human error and a misunderstanding.

I look forward to working with the Board to promptly resolve this matter. If you have any questions or require additional information, please do not hesitate to contact me.

Sincerely,

Nicholas Davis

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2019-5119

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE OUT-OF-STATE PRESCRIPTION DRUG WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MCKESSON CORPORATION, REGISTRATION NO. WHO 7154,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and McKesson Corporation ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2019-5119, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an out-of-state prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2018).

2. Respondent Outlet was originally registered in the State of Colorado on or about January 24, 2007, being issued registration #WHO 7154, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 1995 McKesson St, Ste 101, Aurora, IL 60502.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit to the Board an application detailing a change in designated representative and fee. In this case, 76 days transpired between May 1, 2019, the date the previous designated representative ceased the position, and July 16, 2019, the date the application and fee were received.

6. On or about July 24, 2019, the Board initiated a complaint against Respondent Outlet because of the delay of 76 days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board.

* * *

Pharmacy Board Rules and Regulations

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to section 12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of **One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00)**. The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under section 12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension

or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record**. Upon execution by all parties, this Stipulation and Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Ammie McAsey _____ Dated: October 2, 2019

Authorized Representative

Ammie McAsey / SVP, Distribution Operations

Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this _____day of _____, 2019.

State Board of Pharmacy

BY: _____
Dmitry Kunin
Program Director

McKESSON

August 29, 2019

Lana Hyatte
Program Specialist
Colorado State Board of Pharmacy
Colorado Department of Regulatory Agencies
Division of Professions and Occupations
1560 Broadway
Suite 1350
Denver Colorado, CO 80202

RE: License Number: WHO.7154
Case Number: 2019-5119

Dear Ms. Hyatte:

Enclosed with this letter please find payment of $1,1500 (check number: 0192627) to Case No. 2019-51194 and the copy of the Stipulation and Final Agency Order as requested.

Please contact me at your earliest convenience if you have further questions about this matter.

Very truly yours,

Beatrix Erdei
McKesson Corporation
Tel: 415-983-9247
Email: beatrix.erdei@mckesson.com

McKesson Corporation
6555 North State Hwy 161
Irving, TX 75039

SUMMARY

CHECK NUMBER:	0192627
Check Date:	08/27/2019
CHECK AMOUNT:	$1,150.00

14892733 - 00006

COLORADO STATE BOARD OF PHCY
OFFICE OF LICENSING PHCY
1560 BROADWAY STE 1350
DENVER, CO 802025143

Invoice Date	Reference Number	Net Amount	Gross Amount	Discount Amount
20190819 20190827	CO-8144 CHK PAID VENDOR # 3000008120	$1,150.00	$1,150.00	$0.00
TOTAL		$1,150.00	$1,150.00	$0.00

THE FACE OF THIS DOCUMENT HAS A COLORED BACKGROUND. SECURITY FEATURES INCLUDE THERMOCHROMIC INK, MICROPRINTING, A VOID PANTOGRAPH, AND AN ARTIFICIAL WATERMARK AND SECURITY SCREEN ON THE BACK.

McKesson Corporation
6555 North State Hwy 161
Irving TX 75039

75-1592/912

Check Number	Date
0192627	08/27/2019

Amount
$******1,150.00

PAY EXACTLY *********1,150* DOLLARS AND * 00 * CENTS

TO THE ORDER OF:
COLORADO STATE BOARD OF PHCY
OFFICE OF LICENSING PHCY
1560 BROADWAY STE 1350
DENVER, CO 802025143

usbank

VOID VOID VOID

⑈0000192627⑈ [redacted]

BEFORE THE IOWA BOARD OF PHARMACY

RE: Wholesaler License and Controlled Substances Act Registration of **MCKESSON DRUG COMPANY** License No. 7987 Registration No. 2212001 Respondent	CASE NO. 2019-0047 **COMBINED STATEMENT OF CHARGES, SETTLEMENT AGREEMENT, AND FINAL ORDER**

COME NOW the Iowa Board of Pharmacy ("Board") and McKesson Drug Company ("Respondent"), 2101 12th Ave S, Clear Lake IA 50428, and enter into this Combined Statement of Charges, Settlement Agreement, and Final Order ("Order") pursuant to Iowa Code sections 17A.10 and 272C.3(4), and 657 IAC 35.5. The Board has jurisdiction over Respondent and the subject matter of this case pursuant to Iowa Code chapters 17A, 124, 155A, and 272C (2019), and 657 IAC 36.

A. STATEMENT OF CHARGES

COUNT I
FAILURE TO TAKE COMPLETE INVENTORY

1. Respondent is charged with failing to comply with the requirements in 657 IAC 10.19 to take a complete and accurate inventory of all stocks of controlled substances, and may be disciplined pursuant to Iowa Code sections 124.304(1)(d) and 155A.17(4), and 657 IAC 10.44(5), 36.6(28).

B. FACTUAL CIRCUMSTANCES

2. Respondent's wholesaler license number 7987 is currently active through December 31, 2019. Respondent's Controlled Substances Act registration number 2212001 is currently active through January 31, 2021.

3. Respondent failed to include pseudoephedrine products in the annual controlled substance inventory.

4. Respondent failed to take an initial inventory of butalbital products after such products became schedule III controlled substances on June 26, 2019.

C. SETTLEMENT AGREEMENT AND FINAL ORDER

5. The Board has jurisdiction over the parties and the subject matter of these proceedings.

6. Respondent acknowledges that the allegations in the Statement of Charges, if proven in a contested case hearing, would constitute grounds for the discipline agreed to in this Order.

7. Execution of this Order constitutes the resolution of a contested case. Respondent has a right to hearing before the Board on the charges, but Respondent waives the right to hearing and all attendant rights, including the right to appeal or seek judicial review of the Board's action, by freely and voluntarily entering into this Order. Once entered, this Order shall have the force and effect of a disciplinary order entered following a contested case hearing.

8. Respondent acknowledges that it has the right to be represented by counsel on this matter.

9. Respondent agrees that the State's counsel may present this Order to the Board and may have *ex parte* communications with the Board while presenting it.

10. This Order is subject to approval by a majority of the full Board. If the Board does not approve this Order, it shall be of no force or effect to either party, and shall not be admissible for any purpose in further proceedings in this matter. If the Board approves this Order, it shall be the full and final resolution of this matter.

11. This Order shall be part of Respondent's permanent record and shall be considered by the Board in determining the nature and severity of any disciplinary action to be imposed in the event of any future violations.

12. Respondent understands the Board is required by federal law to report any adverse action to the National Association of Boards of Pharmacy's Disciplinary Clearinghouse and the National Practitioner Data Bank. These reports shall be the only reports or publications the Board will make regarding this settlement.

13. This Order, when fully executed, is a public record and is available for inspection and copying in accordance with the requirements of Iowa Code chapters 22 and 272C.

14. The Board's approval of this Order shall constitute a **FINAL ORDER** of the Board.

IT IS THEREFORE ORDERED:

15. Respondent is hereby **CITED** for failing to comply with the requirements in 657 IAC 10.19 to take a complete and accurate inventory of all stocks of controlled substances and **WARNED** that future violations of the laws and rules governing wholesalers can result in further disciplinary action.

16. Respondent shall pay a **CIVIL PENALTY** in the amount of five thousand dollars ($5,000) within sixty (60) days of this Order. The check shall be made payable to the "Treasurer of Iowa" and shall be deposited in the general fund. The civil penalty should be mailed to the Iowa Board of Pharmacy, Attn: Amanda Woltz, 400 SW 8th St, Ste E, Des Moines IA 50309.

17. Should Respondent violate the terms of this Order, the Board may initiate action to impose other licensee discipline as authorized by Iowa Code chapters 155A and 272C and 657 IAC 36.

By the signature below, Ammie McAsey acknowledges s/he is the SVP Distribution Operations for Respondent and is authorized to sign this Combined Statement of Charges, Settlement Agreement, and Final Order on behalf of Respondent.

1-2-2020
Date

Ammie McAsey
MCKESSON DRUG COMPANY
Respondent

This Combined Statement of Charges, Settlement Agreement, and Final Order is approved by the Iowa Board of Pharmacy on the 7 day of January, 2020.

Tasia Housel
Chairperson
Iowa Board of Pharmacy

Iowa Board of Pharmacy

ANDREW FUNK, PHARM.D.
EXECUTIVE DIRECTOR

ACCEPTANCE OF SERVICE BY ATTORNEY

I, Roger Morris,
(Print name)

as attorney for McKesson Drug Company, acknowledge that I received a copy of the Combined Statement of Charges, Settlement Agreement, and Final *Order dated January 7, 2020 and am authorized to accept service of* this document on behalf of McKesson Drug Company.

By signing this form, I acknowledge that I am accepting service of the document described above.

(Signature) 1/15/2020 (Date)

Please return this form by mail to the address below, by fax to the number below, or by scanning and sending by email to Amanda.woltz@iowa.gov.

400 S.W. EIGHTH STREET, SUITE E • DES MOINES, IA 50309-4688
PHONE: 515-281-5944 • https://pharmacy.iowa.gov • FAX: 515-281-4609

BEFORE THE INDIANA BOARD OF PHARMACY
CAUSE NUMBER: 2019 IBP 0041

IN THE MATTER OF THE LICENSE OF:)
)
McKESSON DRUG COMPANY)
LICENSE NO: 48000550A)



FINAL ORDER ACCEPTING PROPOSED FINDINGS OF FACT, CONCLUSIONS OF LAW, AND ORDER

The State of Indiana ("Petitioner"), by counsel Timothy M. Weber, Deputy Attorney General, and McKesson Drug Company ("Respondent"), by counsel Randall Fearnow, signed a Proposed Settlement Agreement ("Agreement") which purports to resolve all issues involved in the action regarding Respondent's license before the Indiana Board of Pharmacy ("Board"), and which Agreement has been submitted to the Board for approval.

The Board, after reviewing the Agreement at the January 13, 2020 meeting held in Room W064 of the Indiana Government Center South, 402 West Washington Street, Indianapolis, Indiana, now finds it has been entered into fairly and without fraud, duress, or undue influence, and is fair and equitable between the parties. The Board hereby incorporates the Agreement which is attached hereto and incorporated herein as **Exhibit A** and approves and adopts in full the Agreement as a resolution of this matter. The Board approved this Agreement by a vote of 6-0-0. Incorporated into the Agreement was the consensus of both parties to Findings of Fact, Conclusions of Law, and Order.

WHEREFORE, the Board hereby accepts and approves the Agreement, settling all matters in this case consistent with the terms of the Agreement between the parties, and Respondent is hereby **ORDERED** to abide by all the terms of the Agreement as set forth below:

1. Respondent's license to practice as a wholesale drug distributor in the state of Indiana shall be placed on **INDEFINITE PROBATION**. As a term of this probation, and with the exception of the activities discussed in Paragraph 3 below, Respondent may not distribute controlled substances into Indiana effective as of the effective date of the Agreement until Respondent's DEA Registration is fully re-instated on or about February 16, 2021. In the event that Respondent's DEA Registration will remain suspended beyond February 16, 2021, Respondent shall notify the Board prior to the date of the continued suspension of its DEA Registration and the date that the suspension of its DEA Registration will terminate.

2. After the DEA Registration is fully re-instated, Respondent may submit a Petition to Withdraw the Probation to request that the probation be lifted.

3. The restriction of Respondent's ability to distribute controlled substances in the state of Indiana shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under Respondent's exclusive contract with the United States Department of Veteran Affairs.

4. Respondent shall fully comply with the 2017 Agreements and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice and Drug Enforcement Administration, and effective on January 17, 2017.

5. Within **NINETY (90) DAYS** of the final order in this matter, Respondent shall pay a **FINE** in the amount of **ONE THOUSAND DOLLARS ($1,000.00)**. This fine shall be paid by check or money order payable to the Indiana Professional Licensing Agency, and submitted to the following address:

Indiana Professional Licensing Agency
Attn: Board of Pharmacy
402 W. Washington Street, Room W072
Indianapolis, IN 46204

6. Within **NINETY (90) DAYS** of the final order in this matter, Respondent shall, pursuant to Ind. Code § 4-6-14-10(b), pay a **FEE** in the amount of **FIVE DOLLARS ($5.00)** to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund. This fee shall be paid by check or money order payable to the State of Indiana, and submitted to the following address:

Office of the Indiana Attorney General
Attn: Executive Assistant, Consumer Protection Division
302 West Washington Street, 5th Floor
Indianapolis, IN 46204

7. A violation of the Final Order, any non-compliance with the statutes or regulations regarding the practice of wholesale drug distribution, or any violation of this Agreement may result in Petitioner requesting a summary suspension of Respondent's license, an Order to Show Cause as may be issued by the Board, or a new cause of action pursuant to Ind. Code § 25-1-9-4, any or all of which could lead to additional sanctions, up to and including a revocation of Respondent's license.

SO ORDERED, this 19th day of February 2020.

INDIANA BOARD OF PHARMACY

By: Maureen Bennett
for Matt Balla, R. Ph., President

CERTIFICATE OF SERVICE

I certify that a copy of the "Final Order Accepting Proposed Findings of Fact, Conclusions of Law, and Order" has been duly served upon:

McKesson Drug Company
3000 Kenskill Ave
Washington Court House, OH 43160
Service by U.S. Mail

Randall Fearnow
QUARLES & BRADY, LLP
300 N. LaSalle Street, Suite 4000
Chicago, Illinois 60654-3406
Service by U.S. Mail

Timothy M. Weber
OFFICE OF THE INDIANA ATTORNEY GENERAL
Indiana Government Center South, Fifth Floor
302 West Washington Street
Indianapolis, Indiana 46204-2770
Service by Email: timothy.weber@atg.in.gov

2-19-2020
Date

Nathaniel Black Jr., Litigation Specialist

Indiana Board of Pharmacy
Indiana Government Center South
402 West Washington St., Room W072
Indianapolis, IN 46204
Phone: 317-234-2067
Fax: 317-233-4236
Email: pla4@pla.in.gov

Explanation of Service Methods
Personal Service: by delivering a true copy of the aforesaid document(s) personally.
Service by U.S. Mail: by serving a true copy of the aforesaid document(s) by First Class U.S. Mail, postage prepaid.
Service by Email: by sending a true copy of the aforesaid document(s) to the individual's electronic mail address.

BEFORE THE INDIANA BOARD OF PHARMACY
CAUSE NO: 2019 IBP 0041

IN THE MATTER OF THE LICENSE OF:)
)
McKESSON DRUG COMPANY)
LICENSE NO: 48000550A)

FILED
JAN 08 2020
Indiana Professional Licensing Agency

SETTLEMENT AGREEMENT

The State of Indiana ("Petitioner"), by Timothy M. Weber, Deputy Attorney General, and McKesson Drug Company ("Respondent"), by counsel, Randall Fearnow, hereby execute this Settlement Agreement ("Agreement") to resolve all issues raised by the filing of the Petitioner's Complaint in the above captioned matter and the Respondent's objections thereto. This Agreement is subject to the review and approval of the Indiana Board of Pharmacy ("Board") pursuant to Ind. Code § 25-1-9 and Ind. Code § 4-21.5-3.

STIPULATED FACTS

1. Respondent is a licensed wholesale drug distributor in the State of Indiana having been issued license number 48000550A.

2. Respondent's address is 2000 Kenskill Ave., Washington Court House, Ohio 43160.

3. Respondent is one of several wholesale distribution centers operated by its parent company, McKesson Corporation (parent company hereinafter referred to as "McKesson").

4. On January 17, 2017, McKesson entered into a Settlement Agreement and Release and an Administrative Memorandum of Agreement (collectively, the "2017 Agreement") with the Drug Enforcement Agency ("DEA") and the Department of Justice ("DOJ"). Pursuant to the terms of the 2017 Agreement, the parties agreed in relevant part.

EXHIBIT A

a. At times relevant to the 2017 Agreement, McKesson's distribution centers were required to operate in accordance with the statutory provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. §§ 801 *et seq.* ("CSA"), and the regulations promulgated thereunder, 21 C.F.R. Part 1300 *et seq.*

b. The regulations promulgated under the CSA include a requirement to design and operate a system to detect and report "suspicious orders" for controlled substances, as that term is defined in the regulation.

c. In 2006 and 2007, the DEA sent letters to every entity in the United States that was registered with the DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The letters contained guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b).

d. In 2008, McKesson entered into a settlement with the DOJ and a Memorandum of Agreement with the DEA (collectively referred to as the "2008 Agreements").

e. The 2017 Agreement covers the time period of January 1, 2009 through the date of the last signatory to the 2017 Agreement, which was on January 17, 2017 ("Covered Time Period").

5. Pursuant to the 2017 Agreement, Respondent's DEA Certificate of Registration ("DEA Registration") will be suspended between February 16, 2019 and February 16, 2021 with a partial exception to possess and distribute controlled substances related to servicing federal customers that purchase from Respondent under an exclusive contract with the United States Department of Veterans

Affairs. The suspension does not apply to or limit McKesson's authority to distribute, or operations involving List 1 Chemical products.

6. Indiana Code § 25-1-9-4(a)(3) allows the Board to discipline a practitioner if the Board finds that the practitioner has knowingly violated any state statute or rule, or federal statute or regulation, regulating the profession in question.

7. Indiana Code § 25-26-14-17(10) requires a wholesale distributor, if involved in the distribution of controlled substances, to maintain registration with the federal Drug Enforcement Agency.

STIPULATED CONCLUSION OF LAW

The parties further stipulate Respondent's Indiana license is subject to discipline in accordance with Indiana Code § 25-1-9-4(a)(3) because Respondent's DEA Registration was suspended; therefore, it did not maintain registration with the DEA as required by Indiana Code § 25-26-14-17(10).

AGREED DISPOSITION

It is now therefore agreed by Respondent and Petitioner as follows:

1. Both parties voluntarily waive their rights to a public hearing on the Complaint and all other proceedings in this action to which either party may be entitled by law, including judicial review and appeal.

2. This Agreement resolves any and all pending claims or allegations relating to disciplinary action against the Respondent's Indiana wholesale drug distributor license.

3. Respondent's license to practice as a wholesale drug distributor in the state of Indiana is hereby placed on INDEFINITE PROBATION. As a term of this probation, and with the exception of the activities discussed in Paragraph 5 below, Respondent may not distribute controlled substances into Indiana effective as of the effective date of this Agreement until Respondent's DEA Registration is fully

re-instated on or about February 16, 2021. In the event that Respondent's DEA Registration will remain suspended beyond February 16, 2021, Respondent shall notify the Board prior to the date of the continued suspension of its DEA Registration and the date that the suspension of its DEA Registration will terminate.

4. After the DEA Registration is fully re-instated, Respondent may submit a Petition to Withdraw the Probation to request that the probation be lifted.

5. The restriction of Respondent's ability to distribute controlled substances in the state of Indiana shall not apply to or limit Respondent's authority to distribute, or Respondent's operations involving, List 1 chemical products at or from Respondent which are authorized under Respondent's DEA Registration. Respondent is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the United States Department of Veterans Affairs.

6. Respondent shall fully comply with the 2017 Agreement and any amendments or modifications thereto, entered into by Respondent and the United States Department of Justice, Drug Enforcement Administration and effective on January 17, 2017.

7. Within ninety (90) days of the Board's Final Order accepting this Agreement, Respondent shall pay a **FINE** in the amount of **ONE THOUSAND DOLLARS ($1,000.00).** This fine shall be paid by check or money order payable to the Indiana Professional Licensing Agency, and submitted to the following address:

Indiana Professional Licensing Agency
Attn: Board of Pharmacy
402 W. Washington Street, Room W072
Indianapolis, Indiana 46204

8. Within **NINETY (90) DAYS** of the Final Order, Respondent shall, pursuant to Ind. Code § 4-6-14-10(b), pay a **FEE** in the amount of **FIVE DOLLARS ($5.00)** to be deposited into the Health Records and Personal Identifying Information Protection Trust Fund. This fee shall be paid by check or money order payable to the State of Indiana, and submitted to the following address:

Office of the Indiana Attorney General
Attn: Teresa Henson
302 West Washington Street, 5th Floor
Indianapolis, IN 46204

9. Respondent has carefully read and examined this Agreement and fully understands its terms and that, subject to approval by the Board, this Agreement is a final disposition of the Allegations.

10. The hearing set in this matter shall be vacated upon approval of the Board.

IN WITNESS WHEREOF, the undersigned, authorized representatives of the parties, affix their signatures hereto evidencing their acceptance of this Agreement.

Annie McKey — 1-6-2020
Representative for Respondent — Date

1-7-2020
Randall R. Fearnow — Date
Counsel for Respondent

1-7-2020
Timothy M. Weber — Date
Deputy Attorney General

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 Norwalk Boulevard** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 OAH No. 2021050035 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL (AS TO JOHN F. BOHLINGER, ONLY)** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christina Thomas, Deputy Attorney General.

2. Respondent John F. Bohlinger is represented in this proceeding by attorney Alissa Brice Castaneda, whose address is: Quarles & Brady LLP One Renaissance Square Two North Central Avenue Phoenix, AZ 85004-2391

JURISDICTION

3. On or about January 21, 2004, the Board issued Designated Representative License No. EXC 17318 to John F. Bohlinger. The Designated Representative License was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6850 and will expire on January 1, 2023, unless renewed.

4. First Amended Accusation No. 6850 was filed before the Board of Pharmacy, Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on January 4, 2021. Respondent timely filed his Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 6850 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6850. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of his legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at his own expense; the right to confront and cross-examine the witnesses against him; the right to present evidence and to testify on his own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

///

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent denies the allegations in First Amended Accusation No. 6850.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up his right to contest those charges.

10. Respondent agrees that his Designated Representative is subject to discipline and he agrees to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or his counsel. By signing the stipulation, Respondent understands and agrees that he may not withdraw his agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Designated Representative License No. EXC 17318 issued to Respondent John F. Bohlinger shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6850, attached as exhibit A.

Coursework. No later than six months from the effective date of the public reproval, Respondent, at his own expense, shall enroll, successfully complete and submit verification of a six- hour course relevant to the Drug Supply Chain Security as specified by the Board. Respondent shall obtain prior approval from the Board before enrolling in the course. Respondent shall submit to the Board the original transcripts or certificates of completion for the above-required course.

Full Compliance. As a resolution of the charges in First Amended Accusation No. 6850, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Designated Representative License No. EXC 17318.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castaneda. I understand the stipulation and the effect it will have on my Designated Representative License. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

JOHN F. BOHLINGER
Respondent

I have read and fully discussed with Respondent the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

LA2019505103
64760160.docx

DATED: 12/17/21

JOHN F. BOHLINGER
Respondent

I have read and fully discussed with Respondent the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/17/2021

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: December 17, 2021

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

LA2019505103
64760160.docx

Exhibit A

First Amended Accusation No. 6850

XAVIER BECERRA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number WLS 3076 to McKesson Corporation, dba McKesson Drug Company (Respondent

McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, *unless renewed.*

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

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8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

...

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

...

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available... Initial: 0.005 to 0.02 mg/kg/dose 3 times daily... maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg **per year** between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

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Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

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FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at 25802 Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

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a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2020.11.16 05:53:42 -08'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

LA2019505103
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IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor Permit No. 192131	)	**CASE NO: 22-L-0252**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **MCKESSON DRUG COMPANY** which resulted in the filing of a Notice of Hearing and Statement of Charges ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **MCKESSON DRUG COMPANY** has violated the provisions of law based upon the conduct set out in the Statement.

2. **MCKESSON DRUG COMPANY** shall pay an administrative fine in the amount of Twenty-Five Thousand Dollars ($25,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **MCKESSON DRUG COMPANY** attempt to discharge the same.

3. **MCKESSON DRUG COMPANY** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and

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§40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **MCKESSON DRUG COMPANY** further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **MCKESSON DRUG COMPANY** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **MCKESSON DRUG COMPANY** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **MCKESSON DRUG COMPANY's** permit, including, but not limited to revocation.

6. **MCKESSON DRUG COMPANY** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. **MCKESSON DRUG COMPANY** acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 19th of July, 2023.

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MCKESSON DRUG COMPANY

BY: Jimmie McKay

ITS: SVP Customer Distribution

By: _____
Nicholas Meza,
Attorney for
MCKESSON DRUG COMPANY

DONE this the 22nd of July, 2023.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Robert M. Colburn, Jr., R. Ph., President

By: _____
Jennifer Muro Neumann,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

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EXHIBIT A

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IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
MCKESSON DRUG COMPANY	)	**BOARD OF PHARMACY**
	)	
Wholesale Distributor	)	**CASE NO: 22-L-0252**
Permit No. 192131	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: McKesson Drug Company
9501 Norwalk Boulevard
Santa Fe Springs, California 90670

Pursuant to the provisions of Code of Alabama (1975), § 34-23-32, § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on June 20, 2023 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate McKesson Drug Company as a Wholesale Distributor should not be subject to the discipline set out in Board Rule 680-X-2.23(h)(2)(i)(2) based upon any or all of the following, to-wit:

1. Pursuant to Board Rule 680-X-2.23(g)(3), the Board of Pharmacy shall consider, at a minimum, the following factors in reviewing the qualifications of those entities (a wholesaler) permitted for operation within the State of Alabama:

   a. Compliance with licensing requirements under previously granted licenses ((g)(3)(vi)).

   b. Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety.

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((g)(3)(viii)).

2. It is a violation of these rules should any permitted entity operate in such a manner as to endanger the public health. (Board Rule 680-X-2.23(h)(2)(i)(1)).

3. Permitted entities shall operate in compliance with applicable state laws.

4. The Board alleges you have not complied with the licensing requirements under previously granted licenses, you have not operated consistent with public health and safety, you have operated in such a manner as to endanger the public health and/or you have not complied with applicable State law based upon the following:

(a) The entry of a Decision and Order on February 22, 2022 by the California State Board of Pharmacy attached hereto as Exhibit "A" and/or the excessive furnishing of controlled substances as set out in the First Cause for Discipline, and/or delivering drugs when not signed for or received by a pharmacist as set out in the Second and Third Cause for Discipline, those being separate and distinct violations as more particularly described in the First Amended Accusation included in Exhibit "A" hereto[1].

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

[1] This Rule was amended effective October 15, 2020 to add additional entities now regulated by the Board; however, the Rule prior to the Amendment applied to and was in full force and effect as to the permit held by the Respondent at the time of the referenced discipline.

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Dated this the 24th day of August, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

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EXHIBIT "A"

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

MCKESSON CORPORATION, dba
MCKESSON DRUG COMPANY,
Wholesale Permit No. WLS 3076;

and

JOHN F. BOHLINGER,
Designated Representative License No. EXC 17318,

Respondents

Agency Case No. 6850

OAH No. 2021050035

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DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 24, 2022.

It is so ORDERED on February 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Seung W. Oh, Pharm.D.
Board President

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Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 Norwalk Boulevard** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 OAH No. 2021050035 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL (AS TO MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY, ONLY)** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christina Thomas, Deputy Attorney General.

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2. Respondent McKesson Corporation, dba McKesson Drug Company (Respondent) is represented in this proceeding by attorney Alissa Brice Castenada, whose address is: Quarles & Brady LLP One Renaissance Square Two North Central Avenue Phoenix, AZ 85004-2391

JURISDICTION

3. On or about October 2, 1995, the Board issued Wholesale Permit No. WLS 3076 to McKesson Corporation, dba McKesson Drug Company. The Wholesale Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6850 and will expire on October 1, 2022, unless renewed.

4. First Amended Accusation No. 6850 was filed before the Board of Pharmacy, Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on January 4, 2021. Respondent timely filed its Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 6850 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6850. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

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7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent denies the allegations in First Amended Accusation No. 6850.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Wholesale Permit is subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

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supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Wholesale Permit No. WLS 3076 issued to Respondent McKesson Corporation, dba McKesson Drug Company, shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6850, attached as exhibit A.

Cost Recovery. No later than 60 days from the effective date of the Decision, Respondent shall pay $147,780.00 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Wholesale Permit Number until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in First Amended Accusation No. 6850, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Wholesale Permit No. WLS 3076.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castaneda. I understand the stipulation and the effect it will have on my Wholesale Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

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DATED: _____

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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DATED: 12/17/2021

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/17/2021

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 12/17/21

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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Exhibit A

First Amended Accusation No. 6850

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Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
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Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number WLS 3076 to McKesson Corporation, dba McKesson Drug Company (Respondent

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McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

(a) Every license issued may be suspended or revoked.

(b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:

(1) Suspending judgment.

(2) Placing him or her upon probation.

(3) Suspending his or her right to practice for a period not exceeding one year.

(4) Revoking his or her license.

(5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

(a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

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(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

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8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

...

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

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> (b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.
>
> (c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

> (a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.
>
> ...
>
> (c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

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16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

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P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available... Initial: 0.005 to 0.02 mg/kg/dose 3 times daily... maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg per year between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

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Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

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FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at 25802 Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

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a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Signature on File

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

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BEFORE THE GEORGIA STATE BOARD OF PHARMACY
STATE OF GEORGIA

IN THE MATTER OF:	)	
	)	
MCKESSON DRUG COMPANY,	)	**DOCKET NO.**
License No. PHWH000056,	)	
	)	
Respondent.	)	

GEORGIA STATE BOARD OF PHARMACY
APR 12,2024
DOCKET NO. 2024-0056

PUBLIC CONSENT ORDER

By agreement of the Georgia State Board of Pharmacy ("Board") and McKesson Drug Company, ("Respondent"), the following disposition of this matter is entered pursuant to the provisions of O.C.G.A. T. 26, Ch. 4, and T. 43, Ch. 1.

FINDINGS OF FACT

1.

Respondent is licensed to operate as a wholesaler pharmacy in the State of Georgia. Respondent's license was issued on April 22, 1993, and expires on June 30, 2025.

2.

On or about September 16, 2022, during an inspection of Coffee Regional Medical Center by the Georgia Drugs and Narcotics Agency ("GDNA"), it was discovered that Respondent had failed to maintain prescription drugs securely. Specifically, Respondent had 1) left a delivery truck unattended at a loading dock at the rear of Coffee Regional Medical Center, with its rear roll-up door open, and totes of prescription drugs exposed, for more than 10 minutes; 2) left the truck's keys in the ignition; 3) left the truck box unlocked; and 4) did not have a lock to secure the box. Prescription drugs left unsecured in the truck included, but were not limited to, controlled substances such as diazepam, midazolam, hydrocodone, fentanyl, amphetamine, and oxycodone.

3.

Respondent waives any further findings of fact.

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CONCLUSIONS OF LAW

Under O.C.G.A. T. 26, Ch. 4 and § 43-1-19, the Georgia State Board of Pharmacy is authorized to discipline Respondent's license to operate as a pharmacy for the conduct stated above. Respondent waives any further conclusions of law with respect to this matter.

ORDER

The Board, having considered the particular facts and circumstances of this case, hereby ORDERS, and Respondent hereby AGREES, that Respondent's license shall be disciplined as follows:

1.

Respondent shall submit to the Board a fine in the amount of **Ten-Thousand Dollars ($10,000.00)** for failure to maintain prescription drugs securely. Such fine shall be payable within sixty (60) days from the effective date of this Public Consent Order. Payment shall be in the form of a cashier's check or money order made payable to the Georgia State Board of Pharmacy and sent to: Georgia State Board of Pharmacy, Attention: Executive Director, 2 Martin Luther King, Jr. Drive SE, East Tower, 11th Floor, Atlanta, GA 30334. Respondent's failure to pay the fine by the sixtieth day shall subject Respondent's license to further disciplinary action, including revocation.

2.

Respondent shall comply with all State and Federal laws relating to drugs and otherwise regulating pharmacies. Respondent shall also comply with the Rules and Regulations of the Georgia State Board of Pharmacy. The Board hereby puts Respondent on notice that Respondent is required to maintain the integrity and security of drugs being delivered to customers. Failure to comply with all laws and rules relating to the practice of pharmacy may result in further sanction or other discipline as deemed appropriate by the Board.

3.

Approval of this Public Consent Order by the Georgia State Board of Pharmacy shall in no way be construed as condoning Respondent's conduct, and shall not be construed as a waiver of any of the lawful rights possessed by the Board. This Public Consent Order shall not become effective until approved and docketed by the Georgia State Board of Pharmacy.

4.

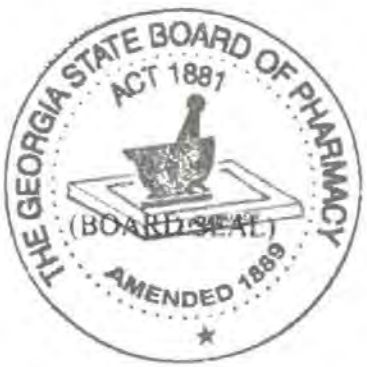
Agent of Respondent, McKesson Drug Company, acknowledges that Agent has read this Public Consent Order and understands its contents. Respondent understands that Respondent has a right to a hearing in this matter, and Respondent freely, knowingly, and voluntarily waives such right by entering into this Public Consent Order. Respondent understands that this Public Consent Order will not become effective until approved and docketed by the Georgia State Board of Pharmacy. Respondent further understands and agrees that the Board shall have the authority to review the investigative file and all relevant evidence in considering this Public Consent Order. Respondent further understands that this Public Consent Order, once approved, shall constitute a public record of the Board. Respondent further understands that if this Public Consent Order is not approved, it shall not constitute an admission against interest in this proceeding or prejudice the ability of the Board to adjudicate this matter. Respondent consents to the terms and sanctions contained herein.

(signatures appear on the following page)

Approved, this 12 day of April, 2024.

GEORGIA STATE BOARD OF PHARMACY

BY: _____
CHARLES E. PAGE, R.Ph.
President



ATTEST: _____
J. CLINTON JOINER, II
Executive Director

CONSENTED TO:

DocuSigned by:
Ammie McAsey
8C6C36205FB40F...
AGENT
Printed Name: Ammie McAsey
ON BEHALF OF
Respondent
MCKESSON DRUG COMPANY

AS TO SIGNATURE OF AGENT ON BEHALF OF RESPONDENT MCKESSON DRUG COMPANY

Sworn to and subscribed before me
this 8th day of March, 2024.

DocuSigned by:
Misti Smart
...
NOTARY PUBLIC
My commission expires:



-THIS IS A RED INK STAMP-
I certify this to be a true and exact copy of the original document on file with the Ohio State Board of Pharmacy.
Steven W. Schierholt, Esq., Executive Dir.
Date: 8/29/2024
-MUST HAVE BOARD SEAL TO BE OFFICIAL-

BEFORE THE OHIO BOARD OF PHARMACY

In the Matter of	:	
	:	**Case No. A-2021-0363**
McKesson Corporation	:	
c/o Todd Spaulding	:	**License No. 01-0977250**
3000 Kenskill Avenue	:	
Washington Court House, OH 43160	:	
	:	
Respondent.	:	

FINAL ORDER OF THE OHIO BOARD OF PHARMACY

McKesson Corporation ("Respondent") was issued a license as a wholesale distributor of dangerous drugs by the Ohio Board of Pharmacy on November 12, 1996. The Board issued a Notice of Opportunity for Hearing ("Notice") to Respondent on September 30, 2022, via certified mail, return receipt requested. Respondent received the Notice on October 3, 2022. Pursuant to Ohio Revised Code (ORC) Section 119.07, Respondent had a right to a hearing if requested within 30 days of mailing. Respondent failed to do so. Accordingly, no hearing was held, and the matter was brought before the Board on August 5, 2024, for final adjudication pursuant to ORC 119.07, and 4729.56(D).

WHEREFORE, after review of the administrative record, the Board finds that Respondent was legally served with the Notice and informed of the allegations contained therein and the rights afforded pursuant to ORC Chapter 119.

WHEREFORE, after review of the administrative record and pursuant to ORC 4729.56(A) and Ohio Administrative Code (OAC) 4729:6-4-01(A), the Board finds and concludes that Respondent engaged in conduct set forth in ORC 4729.56, OAC 4729:6-3-04, OAC 4729:6-4-01, and all violations of law as described in the Notice. Based on the findings contained herein, the Board ORDERS as follows:

1. The Board hereby imposes a written reprimand on Respondent's terminal distributor of dangerous drugs registration no. 01-0977250.

2. The Board hereby imposes a fine in the amount of $2,750.00. This fine will be attached to the registration record and must be paid no later than 180 days from the effective date of this Agreement. To pay this fine, login to www.elicense.ohio.gov and process the items in the cart.

3. This Board disciplinary action must be disclosed to the proper licensing authority of any state or jurisdiction in which Respondent currently holds a professional license, including to the Board on renewal applications or applications for a new license or registration.

Service of this Order shall be perfected in accordance with the requirements of ORC Chapter 119.

Trina Buettner, RPh, moved for the findings and decision of the Board. Jason George, RPh, seconded the motion. Motion passed (Yes-6/No-0).
SO ORDERED.

It is hereby certified by this Board that the above language is a copy of the Order entered upon its journal in this case.

TIME AND METHOD TO PERFECT AN APPEAL

Any party desiring to appeal shall file a Notice of Appeal with the Ohio Board of Pharmacy, 77 South High Street, 17th Floor, Columbus, OH 43215, setting forth the order appealed from and stating that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The notice of appeal may, but need not, set forth the specific grounds of the party's appeal beyond the statement that the agency's order is not supported by reliable, probative, and substantial evidence and is not in accordance with law. The Notice of Appeal shall also be filed by the appellant in the court of common pleas of the county in which the place of business of the licensee is located or the county in which the licensee is a resident. If the appellant is not a resident of and has no place of business in this state, the party may appeal to the court of common pleas of Franklin County. Such notices of appeal shall be filed within fifteen (15) days after the service of the Ohio Board of Pharmacy's Order as provided in Section 119.12 of the Ohio Revised Code.

BY ORDER OF THE OHIO BOARD OF PHARMACY

ORDER MAILED & EFFECTIVE: **August 29, 2024**

By: Steven W. Schierholt

Steven W. Schierholt, Esq., Executive Director

SWS/jak/jrn

STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

BEFORE THE COMMISSION OF PHARMACY

In the Matter of

McKesson Corporation Case No. 2023-477

Settlement Agreement Concerning

Wholesaler of Drugs, Cosmetics and Medical Devices License of McKesson Corporation

This Settlement Agreement by and between McKesson Corporation, hereinafter referred to as "Respondent," and the duly authorized representative of the Commissioner of Consumer Protection, is entered into in accordance with Sections 4-177(c) of the Connecticut General Statutes. In accordance herewith, the parties agree that:

PARAGRAPH ONE: Respondent is the holder of Connecticut Wholesaler of Drugs, Cosmetics, & Medical Devices License No. CSW.0003956.

PARAGRAPH TWO: The Department of Consumer Protection has alleged that Respondent failed to limit entry to only authorized personnel in areas where drugs are held, in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies.

PARAGRAPH THREE: Respondent enters into this Settlement Agreement solely for the purposes of settlement. This Settlement Agreement shall neither be considered an admission of liability or a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection.

PARAGRAPH FOUR: Respondent shall pay, prior to the approval of this Settlement Agreement by the Commissioner, a monetary payment in the amount of One Thousand Five

Hundred Dollars ($1,500.00) into the Consumer Protection Enforcement Account, Account No. 35125.

PARAGRAPH FIVE: Respondent shall be issued a Letter of Reprimand.

PARAGRAPH SIX: Respondent waives:

a) Any right to seek judicial review or otherwise challenge or contest the validity of this Settlement Agreement;

b) Any requirement that this Settlement Agreement contain findings of fact and conclusions of law; and

c) Any right to a hearing or other procedural requirements of the Uniform Administrative Procedure Act, Connecticut General Statutes, Section 4-166 et seq.

PARAGRAPH SEVEN: This Settlement Agreement is a revocable offer of settlement that may be modified by mutual agreement or withdrawn by the Department of Consumer Protection at any time prior to its being executed and shall not become binding unless and until it is accepted and approved by the Commission of Pharmacy.

FOR RESPONDENT

Dated: July 25, 2024

By: Ammie McAsey

Name: Ammie McAsey

Title: Sr. Vice President Customer Experience

FOR THE DEPARTMENT OF CONSUMER PROTECTION

Dated: 5/28/2024 By: _____

Michael Ando, Esq.
Staff Attorney

The above Settlement Agreement concerning Respondent is accepted and approved by the Commission of Pharmacy on _____ 2023.

_____

Angela DeFazio
Chairperson, Commission of Pharmacy

STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

August 28, 2024

Mckesson Corporation
Mckesson Drug Company
10 Hudson Crossing Dr.
Montgomery, NY 12549

Re: LETTER OF REPRIMAND
CSW.0003956, Case No. 2023-477

To Whom It May Concern:

Pursuant to the terms of the Settlement Agreement in Case No. 2023-477 concerning your Connecticut Wholesaler of Drugs, Medical Devices and/or Cosmetics with Controlled Substances, I am issuing this Letter of Reprimand. The Commission of Pharmacy expects that in the future you will exercise extra care and diligence when performing your professional duties.

Sincerely,

Angelo DeFazio
Chairperson, Commission of Pharmacy

450 Columbus Boulevard, Suite 901, Hartford, Connecticut 06103-1840
General Information (860) 713-6100
Website ct.gov/dcp

From: Rogers, Brian
To: McKessonLicensing
Cc: Ando, Michael
Subject: [EXTERNAL] Fully Executed Settlement Agreement - Case No. 2023-477; CSW.0003956
Date: Wednesday, September 25, 2024 9:11:36 AM
Attachments: image001.png
2023-477 Settlement Agreement (signed).pdf

CAUTION: This email was sent from an EXTERNAL source. Use caution when clicking links or opening attachments.

Good Afternoon,

Attached please find a fully executed copy of the Settlement Agreement for Case No. 2023-477. The case is now closed.

Brian Rogers
Paralegal Specialist
Connecticut Consumer Protection
Phone: 860-757-6802
brian.rogers@ct.gov

CONFIDENTIAL INFORMATION: *The information contained in this e-mail is confidential and may be privileged and protected from general disclosure. The information is intended to be used solely by the recipient(s) named. If you are not an intended recipient, be aware that any review, disclosure, copying, distribution or use of this transmission or its contents is prohibited. If you have received this e-mail in error, please notify the sender immediately by replying to this message so that we can take appropriate action and thereafter immediately delete or erase this message.*

STATE OF CONNECTICUT

DEPARTMENT OF CONSUMER PROTECTION

BEFORE THE COMMISSIONER OF CONSUMER PROTECTION

In the Matter of

McKesson Corporation Case No. 2023-522

Settlement Agreement Concerning

Wholesaler of Drugs, Cosmetics and Medical Device License of McKesson Corporation

This Settlement Agreement by and between McKesson Corporation, hereinafter referred to as "Respondent," and the duly authorized representative of the Commissioner of Consumer Protection, is entered into in accordance with Sections 4-177(c) of the Connecticut General Statutes. In accordance herewith, the parties agree that:

PARAGRAPH ONE: Respondent is the holder of Connecticut Wholesaler of Drugs, Cosmetics and Medical Device License No. CSW.0003956.

PARAGRAPH TWO: The Department of Consumer Protection has alleged that Respondent failed to limit entry into areas where drugs are held to authorized personnel, in violation of Section 21a-115-32(b)(4) of the Regulations of Connecticut State Agencies.

PARAGRAPH THREE: Respondent enters into this Settlement Agreement solely for the purposes of settlement. This Settlement Agreement shall neither be considered an admission of liability nor a violation of law for any purpose, nor as evidence supporting the allegations of the Department of Consumer Protection.

PARAGRAPH FOUR: Respondent shall pay, prior to the approval of this Settlement Agreement by the Commissioner, a monetary payment in the amount of Five Thousand Dollars ($5,000.00) into the Consumer Protection Enforcement Account, Account No. 35125.

PARAGRAPH FIVE: Respondent waives:

a) Any right to seek judicial review or otherwise challenge or contest the validity of this Settlement Agreement;

b) Any requirement that this Settlement Agreement contain findings of fact and conclusions of law; and

c) Any right to a hearing or other procedural requirements of the Uniform Administrative Procedure Act, Connecticut General Statutes, Section 4-166 et seq.

PARAGRAPH SIX: This Settlement Agreement is a revocable offer of settlement that may be modified by mutual agreement or withdrawn by the Department of Consumer Protection at any time prior to its execution and shall not become binding unless and until it is accepted and approved by the Commissioner of Consumer Protection.

FOR RESPONDENT

Dated: Sept. 30, 2024

By: Ammie McAsey

Name: Ammie McAsey

Title: Sr. Vice President

FOR THE DEPARTMENT OF CONSUMER PROTECTION

Dated: 10/3/24

By:

Katrina Cessna, Esq.
Staff Attorney

The above Settlement Agreement concerning Respondent is accepted and approved by the Commissioner of Consumer Protection on November 14, 2024.

Bryan Cafferelli
Commissioner of Consumer Protection

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION,	Complainant,	) Case No. 2017-03162
v.		
MCKESSON CORPORATION, License No. 004.002044, License No. 004.001511, License No. 004.000755,	Respondent.	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by attorney Brandon R. Thom, and Respondent McKesson Corporation ("Respondent"), by attorney Roger N. Morris of Quarles & Brady LLP, agree to the following:

STIPULATIONS

Respondent holds multiple Wholesale Drug Distributor licenses in the State of Illinois, including license numbers 004.002044 (Aurora, Colorado), 004.001511 (Livonia, Michigan), and 004.000755 (Washington Court House, Ohio). On January 17, 2017, Respondent entered into a Settlement Agreement and Administrative Memorandum of Agreement with the U.S. Department of Justice-Drug Enforcement Administration ("DEA"). The January 17, 2017 Memorandum of Agreement is attached herein as **Exhibit 1.** The DEA alleged various conduct which the DEA alleged would constitute violations of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 et sequ (the "Act") and regulations promulgated under the Act at 21 C.F.R. Part 1300 *et seq.* To resolve the matter, Respondent made no admissions of liability but agreed to pay a settlement payment of one hundred fifty million dollars ($150,000,000) and agreed to a time-limited suspension of the DEA Certification of Registrations of four (4) of Respondent's distribution centers, including those listed herein. Respondent's actions and/or omissions, if proven true, would constitute violations of the Illinois Wholesale Drug Distribution Licensing Act, 225 ILCS 120/55(a)(1) and (5).

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and parties herein. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person and has not relied upon any representation made by or on behalf of the Department other than those specifically included

herein. Respondent has been advised of the right to accept or reject this Consent Order. Respondent has been advised of the right to a hearing on the Petition for Restoration, the right to contest any charges brought, and the right to administrative review of any Order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Board of Pharmacy ("Board") or Director. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Director in furtherance of the approval of this Consent Order. Respondent has been informed that this Consent Order will be presented to the Director for final approval. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Director. A copy of any original signature(s) shall be given the full force and effect of any original signature(s) affixed to this Consent Order.

Respondent and the Department have agreed, in order to resolve this matter, that Respondent be permitted to enter into a Consent Order with the Department.

CONDITIONS

Wherefore, the Department, by attorney Brandon R. Thom, and Respondent, by attorney Roger N. Morris of Quarles & Brady LLP, agree:

A Respondent's Illinois Wholesale Drug Distributor license no. 004.002044 (Aurora, Colorado), shall be placed on probation for a definite period of three (3) years, effective January 17, 2017 to January 17, 2020. Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. 004.002044 (Aurora, Colorado) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List 1 Chemical products at or from Respondent's Aurora, Colorado distribution center.

B Respondent's Illinois Wholesale Drug Distributor license no. 004.001511 (Livonia, Michigan), shall be placed on probation for a definite period of two (2) years, effective January 17, 2017 to January 17, 2019.

Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. 004.001511 (Livonia, Michigan) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List I Chemical products at or from Respondent's Livonia, Michigan distribution center. Respondent's Livonia, Michigan distribution center is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the U.S. Department of Veterans Affairs.

C. Respondent's Illinois Wholesale Drug Distributor license no. 004.000755 (Washington Court House, Ohio), shall be placed on probation for a definite period of two (2) years, effective February 16, 2019 to February 16, 2021. Throughout the term of this probation, Respondent's Illinois Wholesale Drug Distributor license no. 004.000755 (Washington Court House, Ohio) shall be prohibited from distributing controlled substances in the State of Illinois. This probationary restriction shall not apply to or limit Respondent's authority to distribute, or operations involving, List I Chemical products at or from Respondent's Washington Court House, Ohio distribution center. Respondent's Washington Court House, Ohio distribution center is permitted, at its option, to possess and distribute controlled substances to federal customers under McKesson's exclusive contract with the U.S. Department of Veterans Affairs.

D. Respondent shall comply with all terms and conditions imposed upon Respondent in the January 17, 2017 DEA Memorandum of Agreement, attached hereto as Exhibit 1. Any violation of the Memorandum of Agreement by Respondent shall be deemed a violation of this Consent Order.

E. Respondent shall comply with all terms and conditions of the Wholesale Drug Distribution Licensing Act 225 ILCS 120/1 et seq. and the Rules enacted in furtherance thereof. Respondent's failure to do so shall be deemed a violation of the terms of this Consent Order.

F. Failure by Respondent to comply fully with the terms and conditions of this Consent Order may be grounds for the Director of the Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation to issue an Order mandating the immediate and automatic indefinite suspension of Respondent's Illinois Wholesale Drug Distributor Licenses, numbers 004.002044, 004.001511, and 004.000755. Respondent may file an appropriate Petition within thirty (30) days from date the order was entered to contest the

underlying factual basis of the indefinite suspension. Respondent shall be afforded a hearing on the merits following the filing of the Petition. Respondent waives any statute of limitations defense in any hearing on the indefinite suspension.

G. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes. This Consent Order will be available to the general public.

H. This Consent Order shall become effective upon the Director's approval and signature, as dated below.

April 21, 2021
Date

Department Attorney Brandon R. Thom

April 12, 2021
Date

Respondent McKesson Corporation

April 12, 2021
Date

Roger N. Morris of Quarles & Brady LLP
Attorney for Respondent

4/20/21
Date

Illinois Board of Pharmacy Member

The foregoing Consent Order is approved in full.

Dated this 22nd day of May, 2021.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
ACTING SECRETARY MARIO TRETO, JR.

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No. 2017-03162
License Nos. 004.002044
004.001511
004.000755

ADMINISTRATIVE MEMORANDUM OF AGREEMENT

This Administrative Memorandum of Agreement ("Agreement") is entered into by and between the United States Department of Justice, Drug Enforcement Administration ("DEA") and McKesson Corporation ("McKesson") (each a "Party" and collectively the "Parties").

APPLICABILITY

This Agreement shall be applicable to McKesson and any facility owned or operated by McKesson US Pharmaceutical registered, or who may become registered, with DEA to distribute, or otherwise handle controlled substances. The current list of applicable facilities is identified in Appendix A.

BACKGROUND

1. McKesson is registered with DEA at the facilities listed in Appendix A as distributors of Schedule II-V controlled substances under provisions of the Comprehensive Drug Abuse Prevention and Control Act of 1970, 21 U.S.C. § 801 *et seq.*, ("CSA" or "the Act"). *See* Appendix A. Collectively, the distribution centers listed in Appendix A and the former Landover, Maryland distribution center are referred to herein as the "McKesson Distribution Centers."

2. In May 2008, McKesson entered into a Settlement and Release Agreement and Administrative Memorandum of Agreement ("2008 MOA") with DEA. *See* Appendix B.

3. McKesson's Aurora, Colorado, distribution facility ("McKesson Aurora"), located at 14500 East 39th Ave., Aurora, Colorado 80011, is registered with DEA as a distributor of Schedule II-V controlled substances pursuant to DEA Certificate of Registration PM0018425.

4. On March 12, 2013, DEA executed an Administrative Inspection Warrant ("AIW") at McKesson Aurora.

5. Between March 2013 and the present, DEA executed one (1) additional AIW and served numerous administrative subpoenas and conducted a number of cyclic inspections at various McKesson US Pharmaceutical distribution centers nationwide including McKesson's Washington Court House, Ohio, distribution center ("McKesson WCH"), DEA Certificate of Registration RM0220688, located at 3000 Kenskill Avenue, Washington Court House, Ohio 43160; McKesson's Livonia, Michigan, distribution center ("McKesson Livonia"), DEA Certificate of Registration 0030849, located at 38220 Plymouth Road, Livonia, Michigan 48150; McKesson's Lakeland, Florida, distribution center ("McKesson Lakeland"), DEA Certificate of Registration PM0000771, located at 1515 Kendrick Lane, Lakeland, Florida 33805; McKesson's Methuen distribution center ("McKesson Methuen"), DEA Certificate of Registration PM0020850, located at 9 Aegean Drive, Methuen, Massachusetts 01844; McKesson's Chicago distribution center ("McKesson Chicagoland"), DEA Certificate of Registration RM0380484, located at 1955 McKesson Street, Suite 101, Aurora, Illinois 60502; McKesson's Delran, New Jersey, distribution center ("McKesson Delran"), DEA Certificate of Registration RM0173055, located at 400 Delran Parkway, Delran, New Jersey 08075; McKesson's LaCrosse, Wisconsin

distribution center, ("McKesson LaCrosse"), DEA Certificate of Registration RM0220537, located at 3003 Airport Road, LaCrosse, Wisconsin 54603; McKesson's La Vista, Nebraska, distribution center ("McKesson La Vista"), DEA Certificate of Registration PM0038693, located at 7009 South 108th Street, La Vista, Nebraska 68128; McKesson's Ruther Glen, Virginia, distribution center ("McKesson Ruther Glen"), DEA Certificate of Registration RM0424363, located at 10504 McKesson Drive, Ruther Glen, Virginia 22546; and McKesson's West Sacramento, California, distribution center ("McKesson West Sacramento"), DEA Certificate of Registration PM0021535, located at 3775 Seaport Boulevard, West Sacramento, California 95691.

6. On or about August 13, 2014, McKesson received a letter from the U.S. Attorney for the District of Colorado (the "August 13, 2014 Letter") setting forth allegations that McKesson failed to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failed to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b). This letter described certain civil penalties that the U.S. Attorney for the District of Colorado could seek in Colorado and elsewhere in connection with that alleged conduct.

7. On or about November 14, 2014, McKesson received a letter (dated November 4, 2014) from the DEA Office of Chief Counsel, Diversion Regulatory and Litigation Section, stating that DEA was separately pursuing administrative action against McKesson Aurora for the conduct outlined in the August 13, 2014 Letter. DEA also stated that the allegations regarding McKesson's failure to "maintain[] . . . effective controls against diversion of particular controlled substances," 21 U.S.C. § 823(b)(1), and failure to "design and operate a system to disclose to the registrant suspicious orders of controlled substances," 21 C.F.R. § 1301.74(b) was national in scope, and that DEA was also pursuing administrative investigations of such alleged failures at McKesson WCH, McKesson Livonia, McKesson Lakeland, McKesson Methuen, McKesson Chicagoland, McKesson Delran, McKesson LaCrosse, McKesson La Vista, McKesson Ruther Glen, and McKesson West Sacramento.

8. As of the date of this Agreement, DEA has not issued Orders to Show Cause ("OTSCs") against any of McKesson's DEA-registered distribution centers.

STIPULATION AND AGREEMENT

In lieu of commencing and pursuing administrative litigation against the DEA registrations of an unknown number of McKesson's distribution centers, McKesson and DEA agree as follows:

I. General

1. Intention of Parties to Effect Settlement. In order to avoid the uncertainty and expense of litigation, and in furtherance of the Parties' belief that a settlement is in the public interest, the Parties desire to settle and resolve, and hereby do settle and resolve, the administrative matters within DEA's enforcement authority as those matters relate to the conduct described further

below. The Parties further believe that the terms and conditions of this settlement as set forth below represent a complete resolution of this matter.

2. Acceptance of Responsibility. On or about September 27, 2006, February 7, 2007 and December 27, 2007, DEA's Deputy Assistant Administrator, Office of Diversion Control, sent letters to every entity in the United States that was registered with DEA to manufacture or distribute controlled substances, including McKesson (the "DEA Letters"). The DEA Letters contained, among other things, guidance for the identification and reporting of suspicious orders to DEA, as required by 21 C.F.R. § 1301.74(b). McKesson acknowledges that, at various times during the period from January 1, 2009 up through and including the Effective Date of this Agreement (the "Covered Time Period"), it did not identify or report to DEA certain orders placed by certain pharmacies which should have been detected by McKesson as suspicious based on the guidance contained in the DEA Letters about the requirements set forth in 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

On or about May 2, 2008, DEA and McKesson entered into an Administrative Memorandum of Agreement (the "2008 MOA"). The 2008 MOA provided among other things, that McKesson maintain a compliance program designed to detect and prevent the diversion of controlled substances, inform DEA of suspicious orders as required by 21 C.F.R. § 1301.74(b), and follow procedures established by its Controlled Substance Monitoring Program ("CSMP"). McKesson acknowledges that, at various times during the Covered Time Period, it did not identify or report to DEA certain orders placed by certain pharmacies, which should have been detected by McKesson as suspicious, in a manner fully consistent with the requirements set forth in the 2008 MOA. McKesson has taken steps to prevent such conduct from occurring in the future, including the measures delineated in the Compliance Addendum.

3. Covered Conduct. For purposes of this Agreement, "Covered Conduct" shall mean the following conduct alleged by the Government for the Covered Time Period:

a. McKesson failed to maintain effective controls against diversion of particular controlled substances into other than legitimate medical, scientific and industrial channels by sales to certain of its customers in violation of the CSA and the CSA's implementing regulations, 21 C.F.R. Part 1300 *et seq.*, at the McKesson Distribution Centers, including the following:

Aurora, Colorado;
Aurora, Illinois;
Delran, New Jersey;
LaCrosse, Wisconsin;
Lakeland, Florida;
Landover, Maryland;
La Vista, Nebraska;
Livonia, Michigan;
Methuen, Massachusetts;
Santa Fe Springs, California;

Washington Courthouse, Ohio; and
West Sacramento, California.

b. In 2008, McKesson entered into a Settlement Agreement with the Department of Justice and a Memorandum of Agreement with DEA (collectively referred to herein as the "2008 Agreements") related to, among other things, McKesson's failure to report suspicious orders of controlled substances to DEA when discovered, as required by and in violation of 21 C.F.R. § 1301.74(b) and 21 U.S.C. § 842(a)(5). As a result of the 2008 Agreements, McKesson developed a Controlled Substance Monitoring Program ("CSMP"), in which McKesson recognized that it had a duty to monitor its sales of all controlled substances and report suspicious orders to DEA. McKesson failed to properly monitor its sales of controlled substances and/or report suspicious orders to DEA, in accordance with McKesson's obligations under the 2008 Agreements, the Act, and 21 C.F.R. § 1301.74(b);

c. McKesson failed to follow the procedures and policies set forth in the McKesson CSMP to detect and disclose suspicious orders of controlled substances. Among other things, McKesson failed to conduct adequate due diligence of its customers, failed to keep complete and accurate records in the CSMP files maintained for many of its customers, and bypassed suspicious order reporting procedures set forth in the McKesson CSMP;

d. In addition, McKesson failed to inform the DEA Field Division Offices and/or DEA Headquarters of certain suspicious orders of controlled substances made by its customers during the relevant time period, including orders of unusual size, orders deviating substantially from normal patterns, and orders of unusual frequency, as required by and in violation of 21 C.F.R. § 1301.74(b), 21 U.S.C. § 842(a)(5), and the 2008 Agreements;

e. McKesson failed to report suspicious orders for certain controlled substances in accordance with the standards identified and outlined in the DEA Letters; and

f. The McKesson Distribution Centers distributed controlled substances to pharmacies even though those McKesson Distribution Centers should have known that the pharmacists practicing within those pharmacies had failed to fulfill their corresponding responsibility to ensure that controlled substances were dispensed pursuant to prescriptions issued for legitimate medical purposes by practitioners acting in the usual course of their professional practice, as required by 21 C.F.R § 1306.04(a).

4. Effect of 2008 MOA. To the extent that there are obligations contained in the 2008 MOA that survived the expiration of the stated term of the 2008 MOA, those terms are superseded by the obligations contained in this Agreement.

5. Term of Agreement. The obligations contained in this Agreement shall remain in full force and effect for a period of five (5) years from the Effective Date of this Agreement unless DEA agrees in writing to an earlier termination.

II. Terms and Conditions

1 Obligations of McKesson.

a. McKesson agrees to maintain a compliance program intended to detect and prevent diversion of controlled substances as required under the CSA and applicable implementing regulations. McKesson acknowledges and agrees that the obligations undertaken in this Agreement and the Compliance Addendum are designed, in part, to meet its obligations under the CSA and its implementing regulations.

b. Beginning on the first full calendar month after the Effective Date, McKesson shall provide DEA Headquarters with an unedited file of all transactions of non-ARCOS reportable controlled substances. This information will be in the format that Automation of Reports and Consolidated Orders System ("ARCOS") data is submitted to DEA, and will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. The files shall be due by the 15th of each calendar month for the previous calendar month's report. This requirement does not supplant the requirement to report ARCOS data in the time and manner required by DEA regulations. The Parties agree that the report does not otherwise constitute the basis for McKesson's compliance with recordkeeping and reporting requirements under the CSA or applicable implementing regulations. The Parties agree that such report is not required under the CSA or its implementing regulations and that the accuracy of the report or the failure to file such a report is not a basis for a violation of 21 U.S.C. § 842(a)(5).

c. In satisfaction of its obligation under the CSA's implementing regulations and as agreed to pursuant to this Agreement for each McKesson distribution center registrant to "inform the Field Division Office of the Administration in [its] area of suspicious orders," 21 C.F.R. § 1301.74(b), McKesson shall transmit Suspicious Order Reports to DEA Headquarters at the end of each business day. McKesson shall submit the daily Suspicious Order Reports in the format that ARCOS data is submitted to DEA, and the reports will be uploaded to the following web address: https://www.deadiversion.usdoj.gov/deareports/. This obligation will continue during the term of this Agreement unless and until DEA advises McKesson otherwise in writing.

d. McKesson agrees that its authority to distribute all controlled substances from its McKesson Aurora distribution center, DEA Certificate of Registration PM0018425, will be suspended for a period of three (3) years commencing from the Effective Date of this Agreement (the "Aurora Suspension Period"). This suspension shall not apply to or limit McKesson's authority to distribute, or

operations involving, List I Chemical products at or from the Aurora distribution center, which are authorized under the DEA registration number PM0018425.

e. McKesson agrees that its authority to distribute all controlled substances from its McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, will be suspended for a period of two (2) years commencing from the Effective Date of this Agreement, except for orders placed by Permitted Registrants ("the Livonia Suspension Period").[1] This suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the Livonia distribution center, which are authorized under the DEA registration number PM0030849. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson Livonia distribution center, Certification of Registration PM0030849, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

f. McKesson agrees that its authority to distribute all controlled substances from its McKesson WCH distribution center, DEA Certificate of Registration RM0220688, will be suspended for a period of two (2) years commencing thirty (30) days from the date upon which the DEA Certificate of Registration for the McKesson Livonia distribution center is reinstated, except for orders placed by Permitted Registrants (the "WCH Suspension Period"). In the event the McKesson Livonia distribution center is not reinstated within one hundred and eighty (180) days of completion of the Livonia Suspension Period due to McKesson (i) failing to cure a compliance requirement as identified by DEA in its thirty (30) day advance notice letter described in Section II.2., or (ii) electing to permanently terminate the Livonia registration, the WCH Suspension Period will commence no later than two (2) years and one hundred eighty (180) days from the Effective Date of this Agreement. The McKesson WCH distribution center suspension shall not apply to or limit McKesson's authority to distribute, or operations involving, List I Chemical products at or from the WCH distribution center, which are authorized under the DEA registration number RM0220688. McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Detroit Field

[1] For purposes of this agreement "Permitted Registrants" shall include registrants identified in Appendix C. McKesson shall include updates to the Permitted Registrants in the quarterly reports provided to DEA local offices under II.1 e-g.

Division, Diversion Regulatory Unit, 431 Howard Street, Detroit, Michigan 48226, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of controlled substances aggregated by drug code from its McKesson WCH distribution center, Certification of Registration RM0220688, for each previous quarter. McKesson shall notify the Detroit Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the controlled substance.

g. McKesson agrees that its authority to distribute controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, from its McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, will be suspended for a period of one (1) year commencing from the Effective Date of the Agreement, except for orders placed by Permitted Registrants (the "Lakeland Suspension Period"). McKesson agrees that during this period of suspension, on the 15th of the month following the applicable calendar quarter, it will deliver to DEA, Miami Field Division, Diversion Regulatory Unit, 2100 North Commerce Parkway, Weston, Florida 33326, a compact disc containing an excel spreadsheet, in a readable format, of all distributions of hydromorphone (drug code 9150) from its McKesson Lakeland distribution center, Certification of Registration PM0000771, for each previous quarter. McKesson shall notify the Miami Field Office by email if there are no sales for the applicable period. Within thirty (30) days of the Effective Date, DEA will provide the e-mail address to which McKesson will report to DEA if there are no sales for the applicable period. The data that comprises this spreadsheet shall be taken directly from McKesson's sales data and shall be sorted by the DEA Certification of Registration of the purchaser of the hydromorphone.

h. McKesson agrees to reasonably cooperate with DEA, United States Attorneys' Offices, and any other Federal, state, or local law enforcement agency investigating or prosecuting McKesson's customers for alleged violations or activities related to the Covered Conduct unless such matters would affect the rights or obligations of McKesson in regard to any pending or threatened litigation. Such cooperation shall include, but is not limited to, producing records and making employees available for interviews by DEA or other law enforcement authorities, subject to appropriate requests, *e.g.*, administrative subpoena. However, nothing in this paragraph shall be construed as a waiver by McKesson or its employees of any constitutional rights or rights that the company would have as a party to a matter involving pending or threatened litigation with the government or a third party, including without limitation attorney-client or attorney work product privileges.

i. Pursuant to the 2017 Settlement Agreement and Release, McKesson agrees to a settlement payment to the United States of America in the amount of $150,000,000.00 in settlement of claims or potential claims made by the United States of America for failing to report suspicious orders of controlled substances. McKesson agrees to execute the 2017 Settlement Agreement and Release simultaneously with the execution of this Agreement and to execute any other documents necessary to fully and finally settle all claims of the United States of America under this subparagraph, and to fully pay said settlement payment penalties within five (5) days of the Effective Date of this Agreement.

j. Any material breach by any McKesson facility of subsections II.1.b-g of this Agreement by McKesson after the Effective Date of this Agreement, where McKesson has not cured such breach as may be allowed under relevant law, regulation, this Agreement and Compliance Addendum may be a basis upon which DEA takes administrative action seeking the revocation and/or the suspension of the DEA Certificates of Registration of any of McKesson's distribution centers. However, nothing in this Agreement or the Compliance Addendum shall be deemed a waiver of McKesson's Due Process rights.

k. In any case where a supplier inadvertently ships controlled substances to any McKesson suspended facility, McKesson shall promptly return the product to the supplier. McKesson shall maintain a record of such receipt and return for two (2) years.

l. In any case where a customer inadvertently returns controlled substances to any McKesson suspended facility, McKesson shall promptly send the product to another McKesson DC for processing. McKesson shall maintain a record of such receipt and transfer for two (2) years.

m. Any McKesson suspended facility receiving a DEA Order Form 222 shall promptly endorse such Order Form to another, non-suspended McKesson facility pursuant to 21 C.F.R. § 1305.14. McKesson shall maintain a record of any endorsement and transfer of an order form for two (2) years.

n. In the event that any controlled substance maintained at a suspended McKesson facility is no longer required to be stocked or sold to a Permitted Registrant, the suspended McKesson facility may transfer such controlled substance to another non-suspended McKesson facility. Such transaction shall be reflected in the quarterly transaction report submitted to the appropriate local DEA field office as described in subsection II.1.e-g of this Agreement.

2. Obligations of DEA.

a. DEA does not endorse or approve of any specific system or approach implemented by DEA registrants to satisfy their obligations under 21 C.F.R. § 1301.74(b) or 21 U.S.C. § 823(b)(1). DEA has taken no action during the

negotiation of this Agreement, and is taking no action by entering into this Agreement, that can be interpreted to be directly or indirectly endorsing or approving the system that McKesson is currently utilizing to meet its obligations under the CSA and the implementing regulations. Going forward, DEA's actions in fulfilling the oversight of McKesson under this Agreement, including the receipt of information and/or its participation in meetings with McKesson representatives, shall not be construed or interpreted to be directly or indirectly endorsing or approving the system that McKesson is utilizing to meet its obligations under the CSA and the implementing regulations.

b. DEA agrees to accept at DEA Headquarters the information regarding suspicious orders as described in subsection II.1.c. of this Agreement.

c. In the event that DEA discovers information about conduct during the Covered Time Period that may warrant administrative action, and which is not otherwise included under the Covered Conduct, DEA shall favorably consider McKesson's entry into this Agreement, the Compliance Addendum, and the civil penalties paid pursuant to the Settlement Agreement and Release; all actions taken by McKesson pursuant to this Agreement and Compliance Addendum; any remedial actions taken by McKesson to address the alleged or perceived violative conduct; and the compliance history of McKesson at the particular facility, and at other McKesson facilities.

d. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Aurora's distribution center, DEA Certificate of Registration PM0018425, and, if needed, grant any requisite registration renewal, no later than the end of the Aurora Suspension Period.

e. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson Livonia distribution center, DEA Certificate of Registration PM0030849, and, if needed, grant any requisite registration renewal, no later than the end of the Livonia Suspension Period.

f. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will lift the suspension of McKesson WCH distribution center, DEA Certificate of Registration RM0220688, and, if needed, grant any requisite registration renewal, no later than the end of the WCH Suspension Period.

g. Unless DEA determines that McKesson is in noncompliance with the terms of this Agreement, after providing McKesson with prior written notice of alleged noncompliance with the terms of this Agreement and providing McKesson with at least thirty (30) days to respond to any such notice, DEA agrees that it will reinstate the ability of the McKesson Lakeland distribution center, DEA Certificate of Registration PM0000771, to distribute the controlled substances containing the drug code for Schedule II hydromorphone products, that is, DEA drug code 9150, no later than the end of the Lakeland Suspension Period.

3. Release by DEA. In consideration of the fulfillment of the obligations of McKesson under this Agreement, DEA agrees to:

a. Fully and finally release McKesson, together with its subsidiary entities, distribution facilities, and registrants, along with its officers, directors, employees, successors, and assigns (collectively, the "Released Parties") from any and all administrative claims within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824 related to the Covered Conduct; and

b. Refrain from filing or taking any administrative actions against the Released Parties within DEA's enforcement authority under 21 U.S.C. §§ 823 & 824, based on the Covered Conduct only to extent that such conduct was or could have been discovered by DEA through the exercise of due diligence through the examination of open investigations and inspections in existence as of the Effective Date of this Agreement, and the review of the reports and records McKesson submitted to DEA prior to the Effective Date of this Agreement. This release applies only to administrative actions brought before or by DEA.

Notwithstanding the releases by DEA contained in this Paragraph, DEA reserves the right to seek to admit evidence of the Covered Conduct for proper evidentiary purposes in any other administrative proceeding against the Released Parties for non-Covered Conduct. Further, nothing in this Paragraph shall prohibit or limit any other agency within the Department of Justice, any State attorney general, or any other law enforcement, administrative, or regulatory agency of the United States or any State thereof, from initiating administrative, civil, or criminal proceedings with respect to the Covered Conduct. DEA shall, as obligated in fulfilling its statutory duties, assist and cooperate with any agency that initiates an investigation, action, or proceeding involving the Covered Conduct. At McKesson's request, DEA agrees to disclose the terms of this Agreement to any other agency and will represent, assuming McKesson is in compliance with this Agreement, that the allegations raised by DEA, as defined in the Covered Conduct, have been adequately addressed. This release is applicable only to the Released Parties and is not applicable in any manner to any other individual, partnership, corporation, or entity.

4. Release by McKesson. McKesson fully and finally releases the United States of America, its agencies, employees, servants, and agents from any claims (including attorney's fees, costs, and expenses of every kind and however denominated) which McKesson has asserted, could have asserted, or may assert in the future against the United States of America, its

agencies, employees, servants. and agents, related to the Covered Conduct and the United States' investigation and prosecution thereof.

5. Reservation of Claims. Notwithstanding any term of this Agreement, specifically reserved and excluded from the scope and terms of this Agreement as to any entity or person (including McKesson) are the following:

a. Any potential criminal liability;

b. Any civil, criminal or administrative liability arising under Title 26, U.S. Code (Internal Revenue Code);

c. Any administrative liability to the United States other than administrative claims released in Paragraph II.3.a. and b.

d. Any civil liability to the United States, other than the civil claims released in the 2017 Settlement Agreement and Release; or

e. Any liability based upon any obligation created by or arising under this Agreement.

III. Miscellaneous

1. Binding on Successors. This Agreement is binding on McKesson, and its respective successors, heirs, transferees, and assigns.

2. Costs. Each Party to this Agreement shall bear its own legal and other costs incurred in connection with this matter, including the preparation and performance of this Agreement.

3. No Additional Releases. This Agreement is intended to be for the benefit of the Parties and the Released Parties only, and by this instrument the Parties do not release any claims against any other person or entity other than the Released Parties.

4. Effect of Agreement. This Agreement constitutes the complete agreement between the Parties. All material representations, understandings, and promises of the Parties are contained in this Agreement, and each of the parties expressly agrees and acknowledges that, other than those statements expressly set forth in this Agreement, it is not relying on any statement, whether oral or written, of any person or entity with respect to its entry into this Agreement or to the consummation of the transactions contemplated by this Agreement. Any modifications to this Agreement shall be set forth in writing and signed by all Parties. McKesson represents that this Agreement is entered into with advice of counsel and knowledge of the events described herein. McKesson further represents that this Agreement is voluntarily entered into in order to avoid litigation, without any degree of duress or compulsion.

5. Execution of Agreement. This Agreement shall become effective (*i.e.*, final and binding) on the date of signing by the last signatory (the "Effective Date"). The government agrees to notify McKesson immediately when the final signatory has executed this Agreement.

6. Notices. All communications and notices pursuant to this Agreement shall be made in writing to the following individuals, which notice information may be altered from time to time by either Party by written notification:

a. For DEA or DOJ:

Drug Enforcement Administration, Diversion Control Division, 8701 Morrissette Drive, Springfield, Virginia 22152;

Drug Enforcement Administration, Office of Chief Counsel, Diversion and Regulatory Litigation Section, 8701 Morrissette Drive, Springfield, Virginia 22152; and

U.S. Department of Justice, Criminal Division, Narcotic and Dangerous Drug Section, 145 N St. NE (2 Constitution Square), 2nd Floor, East Wing, Washington, D.C. 20530

b. For McKesson:

Senior Vice President, US Pharmaceutical, Regulatory Affairs and Compliance
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

with copies to:

Vice President, U.S. Pharmaceutical, Regulatory Affairs & Compliance
McKesson Corporation
6535 State Highway 161
Irving, TX 75039-2402

Assistant General Counsel, US Pharmaceutical
McKesson Corporation
One Post Street, 36th Floor
San Francisco, CA 94104

7. Disclosure. McKesson and DEA may each disclose the existence of this Agreement and information about this Agreement to the public except for information designated as confidential.

8. Confidentiality and Designation of Information. McKesson and DEA agree that all transaction reports submitted to DEA contain information this is commercial or financial and privileged or confidential, and therefore exempt from disclosure under the Freedom of

Information Act ("FOIA"), 5 U.S.C. § 552. Such information may be exempt from disclosure under the Freedom of Information Act and any other state or federal law or regulation protecting such information from public disclosure and, upon receipt of a request to release such, DEA agrees to provide McKesson reasonable opportunity to respond to any such requests.

9 Execution in Counterparts. This Agreement may be executed in counterparts, each of which constitutes an original, and all of which shall constitute one and the same agreement. Copies or facsimiles of signatures shall constitute acceptable, binding signatures for purposes of this Agreement.

10. Authorizations. The individuals signing this Agreement on behalf of McKesson represent and warrant that they are authorized by McKesson to execute this Agreement. The individuals signing this Agreement on behalf of DEA represent and warrant that they are signing this Agreement in their official capacities and that they are authorized by DEA to execute this Agreement.

11. Choice of Law and Venue. This Settlement Agreement and Release shall be construed in accordance with the laws of the United States, and either Party may seek judicial enforcement of this Agreement upon a material breach by the other Party. The Parties agree that the jurisdiction and venue for any dispute arising between and among the Parties to this Agreement shall be any federal court of competent jurisdiction. This provision, however, shall not be construed as a waiver of the jurisdictional provisions of the CSA, as amended.

[Signature page to follow]

IN WITNESS WHEREOF, the Parties hereto have duly executed this Administrative Memorandum of Agreement.

On Behalf of McKesson Corporation:

Mark Walchirk
President, US Pharmaceutical
McKesson Corporation

Dated: 1-5-17

On Behalf of the United States Department of Justice, Drug Enforcement Administration:

By direction

Chuck Rosenberg
Acting Administrator
Drug Enforcement Administration

Dated: 1-17-17

Louis J. Milione
Assistant Administrator, Diversion Control Division
Drug Enforcement Administration

Dated: 1-17-17

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL AND OCCUPATIONAL REGULATION
MAINE BOARD OF PHARMACY
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

May 27, 2021

Sent via email: michele.lau@mckesson.com

McKesson Corporation
Michele Lau, VP/Secretary/Director
1 Post Street
San Francisco, CA 94104-5203

Re: Complaint No. 2021-PHA-17215

Dear Ms. Lau:

Enclosed please find the fully executed consent agreement between you, the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $500.00. Your fine is paid in full. As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at (207) 624-8651 with any questions.

Sincerely,

Jessica Gowell

Jessica Gowell, Professional Licensing Supervisor

Enclosure

cc: John Nichols, Esq., Assistant Attorney General
Andrew Black, Esq., Assistant Attorney General
Geraldine L. Betts, Board Administrator & Complainant
Thomas Avery, Board Investigator

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MCKESSON CORPORATION	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17215	)	

PARTIES

This document is a Consent Agreement regarding the pending application of McKesson Corporation for the renewal of its prescription drug wholesaler license. The parties to this Consent Agreement are: McKesson Corporation ("McKesson"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since October 17, 2011, McKesson has been licensed in Maine as a prescription drug wholesaler with a registered location of 1995 McKesson Street, Suite 101, Aurora, Illinois (license number **WH70001735**).

2. On October 4, 2019, the Colorado State Board of Pharmacy imposed discipline against McKesson's Colorado registration as an out-of-state prescription drug wholesaler (Registration # WHO 7154) in Case No. 2019-5119.

3. McKesson then failed to report the Colorado disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On November 22, 2019, McKesson submitted an application for renewal of its Maine license and reported to the Board for the first time that it had been disciplined by the Colorado State Board of Pharmacy.

5. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

6. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny McKesson's application for renewal of its license to be a prescription drug wholesaler. In lieu of the denial, the Board also voted to offer McKesson this Consent Agreement. Unless McKesson either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, by **May 16, 2021,** the preliminary denial of McKesson's application for licensure as a prescription drug wholesaler will become final.

COVENANTS

7. McKesson admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken in another jurisdiction against a professional license no later than 10 days after the action was taken.

8. As discipline for the violation admitted to in paragraph 7 above, McKesson agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of five hundred dollars ($500.00) payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement.

9. Upon receipt of the signed Consent Agreement with the enclosed payment of the civil penalty from McKesson, the Board will renew McKesson's license contingent upon it meeting all other eligibility criteria.

10. Violation of any of the terms or conditions of this Consent Agreement by McKesson shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

11. The Board and McKesson agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless McKesson fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against McKesson, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving McKesson. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against McKesson.

12. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

13. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. McKesson acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: May 5, 2021

MCKESSON CORPORATION

By: _____

Print Name: Michele Lau

Title: Senior VP & Corporate Secretary

DATED: 5/26/21

_____

BRADLEY S. HAMILTON, R.Ph., President
MAINE BOARD OF PHARMACY

DATED: 5/27/21

_____

JOHN NICHOLS
Assistant Attorney General

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

DIVISION OF PROFESSIONAL REGULATION OF THE ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION, Complainant,	)	
v.	)	Case No. 2020-00770
MCKESSON CORPORATION D/B/A MCKESSON DRUG COMPANY, License No. 004.004206, Respondent.	)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by Chief of Health-Related Prosecutions Mary C. Meehan, and Respondent McKesson Corporation d/b/a McKesson Drug Company ("Respondent") through its attorney Alex Cooper of Quarles & Brady, LLP, agree to the following:

STIPULATIONS

Respondent holds Illinois licensed wholesale drug distributor license no. 004.004206, which is currently in active status. On or about January 7, 2020, the Iowa Board of Pharmacy disciplined Respondent based on allegations that Respondent failed to take a full inventory of products in violation of 657 Iowa Administrative Code 10.19. The grounds cited by the Iowa Board of Pharmacy are substantially similar to the 77 Illinois Administrative Code 1510.120(f). Respondent's actions and/or omissions are grounds for discipline under the Pharmacy Practice Act ("Act") at 225 ILCS 120/55(a)(5). Respondent neither admits nor denies the allegations but Respondent acknowledges that should this matter proceed to a contested hearing, the Illinois State Board of Pharmacy ("Board") could find a violation of the Illinois Wholesale Drug Distributor Act. The Department and Respondent stipulate that the above acknowledgement is made only for the purposes of this Consent Order. In the event that this Consent Order is not approved by the Board or the Director of the Division of Professional Regulation of the Department ("Director"), this acknowledgement shall not be admissible in any proceeding and the matter will be set for an evidentiary hearing on the merits as if this Consent Order had not been submitted.

At all times material to the matter set forth in this Order, the Department had jurisdiction over the subject matter and the parties herein. Respondent has been advised of the right to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, the right to contest the pending charges and present mitigating evidence, and the right to administrative review of any order resulting from a hearing. Respondent knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by either the Board or Director. Respondent acknowledges that Respondent has entered into this Consent Order freely and of Respondent's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Respondent acknowledges that the Department attorney may be requested to communicate with the Board or Director in furtherance of the approval of this Consent Order. Respondent acknowledges this Consent Order will be presented to the Director. If this Consent Order is not approved, Respondent waives any right to raise any prejudice resulting from the Director's consideration of this Consent Order. Respondent understands that this Consent Order is not effective unless and until it is adopted by the Director. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Respondent and the Department agree in order to resolve this case that Respondent be permitted to enter into a Consent Order with the Department, providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by Chief of Health-Related Prosecutions Mary C. Meehan, and Respondent, by its attorney Alex Cooper of Quarles & Brady, LLP agree:

A. Respondent's Illinois licensed wholesale drug distributor license no. 004.004206 shall be reprimanded.

B. This Consent Order is a public disciplinary action and will be reported to all applicable public indexes.

C. This Consent Order shall become effective upon the signature of the Director, as dated below.

11/15/2021 Mary C Meehan

Date Chief of Health-Related Prosecutions Mary C. Meehan

10.12.2021 Ammie McAsey, SVP, Customer Distribution Experience, McKesson PSAS

Date Representative for Respondent McKesson Corporation d/b/a McKesson Drug Company

10/12/21

Date Respondent Attorney Alex Cumpata of Quarles & Brady, LLP

11/8/21 Denise Scarpelli

Date Illinois State Board of Pharmacy Member

This Consent Order is approved in full.

Dated this 20th day of December, 2021

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
ACTING SECRETARY MARIO TRETO JR.

Acting Director Cecilia Abundis
Division of Professional Regulation

Case No 2020-00770
License No. 004 004206

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 22, 2022

CERTIFIED MAIL

McKesson Drug Company
Attn: Sandra Zamora
9501 S Norwalk
Santa Fe Springs, CA 90670

RE: Administrative Case No. 6850
McKesson Corporation dba McKesson Drug Company, WLS 3076

Dear Ms. Zamora:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to page 4 of the document.

Effective at 5:00 p.m. on March 24, 2022, Wholesale Permit No. WLS 3076 issued to McKesson Drug Company shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello.

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Christina Thomas, DAG
Amy Levine Heiserman, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 6850
McKesson Drug Company, WLS 3076

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
McKesson Drug Company Attn: Sandra Zamora 9501 S Norwalk Santa Fe Springs, CA 90670	7017 0190 0000 4212 5618
Amy Levine Heiserman, Esq. Quarles & Brady LLP One Renaissance Square Two North Central Avenue, Suite 600 Phoenix, AZ 85004-2322	7017 0190 0000 4212 5625

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 22, 2022, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 22, 2022 at Sacramento, California.

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

MCKESSON CORPORATION, dba
MCKESSON DRUG COMPANY,
Wholesale Permit No. WLS 3076;

and

JOHN F. BOHLINGER,
Designated Representative License No. EXC 17318,

Respondents

Agency Case No. 6850

OAH No. 2021050035

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 24, 2022.

It is so ORDERED on February 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 Norwalk Boulevard** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 OAH No. 2021050035 **STIPULATED SETTLEMENT AND DISCIPLINARY ORDER FOR PUBLIC REPROVAL (AS TO MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY, ONLY)** **[Bus. & Prof. Code § 495]**

IT IS HEREBY STIPULATED AND AGREED by and between the parties to the above-entitled proceedings that the following matters are true:

PARTIES

1. Anne Sodergren (Complainant) is the Executive Officer of the Board of Pharmacy (Board). She brought this action solely in her official capacity and is represented in this matter by Rob Bonta, Attorney General of the State of California, by Christina Thomas, Deputy Attorney General.

2. Respondent McKesson Corporation, dba McKesson Drug Company (Respondent) is represented in this proceeding by attorney Alissa Brice Castenada, whose address is: Quarles & Brady LLP One Renaissance Square Two North Central Avenue Phoenix, AZ 85004-2391

JURISDICTION

3. On or about October 2, 1995, the Board issued Wholesale Permit No. WLS 3076 to McKesson Corporation, dba McKesson Drug Company. The Wholesale Permit was in full force and effect at all times relevant to the charges brought in First Amended Accusation No. 6850 and will expire on October 1, 2022, unless renewed.

4. First Amended Accusation No. 6850 was filed before the Board of Pharmacy, Department of Consumer Affairs and is currently pending against Respondent. The First Amended Accusation and all other statutorily required documents were properly served on Respondent on January 4, 2021. Respondent timely filed its Notice of Defense contesting the First Amended Accusation. A copy of First Amended Accusation No. 6850 is attached as exhibit A and incorporated herein by reference.

ADVISEMENT AND WAIVERS

5. Respondent has carefully read, fully discussed with counsel, and understands the charges and allegations in First Amended Accusation No. 6850. Respondent has also carefully read, fully discussed with counsel, and understands the effects of this Stipulated Settlement and Disciplinary Order for Public Reproval.

6. Respondent is fully aware of its legal rights in this matter, including the right to a hearing on the charges and allegations in the First Amended Accusation; the right to be represented by counsel at its own expense; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on its own behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

7. Respondent voluntarily, knowingly, and intelligently waives and gives up each and every right set forth above.

CULPABILITY

8. Respondent denies the allegations in First Amended Accusation No. 6850.

9. For the purpose of resolving the First Amended Accusation without the expense and uncertainty of further proceedings, Respondent hereby gives up its right to contest those charges.

10. Respondent agrees that its Wholesale Permit is subject to discipline and they agree to be bound by the Disciplinary Order below.

CONTINGENCY

11. This stipulation shall be subject to approval by the Board of Pharmacy. Respondent understands and agrees that counsel for Complainant and the staff of the Board of Pharmacy may communicate directly with the Board regarding this stipulation and settlement, without notice to or participation by Respondent or its counsel. By signing the stipulation, Respondent understands and agrees that they may not withdraw its agreement or seek to rescind the stipulation prior to the time the Board considers and acts upon it. If the Board fails to adopt this stipulation as its Decision and Order, the Stipulated Settlement and Disciplinary Order for Public Reproval shall be of no force or effect, except for this paragraph, it shall be inadmissible in any legal action between the parties, and the Board shall not be disqualified from further action by having considered this matter.

12. The parties understand and agree that Portable Document Format (PDF) and facsimile copies of this Stipulated Settlement and Disciplinary Order for Public Reproval, including PDF and facsimile signatures thereto, shall have the same force and effect as the originals.

13. This Stipulated Settlement and Disciplinary Order for Public Reproval is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Settlement and Disciplinary Order for Public Reproval may not be altered, amended, modified,

supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.

14. In consideration of the foregoing admissions and stipulations, the parties agree that the Board may, without further notice or formal proceeding, issue and enter the following Disciplinary Order:

DISCIPLINARY ORDER

IT IS HEREBY ORDERED that Wholesale Permit No. WLS 3076 issued to Respondent McKesson Corporation, dba McKesson Drug Company, shall be publicly reproved by the Board of Pharmacy under Business and Professions Code section 495 in resolution of First Amended Accusation No. 6850, attached as exhibit A.

Cost Recovery. No later than 60 days from the effective date of the Decision, Respondent shall pay $147,780.00 to the Board for its costs associated with the investigation and enforcement of this matter pursuant to Business and Professions Code section 125.3. If Respondent fails to pay the Board costs as ordered, Respondent shall not be allowed to renew its Wholesale Permit Number until Respondent pays costs in full. In addition, the Board may enforce this order for payment of its costs in any appropriate court, in addition to any other rights the Board may have.

Full Compliance. As a resolution of the charges in First Amended Accusation No. 6850, this stipulated settlement is contingent upon Respondent's full compliance with all conditions of this Order. If Respondent fails to satisfy any of these conditions, such failure to comply constitutes cause for discipline, including outright revocation, of Respondent's Wholesale Permit No. WLS 3076.

ACCEPTANCE

I have carefully read the above Stipulated Settlement and Disciplinary Order for Public Reproval and have fully discussed it with my attorney, Alissa Brice Castaneda. I understand the stipulation and the effect it will have on my Wholesale Permit. I enter into this Stipulated Settlement and Disciplinary Order for Public Reproval voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

DATED: _____

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: _____

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: _____

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

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DATED: 12/17/2021

MCKESSON CORPORATION, DBA
MCKESSON DRUG COMPANY
Respondent

I have read and fully discussed with Respondent McKesson Corporation, dba McKesson Drug Company the terms and conditions and other matters contained in the above Stipulated Settlement and Disciplinary Order for Public Reproval. I approve its form and content.

DATED: 12/17/2021

ALISSA BRICE CASTANEDA
Attorney for Respondent

ENDORSEMENT

The foregoing Stipulated Settlement and Disciplinary Order for Public Reproval is hereby respectfully submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

DATED: 12/17/21

Respectfully submitted,

ROB BONTA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General

CHRISTINA THOMAS
Deputy Attorney General
Attorneys for Complainant

LA2019505103
64760081.docx

Exhibit A

First Amended Accusation No. 6850

XAVIER BECERRA
Attorney General of California
SHAWN P. COOK
Supervising Deputy Attorney General
CHRISTINA THOMAS
Deputy Attorney General
State Bar No. 171168
300 So. Spring Street, Suite 1702
Los Angeles, CA 90013
Telephone: (213) 269-6297
Facsimile: (916) 731-2126
Attorneys for Complainant

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the Accusation Against: **MCKESSON CORPORATION, DBA MCKESSON DRUG COMPANY** **9501 S. Norwalk** **Santa Fe Springs, CA 90670** **Wholesale Permit No. WLS 3076,** **and** **JOHN F. BOHLINGER** **9501 Norwalk Blvd.** **Santa Fe Springs, CA 90670** **Designated Representative No. EXC 17318** Respondents.	Case No. 6850 **FIRST AMENDED ACCUSATION**

PARTIES

1. Anne Sodergren (Complainant) brings this First Amended Accusation solely in her official capacity as the Executive Officer of the Board of Pharmacy, Department of Consumer Affairs.

2. On or about October 2, 1995, the Board of Pharmacy issued Wholesale Permit Number WLS 3076 to McKesson Corporation, dba McKesson Drug Company (Respondent

McKesson). The Wholesale Permit was in full force and effect at all times relevant to the charges brought herein and will expire on October 1, 2021, unless renewed.

3. On or about January 21, 2004, the Board of Pharmacy issued Original Certificate Number EXC 17318 to John F. Bohlinger (Respondent Bohlinger) to act as a Designated Representative. The certificate was in full force and effect at all times relevant to the charges brought herein and will expire on January 1, 2021, unless renewed.

JURISDICTION

4. This Accusation is brought before the Board of Pharmacy (Board), Department of Consumer Affairs, under the authority of the following laws. All section references are to the Business and Professions Code (Code) unless otherwise indicated.

5. Section 4300 of the Code states:

> (a) Every license issued may be suspended or revoked.
>
> (b) The board shall discipline the holder of any license issued by the board, whose default has been entered or whose case has been heard by the board and found guilty, by any of the following methods:
>
> (1) Suspending judgment.
>
> (2) Placing him or her upon probation.
>
> (3) Suspending his or her right to practice for a period not exceeding one year.
>
> (4) Revoking his or her license.
>
> (5) Taking any other action in relation to disciplining him or her as the board in its discretion may deem proper.

6. Section 4307 of the Code states:

> (a) Any person who has been denied a license or whose license has been revoked or is under suspension, or who has failed to renew his or her license while it was under suspension, or who has been a manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of any partnership, corporation, trust, firm, or association whose application for a license has been denied or revoked, is under suspension or has been placed on probation, and while acting as the manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control had knowledge of or knowingly participated in any conduct for which the license was denied, revoked, suspended, or placed on probation, shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, partner, or in any other position with management or control of a licensee as follows:

(1) Where a probationary license is issued or where an existing license is placed on probation, this prohibition shall remain in effect for a period not to exceed five years.

(2) Where the license is denied or revoked, the prohibition shall continue until the license is issued or reinstated.

(b) "Manager, administrator, owner, member, officer, director, associate, partner, or any other person with management or control of a license" as used in this section and Section 4308, may refer to a pharmacist or to any other person who serves in such capacity in or for a licensee.

(c) The provisions of subdivision (a) may be alleged in any pleading filed pursuant to Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. However, no order may be issued in that case except as to a person who is named in the caption, as to whom the pleading alleges the applicability of this section, and where the person has been given notice of the proceeding as required by Chapter 5 (commencing with Section 11500) of Part 1 of Division 3 of the Government Code. The authority to proceed as provided by this subdivision shall be in addition to the board's authority to proceed under Section 4339 or any other provision of law.

STATUTORY PROVISIONS

7. Section 4301 of the Code states, in pertinent part:

The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

...

(e) The clearly excessive furnishing of controlled substances in violation of subdivision (a) of Section 11153.5 of the Health and Safety Code. Factors to be considered in determining whether the furnishing of controlled substances is clearly excessive shall include, but not be limited to, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes its product.

...

(j) The violation of any of the statutes of this state, of any other state, or of the United States regulating controlled substances and dangerous drugs.

...

(*o*) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency.

///

8. California Health and Safety Code section 11153.5 states, in pertinent part:

(a) No wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, shall furnish controlled substances for other than legitimate medical purposes."

...

(c) Factors to be considered in determining whether a wholesaler or manufacturer, or agent or employee of a wholesaler or manufacturer, furnished controlled substances knowing or having a conscious disregard for the fact that the controlled substances are for other than legitimate medical purposes shall include, but not be limited to, whether the use of controlled substances was for purposes of increasing athletic ability or performance, the amount of controlled substances furnished, the previous ordering pattern of the customer (including size and frequency of orders), the type and size of the customer, and where and to whom the customer distributes the product.

9. Section 4169.1 of the Code (effective January 1, 2018), states:

A wholesaler, upon discovery, shall notify the board in writing of any suspicious orders of controlled substances placed by a California-licensed pharmacy or wholesaler by providing the board a copy of the information that the wholesaler provides to the United States Drug Enforcement Administration. Suspicious orders include, but are not limited to, orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

10. Section 4059.5, subsection (a), of the Code states:

(a) Except as otherwise provided in this chapter, dangerous drugs or dangerous devices may only be ordered by an entity licensed by the board and shall be delivered to the licensed premises and signed for and received by a pharmacist. Where a licensee is permitted to operate through a designated representative, or in the case of a reverse distributor a designated representative-reverse distributor, that individual shall sign for and receive the delivery.

REGULATORY PROVISIONS

11. Code of Federal Regulations, title 21, section 1301.74, subsection (b), states:

The registrant shall design and operate a system to disclose to the registrant suspicious orders of controlled substances. The registrant shall inform the Field Division Office of the Administration in his area of suspicious orders when discovered by the registrant. Suspicious orders include orders of unusual size, orders deviating substantially from a normal pattern, and orders of unusual frequency.

12. California Code of Regulations, title 16, section 1783, states, in pertinent part:

(a) A manufacturer or wholesaler shall furnish dangerous drugs or devices only to an authorized person; prior to furnishing dangerous drugs and devices to a person not known to the furnisher, the manufacturer or wholesaler shall contact the board or, if the person is licensed or registered by another government entity, that entity, to confirm the recipient is an authorized person.

(b) "Authorized person" means a person to whom the board has issued a permit which enables the permit holder to purchase dangerous drugs or devices for use within the scope of its permit. "Authorized person" also means any person in this state or in another jurisdiction within the United States to the extent such furnishing is authorized by the law of this state, any applicable federal law, and the law of the jurisdiction in which that person is located. The manufacturer or wholesaler furnishing to such person shall, prior to furnishing the dangerous drugs and devices, establish the intended recipient is legally authorized to receive the dangerous drugs or devices.

(c) Dangerous drugs or devices furnished by a manufacturer or wholesaler shall be delivered only to the premises listed on the permit; provided that a manufacturer or wholesaler may furnish drugs to an authorized person or an agent of that person at the premises of the manufacturer or wholesaler if (1) the identity and authorization of the recipient is properly established and (2) this method of receipt is employed only to meet the immediate needs of a particular patient of the authorized person. Dangerous drugs or devices may be furnished to a hospital pharmacy receiving area provided that a pharmacist or authorized receiving personnel signs, at the time of delivery, a receipt showing the type and quantity of the dangerous drugs or devices so received. Any discrepancy between the receipt and the type and quantity of dangerous drugs and devices actually received shall be reported to the delivering manufacturer or wholesaler by the next business day after the delivery to the pharmacy receiving area.

COST RECOVERY

13. Section 125.3 of the Code states, in pertinent part, that the Board may request the administrative law judge to direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case.

CONTROLLED SUBSTANCES / DANGEROUS DRUGS

14. Section 4021 of the Code states: "'Controlled substance' means any substance listed in Chapter 2 (commencing with Section 11053) of Division 10 of the Health and Safety Code."

15. Section 4022 of the Code states: "'Dangerous drug' or 'dangerous device' means any drug or device unsafe for self use, except veterinary drugs that are labeled as such, and includes the following:

(a) Any drug that bears the legend: 'Caution: federal law prohibits dispensing without prescription,' 'Rx only,' or words of similar import.

...

(c) Any other drug or device that by federal or state law can be lawfully dispensed only on prescription or furnished pursuant to Section 4006."

16. Phenergan with Codeine Syrup 6.25 mg – 10 mg / 5 ml is the brand name for promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C), a Schedule V controlled substance designated by California Health and Safety Code section 11058(c)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat coughing.

17. Xanax is the brand name for alprazolam, a Schedule IV controlled substance designated by California Health and Safety Code section 11057(d)(1) and a dangerous drug designated by California Business and Professions Code section 4022. It is used to treat anxiety.

FACTUAL ALLEGATIONS – CHILDREN'S MEDICAL CENTER PHARMACY

18. At all times relevant herein, the Children's Medical Center Pharmacy, also known as the Rady Children's Outpatient Pharmacy (Rady Pharmacy), was part of the Rady Children's Hospital of San Diego. According to its website, it is the only hospital in the San Diego area dedicated exclusively to pediatric healthcare.

19. Between May 7, 2017 and June 26, 2018, the Rady Pharmacy could not account for an inventory shortage of approximately 119 pints of P/C and 5,300 tablets of alprazolam 2mg. A pharmacy technician at the Rady Pharmacy had stolen these dangerous drugs and controlled substances for herself and her friends.

Promethazine with codeine syrup 6.25 mg-10 mg / 5 ml (P/C)

20. Based on Lexicomp Online, a collection of clinical database and clinical decision support tools, P/C is not recommended in pediatrics due to risk of adverse effects, such as slowed or difficult breathing, misuse, abuse, addiction, overdose, and death.

21. According to the pharmacy manager, the Rady Pharmacy did not use or dispense P/C because pediatric doctors did not prescribe P/C to children. On the rare occasion the doctor prescribed P/C, it would be during the winter season according to the pharmacy manager.

22. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, less than two 16-ounce bottles of P/C **per year** to the Rady Pharmacy between January 2014 and August 2017. Beginning in September 2017, the sales of P/C displayed an irregular pattern compared to the previous ordering pattern:

P/C Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (16oz) of P/C Sold**
September 2017	11
October 2017	7
November 2017	7
December 2017	10
January 2018	14
February 2018	10
March 2018	15
April 2018	10
May 2018	18
June 2018	17

23. When calculating the monthly percentage change in sales, there were sales of P/C which varied from 40% to 80% more than the sale from the previous month.

24. The orders for P/C beginning in September 2017 were significantly larger and were shipped in consecutive months from September 2017 to June 2018, which totaled approximately 119 pints or 56,287 ml of P/C.

Alprazolam 2mg

25. Alprazolam is available in dosages of 0.25 mg, 0.5 mg, 1 mg, and 2mg.

26. According to Lexicomp Online, alprazolam should be titrated and used at the lowest effective dose. Lexicomp provided the following dosing information: "*Children ≥ 7 years and Adolescents < 18 years: Limited data available... Initial: 0.005 to 0.02 mg/kg/dose 3 times daily... maximum of 0.02 mg/kg/dose.*" For example, if a child is 40 kg (about 88 pounds), the dosing range is from 0.2 to 0.8 mg per dose.

27. According to Respondent McKesson's sales records, Respondent McKesson sold, on average, one bottle of 100-count alprazolam 2mg **per year** between January 2014 and September 2017. Beginning in October 2017, the sales of alprazolam 2mg displayed an irregular pattern compared to the previous ordering pattern:

///

///

///

///

Alprazolam 2mg Sold from Respondent McKesson to the Rady Pharmacy	
Date	**Bottles (100-count) of alprazolam 2mg Sold**
October 2017	7
November 2017	9
December 2017	8
January 2018	4
February 2018	4
March 2018	4
April 2018	0
May 2018	15

28. When calculating the monthly percentage change in sales, there were sales of alprazolam 2mg which varied from 250% to 275% more than the sale from the previous month.

29. The orders for alprazolam 2mg beginning in October 2017 were significantly larger and were shipped in consecutive months (except April 2018) from October 2017 to May 2018, which totaled approximately 5,100 tablets of alprazolam 2 mg.

FIRST CAUSE FOR DISCIPLINE

(Unprofessional Conduct – Excessive Furnishing of Controlled Substances)

30. Respondents are subject to disciplinary action under Code section 4301, subsection (e), in that Respondents clearly and excessively furnished controlled substances in violation of California Health and Safety Code section 11153.5, subsection (a), as follows:

a. Respondents furnished the Rady Pharmacy one to two pints of P/C in non-consecutive months from January 2014 to August 2017. Sales increased to seven to 18 pints ordered in consecutive months from September 2017 to June 2018.

b. Respondents furnished the Rady Pharmacy 100 to 200 tablets of alprazolam 2mg in non-consecutive months from January 2014 to September 2017. Sales increased to 400 to 1,500 tablets ordered in consecutive months from October 2017 to May 2018 (except April 2018).

c. Respondents furnished the Rady Pharmacy large quantities of controlled substances (P/C and alprazolam 2mg) that are not typically distributed to pediatric patients.

d. The P/C and alprazolam 2mg furnished by Respondents were not dispensed to patients for legitimate medical purposes but were diverted by a pharmacy technician.

Paragraphs 18 to 29 are re-alleged as if fully set forth herein.

///

FACTUAL ALLEGATIONS – CARING PHARMACY

31. On January 7, 2020, a Board inspector conducted an inspection of Caring Pharmacy (Caring Pharmacy), located at 25802 Hemingway Avenue #103, Stevenson Ranch, CA 91381. K.F. is a licensed pharmacist and the owner of Caring Pharmacy. S.F. is K.F's wife and is an unlicensed individual.

32. During this inspection at approximately 9:30 a.m., the Board inspector observed Respondent McKesson's delivery driver bring a drug tote (Drug Tote) to S.F.'s car in front of Caring Pharmacy. S.F. signed for the delivery, and the delivery driver left. S.F. subsequently brought the Drug Tote into Caring Pharmacy.

33. Shortly thereafter, the Board inspector entered Caring Pharmacy, and S.F. stated that no pharmacist was present at Caring Pharmacy at that time. The invoice that accompanied the Drug Tote revealed that the Drug Tote consisted of Emgality and Repatha, both of which are dangerous drugs under California Business and Professions Code section 4022.

SECOND CAUSE FOR DISCIPLINE

(Violation of Statute Regulating Dangerous Drugs)

34. Respondents are subject to disciplinary action under Code section 4301, subsection (j), in that Respondents committed unprofessional conduct by violating California Business and Professions Code section 4059.5, subsection (a). Specifically, on or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for or received by a pharmacist. The drugs were signed for by an unlicensed individual.

THIRD CAUSE FOR DISCIPLINE

(Violation of Pharmacy Law)

35. Respondents are subject to disciplinary action under Code section 4301, subsection (o), in that Respondents committed unprofessional conduct by violating the following Pharmacy Law and regulations:

///

///

///

a. California Business and Professions Code section 4059.5, subsection (a): On or about January 7, 2020, Respondents delivered dangerous drugs to Caring Pharmacy, but the drugs were not signed for and received by a pharmacist. The drugs were signed for by an unlicensed individual.

b. California Code of Regulations, title 16, section 1783: On or about January 7, 2020, Respondents delivered dangerous drugs to an unlicensed person at Caring Pharmacy who was not an "authorized person" under California Code of Regulations, title 16, section 1783, subsection (b).

DISCIPLINARY CONSIDERATIONS

36. On April 5, 2018, the Board issued Citation No. CI 2014 63111 to Respondent McKesson for violating California Health and Safety Code section 11153.5 [wholesaler furnishing controlled substance other than for legitimate medical purposes] and assessed a fine of $5,000.00. Respondent McKesson has paid the fine.

37. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

38. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent McKesson for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

39. On June 27, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code sections 4163(a) [unauthorized furnishing by wholesaler]; 4169(a)(1) [prohibited acts; purchase, trade, sell, or transfer dangerous drugs to unlicensed person or entity]; and 4059.5 [who may order dangerous drugs or devices].

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40. On September 21, 2018, the Board issued a Letter of Admonishment to Respondent Bohlinger for violating California Business and Professions Code section 4059.5(a) [dangerous drugs and devices may only be ordered by and shall be delivered to licensed premises and signed for and received by a pharmacist].

OTHER MATTERS

41. Pursuant to Code section 4307, if discipline is imposed on Wholesale Permit Number WLS 3076 issued to McKesson Corporation, McKesson Corporation shall be prohibited from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if it is revoked.

PRAYER

WHEREFORE, Complainant requests that a hearing be held on the matters herein alleged, and that following the hearing, the Board of Pharmacy issue a decision:

1. Revoking or suspending Wholesale Permit Number WLS 3076, issued to McKesson Corporation, dba McKesson Drug Company;

2. Revoking or suspending Designated Representative Number EXC 17318, issued to John F. Bohlinger;

3. Prohibiting McKesson Corporation from serving as a manager, administrator, owner, member, officer, director, associate, or partner of a licensee for five years if Wholesale Permit Number WLS 3076 is placed on probation or until Wholesale Permit Number WLS 3076 is reinstated if Wholesale Permit Number WLS 3076 issued to McKesson Corporation is revoked;

4. Ordering McKesson Corporation and John F. Bohlinger to pay the Board of Pharmacy the reasonable costs of the investigation and enforcement of this case, pursuant to Business and Professions Code section 125.3; and,

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5. Taking such other and further action as deemed necessary and proper.

DATED: 11/16/2020

Sodergren, Anne@DCA
Digitally signed by Sodergren, Anne@DCA
Date: 2020.11.16 05:53:42 -08'00'

ANNE SODERGREN
Executive Officer
Board of Pharmacy
Department of Consumer Affairs
State of California
Complainant

LA2019505103
53952541.docx

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 22, 2022

CERTIFIED MAIL

John F. Bohlinger
9501 Norwalk Blvd.
Santa Fe Springs, CA 90670

RE: Administrative Case No. 6850
John F. Bohlinger, EXC 17318

Dear Mr. Bohlinger:

Attached is the Board of Pharmacy's Stipulated Settlement and Disciplinary Order for Public Reproval regarding the above-referenced matter. Your attention is directed to page 4 of the document.

Effective at 5:00 p.m. on March 24, 2022, Designated Representative No. EXC 17318 issued to John F. Bohlinger shall be publicly reproved by the Board and shall also be subject to terms and conditions in the decision.

If you wish to file a petition for reconsideration pursuant to Government Code section 11521, the petition must be received prior to the effective date of the decision. However, please be aware the Board needs approximately five days to process a petition for reconsideration. Attached is a copy of the Government Code section for your review. **Please note that reconsideration is NOT available to you if you entered into a stipulated settlement with the Board.**

If you have any questions concerning this matter, you may contact Lupe Baltazar, at lupe.baltazar@dca.ca.gov or (916) 518-3009. Should you have any questions related to litigation of this matter, please contact the Deputy Attorney General handling this matter.

Sincerely,

ANNE SODERGREN
Executive Officer

By Susan Cappello

Susan Cappello
Enforcement Manager

SC:lb
Enclosure(s)

cc: Christina Thomas, DAG
Amy Levine Heiserman, Esq.

DECLARATION OF SERVICE BY CERTIFIED MAIL

RE: Administrative Case No. 6850
John F. Bohlinger, EXC 17318

I am over 18 years of age, and not a party to the within cause; my business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833. I served a copy of the:

LETTER AND DECISION

on each of the following, by placing same in an envelope(s) addressed to as follows:

NAME	CERTIFIED NO.
John F. Bohlinger 9501 Norwalk Blvd. Santa Fe Springs, CA 90670	7017 0190 0000 4212 5632
Amy Levine Heiserman, Esq. Quarles & Brady LLP One Renaissance Square Two North Central Avenue, Suite 600 Phoenix, AZ 85004-2322	7017 0190 0000 4212 5625

and that said envelope was then sealed and deposited and certified in the United States Post Office at Sacramento, California, on February 22, 2022, as certified mail with postage fully prepaid thereon and return receipt service by United States mail between the place of mailing and the place so addressed.

I declare under penalty of perjury that the foregoing is true and correct. Executed on February 22, 2022 at Sacramento, California.

Lupe Baltazar, Administrative Case Analyst

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

In the Matter of the First Amended Accusation Against:

MCKESSON CORPORATION, dba
MCKESSON DRUG COMPANY,
Wholesale Permit No. WLS 3076;

and

JOHN F. BOHLINGER,
Designated Representative License No. EXC 17318,

Respondents

Agency Case No. 6850

OAH No. 2021050035

DECISION AND ORDER

The attached Stipulated Settlement and Disciplinary Order for Public Reproval is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on March 24, 2022.

It is so ORDERED on February 22, 2022.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

By 

Seung W. Oh, Pharm.D.
Board President

4Q

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Alpha Cognition, USA, Inc.

Physical Address: Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200

City: Grapevine State: TX Zip: 76051

Mailing Address (if different from physical address): Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200

City: Grapevine State: TX Zip: 76051

Telephone: 8134806138 Website: https://www.alphacognition.com/

Name of Designated Representative (DR): Lauren Dangelo

Licensing Company Email: ldangelo@alphacognition.com DR Email: ldangelo@alphacognition.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☑ Retail pharmacy wholesale distributor
☒ Others: Long-term care/assisted living		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: TX

Parent Company (if any): Alpha Cognition, USA, Inc.

Corporation Name: Alpha Cognition USA, Inc.

Mailing Address: Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200

City: Grapevine State: TX Zip: 76051

Telephone: 8134806138 Email: ldangelo@alphacognition.com

Contact Person Name: Lauren DeAngelo

Date of SEC Registration: 10/16/2015	SEC Registration Number: 1655923	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Alpha Cognition, USA, Inc.
Facility Name

Michael McFadden
Print Name of Authorized Person Submitting Application

Michael McFadden
Original signature of Authorized Person (copies or stamps not accepted)

12/22/2024
Date

Board Use Only	Date Received: 1/30/25	Amount: $1000-CK 2947 ✓

An official website of the United States government Here's how you know

FDA

Home > Drug Databases > NDC > Search Result

Share Tweet LinkedIn Email Print

Current through October 10, 2024

You have searched Finished drug products

Search Results: *'alpha cognition'*

Back to Search Page

Keyword Search RESET

Showing 1 to 3 of 3 entries Show 50 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC
ZUNVEYL	84054-005-60	5mg/1	TABLET, DELAYED RELEASE	ORAL	NDA218549	Alpha Cognition, Inc.	84054-005
ZUNVEYL	84054-010-60	10mg/1	TABLET, DELAYED RELEASE	ORAL	NDA218549	Alpha Cognition, Inc.	84054-010

0820

Description of Operations

Alpha Cognition, USA, Inc. is a VirtualManufacturer. Alpha Cognition, USA, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed to Wholesalers by their Third-Party Logistics Provider, Cardinal Health , who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Alcami
1726 North 23rd Street
Wilmington, NC 28405
FDA Establishment Number: 1049418

Contact Person: Cale Murray
Contact Number: (800) 575-4424

Alcami manufactures Alpha Cognition, USA, Inc.'s product and packages finished product. At no time does Alcami own the product, contract with Alpha Cognition, USA, Inc.'s customers, invoice, nor sell a Alpha Cognition, USA, Inc. product. Alpha Cognition, USA, Inc.'s products are not Controlled Substances.

Labeler Code:
84054

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal Health acts as Alpha Cognition, USA, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of Alpha Cognition, USA, Inc.'s product-throughout the United States. Cardinal Health's address is:

Cardinal Health
501 Mason Rd
Lavergne, TN 37086
Joe Bowman
(330) 268-4465

Alpha Cognition, USA, Inc. has 4 employees working on site during normal business hours.

Alpha Cognition, USA, Inc.'s hours of operation are 9:00 am – 5:00pm Monday through Friday.

Alpha Cognition, USA, Inc.'s records are stored at:

Cardinal Health
501 Mason Rd
Lavergne, TN 37086

Alpha Cognition, USA, Inc.'s facility square footage is 90sq ft.

Company Information

Company Name: Alpha Cognition, USA, Inc.
Address: Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200
City, State, Zip: Grapevine, TX 76054
Phone: (813) 480-6138
Website: https://www.alphacognition.com/
E-mail: ldangelo@alphacognition.com

FEIN:
State of Formation: Texas
Date Incorporated:03/08/2022
File Number:804493646

Ownership Information

Alpha Cognition, USA, Inc. is 100% owned by Alpha Cognition Canada Inc.

Parent Company Address: 67 East 5th Avenue, Vancouver, BC, V5T 1G7
Parent Company Phone: 858-344-4375
Parent Company FEIN:N/A – Canadian Corporation

Officers

Michael McFadden, CEO
Business Address: Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200, Grapevine, TX 76051
Business Phone: (858) 344-4375
Email: mmcfadden@alphacognition.com

Lauren D'Angelo, COO
Business Address: Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200, Grapevine, TX 76051
Business Phone: (813) 480-6138
Email: ldangelo@alphacognition.com

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Conversion for Alpha Cognition USA, Inc. (file number 804493646), a Domestic For-Profit Corporation, was filed in this office on March 08, 2022.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on January 29, 2025.

Jane Nelson
Secretary of State

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/drug-manufacturers-distributors/applications-forms-drug-manufacturers-distributor**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

ALPHA COGNITION USA INC
1452 HUGHES RD STE 200 GRAPEVINE VINEYARD-REGUS
GRAPEVINE TX 76051

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

ALPHA COGNITION USA INC

1452 HUGHES RD STE 200 GRAPEVINE VINEYARD II-REGUS
GRAPEVINE, TX 76051

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003950
Expires: August 26, 2026

NON-TRANSFERABLE

Commissioner

518824

Lauren D'Angelo

[redacted]

Experienced and Accomplished
Biotech Executive

Forward thinking, senior executive with 23+ years experience in pharmaceuticals marketing, sales, and operations, with broad reaching clinical experience across 13 products within ten therapeutic areas. Therapeutic emphasis includes CNS, Neurology, Cardiovascular, Diabetes, Urology, Oncology, Respiratory, GI, Pain, and Rare Disease.

Deep experience in small and large organizations from pre-commercialization to launch and post-launch, with demonstrated success building commercialization and launch plans for US and global markets, and managing P&L. Experience securing funding from both private and public sources, with successful IPO experience.

Demonstrated ability in building and leading marketing and sales teams, building commercial organizations, and building great company culture, with an emphasis on strong leadership and development and cross-functional collaboration. Developed and led 15+ launch plans and successfully launched 10 products, new indications, and line extensions, in varying leadership roles.

Professional Experience

Chief Operating Officer September 2023 - Present
Chief Commercial Officer May 2021 – Present
ALPHA COGNITION, Dallas, TX

As a member of the executive leadership team and first commercial hire, spearhead the global commercial strategy and roadmap to enable growth of newly-formed pharma start-up company innovating in Alzheimer's disease and neurodegenerative diseases.

- Establish and oversee organizations for corporate communications, global marketing, sales, market access, the product lifecycle, business analytics, forecasting, market research/planning, business development, PR, medical affairs, regulatory, CMC, human resources and IT.
- Develop, refine and deliver strategic communications to investors, bankers and Wall Street analysts to secure funding for the company; closed $32 million in financing in 2021 and 2022.
- Lead all corporate and business development activities by supporting assessments of in-licensing/acquisition opportunities and consult across the organization to ensure alignment with commercial plans and advise on strategies for clinical trial design/protocols, medical activities, and research and development.

Chief Operating Officer July 2023 – Present
ALPHA SEVEN THERAPEUTICS, Dallas, TX
Founding member of Alpha Seven Therapeutics, Inc. , a private company formed as a spin-off from Alpha Cognition in July 2023 to develop and commercialize its lead asset in TBI and related disorders.

Vice President, Marketing and Commercial Strategy Oct 2017 – May 2021
Interim Chief Commercial Officer (CCO) Aug 2018 – Aug 2020
UROVANT SCIENCES, Irvine, CA

Joined the organization as first commercial hire and employee #3, building the company from the ground up. Built the commercial infrastructure, investor presentations, corporate branding, launch strategy and tactical plans, sales launch readiness, and responsible for every aspect of the launch of GEMTESA, the company's first asset in Urology. Led business insights, sales, sales training, and marketing, including HCP, consumer, digital, and KOL marketing. Led managed markets function, including strategy development, pricing, and discount strategies for payers. Commercial lead and core team member for all clinical development/life-cycle management activities. Led early commercialization strategy and assessment of business development opportunities, as well as long term strategic planning across the company.

- Completed a successful IPO, resulting in $140M total gross proceeds in October 2018; Led the diligence p[redacted] and

secured up to $100 million in debt financing capacity with Hercules Capital in February 2019; Company acquired by Sumitovant Biopharma, with an enterprise value of $680M in April 2021.

- Delivered a successful pre-launch, non-branded promotional campaign with over 6 million unique engagements, and 25,000 patients captured in CRM database for launch.
- Recruited and hired 2 salesforces (Specialty and Long Term Care) from top to bottom in 6 months. (3 Area Vice Presidents, 16 Regional Sales Managers, 158 sales representatives)
- Led and secured 2 co-promotion deals with Sunovion Pharmaceuticals. (Distribution; PCP sales co-promotion)

Senior Director, Head of Marketing Oct 2015 – Oct 2017
AVANIR PHARMACEUTICALS, Aliso Viejo, CA

Led the NUEDEXTA brand team consisting of 14 marketers responsible for Avanir's largest asset within the neuroscience space. Responsible for all HCP, consumer, digital, key customer, and managed care marketing initiatives that included neurologists, primary care (IM/PCP), and the Long-Term Care (LTC) sector, with full P&L accountability. Collaborated with executive leadership, and cross-functional partners including finance, sales, managed markets, medical, supply chain, R&D, clinical, regulatory, compliance and legal, to maximize brand visibility and growth.

- Designed and implemented strategic marketing plans that grew top line U.S. sales to over 40% YoY growth.
- Strategically shifted brand resources toward digital; developed and implemented digital strategy, increased digital spend by 1000%, and enhanced brand presence and customer interactions across digital channels, while achieving a 300% ROI.
- Created, executed and optimized direct to consumer campaign(s) for non-branded PBA (Danny Glover) and branded NUEDEXTA across television, radio, print, and digital platforms.

Director, Head of Oncology and Urology Marketing Jul 2014 – Oct 2015
MEDIVATION, San Francisco, CA

Launched XTANDI and delivered HCP and patient brand strategy and promotions in Urology and Oncology, with direct P&L ownership. Collaborated with Astellas to maximize the effectiveness and alignment of the co-promotion partnership, including representing commercial leadership as Chair on Joint Commercialization Committee.

- Led and developed key brand deliverables such as launch readiness reviews, brand plans, tactical plans, quarterly business assessments, brand performance updates, and board presentations.
- Significantly exceeded sales forecast and delivered over a billion dollars in sales within a year of launch.

Group Product Director, HCP and Key Customer Apr 2012 - Jul 2014
GENENTECH, San Francisco, CA

Led pre-launch market development activities and brand launch readiness including positioning, disease state campaign development, branding, creative concept development, internal campaign, key customer and congress activities, and the creation and implementation of all pre-launch market development and promotional strategies and tactics.

- Led the Customer Facing Organization (CFO); established customer facing roles and internal infrastructure support, defined a comprehensive plan for an effective field organization, designed company-wide Market Access model and infrastructure, and delivered a best-in-class customer facing team structure to launch Bitopertin.
- US Commercial representative on the Global Product Team, Medical Team, Global Publications Team, and ENTA (global team consisting of key leaders across various countries to prepare Genentech for "Entering New Therapeutic Areas".)

HCP/Consumer Brand Director Aug 2010 - Apr 2012
ASTRAZENECA PHARMACEUTICALS, Wilmington, DE

Developed the branding, positioning, messaging and pricing strategies for the US launch of TC-5214 and NKTR-118 (Phase III products), and delivered a fully integrated launch plan across all customer groups. Provided U.S. commercial views into target product profiles, target product claims, global brand strategy, product naming, trademarks, packaging, clinical trial primary and secondary end point selection, and life cycle management programs.

- Confirmed US business opportunity and strategic scenarios around target product profiles, provided commercial input into NDA submission, and conducted label scenario planning.

- Contributed to shaping the clinical and development strategy by integrating market dynamics, competitive intelligence and input from external experts.
- Cultivated and enhanced external relationships by engaging key opinion leaders, national professional organizations and patient associations.

Senior Brand Manager Apr 2009 - Aug 2010

Led marketing activities for the CERTRIAD product launch (co-promotion with Abbott), including positioning, strategies, messaging, logo development, the creation of launch and market development campaigns, sales training, peer-to-peer programs, advisory boards, conventions, sales force integration, and launch meeting planning.

- Developed the CRESTOR/CERTRIAD Franchise Strategy; led the CV portfolio planning team, with an emphasis on launching CERTRIAD into the cardiovascular market with other CV portfolio products.

Brand Planning Manager, Strategy April 2008 – April 2009

Key member of the CRESTOR leadership team (Chief of Staff to Franchise Leader) that provided leadership and direction for all brand activities, maximized the long and short-term value of the brand, optimized and delivered the P&L, and managed the allocation of resources to ensure the most efficient and effective brand investments possible.

- Led, managed and contributed to all key aspects of the Brand Team's strategic and operational planning resulting in the development of an integrated brand strategy and an aligned operational plan across all customer groups (budget 250M).
- Led and developed the launch strategy for the atherosclerosis and primary prevention indications, as well as the CRESTOR 10-year growth strategy and plan.

Additional AstraZeneca Experience:

Regional Sales & Marketing Manager (2007 - 2008) | **Medical Care District Sales Manager** (2004 - 2007) | **Regional Business Analyst** (2003 - 2004) | **Pharmaceutical Sales Specialist** (2002-2003)
PricewaterhouseCoopers, Management Consultant (2000-2002)

Career Accomplishments

- **2024 Women in Bio Boardroom Ready Cohort,** designed to optimize a trailblazing C-suite female executive's chance of success in finding a board appointment - 2024
- **2023 *PharmaVoice 100,*** salutes standout leaders who go above and beyond the call of duty to push the industry forward while making a deep and lasting impact on their companies, colleagues, and industry - 2023
- **Medical Marketing & Media, *MM+M 2022 Women of Distinction,*** which recognizes the industry's most successful and respected veteran leaders and represent the best of what the medical marketing business has to offer - 2022
- **PM360 Trailblazer, *Product Launch of the Year, GEMTESA,*** recognizes a new product that has revolutionized the life sciences industry through both its impact on patients and its exceptional marketing and branding strategies, focusing on all marketing initiatives developed for the product's launch - 2021
- **Pharmaceutical Executive, *Emerging Pharma Leader for 2020***, which recognizes professional accomplishments to be in line with the executives most likely to inhabit key "c suite" functions - 2020
- **Medical Marketing & Media, *MM&M Women to Watch,*** salutes 20 aspiring healthcare commercial and marketing execs who are distinguishing themselves at the mid stages of their careers - 2017

Additional Accomplishments: *Web Marketing Association Internet Advertising Competition (IAC) Award, Best Pharmaceutical Website (2014); DTC Perspectives National Advertising Awards: Best Disease Education Television Campaign, Best Disease Education Print Campaign,* and *Best Celebrity Campaign (2016); Genentech Marketing Excellence Award (2013); AstraZeneca Marketing Excellence Award (2011); Special Achievement Award (2011); MM&M All Stars Large Pharma Marketing Team of the Year (2009); Pharmaceutical Executive, Brand of the Year (2008); CRESTOR Leadership Award (2008); Special Achievement Sales Leadership Award (2007); Mid-Atlantic Outstanding Leadership Award (2006); National Pace Setter Sales Award (2006); Mid- Atlantic Outstanding Leadership Award (2005); 'NexDimension' Award (2004); Special Achievement Sales Award (2004); New Consultant of the Year (2001); Customer Excellence Award (2001)*

Educational Background

Master of Business Administration (MBA)
UNIVERSITY OF FLORIDA, Warrington College of Business; GPA 4.0 / 4.0
Bachelor of Science - Management Information Systems (MIS) and Finance
FLORIDA STATE UNIVERSITY; GPA 4.0 / 4.0

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Alpha Cognition, USA, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200

City Grapevine State TX Zip 76051

Mailing Address (if different from physical address) Grapevine Vineyard II - Regus 1452 Hughes Road, Suite#200

City Grapevine State TX Zip 76051

Telephone 8134806138 Website https://www.alphacognition.com/

Licensing Company Email ldangelo@alphacognition.com

Section 2: Personal Information

First Lauren Middle Reed Last Dangelo

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address 1452 Hughes Road, Suite#200

City Grapevine State TX Zip 76051

Telephone 8134806138 Email ldangelo@alphacognition.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Florida, Warrington College of Business			
Address	**City**	**State**	**Zip**
1384 Union Road Bryan, Hall 100,	Gainesville	FL	32611
Diploma/Degree obtained, if any			
MBA			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2021 - Present	[redacted]	Southlake	TX	[redacted]
11/2015 -		Ladera Ranch	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
See attached resume			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Lauren D'Agostino
Original Signature (electronic, copies or stamps not accepted)

12/23/2024
Date

I, Lauren Dangelo, **certify that as the designated representative for**

Alpha Cognition, USA, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Lauren Dangelo

Print Name (First, Last)

Lauren D'Angelo

Original Signature (electronic, copies or stamps not accepted)

12/23/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Lauren Dangelo
Print Name (First, Last)

Lauren D'Angelo
Original Signature (electronic, copies or stamps not accepted)

12/23/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Tarrant

I, ~~[illegible]~~ Lauren D'Angelo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Lauren D'Angelo
Original Signature

12/23/2024
Date

Subscribed and Sworn to before me this 23rd day of December.

T. McLeod
Notary Public Signature

TYRIQUE MCLEOD
Notary ID #135134021
My Commission Expires
October 18, 2028

(Seal)

Maria Herrera

From: Nanette McMahon-White <nanette.mcmahon-white@twolabs.com>
Sent: Wednesday, March 5, 2025 1:01 PM
To: Maria Herrera
Subject: Re: Nevada Out-of-State Wholesaler Application-Alpha Cognition, USA, Inc.
Attachments: Lauren DAngeloResume June 2024.pdf; COGS_TX SoS Certificate of Fact-Status 2025-01-29.pdf; AlphaCognition_TX_8.26.2026.pdf

Categories: waiting for Agenda Placement, Already Printed

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good afternoon,

Please see attached, along with that the full employee list are the following:

Lauren D'Angelo
Michael McFadden

Thank you!

Nanette McMahon-White
Licensing Analyst
Commercial-Regulatory

TwoLabs
PHARMA SERVICES
mobile 315-883-7728
website | **email**

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From: Maria Herrera <m.herrera@pharmacy.nv.gov>
Sent: Thursday, February 6, 2025 12:16 PM
To: Nanette McMahon-White <nanette.mcmahon-white@twolabs.com>
Cc: ldangelo@alphacognition.com <ldangelo@alphacognition.com>
Subject: Nevada Out-of-State Wholesaler Application-Alpha Cognition, USA, Inc.

The Nevada State Board of Pharmacy received an Out-of-State Wholesaler application from Alpha Cognition, USA, Inc. The application is incomplete due to the following missing item(s).

- Please provide the resume for Lauren Dangelo, there was none included
- Provide a copy of the Certificate of Corporate Status or Certificate of Good Standing obtained from the Secretary of State's Office in the State where the business is incorporated, dated within the last 12 months
- Copy of the Home State license
- Full employee list in the facility Pursuant to **NRS 639.500 (2)**

All items must be received to move forward with processing your application.

Please let me know if you have any questions.

Thank you,

Maria Herrera
Licensing Specialist
Nevada State Board of Pharmacy
775-850-1440
m.herrera@pharmacy.nv.gov

Inline Viewer

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ **QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the quarterly period ended September 30, 2024

or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to

Commission file number: 001-42403



Alpha Cognition Inc.
(Exact Name of Registrant as Specified in its Charter)

British Columbia	**N/A**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1200 - 750 West Pender Street Vancouver, British Columbia	**V6C**
(Address of Principal Executive Offices)	(Zip Code)

(604) 564-9244
(Registrant's Telephone Number, including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Title of each class:	Trading Symbol	Name of each exchange on which registered:
Common Shares, no par value	ACOG	The Nasdaq Stock Market LLC

Indicate by checkmark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller

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Facts 1,221

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-Q

(Mark One)

☒ QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended June 30, 2024

or

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from to

Commission file number: 333-278997

Alpha Cognition Inc.

(Exact Name of Registrant as Specified in its Charter)

British Columbia	N/A
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

[redacted]

Vancouver, British Columbia	V6C
(Address of Principal Executive Offices)	(Zip Code)

[redacted]

(Registrant's Telephone Number, including Area Code)

Securities registered pursuant to Section 12(b) of the Act: None

Indicate by checkmark whether the registrant (1) filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act:

Large Accelerated Filer ☐ Accelerated Filer ☐ Non-Accelerated Filer ☒

Smaller Reporting Company ☒ Emerging Growth Company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act): Yes ☐ No ☒

Indicate the number of shares outstanding of each of the issuer's classes of common stock, as of the latest practical date: 150,855,536 common shares, without par value, outstanding as of August 8, 2024.

ALPHA COGNITION INC.

FORM 10-Q

For the Quarter Ended June 30, 2024

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ALPHA COGNITION INC.

CONDENSED INTERIM CONSOLIDATED BALANCE SHEETS

PART I

ITEM 1. CONDENSED CONSOLIDATED FINANCIAL STATEMENTS.

ALPHA COGNITION INC.

UNAUDITED CONDENSED CONSOLIDATED BALANCE SHEETS

(Dollar amounts in U.S. dollars)

	(Unaudited)	
	June 30,	December 31,

	2024	2023
ASSETS		
Current assets		
Cash and cash equivalents	$ 1,018,862	$ 1,404,160
Restricted cash	175,321	90,413
Prepaid expenses and other current assets	319,796	366,316
Related party note receivable, net	-	57,550
Total current assets	1,513,979	1,918,439
Other assets	114,286	-
Equipment, net	1,247	1,721
Intangible assets, net	452,490	532,010
Total assets	$ 2,082,002	$ 2,452,170
LIABILITIES AND STOCKHOLDERS' DEFICIENCY		
Current liabilities		
Accounts payable and accrued liabilities	$ 1,242,237	$ 1,394,117
Current portion of promissory note - related party	300,000	1,211,463
Deferred income	28,898	10,413
Total current liabilities	1,571,135	2,615,993
Warrant liability	946,105	4,455,747

Other long-term liabilities	46,765	84,125
Promissory note – related party	911,463	-
Total liabilities	3,475,468	7,155,865
Stockholders' deficiency		
Common shares, no par value, unlimited shares authorized, 150,505,536 and 118,208,989 shares issued and outstanding as of June 30, 2024, and December 31, 2023	49,009,464	39,760,287
Class B preferred shares, $0.25 par value, unlimited shares authorized, 7,916,380 shares issued and outstanding as of June 30, 2024, and December 31, 2023	62	62
Additional paid-in capital	18,467,705	17,288,430
Accumulated other comprehensive loss	(104,301)	(104,301)
Accumulated deficit	(68,766,396)	(61,648,173)
Total stockholders' deficiency	(1,393,466)	(4,703,695)
Total liabilities and stockholders' deficiency	$ 2,082,002	$ 2,452,170

The accompanying notes to the consolidated financial statements are an integral part of these statements.

ALPHA COGNITION INC.

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(UNAUDITED)

	For the Three Months Ended June 30,		For the Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses				
Research and development	$ 967,200	$ 1,246,226	$ 1,883,916	$ 2,344,164
General and administrative expenses	1,454,011	1,481,832	4,948,813	2,370,241

Total operating expenses	2,421,211	2,728,058	6,832,729	4,714,405				
Net operating loss	(2,421,211)	(2,728,058)	(6,832,729)	(4,714,405)				
Other income (expenses)								
Foreign exchange (loss) gain	(6,862)	(18,302)	(21,491)	9,717				
Interest income	2,160	2,175	14,230	2,347				
Grant income	138,561	-	272,340	-				
Interest expense	(15,216)	(1,533)	(23,474)	(4,408)				
Impairment of intangible assets	-	-	(39,166)	-				
Change in fair value of warrant liability	187,056	(16,658)	(71,856)	(432,933)				
Provision for loan losses	-	-	(55,000)	-				
Total other income (expenses)	305,699	(9,002)	(89,516)	(285,494)				
Net loss	(2,115,512)	(2,817,574)	(7,118,223)	(4,723,407)				

| | | |

CONDENSED INTERIM CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIENCY)

(UNAUDITED)

For the Three and Six Months Ended June 30, 2024 and 2023

For the three months ended June 30, 2024

	Common Shares		Class A Restricted Shares		Additional Paid-In	Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total

Balance, March 31, 2024			149,925,536			$	48,758,033
	-		$ -				7,916,380
	$ 62		$ 18,182,009				$
(104,301	)	$	(66,650,884	)		$	184,919
Options exercised			180,000				91,431
-			-		-		
-			(89,631	)			-
-			1,800				
Warrants exercised			400,000				160,000
	-		-				-
-			-		-		
-			160,000				
Share-based compensation			-				-
-			-		-		
-			375,327				-
-			375,327				
Net loss	-		-				-
	-			-			-
	-			-			(2,115,512)
	(2,115,512)						
Balance, June 30, 2024			150,505,536			$	49,009,464
	-		$ -				7,916,380
	$ 62		$ 18,467,705				$
(104,301	)	$	(68,766,396	)		$	(1,393,466
)							

For the three months ended June 30, 2023

	Common Shares		Class A Restricted Shares		Additional Paid-In	Other Comprehensive	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Loss	Deficit	Total
Balance, March 31, 2023	86,900,664	$ 32,180,506	7,000,000	$ 3,103,620	7,916,380	$ 62	$ 15,901,310	$ (120,967)	$ (49,790,348)	$ 1,274,183
Options exercised	1,050,000	687,132	-	-	-	-	(676,632)	-	10,500
Share-based compensation	-	-	-	-	-	963,293	-	963,293
Foreign exchange on translation	-	-	-	-	-	27,898	-	27,898
Net loss	-	-	-	-	-	-	-	-

4R

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Chimerix, Inc.

Physical Address: 2505 Meridian Pkwy, Ste 100

City: Durham State: NC Zip: 27713

Mailing Address (if different from physical address): 2505 Meridian Parkway, Suite 100

City: Durham State: NC Zip: 27713

Telephone: (919) 806-1074 Website: https://www.chimerix.com/

Name of Designated Representative (DR): Roy Ware, Jr.

Licensing Company Email: statelicensing@chimerix.com DR Email: rware@chimerix.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty distributor, specialty pharmacy		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): _____

Corporation Name: Chimerix, Inc.

Mailing Address: 2505 Meridian Parkway, Suite 100

City: Durham State: NC Zip: 27713

Telephone: (919) 806-1074 Email: statelicensing@chimerix.com

Contact Person Name: Roy Wendell Ware Jr.

Date of SEC Registration: 08/05/2002	SEC Registration Number: 0001117480	Stock Exchange Symbol: CMRX

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

3/13/2025
Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Chimerix, Inc.
Facility Name

Roy Ware, Jr.
Print Name of Authorized Person Submitting Application

Roy Ware, Jr.
Original signature of Authorized Person (copies or stamps not accepted)

3/13/2025
Date

Board Use Only	Date Received: 3/13/25	Amount: $1000-ck 3474

CHIMERIX

Description of Operations

Chimerix, Inc. is a Virtual Manufacturer. Chimerix, Inc.'s products are manufactured by a Contract Manufacturer and will be distributed by their Third-Party Logistics Provider, who is licensed to ship pharmaceutical products into your state.

Labeler Code:
79622

Chimerix, Inc. has 89 employees working on site during normal business hours.
Chimerix, Inc.'s hours of operation are 8:00 am – 5:00pm Monday through Friday.
Chimerix, Inc.'s facility square footage is 21325 square feet .

Contract Manufacturer Information:
Frontida BioPharm, LLC manufactures and packages Chimerix, Inc's finished product. At no time does Frontida BioPharm, LLC own the product, contract with Chimerix, Inc.'s customers, invoice, or sell Chimerix, Inc's. product. Chimerix, Inc's products are not Controlled Substances.

Frontida BioPharm, LLC.
1100 Orthodox Street
Philadelphia, PA 19124
FDA Establishment Number: 2523348

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Solutions, LLC acts as Chimerix, Inc.'s Third Party Logistics (3PL) provider to manage the storage and distribution of Chimerix, Inc.'s product-throughout the United States. Chimerix, Inc.'s records are stored with the 3PL at their location.

Integrated Commercialization Solutions, LLC's address is:

Integrated Commercialization Solutions, LLC
420 International Blvd, Suite 500, Brooks, KY 40109
Contact: Josh Sutherland at 502-955-3626



Company Information

Chimerix, Inc.
2505 Meridian Pkwy, Ste 100
Durham, NC 27713
919-806-1074
Website: https://www.chimerix.com/
E-mail: statelicensing@chimerix.com

FEIN: 33-0903395
State of Formation: Delaware
Date Incorporated: 4/7/2000
File Number: 3195203

Ownership Information

Chimerix, Inc. is a Publicly Traded company on the NASDAQ stock exchange under the symbol CMRX.

Officers

Thomas John Riga, Chief Operating and Commercial Officer
Business Address: 2505 Meridian Parkway, Suite 100, Durham, NC 27713
Business Phone: (561) 521-1476

Michelle Lynn LaSpaluto, Chief Financial Officer
Business Address: 2505 Meridian Parkway, Suite 100, Durham, NC 27713
Business Phone: (919) 972-7115

Roy Wendell Ware, Jr, Ph.D., M.B.A, Chief Manufacturing and Technology Officer
Business Address: 2505 Meridian Parkway, Suite 100, Durham, NC 27713
Business Phone: (919) 618-3395

Delaware

The First State

I, CHARUNI P. SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CHIMERIX, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SIXTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CHIMERIX, INC." WAS INCORPORATED ON THE SEVENTH DAY OF APRIL, A.D. 2000.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni P. Sanchez, Secretary of State

3195203 8300

SR# 20250418796

Authentication: 202875242

Date: 02-06-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Steve Troxler
Commissioner

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita McMullen
Division Director

North Carolina Department of Agriculture & Consumer Services

Food and Drug - Perscription Drug

License Details for CHIMERIX, INC.

Licensee Details

Firm Name: CHIMERIX, INC.	**License Type:** Virtual Manufacturer
Address: 2505 MERIDIAN PKWY STE 100, DURHAM, NC 27713	**License Number:** 1929
License Status: Active – Conditional	**Discipline:** No
Current Issue Date: 1/1/0001	**License Expiration:** 12/31/2025
Original Issue Date: 2/24/2025	

Search URL: https://apps.ncagr.gov/AgRSysPortalV2/licensesearch/fdpd/447034

NCDA&CS
1090 Mail Service Center, Raleigh, NC 27699-1090
Main 919-733-3556 : Fax: 919-733-9796

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Chimerix, Inc.

Pharmacy/Wholesaler License # (if applicable) New application

Physical Address 2505 Meridian Pkwy, Ste 100

City Durham State NC Zip 27713

Mailing Address (if different from physical address) 2505 Meridian Parkway, Suite 100

City Durham State NC Zip 27713

Telephone (919) 806-1074 Website https://www.chimerix.com/

Licensing Company Email statelicensing@chimerix.com

Section 2: Personal Information

First Roy Middle Wendell Last Ware, Jr.

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 2505 Meridian Parkway Suite 100

City Durham State NC Zip 27713

Telephone (919) 806-1074 Email rware@chimerix.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The University of North Carolina		08/04 - 10/06	
Address	**City**	**State**	**Zip**
145 E Cameron Ave	Chapel Hill	NC	27514
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Wake Forest University		08/96 - 12/00	
Address	**City**	**State**	**Zip**
1834 Wake Forest Rd	Winston-Salem	NC	27109
Diploma/Degree obtained, if any			
Ph. D. Organic Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/06 - Present	[redacted]	Raleigh	NC	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Chimerix, Inc.			12/07 - Present
Business Address	**City**	**State**	**Zip**
2505 Meridian Parkway, Ste 100	Durham	NC	27713
Phone	**Title**	**Number of Employed Hours**	
(919) 806-1074	CMO, CTO	40 hrs per week	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/13/2025
Date

I, Roy Ware, Jr., **certify that as the designated representative for**

Chimerix, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RW I am at least 21 years of age;
3. RW I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RW I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RW I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RW I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RW I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Roy Ware, Jr.

Print Name (First, Last)

Roy Ware, Jr.

Original Signature (electronic, copies or stamps not accepted)

3/13/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roy Ware, Jr.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/13/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Durham

I, ROY WARE JR, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/13/2025

Date

Subscribed and Sworn to before me this 13th day of March, 2025.

Notary Public Signature

OLIVIA CLEARY
Notary Public, North Carolina
Durham County
My Commission Expires
May 12, 2027

(Seal)

Roy W. Ware, Ph.D., M.B.A.

[redacted]

CHIEF MANUFACTURING AND TECHNOLOGY OFFICER

Creative and results-oriented leader focused on delivering maximum results in dynamic environments that demand continuous improvement, innovation, and strategic thinking. Successful in driving assets from discovery stage to clinical candidate selection and developing supply chains to support phase 1-3 clinical studies and commercial production. Respected for building, motivating, inspiring and empowering multi-functional teams that consistently exceed corporate expectations while demonstrating core corporate values of accountability, innovation, integrity, respect, and transparency.

Areas of Expertise

- Executive Leadership
- Strategic Planning and Execution
- Intellectual Property Creation & Extension
- Medicinal & Process Chemistry
- Non-GMP and cGMP Manufacturing
- Pre-IND/IND, IMPD, NDA, MAA, NDS Preparation
- Technology Evaluation/Due Diligence
- Process Development and Optimization
- International CRO/CDMO Selection/Management
- Global Supply Chain Management
- Budgeting/Forecasting

Therapeutic Areas/Technologies

- Infectious Diseases
- Respiratory Diseases
- Oncology
- Central Nervous System
- Rheumatoid Arthritis
- Drug Addiction Therapy
- Drug Delivery Technologies
- Platform Technologies
- Scale-up Technologies

PROFESSIONAL EXPERIENCE

Chimerix, Inc., Durham, NC
December 2007 – Present
2505 Meridian Parkway, Durham, NC 27713
(919) 806-1074

Chief Manufacturing and Technology Officer

- Lead and develop strategic vision for Chemistry, Manufacturing, and Global Supply Chain operations for Dordaviprone® (ONC201), ONC206, and CMX521.
- Led Tembexa® (brincidofovir, BCV) CMC technical team activities for NDA submission which was granted approval for smallpox by the FDA in June 2022; ~$35M USD in sales internationally in 2022 prior to out-licensing.
- CMC strategic discussion leader with the World Health Organization (WHO), European Medicines Agency (EMA), Health Emergency preparedness and Response Authority (HERA), Health Canada, and multiple other international regulatory agencies before and during monkeypox global health emergency in 2022.
- Member of the Chimerix Executive Team, Policy and Strategy Team (PSC), Sr. Staff, and Patent Committee
- Present chemistry, manufacturing, and supply chain strategies to C-level executives, Board of Directors, investors, analysts, and key stakeholders
- Develop functional and operational strategies to transition drug candidates from discovery into clinical development and regulated manufacturing environments.
- Responsible for building and maintaining a highly talented, high-performing, flexible Chemistry, Manufacturing and Supply Chain (CMSC) Team
- Manage CMC due diligence activities for evaluating in-/out-licensing opportunities.

Vice President, Chemistry

- Directly supervised the daily operations of drug product development activities, including solid oral dose, suspension, and intravenous formulations.
- Head of drug substance and drug product manufacturing for Tembexa®

- Directed medicinal chemistry activities from hit to lead and lead optimization for preclinical assets.
- Managed and directed all internal and outsourced chemistry and manufacturing activities.
- Managed analytical chemistry activities related to drug substance and drug product method validations, release, and stability testing.
- Directed supply chain activities and sourced bulk raw materials to support manufacturing activities for BCV, CMX203 (late-stage BCV intermediate), and CMX521 (norovirus candidate)
- Developed CMC development plans and budget and ensure projects are completed on time and within budget.
- Compiled and communicated project risks and status to the management team.
- Directed R&D efforts and liaised with outside patent counsel to significantly extend the composition of matter patents for BCV to 2034 and CMX157 (out-licensed to Contravir) to 2033.
- Chimerix Patent Committee Member and active participant in determining corporate patent strategy; review and approve patent related office actions.
- Ensured patent strategy aligned with corporate goals and initiatives.
- Authored, reviewed, and approved drug substance, drug product, and analytical methods sections for regulatory submissions, INDs, NDA, IMPDs, Canadian CTA, NDS etc.
- Oversight of packaging, labeling, and worldwide distribution of CTM for clinical studies and compassionate use requests
- Chemistry/manufacturing representative for evaluating in/out-licensing opportunities.

Senior Director, Chemistry
Director, Chemistry

- Head of drug substance manufacturing for BCV
- Drug Substance Manufacturing Control Account Manager (CAM) for Biomedical Advanced Research and Development Authority (BARDA) for Chimerix's BCV Smallpox Program
- Developed a process to identify and select HPAPI manufacturers suitable to manufacture BCV.
- Lead the technical transfer and validation campaigns of BCV at two different manufacturing sites.
- Interacted with contract manufacturers and third-party logistics providers to develop strategies and tactical plans to meet supply chain performance measures.
- Advised management and BARDA of the current and future status of product supply.
- Managed the Chimerix intellectual property docket, liaison with in-house and outside patent counsel on all patent related issues.
- Participated on acquisition/new product introduction team to ensure product availability and subcontractor systems are aligned in support of timelines.
- Identified and sourced bulk raw materials to support manufacturing campaign.
- Conducted technical audits of potential CROs and CMOs in the US, Europe, and Asia
- Established secondary sources for all key raw materials used in commercial manufacturing.
- Coordinated the outsourcing and preparation of bioanalytical/analytical reference standards and markers, including radiolabeled and stable-labeled materials.
- Managed and directed the daily operations of the Chimerix Chemistry Laboratory which included the supervision of both in-house and contract scientists (BS, MS, and PhD levels), purchasing capital equipment, developing, and maintaining annual budget, managing process development and medicinal chemistry projects.

Group Leader, Chemistry
Senior Research Scientist

- Managed and actively lead the chemistry in the non-GMP and cGMP chemical development of BCV from laboratory scale to manufacturing scale.
- Managed and actively lead the non-GMP and cGMP chemical development of CMX157 from laboratory scale to multi-kilogram scale to provide material for toxicology studies and clinical trials.
- Managed and actively lead the chemical development of CMX203 from laboratory scale to manufacturing scale.
- Lead the domestic and international outsourcing of process development and medicinal chemistry projects involving multiple teams of chemists.

- Prepared market analysis reports, including S.W.O.T. diagrams, niche market space projections, and competitive and patent landscape analyses of targeted therapeutic areas.
- Prepared chemical manufacturing sections of Investigational New Drug Applications (INDs).
- Evaluated internal and competitor intellectual property positions to guide patent strategy.
- Drafted patent applications and liaison with patent attorneys on strategy and filings.
- Key initiator and driver of the development of Chimerix's Chemical/Biology Database.
- Conduct on-site audits of CROs and CMOs non-GMP and cGMP research facilities.
- Co-inventor on multiple patent applications covering Chimerix's technology, chemical processes, and new compound entities.

Pharmacore, Inc., High Point, NC
Acquired by Cambrex in October 2016
4170 Mendenhall Oaks Parkway, High Point, NC 27265
(336) 841-5250

Research Scientist, April 2007 – December 2007

- Managed the process development and scale-up of multiple Advanced Pharmaceutical Ingredients (API's), clinical trial candidates, reference standards, and final drug products under both cGMP and non-GMP conditions for assets across multiple therapeutic areas.
- Synthesized a wide range of proprietary therapeutic scaffolds/medicinal chemistry analogs for research and commercial purposes.
- Consistently beat project timeline goals and allotted budgets.
- Prepared technical reports, Certificates of Analyses, and project presentations.
- Conveyed results/challenges to international clients on a daily/weekly basis.

Scynexis, Inc., Durham, NC
Acquired by Avista Pharma Solutions in Jul 2015
Avista Pharma Solutions acquired by Cambrex in January 2019
3501 Tricenter Blvd., Suite C, Durham, NC 27713
(919) 544-8600

Process Development Chemist (*Contractor*), March 2006 – April 2007

- Performed process development and scale-up of Advanced Pharmaceutical Ingredients (API's) and clinical trial candidates for commercial clients across multiple therapeutic areas.
- Increased overall process yield by 117% for an oncology clinical candidate which allowed for phase 3 development.
- Synthesized and characterized medicinal chemistry libraries for industrial clients.
- Conveyed results/challenges to clients on a daily/weekly basis.
- Compiled client-specific reports including weekly updates, Final Reports, Certificate of Analyses, Material Safety Data Sheets, and all other accompanying analytical data.
- Presented research results at weekly Process Development Group meetings.

Serenex, Inc., Durham, NC
Acquired by Pfizer in March 2008

Research Scientist/Research Chemist, May 2002 – March 2005

- Evaluated internal and competitor intellectual property positions on given assets.
- Conducted literature and market research on competitors' products and drug pipelines.
- Involved in evaluating and determining strategy surrounding drug discovery projects.
- Designed synthetic routes which were applied to the scale up of nucleoside mono-, di-, and triphosphate derivatives to support the innovation and advancement of proprietary platform technology.
- Medicinal Chemistry leader on oncology, malaria, and rheumatoid arthritis (RA) projects.
- Designed and synthesized multiple highly potent kinase inhibitors (1, 8-naphthyridine derivatives) to support multiple oncology and RA discovery projects.
- Designed and synthesized lead compound for malaria project targeted at quinone reductase II.

- Supervised scientific staff of MS and PhD scientists.

Research Triangle Institute, RTP, NC
3040 Cornwallis Rd., Durham, NC 27709
(919) 541-6000
Postdoctoral Chemist (Dr. F. Ivy Carroll), January 2001 – May 2002

- Designed and executed a more expedient synthetic route to proposed epibatidine analogs (pain relief). This improvement led to a safer and accelerated method of preparation for novel fluorinated epibatidine derivatives.
- Proposed and synthesized tropane (cocaine) derivatives designed to interact with dopamine, serotonin, and norepinephrine transporters.
- Designed and synthesized most potent cocaine analog to date (>200,000 times more active).

DISSERTATION EXPERIENCE

Wake Forest University, Winston-Salem, NC
Department of Chemistry, Salem Hall
30 Gulley Dr., Winston-Salem, NC 27109
(336) 758-6139
Doctoral Candidate Research Assistant, August 1996 – December 2000

- Designed and synthesized organophosphorus heterocycles and phosphorus-containing amino acids which acted as inhibitor of nitric oxide synthase and demonstrated anti-cancer activity.
- Designed and prepared new sulfonyl-, xanthyl-, and phosphoryl-based amino acids as nitric oxide synthase inhibitors.
- Selected as the graduate student representative on the Chemistry Department Review Board.
- Mentored undergraduate research assistants and tutored organic chemistry students.

EDUCATION

The University of North Carolina, Chapel Hill, NC
Kenan-Flagler Business School
Master of Business Administration

Wake Forest University, Winston-Salem, NC
Ph. D. Organic Chemistry

- American Institute of Chemists Award

The University of North Carolina at Greensboro, Greensboro, NC
Bachelor of Arts in Chemistry, magna cum laude

- Phi Beta Kappa
- University Student Excellence Award, University Marshall
- Several Chemistry Departmental Awards for Outstanding Chemistry Student

PUBLICATIONS

- F. Ivy Carroll, **Roy Ware**, Lawrence E. Brieaddy, Hernan A. Navarro, M. I. Damaj, and Billy Martin; "Synthesis, Nicotinic Acetylcholine Receptor Binding, and Antinoceptive Properties of 2'-Fluoro-3'-(substituted-phenyl) deschloroepibatidine analogs. Novel Nicotinic Antagonist." *J. Med. Chem.*, **2004**; *47*, 4588-4594.
- **Ware, R. W., Jr.**; Day, C. S.; King, S. B. "Diastereoselective and Intramolecular Cycloadditions of Asymmetric P-Nitroso Phosphine Oxides," *J. Org. Chem.* **2002**, *67*, 6174-6180.

- **Ware, Jr., R. W.**; King, S. B. "*P*-Nitroso Phosphate Compounds: New N-O Heterodienophiles and Nitroxyl Delivery Agents," *J. Org. Chem.* **2000**, *65*, 8725-8729.
- **Ware, Jr., R. W.**; King, S. B. "Evaluation of New L-Thiocitrulline Derivatives as Inhibitors of Nitric Oxide Synthase," *Bioorg. Med. Chem. Lett.* **2000**, *10*, 2779-2781.
- Jenkins, N. E.; **Ware, Jr., R. W.**; Atkinson, R. N.; King, S. B. "Generation of Acyl Nitroso Compounds by the Oxidation of Hydroxamic Acids, *N*-Hydroxyureas and *N*-Hydroxycarbamates with Dess-Martin Periodinane," *Synthetic Communications.* **2000**, 30, *5*, 947-953.
- **Ware, Jr., R. W.**; King, S. B. "*N*-Phosphinoylnitroso Compounds: New Asymmetric N-O Heterodienophiles and Nitroxyl Delivery Agents," *J. Am. Chem. Soc.* **1999**, *121*, 6769-6970.

SELECT PATENTS and PATENT APPLICATIONS

- **Ware, Roy;** Downey, Aaron Leigh; "Morphic Forms of Hexadecyloxypropyl-Phosphonate Esters and Methods of Synthesis Thereof," *US 8,962,829*.
- **Ware, Roy;** Downey, Aaron Leigh; "Morphic Forms of Hexadecyloxypropyl-Phosphonate Esters and Methods of Synthesis Thereof," *US 10,112,909*.
- **Ware, Roy;** Downey, Aaron Leigh; "Morphic Forms of Hexadecyloxypropyl-Phosphonate Esters and Methods of Synthesis Thereof," *US 10,487,061*.
- **Ware, Roy;** Changalvala, Ramamurty V.S.; Bougher, John Henry; McIver, Andrew Louis; Robertson, Bradley David; "Pyrrolopyrimidine Nucleosides and Analogs Thereof," *US 9,708,359.*
- **Ware, Roy;** Changalvala, Ramamurty V.S.; Bougher, John Henry; McIver, Andrew Louis; Robertson, Bradley David; "Pyrrolopyrimidine Nucleosides and Analogs Thereof," *US 9,701,706.*
- **Ware, Roy;** Almond, Merrick; Lampert, Bernhard; Lanier, Ernest Randall; "Nucleoside Phosphonate Salts," *US 9,006,218*.
- **Ware, Roy;** Almond, Merrick; Lampert, Bernhard; "Phosphonate Ester Derivatives and Methods of Synthesis Thereof," *US 8,569,321*.
- Klaas P. Hardeman, Steven E. Hall, **Roy W. Ware**, Lindsay A. Hinkley and Mathew Jenks; "Alkyl-Linked Nucleotide Compositions," *US 7,371,852*.
- Hanson; Gunnar J.; **Ware, Roy W. Jr.**; Barta, Thomas E.; Huang, He; "2,8-Disubstituted naphthyridine derivatives," *US 7,282,506.*
- **Ware, Roy; et al.**; "Branched Chain Acyclic Nucleoside Phosphonate Esters and Methods of Synthesis and Uses Thereof," *PCT/US14/68932.*
- **Ware, Roy;** Changalvala, Ramamurty V.S.; Bougher, John Henry; McIver, Andrew Louis; Robertson, Bradley David; "Phospholipid Conjugates of Antiviral Compounds," *US PTO Appln. No 62/174,402.*
- **Ware, Roy;** Changalvala, Ramamurty V.S.; Bougher, John Henry; McIver, Andrew Louis; Robertson, Bradley David; "Phospholipid Conjugates of Deoxyribose-Fluoropyrimidinone and Analogs Thereof," *US PTO Appln. No 62/174,404.*
- **Ware, Roy**; Almond, Merrick; "Methods of Synthesis of Adenine-Based Phosphonate Ester Derivatives," *US PTO Patent Appln. No 61/389,821*.
- **Ware, Roy**; Almond, Merrick; "Methods of Synthesis of Phosphonate Ester Derivatives," *US PTO Patent Appln. No 61/378,743*.
- **Ware, Roy**; Almond, Merrick; "Compounds, Compositions, and Methods for Treating Viral Infections," *US PTO Patent Appln. No 61/366,431.*
- **Ware, Roy**; Almond, Merrick; "Compounds, Compositions, and Methods for Treating Viral Infections," *US PTO Patent Appln. No 61/366,435.*
- **Ware, Roy**; Almond, Merrick; "Lipid Prodrugs for Oral Administration," *US PTO Patent Appln. No 61/360,742.*
- **Ware, Roy**; Almond, Merrick; "Compounds, Compositions, and Methods for Treating Viral Infections," *US PTO Patent Appln. No 61/361,088.*
- **Ware, Roy**; Almond, Merrick; "Aromatic and Heterocyclic Compounds as Therapeutics for Respiratory Syncytial Virus Infection," *US PTO Patent Appln. No 61/349,372.*

- **Ware, Roy W. Jr.**; Hinkley, Lindsay A.; Hardeman, Klaas P.; Jenks, Matthew G.; "Substituted quinoline and quinazoline inhibitors of quinone reductase 2," *US PTO Patent Appln. No. 2006-0074105*.
- Hanson; Gunnar J.; Barta, Thomas E.; Veal, James Marvin; **Ware, Roy Wendell Jr.**; "Methotrexate derivatives useful for treating cancer and arthritis," *US PTO Patent Appln. No. 2006-0035901*.

SELECTED PRESENTATIONS

- Invited Panelist "An Artisan Approach: One Stop Shop vs. Specialty Companies," Informex; Anaheim, CA, February 2013.
- **Ware, Jr., R. W.**; King, S. B. "Examining the Stereoselectivity of *N*-Phosphinoylnitroso Compound Cycloadducts," *Abstracts of Papers*, 220th National Meeting of the American Chemical Society, Washington, D. C.; American Chemical Society: Washington, D. C., 2000, ORGN 558.
- **Ware, Jr., R. W.**; King, S. B. "*N*-Phosphinoylnitroso Compounds as New N-O Heterodienophiles and Nitroxyl Releasing Agents," National Institutes of Health-National Cancer Institute, Frederick, MD, July 2000.
- **Ware, Jr., R. W.**; King, S. B. "Synthesis and Evaluation of New Phosphorus Containing L-Arginine Derivatives as Inhibitors of Nitric Oxide Synthase," *Abstracts of Papers*, 51st Southeast Regional Meeting of the American Chemical Society, Knoxville, TN; American Chemical Society: Washington, D. C., 1999, ORGN 347.

OTHER ACTIVITIES

- Chairman, Steering Committee, Wake Forest University Friends of Chemistry, Term Fall 2014-Fall 2015
- Steering Committee Member, Wake Forest University Friends of Chemistry, Term Fall 2012-Fall 2015
- Patent Resources Group Patent Bar Review Course, San Francisco, CA; November 2012

Employee Last Name	Employee First Name
Azerbal	Linda
Simpson	Charles
Croissant	Lisa
Halterman	Patti
Chaudhry	Basharat (Bash)
Katz	Heather
Summers	Michelle
Barletta	Matthew (Matt)
Kabir	Bikram
Krause	Kimberly (Kim)
Franzinger	Sebastian
Khaja	Raheemuddin (Raheem)
Turowski	Eric
Anderson	David
Bernatz	Mark
Grabow	Michael (Mike)
Axelrod	Mark
Wojtynek	Nicholas (Nick)
Mayo	Carlos
Sebo	Stephanie
Armstead	Andrea
McGrath	Danielle
Wells	Sandra (Sandy)
Lee	Sang (Pablo)
Riga	Thomas (Tom)
Ferslew	Jayme
Buffington	Ann
Jordan	Christopher (CJ)
Wilburn	Vanessa
Rodebaugh	Tabatha
Evans	Tanya
Sullivan	Meghan
Mattocks	Danna
Yeh	Ting-Chun (Ting)
Maranto	Cristina
Schneider	Patricia (Patty)
Ingram	Adrienne
Buskirk	Vickey
Zitt	Melanie
Howe	Kirby
Moraris	Rebecca
Dunn	Deidra
Felkins	Amy
Teffera	Yohannes
Williamson	Jacqueline (Jackie)
Camaione	Victoria
Godfrey	Sarah
Rogers	Andrew
Bartkus	Angela (Angie)
Cutchin	Kana
Lee	Andrew
Morrow	Sara

Prabhu	Varun Vijay (Varun)
Sabatina	Carolyn
Tarapore	Rohinton
Dampf	John
Ramage	Samuel (Sam)
Allen	Joshua (Josh)
Masoud	Zahra
Sturdivant	Norlonn
Melemed	Allen
Stone	Patricia (Pati)
MacLeod	Elizabeth
Cleary	Olivia
Barnett	Caryn
Andriole	Michael (Mike)
Michael	Joshua (Josh)
Jasper	Stacy
Joshi	Biren
Democko	Gregory (Greg)
Mullin	Mark
Sumner	Erica
Everhart	M. Ken (Ken)
Kabir	Mohammed (Kabir)
Baranchak	Staci
Kramer	Nancy
Colton	Heidi
Stone	Lisa
Lakshmanan	Venkatraman (Venkat)
Naderer	Odin
Ervin	Jennifer
Morrison	Marion
Alrutz	Michael
Brundage	Thomas (Tom)
LaSpaluto	Michelle
Crowson	Elaine
Tippin	Timothy (Tim)
Jakeman	David (Dave)
Downey	Aaron
Foster	Scott
Ware	Roy

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, DC 20549

Form 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2024
or

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from to
Commission file number: 001-35867

Chimerix, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware **(State or Other Jurisdiction of Incorporation or Organization)**	**33-0903395** **(I.R.S. Employer Identification No.)**
2505 Meridian Parkway, Suite 100 **Durham, North Carolina** **(Address of Principal Executive Offices)**	**27713** **(Zip Code)**

(919) 806-1074
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	CMRX	The Nasdaq Global Market

Securities registered pursuant to Section 12(g) of the Act: None

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Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant: (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, smaller reporting company, or an emerging growth company. See definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.:

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Securities Exchange Act of 1934). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the registrant based upon the closing price of its Common Stock on The Nasdaq Global Market on June 28, 2024 was $74,314,290.

The number of outstanding shares of the registrant's common stock, par value $0.001 per share, as of March 14, 2025 was 93,803,846.

DOCUMENTS INCORPORATED BY REFERENCE

Document Description	10-K Part
Portions of the registrant's notice of annual meeting of stockholders and proxy statement to be filed pursuant to Regulation 14A within 120 days after registrant's fiscal year end of December 31, 2024 are incorporated by reference into Part III of this annual report. If such proxy statement is not filed within 120 days after the fiscal year end of December 31, 2024, such information will be included in an amendment to this annual report to be filed within such 120-day period.	III

CHIMERIX, INC.
FORM 10-K
For the Fiscal Year Ended December 31, 2024
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Forward-Looking Statements

This Annual Report on Form 10-K (Annual Report) may contain "forward-looking statements" within the meaning of the federal securities laws made pursuant to the safe harbor provisions of the Private Securities Litigation Reform Act of 1995. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those set forth below under Part I, Item 1A, "Risk Factors" in this Annual Report. Except as required by law, we assume no obligation to update these forward-looking statements, whether as a result of new information, future events or otherwise. These statements, which represent our current expectations or beliefs concerning various future events that are subject to risks and uncertainties, may contain words such as "may," "will," "would," "could," "expect," "anticipate," "intend," "plan," "believe," "estimate," "project" or other words indicating future results. Such statements may include, but are not limited to, statements concerning the following:

- the initiation, cost, enrollment, timing, progress and results of our research and development activities, preclinical studies and future clinical trials;
- our ability to obtain and maintain regulatory approval of our current and future product candidates, such as dordaviprone, and any related restrictions, requirements, including the need to develop a companion diagnostic, limitations, and/or warnings in the label of an approved product candidate;
- our ability to obtain funding for our operations;
- our ability to leverage external capital to develop our early-stage pipeline of product candidates;
- the election of the U.S. government to exercise future procurement options for TEMBEXA®;
- the potential for royalty and milestone revenue from our strategic collaborations;
- our plans to research, develop and commercialize our future product candidates;
- our strategic alliance partners' election to pursue development and commercialization;
- our ability to attract collaborators with development, regulatory and commercialization expertise;
- our ability to obtain and maintain intellectual property protection for our future product candidates;
- the size and growth potential of the markets for our current and future product candidates, and our ability to serve those markets;
- our ability to successfully commercialize our current and future product candidates, such as dordaviprone if approved;
- the rate and degree of market acceptance of our current and future product candidates, including dordaviprone's potential to rapidly become a standard of care and a meaningful therapy for patients with limited treatment options;
- our ability to develop sales and marketing capabilities, whether alone or with potential future collaborators;
- regulatory developments in the United States and foreign countries;
- the performance of our third-party suppliers and manufacturers;
- the success of competing therapies that are or become available;
- the loss of key scientific or management personnel;
- our use of the proceeds from our public offerings;
- our ability to enter into transactions to build our product candidate pipeline;
- the accuracy of our estimates regarding expenses, future revenues, capital requirements and need for additional financing; and
- the anticipated occurrence, manner and timing of Jazz Pharmaceuticals Public Limited Company (Jazz)'s proposed acquisition of us and its effects on our relationships with employees, customers, suppliers, other business partners or governmental entities.

Summary of Risk Factors

Below is a summary of material factors that make an investment in our common stock speculative or risky. Importantly, this summary does not address all of the risks and uncertainties that we face. Additional discussion of the risks and uncertainties summarized in this risk factor summary, as well as other risks and uncertainties that we face, can be found under "Risk Factors" in Part I, Item 1A of this Annual Report. The below summary is qualified in its entirety by that more complete discussion of such risks and uncertainties. You should consider carefully the risks and uncertainties described under "Risk Factors" in Part I, Item 1A of this Annual Report as part of your evaluation of an investment in our common stock.

- The pending merger with Jazz is subject to a number of conditions beyond our control. We may not complete the merger within the time frame we anticipate or at all, which could have an adverse effect on our business, financial results, and/or operations.

- The pendency of the merger with Jazz could adversely affect our business, financial results and/or results of operations and may impair our ability to attract and retain qualified employees or retain or maintain relationships with our customers, suppliers, other business partners or governmental entities.
- While the Merger Agreement with Jazz is in effect, we are subject to restrictions on our business activities.
- We anticipate that we will continue to incur significant losses for the foreseeable future, and we may never achieve or maintain profitability.
- All of our product candidates are still under clinical development and may not obtain regulatory approval or be successfully commercialized.
- We may be unable to obtain, or may be delayed in obtaining, regulatory approval for our clinical candidates, including our most advanced clinical candidate, dordaviprone.
- Our ability to generate future revenues from product sales is uncertain and depends upon our ability to successfully develop, obtain regulatory approval for, and commercialize product candidates, and even if we generate future revenues, they may not be sufficient to lead to profitability.
- Following regulatory approval for any of our product candidates, including dordaviprone, we will still face extensive regulatory requirements and our products may face future development and regulatory difficulties.
- We rely on third-party manufacturers to produce our preclinical drug supplies and clinical drug supplies, and intend to rely on third parties to produce commercial supplies of any approved product candidates.
- We routinely evaluate external assets to build our pipeline of product candidates and there can be no assurance that we will be successful in identifying or completing a transaction for a candidate, that any such transaction will result in additional value for our stockholders or that the process will not have an adverse impact on our business.
- The anticipated benefits of the sale of our TEMBEXA assets to Emergent Biodefense Operations Lansing LLC, (Emergent) may not be realized fully or at all or may take longer to realize than expected.
- Our ability to receive future contingent consideration from the sale of TEMBEXA depends on, among other things, Emergent's ability to successfully develop and commercialize TEMBEXA.
- If we are unable to obtain or protect intellectual property rights related to our products and product candidates, we may not be able to compete effectively in our market.
- Increasing demand for compassionate use or third-party supply of our unapproved therapies could impair or delay the completion of our controlled clinical trials or otherwise result in losses.
- If we fail to comply with the extensive legal and regulatory requirements affecting the health care industry, we could face increased costs, delays in the development of our product candidates, penalties and a loss of business.
- Our common stock may be delisted from The Nasdaq Global Market which could negatively impact the price of our common stock, liquidity and our ability to access the capital markets.

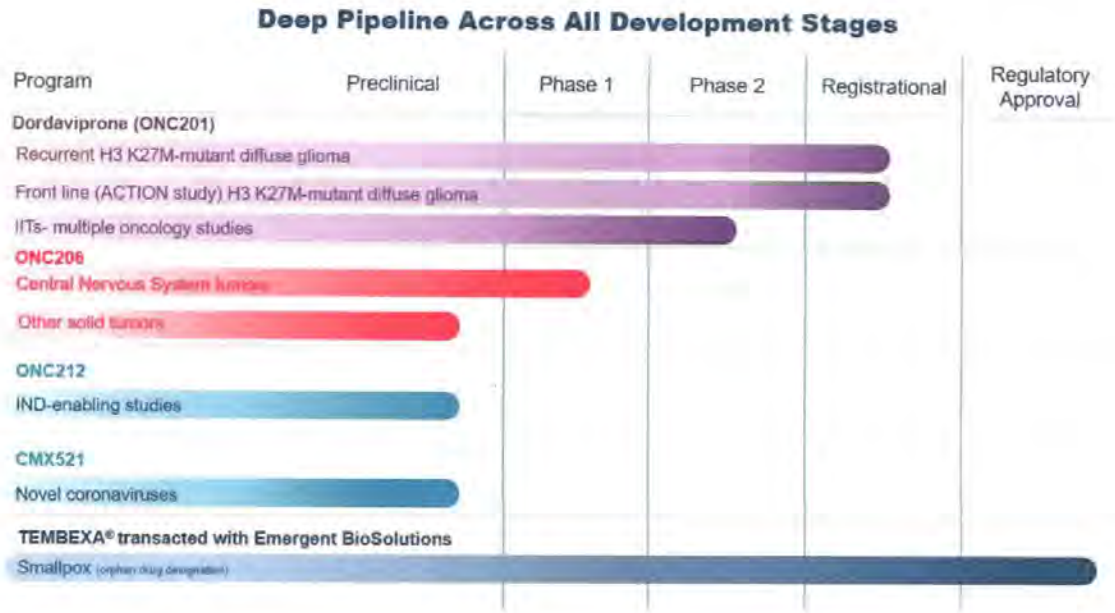
Market, Industry and Other Data

This Annual Report contains estimates, projections and other information concerning our industry, our business and relevant markets, including data regarding the estimated size of relevant markets, patient populations, projected diagnosis rates and the perceptions and preferences of patients and physicians regarding certain therapies, as well as data regarding market research and estimates. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances that are assumed in this information. Unless otherwise expressly stated, we obtained this industry, business, market and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data and similar sources that we believe to be reliable. In some cases, we do not expressly refer to the sources from which this data is derived. In that regard, when we refer to one or more sources of this type of data in any paragraph, you should assume that other data of this type appearing in the same paragraph are derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

ITEM 1. BUSINESS

Chimerix Overview

Chimerix (Chimerix, we, our, us or the Company) is a biopharmaceutical company whose mission it is to develop medicines that meaningfully improve and extend the lives of patients facing deadly diseases. The Company is focused on developing imipridones as a potential new class of selective cancer therapies. The most advanced imipridone is dordaviprone (ONC201), which is in clinical-stage development for H3 K27M-mutant diffuse glioma as its lead indication. In addition, a second-generation imipridone (ONC206) is currently in dose escalating clinical trials for adult and pediatric patients with primary central nervous system tumors.



Agreement and Plan of Merger

On March 4, 2025, we entered into an Agreement and Plan of Merger (the Merger Agreement) with Jazz Pharmaceuticals Public Limited Company, an Irish public limited company (Jazz), and Pinetree Acquisition Sub, Inc., a Delaware corporation and an indirect wholly owned subsidiary of Jazz (Purchaser). Pursuant to the Merger Agreement, and upon the terms and subject to the conditions thereof, Jazz has agreed to cause Purchaser to commence a tender offer to acquire all of our outstanding shares at a price of $8.55 per share in cash, without interest and subject to reduction for any applicable withholding taxes (the Offer Price), representing a total consideration of approximately $935 million. Upon the successful completion of the tender offer, Jazz will acquire all shares not acquired in the tender through a second-step merger for the same consideration per share paid in the tender offer. Our Board of Directors unanimously recommended that our shareholders tender their shares in the tender offer.

The transaction is subject to customary closing conditions, including the tender of a majority of the outstanding shares of our voting common stock and other conditions. At the Effective Time (as defined in the Merger Agreement), each outstanding share of the Company (other than certain exceptions as described therein) will automatically be converted into the right to receive the Offer Price, without any interest thereon and subject to any withholding of applicable taxes. We anticipate the transaction will close in the second quarter of 2025. Following the completion of the tender offer and subject to the terms and conditions of the Merger Agreement, the Company will survive as a wholly owned subsidiary of Jazz and cease to be a publicly traded company.

The Merger Agreement contains customary termination rights for us and Jazz. If the Merger Agreement is terminated under specified circumstances, we will be required to pay Jazz a termination fee of $35 million in cash.

Additional Information and Where to Find It

The tender offer referenced in this Annual Report has not yet commenced. This Annual Report is for informational purposes only and is not a substitute for the tender offer materials that Jazz and Purchaser are expected to file with the SEC upon the commencement of the tender offer. The solicitation and offer to tender and the offer to buy Chimerix stock will only be made pursuant to the tender offer statement on Schedule TO, including an Offer to Purchase and related tender offer materials that Jazz and Purchaser are expected to file with the SEC. CHIMERIX'S STOCKHOLDERS AND OTHER INVESTORS ARE URGED TO READ CAREFULLY THE TENDER OFFER MATERIALS (INCLUDING AN OFFER TO PURCHASE, A RELATED LETTER OF TRANSMITTAL AND CERTAIN OTHER TENDER OFFER DOCUMENTS), AS WELL AS THE SOLICITATION/RECOMMENDATION STATEMENT ON SCHEDULE 14D-9 BECAUSE THEY EACH CONTAIN IMPORTANT INFORMATION THAT HOLDERS OF CHIMERIX SECURITIES AND OTHER INVESTORS SHOULD CONSIDER BEFORE MAKING ANY DECISION WITH RESPECT TO THE TENDER OFFER. The Offer to Purchase, the

related Letter of Transmittal, certain other tender offer documents, as well as the Solicitation/Recommendation Statement on Schedule 14D-9, will be available to all stockholders of Chimerix at no expense to them and will also be available for free at the SEC's website at www.sec.gov. Additional copies may be obtained for free by contacting either Jazz or Chimerix. Copies of the documents filed with the SEC by Chimerix will be available free of charge on Chimerix's website at https://www.chimerix.com or by contacting Chimerix at IR@chimerix.com. Copies of the documents filed with the SEC by Jazz will be available free of charge on Jazz's website at https://investor.jazzpharma.com or by contacting Jazz's Investor Relations Department at investorinfo@jazzpharma.com.

In addition to the Offer to Purchase, the related Letter of Transmittal and certain other tender offer documents, as well as the Solicitation/Recommendation Statement on Schedule 14D-9, Jazz and Chimerix each file annual, quarterly and current reports, proxy statements and other information with the SEC, which are available to the public over the internet at the SEC's website at http://www.sec.gov.

Imipridones and Dordaviprone

New Drug Application for Accelerated Approval of Dordaviprone

On February 14, 2025, the U.S. Food and Drug Administration (FDA) accepted for filing our New Drug Application (NDA) seeking accelerated approval of dordaviprone for the treatment of patients with recurrent H3 K27M-mutant diffuse glioma. In its acceptance, FDA confirmed that the NDA will receive Priority Review under the terms of the Prescription Drug User Fee Act (PDUFA). The target date for completion of FDA's review of the NDA (i.e. the PDUFA date) is August 18, 2025. FDA has indicated that it is not planning to hold an Oncologic Drug Advisory Committee (ODAC) meeting at this time.

Background

In December 2024, the Company announced its submission of an NDA seeking accelerated approval of dordaviprone for the treatment of patients with recurrent H3 K27M-mutant diffuse glioma. The NDA was based on recent program milestones and additional supportive data:

- Substantial enrollment of the Phase 3 ACTION study;
- Phase 2 objective response rate of the 50-patient primary efficacy analysis assessed by blinded independent central review as the primary basis of efficacy in the NDA;
- Several response assessments, including the most contemporary response assessment criteria for gliomas, Response Assessment in Neuro-Oncology 2.0 (RANO 2.0), under which dordaviprone demonstrated an objective response rate of 28%, a median duration of response of 10.4 months and a median time to response of 4.6 months;
- Additional clinical data sets and patient narratives supportive of the primary efficacy analysis observed to date;
- Clinical and nonclinical demonstration of dordaviprone-driven reversal of the central hallmark of H3 K27M-mutant glioma, H3K27 trimethyl loss;
- Comprehensive safety database of glioma patients and healthy volunteers that supports a favorable benefit/risk profile observed to date; and
- Comprehensive clinical pharmacology and chemistry, manufacturing, and controls studies.

Additionally, dordaviprone for H3 K27M-mutant diffuse glioma has received FDA rare pediatric disease designation. Should the Company be awarded a rare pediatric disease priority review voucher with approval of the NDA and subsequently sell such rare pediatric disease priority review voucher to a third party, 50% of the net proceeds from such sale would be payable to the former securityholders of Oncoceutics, Inc. pursuant to the Agreement and Plan of Merger with Oncoceutics, Inc., dated as of January 7, 2021.

Phase 3 ACTION Study of Dordaviprone

Dordaviprone is currently in a global randomized Phase 3 trial (the ACTION Study) for patients with diffuse glioma, or diffuse midline glioma (DMG), which harbor a H3 K27M mutation. Frontline radiotherapy is the standard of care for these patients. DMGs that harbor the H3 K27M mutation are considered Grade IV by the World Health Organization. This patient population has few treatment options and poor prognoses.

The Phase 3 ACTION Study is currently enrolling H3 K27M-mutant glioma patients in 18 countries in North and South America, Europe, the UK, Israel, Australia and Asia. Management expects interim overall survival (OS) data from the trial to be available in 2026. The ACTION Study enrolls patients shortly after they have completed front-line radiation therapy that is the standard of care for glioma. The study is designed to enroll 450 patients randomized 1:1:1 to receive dordaviprone at one of

two dosing frequencies or placebo. Participants are randomized to receive either: (i) 625mg of dordaviprone once per week, (ii) 625mg twice per week on two consecutive days or (iii) placebo. The study is open to pediatric and adult patients >10kg body weight and the dose will be scaled by body weight for patients weighing less than 52.5kg. Primary endpoints include OS and progression-free survival (PFS). OS will be assessed for efficacy at three alpha-allocated timepoints consisting of two interim assessments by the Independent Data Monitoring Committee (IDMC) at 164 events and 246 events, respectively, and a final assessment at 327 events. The final PFS analysis will be performed after 286 events, with progression assessed using response assessment in neuro-oncology-high grade glioma (RANO) criteria by blinded independent central review (BICR). Secondary endpoints include corticosteroid response, performance status response, change from baseline in quality of life (QoL) assessments and change from baseline in neurologic function as assessed by the Neurologic Assessment in Neuro-Oncology (NANO) scale. A pre-specified safety review of patients in the ACTION Study was conducted by the IDMC, which did not identify any safety concerns, and recommended that the study continue as planned and designed. The ACTION study remains an important study as it is evaluating dordaviprone in a different line of therapy (front-line/pre-recurrence) than the potential accelerated approval NDA in the recurrent H3 K27M-mutant diffuse glioma setting. Additionally, should the currently submitted NDA for dordaviprone lead to an accelerated approval in the recurrent setting, it is possible the FDA may identify the ACTION study as a confirmatory study for full approval.

Significant Peer Reviewed Journal Publications and Presentations

In November 2024, we presented an updated Phase 2 response assessment of dordaviprone in recurrent H3 K27M glioma at the 2024 Society for Neuro Oncology (SNO) meeting. The presentation provided an updated assessment of objective response to dordaviprone previously reported in the BICR cohort in recurrent H3 K27M-mutant diffuse glioma using RANO 2.0, the most recently established criteria for this disease currently. The updated analysis demonstrated an overall response rate of 28.0%, a median time to response of 4.6 months plus a median duration of response of 10.4 months.

In February 2024, "ONC201 (dordaviprone) in Recurrent H3 K27M-mutant Diffuse Midline Glioma" was published in the Journal of Clinical Oncology (JCO), a peer reviewed journal of the American Society of Clinical Oncology (ASCO). The manuscript reports in detail the results of 50 patients with recurrent H3 K27M-mutant diffuse midline gliomas (H3K27M-DMG) treated with monotherapy dordaviprone who were evaluable for objective response by RANO high grade glioma (HGG) criteria. Dordaviprone demonstrated a median overall survival (mOS) of 13.7 months (95% CI: 8.0-20.3), with an overall two-year rate of survival of 35% (95% CI: 21-49) from the start of dordaviprone treatment post-recurrence. We previously conducted a natural disease history study (n=43) in the recurrent setting evaluating patients who did not receive dordaviprone which showed an mOS of 5.1 months (95% CI: 3.9-7.1) with an overall two-year survival rate of 11% (95% CI: 3.3-24.2). We had previously disclosed the top-line data from this JCO publication.

In August 2023, data in support of dordaviprone as a treatment for H3K27M-DMG appeared in the peer-reviewed journal, Cancer Discovery, a journal of the American Association for Cancer Research. The manuscript titled, "Clinical efficacy of ONC201 in H3K27M-mutant diffuse midline gliomas is driven by disruption of integrated metabolic and epigenetic pathways," reported survival analyses of 71 patients with H3K27M-DMG treated with dordaviprone, which demonstrated promising results in a patient population with a poor prognosis and few treatment options. In addition to assessing clinical outcomes, the study corroborated mechanistic findings from laboratory models in samples from treated patients that demonstrated the ability of dordaviprone to disrupt metabolic pathways and reverse a molecular signature of the H3 K27M mutation in patient's tumor samples. According to the survival analyses in this study, dordaviprone frontline treatment, administered post radiation therapy, demonstrated a significant increase in mOS from diagnosis in dordaviprone-treated versus in historical controls (21.7 months mOS vs. 12 months mOS, $p<0.0001$). The study was led by a team of researchers from the University of Michigan and other collaborators including several authors from Chimerix.

Eligibility for Primary Efficacy Analysis Aligned with FDA

We aligned with the FDA on the eligibility requirements to evaluate monotherapy efficacy of dordaviprone in recurrent H3K27M-DMG by dual-reader BICR in the first 50 subjects who met the agreed upon criteria. The data submitted in the NDA to the FDA included primary efficacy analysis by RANO 2.0, RANO high grade glioma (RANO HGG) and RANO low grade glioma (RANO LGG). The table below summarizes the findings by all three criteria.

n=50	RANO 2.0	RANO-HGG	RANO-LGG
Objective Response Rate, n (%) [95% CI]	**14 (28.0) [16.2-42.5]**	**10 (20.0) [10.0-33.7]**	**13 (26.0) [14.6-40.3]**
Complete Response	0	1 (2.0)	0
Partial Response	10 (20.0)	9 (18.0)	6 (12.0)
Minor Response	4 (8.0)	NA	7 (14.0)
Stable Disease	6 (12.0)[1]	10 (20.0)	8 (16.0)
Not Evaluable	11 (22.0)	8 (16.0)[2]	11 (22.0)[3]
Progressive Disease	15 (30.0)	18 (36.0)	14 (28.0)
Not Applicable	4 (8.0)	4 (8.0)	4 (8.0)
Disease Control Rate, n (%) [95% CI]	20 (40.0) [26.4-54.8]	20 (40.0) [26.4-54.8]	21 (42.0) [28.2-56.8]
Median Time to Response, months [range]	4.6 [1.6-15.9]	8.3 [1.9-15.9]	3.6 [1.6-17.8]
Median Duration of Response, months, [95% CI]	10.4 [7.4-15.4]	11.2 [3.8-NR]	10.4 [3.6-12.7]
Overall Survival, months, median [95% CI]		14.0 [8.0-26.1]	
12-month survival estimate, [95% CI]		57.5% [41.7-70.5]	
24-month survival estimate, [95% CI]		37.6% [23.2-51.9]	

[1] Includes one patient with unconfirmed response by RANO 2.0.
[2] Five overall radiographic SD accompanied by increase in corticosteroids; three overall radiographic PD accompanied by decrease in corticosteroids.
[3] Eight overall radiographic SD accompanied by increase in corticosteroids; three overall radiographic PD accompanied by decrease in corticosteroids.

Dordaviprone Clinical Pharmacology and Safety Assessment

In clinical pharmacology studies comprising 245 participants, dordaviprone was well tolerated at dose levels ranging from 125mg to 750mg. The majority of treatment-related adverse events were Grade 1 (mild) and transient. The most common treatment-related adverse events (AE) were Grade 1 nausea and dizziness.

In completed glioma patient studies, the most common AEs were fatigue, headache, vomiting and nausea. The majority of the adverse events were mild to moderate. Investigators reported serious adverse events they considered possibly related to dordaviprone in only 15 patients (3.6%). Overall, only 10 patients (2.4%) experienced a treatment-related AE that led to study drug modification or discontinuation.

Fast Track Designation by FDA

The FDA has granted dordaviprone Fast Track Designation for the treatment of adult recurrent H3 K27M-mutant high-grade glioma, Rare Pediatric Disease Designation for treatment of H3K27M-DMG, and Orphan Drug Designations for the treatment of glioblastoma and for the treatment of malignant glioma.

ONC206

ONC206 is a second generation imipridone ClpP agonist and DRD2 antagonist that has demonstrated monotherapy activity in advanced solid tumor models. Oral ONC206 was well tolerated and achieved prolonged exposures above target thresholds in Phase 1 dose escalation trials at dose frequencies up to twice per day on three consecutive days per week (BID TIW).

The dose escalation studies of ONC206 have enrolled over 100 pediatric and adult patients with CNS tumors. Thus far, a similar safety profile has been observed in the pediatric and adult populations, with the majority of treatment-related adverse events (fatigue, lymphocyte count decrease and vomiting) being mild to moderate. No significant change in the overall safety profile has been reported to date as dosing has escalated and intensified in frequency from once per week to twice per day on three consecutive days per week. Completion of dose escalation is expected to occur in Q2 of 2025.

Nonclinical studies remain ongoing to identify additional oncology indications for further development of ONC206.

Early Pipeline Development, ONC212 and CMX521

ONC212 is an imipridone, investigational agonist of the orphan GPCR tumor suppressor GPR132, as well as ClpP. Similar to the potential downstream effects of dordaviprone and ONC206, in vitro studies of ONC212 demonstrate activation of integrated stress response, inhibition of Ras signaling and selective killing of tumor cells.

Initial IND-enabling studies with ONC212 have been completed and pre-clinical studies are on-going in collaborations with the University of Texas MD Anderson Cancer Center and Brown University. These preclinical studies look to evaluate potential oncology indications and predictive ONC212 biomarkers that could be suitable for clinical development.

CMX521 is a nucleoside analog antiviral drug candidate for the treatment of novel coronaviruses. CMX521 is not mutagenic, clastogenic, or associated with mitochondrial toxicity. In addition, oral CMX521 demonstrated a favorable profile in GLP toxicology studies and was well-tolerated up to 2,400 mg in a healthy volunteer Phase 1 study for a different indication.

Pursuant to a 2006 agreement between the Company and The Regents of the University of Michigan (UM), the Company obtained an exclusive, worldwide license to UM's patent rights in certain inventions related to certain compounds originally synthesized at UM, including CMX521 (the UM Patent Rights). Under the license agreement, the Company is permitted to research, develop, manufacture and commercialize products utilizing the UM Patent Rights, and to sublicense such rights subject to certain sublicensing fees and royalty payments.

We are currently working with the Rapidly Emerging Antiviral Drug Development Initiative (READDI) at the University of North Carolina at Chapel Hill (UNC) for the development of CMX521 as a potential treatment for novel coronaviruses. UNC is the co-recipient of a grant for approximately $1.7 million from the state of North Carolina which will defray the majority of the costs on this effort. The grant is expected to fund prodrug synthesis and animal studies to optimize delivery of CMX521 to the lungs via a convenient oral formulation. Multiple prodrugs have been synthesized and efforts are underway to determine efficacy against a diverse panel of coronaviruses including circulating and pre-emergent strains. In addition, UNC intends to conduct coronavirus disease mouse efficacy model studies and evaluate lung delivery of the active antiviral.

Chimerix Antiviral Chemical Library

The Chimerix Chemical Library contains over 10,000 heterocyclic ring systems and nucleosides. This library includes approximately 3,500 nucleoside analog compounds, most of which are candidates for lipid conjugation. In a collaboration with the scientists at UNC and the University of Wisconsin-Madison, we continue to evaluate our library of antiviral molecules to identify candidates that may have the potential to accelerate pandemic preparedness or response to SARS-CoV-2 (for example, COVID-19) or other potential future pandemics.

TEMBEXA (brincidofovir, BCV)

TEMBEXA is a lipid conjugate which acts via inhibition of viral DNA synthesis that is a medical countermeasure for smallpox. On June 4, 2021, the FDA granted TEMBEXA approval for the treatment of smallpox. TEMBEXA is available in tablets and oral suspension. It is approved for adult and pediatric patients, including neonates. TEMBEXA was developed as a medical countermeasure for the treatment of smallpox under a collaboration with Biomedical Advanced Research and Development Authority (BARDA).

On September 26, 2022, the Company sold its exclusive worldwide rights to brincidofovir, including TEMBEXA® and specified related assets (the Asset Sale) to Emergent. Upon closing of the Asset Purchase Agreement for the Asset Sale, the Company received $238 million upfront and could receive additional milestone payment of up to $136.5 million to be paid contingent upon the execution of optional future procurement awards from BARDA and other development milestones. The Company may also earn a 20% royalty on future gross profit of TEMBEXA in the United States associated with volumes above 1.7 million treatment courses of therapy during the exclusivity period of TEMBEXA. The agreement also allows the Company to earn a 15% royalty on all gross profit associated with TEMBEXA sales outside of the United States during the exclusivity period of TEMBEXA on a market-to-market basis. In September 2024, BARDA and Emergent agreed to amend the terms of the BARDA Agreement for sales of TEMBEXA. We are currently evaluating our next steps with respect to Emergent regarding the effect of the amended BARDA Agreement on the achievement of the sales milestones set forth in the Asset Purchase Agreement.

Our Strategy

The principal components of our business strategy are to:

- **Successfully commercialize dordaviprone.** Dordaviprone could receive marketing authorization in the United States as soon as August 18, 2025. Therefore, we plan to build a platform to support a potential commercial launch in the United States in the third quarter of 2025. Patients with H3 K27M mutant diffuse glioma are faced with a terminal disease with no known effective therapeutic options beyond radiation. In the current neuro-oncology community, there exists high awareness of dordaviprone which we believe will aid in the potential commercialization.
- **Successfully execute the randomized controlled Phase 3 ACTION Study.** Dordaviprone is being developed for H3 K27M-mutant diffuse glioma. Currently, we are enrolling Phase 3 ACTION Study, a randomized, double-blind, placebo-controlled, multi-center Phase 3 international trial for newly diagnosed patients with H3 K27M-mutant diffuse glioma shortly following radiation with targeted enrollment of approximately 450 patients randomized 1:1:1 to receive dordaviprone at one of two dosing frequencies or placebo. Available Phase 2 data demonstrate durable responses (as measured by RANO 2.0, RANO HGG and RANO LGG) in recurrent H3 K27M-mutant diffuse midline glioma associated with other forms of clinical benefit. Results from both independent and company sponsored natural disease history studies are consistent with the existence of a potential survival advantage. The genetically selected patient population limits patient heterogeneity. In the current neuro-oncology community there exists high awareness of dordaviprone that has aided in the enrollment of Phase 3 ACTION Study.
- **Complete the Phase 1 ONC206 study and evaluate Phase 2 development indications.**
- **Maintain corporate capability and financial flexibility.** Our leadership team has successfully executed large-scale clinical studies and regulatory approvals of investigational agents. We intend to continue to leverage external capital to develop our early-stage pipeline consisting of ONC212 and derivatives of CMX521.
- **Seek opportunities to in-license other development programs.** We continue to review transactions designed to build our product candidate pipeline, including, but not limited to, merger or acquisition transactions, or the license, purchase or sale of specific assets, in addition to other potential actions aimed at maximizing stockholder value. There can be no assurance that this review will result in the identification or consummation of any additional transaction.

Significant Agreements

Emergent Biodefense Operations Lansing LLC

On September 26, 2022, the Company completed the Asset Sale to Emergent of the Company's exclusive worldwide rights to brincidofovir, including TEMBEXA® and specified related assets (the Asset Sale). Emergent paid the Company an upfront cash payment of approximately $238 million upon the closing of the Asset Sale. In addition, pursuant to the Asset Purchase Agreement, the Company is eligible to receive from Emergent: (i) up to an aggregate of approximately $124 million in milestone payments payable upon the exercise of the options under the BARDA Agreement for the delivery of up to 1.7 million treatment courses of tablet and suspension formulations of TEMBEXA to the U.S. government; (ii) royalty payments equal to 15% of the gross profits from the sales of TEMBEXA made outside of the United States; (iii) royalty payments equal to 20% of the gross profits from the sales of TEMBEXA made in the United States in excess of 1.7 million treatment courses; and (iv) up to an additional $12.5 million upon the achievement of certain other developmental milestones.

The period under which we were contracted to provide the majority of operational support services to Emergent in furtherance of its obligations under the Asset Purchase Agreement and the BARDA Agreement concluded on March 26, 2023, except for certain services which the parties agreed would continue until the occurrence of a specific event, or in some cases a predetermined end date. The BARDA Agreement was novated to Emergent in December 2022.

Merger Agreement with Oncoceutics

On January 7, 2021, we entered into an agreement to acquire Oncoceutics, a privately-held, clinical-stage biotechnology company developing imipridones, a novel potential class of compounds. As consideration for the acquisition, we (a) paid an upfront cash payment of approximately $25.0 million, (b) issued an aggregate of 8,723,769 shares of our common stock, (c) made an additional cash payment of $14.0 million upon the one year anniversary of the closing of the acquisition, and (d) agreed to make contingent payments up to an aggregate of $360.0 million based on the achievement of certain development, regulatory and commercialization events, as well as additional tiered royalty payments based upon combined future net sales of ONC201 and ONC206 products of 15% up to $750 million in annual revenue and 20% above $750 million in annual revenue.

subject to certain reductions, and a contingent payment in the event we receive any proceeds from the sale of a rare pediatric disease priority review voucher based on the Oncoceutics products. Pursuant to the merger agreement we have certain diligence obligations with respect to further development and commercialization of the Oncoceutics product candidates.

Ohara Pharmaceutical Co., Ltd. (Ohara)

In 2019, Oncoceutics entered into a license, development and commercialization agreement with Ohara Pharmaceutical Co., Ltd. for ONC201 in Japan. We are entitled to receive up to $2.5 million in nonrefundable regulatory milestone payments, and to tiered royalties based on the aggregate annual net sales of all products, as defined in the agreement, in Japan.

In September 2024, we entered into an addendum to such license, development and commercialization agreement with Ohara in which the parties agreed to collaboratively conduct development activities for dordaviprone in Japan, including expanding the ACTION Study into Japan (the Ohara License Addendum). Under the Ohara License Addendum, Ohara agreed to reimburse us for certain of its development costs incurred from its sponsorship of the ACTION Study in Japan, including fixed overhead payments totaling $3.3 million paid in quarterly installments through December 31, 2026, as well as site activation and subject enrollment-based payments. Amounts due under the Ohara License Addendum will be recognized in accordance with ASC 808 *Collaborative Arrangements*, as this agreement meets both requirements of a collaborative arrangement outlined in that guidance.

China Resources Sanjiu Medical & Pharmaceutical Co., Ltd. (CR Sanjiu)

In December 2020, Oncoceutics entered into a license, development and commercialization agreement for ONC201 with China Resources Sanjiu Medical & Pharmaceutical Co., Ltd. (CR Sanjiu). Oncoceutics granted CR Sanjiu an exclusive royalty bearing license to develop and commercialize ONC201 in China, Hong Kong, Macau and Taiwan (CR Sanjiu Territory). We are entitled to receive up to $5.0 million in nonrefundable regulatory milestone payments, and to tiered royalties based on the aggregate annual net sales of all licensed products, as defined in the agreement, in the CR Sanjiu Territory.

Commercial Operations

If dordaviprone is approved for H3 K27M-mutant diffuse glioma, we plan to build a platform to support a potential commercial launch for dordaviprone in the United States in the third quarter of 2025. We anticipate that commercialization would entail a relatively small commercial infrastructure, which may include a contract sales force, partner sales force, or an internally developed commercial organization.

Outside of the United States, subject to obtaining necessary marketing approvals, we may seek to commercialize dordaviprone ourselves or through distribution or other collaboration arrangements. If we elect to develop dordaviprone for other indications, we will plan to do so selectively either on our own or by establishing alliances with one or more pharmaceutical company collaborators, depending on, among other things, the applicable indications, the related development costs, reimbursement complexities and our available resources.

Competition

Our industry is highly competitive and subject to rapid and significant technological change. While we believe that our therapeutic experience, scientific and commercial knowledge provide us with competitive advantages, we will face competition from large and small pharmaceutical and biotechnology companies, including specialty pharmaceutical and generic drug companies, and other emerging technologies.

We believe that the key competitive factors that will affect the commercial success of dordaviprone and our other product candidates are the efficacy, safety and tolerability profile and the risk-benefit trade-off compared to alternative therapies or procedures. Securing market access and reimbursement will be an important element of product uptake and market penetration. Our commercial opportunity could be negatively impacted if our competitors develop or market products or other technologies that are more effective, better tolerated, safer, more convenient or have greater market access than dordaviprone or any product candidate, or obtain regulatory approval for their products more rapidly than we do. In addition, our ability to compete will be affected by the availability of generic products.

Dordaviprone is the most clinically advanced program in the industry for potentially treating tumors which harbor the H3 K27M mutation. If approved, treatment with dordaviprone is expected to be targeted to patients whose tumor harbors the H3 K27M mutation. There are currently no commercially available treatments that target the H3 K27M mutant patient population.

If approved, dordaviprone could compete with a number of existing products, new products in development and possible combination therapies used for brain cancers including generic drugs such as chemotherapy, targeted agents, immunotherapies, and other therapies. Select products that are currently used, or being developed for use, to treat brain cancers include, but are not limited to:

- Systemic therapies approved to treat brain cancer: temozolomide, lomustine, carmustine, everolimus, and bevacizumab;
- Tumor-treating fields such as Optune®; and
- Other investigational agents for the treatment of brain cancer: immunotherapies (CAR-T, durvalumab, VBI-1901, etc), viral therapies (DCVax-L, etc.), targeted agents (selinexor, paxalisib, MDNA55), and other therapies.

Changes in the health care system may limit our ability to price dordaviprone and our other product candidates at a level that would allow recovery of our research and development costs and may impede our ability to generate or maintain a profit.

We believe that dordaviprone has potential benefits over existing and potential competitive products, and, as a result, we believe that our products should be well positioned to gain adoption if we obtain the required regulatory approvals. However, even with those benefits, we may not be able to make promotional claims that these products are superior to competing products without conducting additional studies, which delivers differentiated data. See "Risk Factors – Risks Related to Commercialization of Our Product Candidates."

Our Intellectual Property

We strive to protect and enhance the proprietary technologies we believe are important to our business, including by seeking and maintaining patents intended to cover our products and compositions, their methods of use and any other inventions that are important to the development of our business. We also rely on trade secrets to protect aspects of our business that are not amenable to, or that we do not consider appropriate for, patent protection.

Our success will depend significantly on our ability to obtain and maintain patent and other proprietary protection for commercially important technology, inventions and know-how related to our business, defend and enforce our patents, maintain licenses to our intellectual property owned by third parties, preserve the confidentiality of our trade secrets and operate without infringing the valid and enforceable patents and proprietary rights of third parties.

Imipridone Patent Portfolio

At February 17, 2025, our worldwide imipridone patent portfolio included:

- 632 patents or patent applications related to imipridones that we have acquired rights to through our merger with Oncoceutics, Inc. (owned or in-licensed by Oncoceutics);
- This includes 350 US and foreign issued patents and 77 pending US and foreign applications related to dordaviprone; and
- Patent protection for dordaviprone's lead indication is expected to extend into 2037 in the U.S., with the potential for additional patent term extension.

Antiviral Patent Portfolio

At February 17, 2025, our worldwide antiviral patent portfolio included:

- 26 patents or patent applications that we own or have in-licensed from academic institutions, related to antivirals, which is the same as the number of patents in our patent portfolio at the end of fiscal year 2024;
- This includes 18 US and foreign exclusively and jointly owned patents and 8 US and foreign applications related to antivirals. Granted European patents are counted as one patent and have been validated throughout Europe;
- Eight jointly-owned US and foreign patents and five jointly-owned US patent applications related to our agreement with UM regarding our proprietary Chemical Library; and
- One US patent, two US patent applications, and one European patent exclusively owned by Chimerix directed to a morphic form of a compound from the Chemical Library.

Patents generally have a term of twenty years from the date they are filed. As our patent portfolio has been built over time, the remaining terms of the individual patents across our patent portfolio vary. We believe that our patents and patent applications are important for maintaining the competitive differentiation of our portfolio, enhancing our freedom of action to exclusively

sell our products, upon appropriate regulatory approvals, in markets in which we choose to participate, and maximizing our return on research and development investments. No single patent is itself essential to the conduct of our business as a whole.

We also seek to expand our intellectual property portfolio through licensing intellectual property from third parties as we deem appropriate. We have granted, and will continue to grant to others, licenses under our patents when we consider these arrangements to be in our interest.

Manufacturing

We do not own or operate, and we do not expect to own or operate, facilities for product manufacturing, storage and distribution, or testing. In the past, we have relied on third-party manufacturers for supply of our product candidates.

We expect that in the future we will rely on such manufacturers for supply of drug substance and drug product that will be used in clinical trials of dordaviprone, our expanded access program for dordaviprone and other clinical trials as well as for commercial purposes should dordaviprone be approved. When produced on a commercial scale, we expect that cost-of-goods-sold relating to the imipridone class of assets will generally be in-line with that of other targeted oncology therapies.

The manufacturing processes for dordaviprone drug substance and drug product are relatively straight-forward and generally in-line with other small molecule pharmaceutical compounds in terms of cost and complexity. The processes are robust and reproducible and do not require dedicated reactors or specialized equipment. The drug substance process uses common synthetic chemistry and readily available materials, including off-the-shelf and made-to-order starting materials, and is readily transferable. The drug product process uses common excipients and readily available materials, and is also readily transferable.

Manufacturers of drug components must meet certain FDA qualifications with respect to manufacturing standards. At present, we have qualified only one firm as a supplier of drug substance for dordaviprone. We continually assess our manufacturing needs and may seek to engage additional qualified vendors as circumstances dictate. To ensure continuity in our supply chain, we plan to establish supply arrangements with alternative suppliers for certain portions of our supply chain, as appropriate.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our systems and contractors are required to be in compliance with these regulations, and this is assessed regularly through monitoring of performance and a formal audit program. We have personnel with extensive technical, manufacturing, analytical and quality experience and strong project management discipline to oversee contract manufacturing and testing activities, and to compile manufacturing and quality information for our regulatory submissions.

Government Regulation and Product Approval

Government authorities in the United States, at the federal, state and local level, and government authorities of member states of the EU and other countries extensively regulate, among other things, the research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, record-keeping, promotion, advertising, distribution, post-approval monitoring and reporting, marketing and export and import of products such as those we are developing. Any product candidate that we develop must be approved by the FDA or European Medicines Agency (the EMA) before it may be legally marketed in the United States, EU or in other countries by the responsible national regulatory agency.

U.S. Drug Development Process

In the United States, the FDA regulates drugs under the Federal Food, Drug and Cosmetic Act (FDCA), and implementing regulations. Drugs are also subject to other federal, state and local statutes and regulations. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources. Failure to comply with the applicable U.S. requirements at any time during the product development process, FDA approval process or after FDA approval, may subject an applicant to administrative or judicial civil or criminal sanctions. FDA sanctions could include refusal to approve pending applications, withdrawal of an approval, clinical hold, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, refusals of government contracts, debarment, restitution, disgorgement or civil or criminal penalties. Any agency or judicial enforcement action, whether before or after the FDA approval process, could have a

material adverse effect on us. The process required by the FDA before a drug may be marketed in the United States generally involves the following:

- completion of nonclinical laboratory tests, animal studies and formulation studies according to good laboratory practices (GLP), or other applicable regulations;
- submission to the FDA of an application for an IND, which must become effective before human clinical trials may begin;
- performance of adequate and well-controlled human clinical trials according to the FDA's regulations commonly referred to as current good clinical practices (GCPs), to establish the safety and efficacy of the proposed drug for its intended use;
- submission to the FDA of an NDA for a new drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities where the drug is produced to assess compliance with the FDA's current good manufacturing practice standards (cGMP), to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- potential FDA inspection of the nonclinical and clinical trial sites that generated the data in support of the NDA; and FDA review of the NDA.

The lengthy process of seeking required approvals and the continuing need for compliance with applicable statutes and regulations require the expenditure of substantial resources and approvals are inherently uncertain.

Before testing any compounds with potential therapeutic value in humans, the drug candidate enters the preclinical testing stage. Preclinical tests, also referred to as nonclinical studies, include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies to assess the potential safety and activity of the drug candidate. The conduct of the preclinical tests must comply with federal regulations and requirements including GLP. The sponsor must submit the results of the preclinical tests, together with manufacturing information, analytical data, any available clinical data or literature and a proposed clinical protocol to the FDA as part of an investigational new drug (IND). The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA places the clinical trial on a clinical hold within that 30-day time period. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. The FDA may also impose clinical holds on a drug candidate at any time before or during clinical trials due to safety concerns or non-compliance. Accordingly, we cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such trial.

Clinical trials involve the administration of the drug candidate to healthy subjects or affected patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control. Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria, and the parameters to be used to monitor subject safety. Each protocol must be submitted to the FDA as part of the IND. Patients not meeting protocol inclusion and exclusion criteria may be considered for our expanded access program under the IND. Clinical trials must be conducted in accordance with the FDA's regulations comprising the good clinical practices requirements. Further, each clinical trial must be reviewed and approved by an independent institutional review board (IRB), at or servicing each institution at which the clinical trial will be conducted. An IRB is charged with protecting the welfare and rights of trial participants and considers such items as whether the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to anticipated benefits. The IRB also approves the form and content of the informed consent that must be signed by each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

- Phase 1. The drug is initially introduced into healthy human subjects and tested for safety, dosage tolerance, absorption, metabolism, distribution and excretion. In the case of some products for severe or life-threatening diseases, especially when the product may be too inherently toxic to ethically administer to healthy volunteers, the initial human testing is often conducted in patients.
- Phase 2. The drug is evaluated in a limited patient population to identify possible adverse effects and safety risks, to preliminarily evaluate the efficacy of the product for specific targeted diseases and to determine dosage tolerance, optimal dosage and dosing schedule.
- Phase 3. Clinical trials are undertaken to further evaluate dosage, clinical efficacy and safety in an expanded patient population at geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the product and provide an adequate basis for product labeling. Generally, two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

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Upgrade Now

NasdaqGM - Nasdaq Real Time Price•USD

Chimerix, Inc. (CMRX) Follow Compare

8.51+0.01(+0.12%)

As of 2:46:16 PM EDT. Market Open.

Major Holders

Breakdown

6.75%	% of Shares Held by All Insider
52.90%	% of Shares Held by Institutions
56.73%	% of Float Held by Institutions
88	Number of Institutions Holding Shares

Top Institutional Holders

Holder	Shares	Date Reported	% Out	Value
RA Capital Management, L.P.	8.8M	Dec 31, 2024	9.78%	74,844,001
Vanguard Group Inc	4.04M	Dec 31, 2024	4.50%	34,401,679
Deerfield Management Company, L.P. (Series C)	3.77M	Dec 31, 2024	4.19%	32,075,264
Rosalind Advisors, Inc.	3.05M	Dec 31, 2024	3.39%	25,940,250
Monaco Asset Management SAM	2.82M	Dec 31, 2024	3.14%	23,990,836
Millennium Management Llc	2.56M	Dec 31, 2024	2.84%	21,751,792
Armistice Capital, LLC	2.24M	Dec 31, 2024	2.49%	19,017,180
Marshall Wace LLP	2.21M	Dec 31, 2024	2.46%	18,829,559
Boxer Capital Management, LLC	2.06M	Dec 31, 2024	2.29%	17,520,300
Acadian Asset Management, LLC	2.01M	Dec 31, 2024	2.23%	17,093,451

Top Mutual Fund Holders

Holder	Shares	Date Reported	% Out	Value
Vanguard Total Stock Market Index Fund	2.89M	Dec 31, 2024	3.21%	24,587,513
Vanguard Extended Market Index Fund	1.04M	Dec 31, 2024	1.15%	8,817,958
Ultra-Small Company Fund	860.12k	Dec 31, 2024	0.96%	7,315,354
Fidelity Extended Market Index Fund	409.71k	Dec 31, 2024	0.46%	3,484,592
SMALL CAP VALUE FUND	321.55k	Dec 31, 2024	0.36%	2,734,748
Ultra-Small Company Market Fund	205.79k	Dec 31, 2024	0.23%	1,750,243
Fidelity Total Market Index Fund	154.36k	Dec 31, 2024	0.17%	1,312,831
Fidelity Series Total Market Index Fund	95.81k	Dec 31, 2024	0.11%	814,838
Fidelity Nasdaq Composite Index Fund	65.23k	Dec 31, 2024	0.07%	554,747
VANGUARD BALANCED INDEX FUND	57.13k	Dec 31, 2024	0.06%	485,933

Related Tickers

JAZZ	EWTX	SWTX	TRVI	MLYS	VRNA	DAWN	SRRK	CR
Jazz Pharmaceutic...	Edgewise Therape...	SpringWorks Thera...	Trevi Therapeutics,...	Mineralys Therape...	Verona Pharma plc	Day One Biopharm...	Scholar Rock Holdi...	CAI
141.70 +2.12%	**23.02** -2.50%	**49.35** -1.08%	**6.43** -0.62%	**16.78** -0.53%	**66.44** -0.55%	**8.44** +2.49%	**32.95** -0.30%	**4.21**

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POPULAR QUOTES
Dow Jones
S&P 500
DAX Index
Nvidia
Tesla
DJT
Tariffs

EXPLORE MORE
Mortgages
Credit Cards
Sectors
Crypto Heatmap
Financial News

ABOUT
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Help
Feedback
Sitemap
Licensing
What's New
About Our Ads
Premium Plans
Terms and

North Carolina Department of Agriculture
and Consumer Services
Food and Drug Protection Division

Inspection Report

Chimerix, Inc.
2505 Meridian Parkway, Suite 100
Durham, NC 27713
(919) 806-1074

Inspected 03/19/2025
By: Angela Harrison
Drug Specialist

Steven W. Troxler
Commissioner

North Carolina Department of Agriculture and Consumer Services
Food and Drug Protection Division

Christina L. Waggett
Assistant Commissioner
for Consumer Protection

Anita MacMullan
Director

Inspection Report

Chimerix, Inc.
2505 Meridian Parkway, Suite 100
Durham, NC 27713
(919) 806-1074

Inspected 03/19/2025
By: Angela Harrison

History of Business

Chimerix, Inc., is a biopharmaceutical company focusing on oncology therapy with its headquarters located in Durham, North Carolina. The company was incorporated in the state of Delaware in 2000. Chimerix, Inc. applied for a virtual manufacturers license with the NCDA&CS on February 24, 2025.

Corporate Address

Chimerix, Inc.
2505 Meridian Parkway, Suite 100
Durham, NC 27713

Corporate Officers

Michael T. Andriole	President and Chief Executive Officer
Thomas Riga	Chief Operating and Commercial Officer
Roy W. Ware, PhD	Chief Manufacturing and Technology Officer
Michelle LaSpaluto	Chief Financial Officer

Person(s) Interviewed and Individual Responsibility

Credentials were presented to and Notice of Inspection issued to Mr. Norlonn Sturdivant, Executive Director, Quality Assurance. He, Mr. Roy W. Ware, Chief Manufacturing and Technology Officer, Ms. Jennifer Butler Ervin, Senior Director, Global Supply Chain, and Ms. Erica Sumner, Director Quality Assurance GMP, accompanied me during a tour of the facility and responded to all questions concerning future operations and the handling of drug products and supplied the requested documents.

Background

This visit was the initial inspection of this virtual prescription drug manufacturer following receipt of an application for licensure as a Virtual Manufacturer. The purpose of this inspection was to verify compliance with North Carolina General Statutes §106 Article 12 (Food, Drugs and Cosmetics) and Article 12A (Wholesale Prescription Drug Distributors) prior to approval and release of the license.

Operations

This facility consists of 7,700 square feet of administrative space, located on the first floor and 14,489 square feet of administrative space on the third floor. The office building is equipped with a continuously monitored security system, consisting of door access controls located on the first and third floors. The entry door to Suite 100 is locked and only accessible via employee issued access cards. Guests visiting Chimerix, Inc. must announce themselves at the front door of the suite. The Chimerix, Inc. front desk receptionist visually identifies the guest before granting access into the office. Guests entering and exiting are required to sign in and out.

The firm utilizes a contract organization for manufacturing and packaging and a third-party logistics (3PL) provider for drug product storage and distribution; there are no prescription drug products manufactured, received, or stored for distribution at this location. A written policy has been established defining the appropriate steps to be taken should any prescription drug product be presented for delivery at this location. A metal file cabinet is designated for non-routine secure storage and quarantine of drug products, if necessary; this cabinet is located within a file room. Access into this room and storage cabinet is limited to authorized personnel. Environmental conditions are maintained using a conventional thermostatically controlled HVAC system. Any drug products inadvertently shipped to this location will be manually logged onto a controlled form, secured in the cabinet and will not re-enter the commercial supply chain.

Standard Operating Procedures for this facility have been established in compliance with the requirements provided in NCGS§106 Article 12A (Wholesale Prescription Drug Distributors) applicable to firms operating as a virtual manufacturer.

Observations

There were no significant objectionable conditions noted during this inspection, and the Virtual Manufacturer license (092-1929) is approved for release as Active-Conditional; the license status will be revised as Active-In Good Standing following approval for commercial manufacturing by the FDA.

Compliance

Future NCDA&CS inspections of this facility will be conducted on a routine or as-needed basis.

Attachments

Notice of Inspection

4S

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	■ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Dentsply North America LLC

Physical Address: 13320-B Ballantyne Corporate Place

City: Charlotte State: NC Zip: 28277

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 910-988-7937 Website: www.dentsplysirona.com

Name of Designated Representative (DR): Mandrell McGill

Licensing Company Email: dsstatelic@dentsplysirona.com DR Email: dsstatelic@dentsplysirona.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
5/25/2021	N/A	GA		

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2021-0051	Georgia Board of Pharmacy

Reason/Charge
Voluntary Cease and Desist Order

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Dentsply North America LLC	

Name of Business/Industry/Entity
Dentsply North America LLC

Provide explanation below:

Dentsply North America LLC primarily distributes professional dental solutions that include medical devices such as dental filling and crown materials, implants, imaging devices, dental instruments, orthodontic devices, and the like. Dentsply North America LLC also distributes a small number of prescription pharmaceutical products for use by dental professionals during procedures such as Xylocaine, Nupro Fluoride Rinse, and Topex Anesthetic Gel in certain jurisdictions.
While we are not certain that this matter qualifies as a "discipline" for purposes of our application, we are disclosing this matter out of an abundance of caution. On June 8, 2021, our Pennsylvania location received a letter from the Georgia Board of Pharmacy indicating that Dentsply North America LLC's distribution of prescription pharmaceutical products triggered a requirement to possess a Drug Wholesale Distribution License in the State of Georgia. After receiving the letter from the Georgia Board of Pharmacy, Dentsply North America LLC placed all product shipment to the State of Georgia on hold and prepared an application for the State of Georgia's Drug Wholesale Distribution License. We submitted the application on June 17, 2021. Dentsply North America LLC also signed a Voluntary Cease and Desist Order dated July 6, 2021, (Docket No. 2021-0051) stating that we will voluntarily stop any practice requiring a Georgia license until licensed. The original letter and Order are attached.

On August 19, 2021, the State of Georgia Board of Pharmacy granted the Pennsylvania location of Dentsply North America LLC a license, Wholesaler Pharmacy License No. PHWH005100.

We made every effort to remedy this situation as soon as it was brought to our attention. We are not aware of any disciplinary or further action under consideration related to this lapse in licensure. This matter predated our establishment of distribution operations in North Carolina and licensure by the State of North Carolina. Dentsply North America LLC has had no additional issues that could be considered to fall under the definition of "discipline."

Original Signature (electronic, copies or stamps not accepted)

11/14/24
Date

Dentsply North America LLC
13320-B Ballantyne Corporate Place
Charlotte, NC 28277
USA

Dentsply Sirona

QUESTION 3 Explanation

Dentsply North America LLC primarily distributes professional dental solutions that include medical devices such as dental filling and crown materials, implants, imaging devices, dental instruments, orthodontic devices, and the like. Dentsply North America LLC also distributes a small number of prescription pharmaceutical products for use by dental professionals during procedures such as Xylocaine, Nupro Fluoride Rinse, and Topex Anesthetic Gel in certain jurisdictions.

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Laura Duquette

Regulatory Compliance Specialist

BEFORE THE GEORGIA STATE BOARD OF PHARMACY

STATE OF GEORGIA

GEORGIA STATE BOARD OF PHARMACY
JUL 06 2021
DOCKET NO. 2021-0051

IN THE MATTER OF: *

*

Dentsply North America, LLC *

*

Respondent. *

VOLUNTARY CEASE AND DESIST ORDER

Respondent, Dentsply North America, LLC, operating at 221 W. Philadelphia Street, Suite 60W, York, PA 17401,

is not licensed to engage in the distribution of drugs or devices in the State of Georgia, pursuant to the Official Code of Georgia Annotated (O.C.G.A.) T. 26, Ch. 4 or T. 16, Ch. 13, as amended. Potential violations of O.C.G.A. T. 26, Ch. 4 and T. 16, Ch. 13 having been called to Respondent's attention, Respondent, through the signing agent, hereby agrees to voluntarily cease and desist from any practice that would require licensure under O.C.G.A. T. 26, Ch. 4, or T. 16, Ch. 13, as amended, until such time as Respondent may become properly licensed or registered by the Georgia State Board of Pharmacy ("Board"). Respondent, through the signing agent, agrees that this includes distribution or delivery of drugs or devices to or receipt of drugs or devices from any person or firm in this state other than intracompany transfers to or from a licensed firm in this state under common ownership.

The Agent of Respondent understands that he/she has a right to a hearing in this matter, and hereby freely, knowingly, and voluntarily waives such right. The Agent of Respondent also understands that should he/she apply for licensure with the Board, the Board shall have access to this Order and to the entire investigative file on this matter.

This Order shall become effective immediately upon acceptance thereof and docketing by the Georgia State Board of Pharmacy and shall remain in effect until such time as the

Respondent becomes licensed with the Board, or until further order. The Agent of Respondent understands that this document will be considered to be a public record entered as the final disposition of any injunction or cease and desist proceedings presently pending or which could be brought against Respondent by the Board, and that this action shall be considered to be and may be recorded as a final order of the Board. **This Order is not intended and shall not be construed as prohibiting the prosecution of Respondent by any other state or federal agency for Respondent's conduct nor shall it be construed as limiting the Board's authority to subsequently impose a fine or conditions upon licensure with the Board.**

Any violation of this Order shall subject the Respondent to a fine not to exceed $500.00 for each transaction constituting a violation thereof, pursuant to O.C.G.A. § 43-1-20.1.

CONSENTED TO:

_____ (Signature)

DANIEL P. KEY (Print)

Agent of Respondent

AS TO SIGNATURE OF RESPONDENT ONLY

Sworn to and subscribed before me this 24th **day of** June, 2021.

L. D. Nathan

NOTARY PUBLIC

My commission expires:

L DENISE NATHAN NOTARY PUBLIC MECKLENBURG COUNTY, NC My Commission Expires 11-07-2024

This voluntary cease and desist is hereby accepted this 6th day of July, 2021.

GEORGIA STATE BOARD OF PHARMACY

BY: _____
MICHAEL BRINSON, R.Ph.
President

with express permission by Eric Lacefield, Executive Director

ATTEST: _____
ERIC R. LACEFIELD
Executive Director

(Board Seal)

GEORGIA BOARD OF PHARMACY

GOVERNOR
Brian P. Kemp

EXECUTIVE DIRECTOR
Eric R. Lacefield

2 Peachtree St. N.W., 6th Floor • Atlanta, Georgia 30303 • Tel: 404.651.8000 • Fax 470.386.6137
www.gbp.georgia.gov

May 25, 2021

RECEIVED
JUN - 8 2021
DENTSPLY SIRONA LEGAL DEPT.

Sent via Certified Mail: 7018 1830 0000 6103 6419

Dentsply North America, LLC
221 W. Philadelphia St., Ste. 60W
York, PA 17401

Re: Voluntary Cease and Desist

Dear Agent of Dentsply North America, LLC:

The Georgia Board of Pharmacy ("Board") has been made aware that Dentsply North America, LLC has shipped prescription drugs into Georgia without obtaining proper licensure to conduct such business. See O.C.G.A. §§ 16-13-35, 16-13-72, 26-4-110(a), 26-4-113, and 26-4-115. Shipping drugs into Georgia without proper licensure is a criminal offense. To date the Board has not received an application for licensure.

Please find enclosed a Voluntary Cease and Desist from the Georgia Board of Pharmacy. This document should be reviewed by Dentsply North America, LLC's independent counsel, signed by a representative with the authority to do so, and returned to the Board. If Dentsply North America, LLC chooses not to sign the cease and desist voluntarily, please respond with a statement to the Board containing an explanation so next steps can be determined.

Please return the signed form or explanation statement by June 25, 2021.

If you have any questions regarding this matter or any other matter related to the practice of pharmacy in Georgia, please contact the staff at the Board's office at your convenience: (404) 651-8000.

Sincerely,

Georgia State Board of Pharmacy

Enclosures

BEFORE THE GEORGIA STATE BOARD OF PHARMACY

STATE OF GEORGIA

IN THE MATTER OF:	*
	*
Dentsply North America, LLC	*
	*
Respondent.	*

VOLUNTARY CEASE AND DESIST ORDER

Respondent, Dentsply North America, LLC, operating at 221 W. Philadelphia Street, Suite 60W, York, PA 17401,

is not licensed to engage in the distribution of drugs or devices in the State of Georgia, pursuant to the Official Code of Georgia Annotated (O.C.G.A.) T. 26, Ch. 4 or T. 16, Ch. 13, as amended. Potential violations of O.C.G.A. T. 26, Ch. 4 and T. 16, Ch. 13 having been called to Respondent's attention, Respondent, through the signing agent, hereby agrees to voluntarily cease and desist from any practice that would require licensure under O.C.G.A. T. 26, Ch. 4, or T. 16, Ch. 13, as amended, until such time as Respondent may become properly licensed or registered by the Georgia State Board of Pharmacy ("Board"). Respondent, through the signing agent, agrees that this includes distribution or delivery of drugs or devices to or receipt of drugs or devices from any person or firm in this state other than intracompany transfers to or from a licensed firm in this state under common ownership.

The Agent of Respondent understands that he/she has a right to a hearing in this matter, and hereby freely, knowingly, and voluntarily waives such right. The Agent of Respondent also understands that should he/she apply for licensure with the Board, the Board shall have access to this Order and to the entire investigative file on this matter.

This Order shall become effective immediately upon acceptance thereof and docketing by the Georgia State Board of Pharmacy and shall remain in effect until such time as the

Respondent becomes licensed with the Board, or until further order. The Agent of Respondent understands that this document will be considered to be a public record entered as the final disposition of any injunction or cease and desist proceedings presently pending or which could be brought against Respondent by the Board, and that this action shall be considered to be and may be recorded as a final order of the Board. **This Order is not intended and shall not be construed as prohibiting the prosecution of Respondent by any other state or federal agency for Respondent's conduct nor shall it be construed as limiting the Board's authority to subsequently impose a fine or conditions upon licensure with the Board.**

Any violation of this Order shall subject the Respondent to a fine not to exceed $500.00 for each transaction constituting a violation thereof, pursuant to O.C.G.A. § 43-1-20.1.

CONSENTED TO:

_____ (Signature)

_____ (Print)
Agent of Respondent

AS TO SIGNATURE OF RESPONDENT ONLY
Sworn to and subscribed before me this _____ day of _____, 20___.

_____
NOTARY PUBLIC
My commission expires:

This voluntary cease and desist is hereby accepted this ___ day of _____, 20___.

GEORGIA STATE BOARD OF PHARMACY

BY:_____
MICHAEL BRINSON, R.Ph.
President

ATTEST:_____
ERIC R. LACEFIELD
Executive Director

(Board Seal)

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Dentsply LLC

Address: 1301 Smile Way City: York State: PA Zip: 17404

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Name:

Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation: Delaware

Parent Company (if any): Dentsply Sirona Inc.

Corporation Name: Dentsply North America LLC

Mailing Address: 13320-B Ballantyne Corporate Place

City: Charlotte State: NC Zip: 28277

Telephone: 910-988-7937 Email: dsstatelic@dentsplysirona.com

Contact Person Name: Mandrell McGill

Date of SEC Registration: 02/29/2016 | SEC Registration Number: CIK 0000818479 | Stock Exchange Symbol: XRAY

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization:

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 6: Partnership

Partnership Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Sole Owner

Owner's Name:

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Dentsply North America LLC

Facility Name

Robert Anthony Johnson

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/14/24

Date

Board Use Only	Date Received: 11/15/25	Amount: $1,000 cc

Annual Registration Successful

Facility: Dentsply North America LLC, Charlotte, North Carolina, UNITED STATES

You have successfully updated your registration and listing information for 2025.

Your registration will be valid through Dec 31, 2025.

Be sure to print this page for your records.

The next registration renewal period is October 1 - December 31, 2025.

Registering your facility and listing devices does not, in any way, constitute FDA approval of your facility or devices.

You may contact the FDA with any questions at reglist@cdrh.fda.gov.

The Owner/Operator Number for this Registration is: 2511302.

Facility Information

Registration Number:	**3014536760**
Initial Importer:	**Y**
Facility Name:	**Dentsply North America LLC**
Legal Name:	**Dentsply North America LLC**
Address:	**13320B Ballantyne Corporate PL., Charlotte, North Carolina, 28277, UNITED STATES**
DUNS Number:	
Foreign Trade Zone:	**N**
Facility URL:	
Other Business Trade Name(s):	
Establishment located on a campus:	

Owner/Operator Information

Owner/Operator Number:	**2511302**
Contact Name:	**Eliane Schaefer**
Company:	**DENTSPLY SIRONA INC**
Address:	**221 WEST PHILADELPHIA ST., SUITE 60W York, PENNSYLVANIA, 17401, UNITED STATES**
Telephone:	**201 - 2945024**
Fax:	**717 - 8494343**
E-mail:	**corporate-ra@dentsplysirona.com**
DUNS Number:	

Official Correspondent Information

Contact Name:	**Eliane Schaefer**
Company:	**Charlotte Ballantyne**
Address:	**221 West Philadelphia Street, Suite 60W York, PENNSYLVANIA, 17401, UNITED STATES**
Telephone:	**1 - 717 - 8494720**
Fax:	**-**
E-mail:	**CharlotteNC-SDS-correspondent@dentsplysirona.com**
DUNS Number:	

No Listings Required.

Imported Products and Manufacturers

Manufacturer(s) Name	Address	Product Code	Device Name	Premarket Submission Number
DEGUDENT GMBH	RODENBACHER CHAUSSEE 4, HANAU, Hesse, 63457, GERMANY	EIH	POWDER, PORCELAIN	K123545
MAILLEFER INSTRUMENTS HOLDING SARL	CH. DU VERGER 3, BALLAIGUES, Vaud, CH-1338, SWITZERLAND	EJL	BUR, DENTAL	
DETAX GMBH	CARL-ZEISS-STR. 4, ETTLINGEN, Baden-Wurttemberg, D-76275, GERMANY	EBH	MATERIAL, IMPRESSION TRAY, RESIN	

DETAX GMBH	CARL-ZEISS-STR. 4, ETTLINGEN, Baden-Wurttemberg, D-76275, GERMANY	KMY	POSITIONER, TOOTH, PREFORMED	
DETAX GMBH	CARL-ZEISS-STR. 4, ETTLINGEN, Baden-Wurttemberg, D-76275, GERMANY	NDP	Accessories, implant, dental, endosseous	
DETAX GMBH	CARL-ZEISS-STR. 4, ETTLINGEN, Baden-Wurttemberg, D-76275, GERMANY	DYT	MAINTAINER, SPACE PREFORMED, ORTHODONTIC	
DETAX GMBH	CARL-ZEISS-STR. 4, ETTLINGEN, Baden-Wurttemberg, D-76275, GERMANY	DYJ	RETAINER, SCREW EXPANSION, ORTHODONTIC	
DETAX GMBH	CARL-ZEISS-STR. 4, ETTLINGEN, Baden-Wurttemberg, D-76275, GERMANY	EBG	CROWN AND BRIDGE, TEMPORARY, RESIN	K200273
DETAX GMBH	CARL-ZEISS-STR. 4, ETTLINGEN, Baden-Wurttemberg, D-76275, GERMANY	KMY	POSITIONER, TOOTH, PREFORMED	K232448
		MQC	Mouthguard, prescription	
VITA ZAHNFABRIK H. RAUTER GMBH & CO. KG.	SPITALGASSE 3, BAD SACKINGEN, Baden-Wurttemberg, D-79704, GERMANY	EIH	POWDER, PORCELAIN	K102128
VITA ZAHNFABRIK H. RAUTER GMBH & CO. KG.	SPITALGASSE 3, BAD SACKINGEN, Baden-Wurttemberg, D-79704, GERMANY	EIH	POWDER, PORCELAIN	K180703
OMNIA SRL	VIA F.DELNEVO 190, FIDENZA, Parma, 43036, ITALY	EFS	UNIT, ORAL IRRIGATION	
SATELEC-ACTEON GROUP	Z.I. DU PHARE, 17, AVENUE GUSTAVE EIFFEL, MERIGNAC, Gironde, 33708, FRANCE	EBZ	ACTIVATOR, ULTRAVIOLET, FOR POLYMERIZATION	K040808
SICAT GMBH & CO. KG	Friesdorfer Strasse 131-135, BONN, North Rhine-Westphalia, 53175, GERMANY	LLZ	System, image processing, radiological	K133320
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EAZ	LIGHT, OPERATING, DENTAL	
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	ELC	Scaler, ultrasonic	K052334
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	NHA	Abutment, implant, dental, endosseous	K111421
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EKX	Handpiece, direct drive, ac-powered	K051661
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EIA	Unit, operative dental	K151045
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	LLZ	System, image processing, radiological	K132773
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	OAS	X-ray, tomography, computed, dental	K103711
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EHD	Unit, x-ray, extraoral with timer	K083344
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	ELW	MATERIAL, IMPRESSION	K080882
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EFA	Handpiece, belt and/or gear driven, dental	K965238
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EBW	Controller, foot, handpiece and cord	K150909
		EIA	Unit, operative dental	
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EHD	Unit, x-ray, extraoral with timer	K033073
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	ILY	Lamp, infrared, therapeutic heating	K180044
		GEX	Powered laser surgical instrument	

SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	ELC	Scaler, ultrasonic	K033640
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	ILY	Lamp, infrared, therapeutic heating	K170500
		GEX	Powered laser surgical instrument	
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	MUH	System, x-ray, extraoral source, digital	K081903
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	NHA	Abutment, implant, dental, endosseous	K100152
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	OAS	X-ray, tomography, computed, dental	K123070
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	OAS	X-ray, tomography, computed, dental	K150217
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	PNP	Dental abutment design software for dental laboratory	K181520
		NHA	Abutment, implant, dental, endosseous	
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	PNN	Orthodontic software	K171122
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	OAS	X-ray, tomography, computed, dental	K191616
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	NDP	Accessories, implant, dental, endosseous	K190059
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	OAS	X-ray, tomography, computed, dental	K201140
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	PNP	Dental abutment design software for dental laboratory	K193408
		NHA	Abutment, implant, dental, endosseous	
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	NOF	System, optical impression, computer assisted design and manufacturing (cad/cam) of dental restorations	
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	EJH	ALLOY, METAL, BASE	
SIRONA DENTAL SYSTEMS GMBH	FABRIKSTRASSE 31, BENSHEIM, Hesse, D-64625, GERMANY	NDP	Accessories, implant, dental, endosseous	
MEDFRUITION ELECTRONICS TECHNOLOGY CO., LTD	Floor 201, Floor 301, Floor 401, Floor 501, Building 12, Liandong Youchuang Park, No. 7 Lianzhong Road, Shishan Town, Nanhai District, Foshan City, Guangdong, 528225, CHINA	EAZ	LIGHT, OPERATING, DENTAL	
Zetta25 AG	Albisriederstrasse 253, Zurich, Zurich, 8047, SWITZERLAND	NOF	System, optical impression, computer assisted design and manufacturing (cad/cam) of dental restorations	
PROTECT-LASERSCHUTZ GMBH	Muehlhofer Hauptstr. 7, Nuremburg, Bavaria, 90453, GERMANY	IWS	Shield, eye, radiological	

Date of Initial Registration: 2023-11-30 10:23:08.0

List of Officers and Directors of Dentsply North America LLC (NOT OWNERS):

Robert Anthony Johnson, Chief Executive Manager (Officer)

- Business address: 13320-B Ballantyne Corporate Place, Charlotte, NC 28277
- [redacted]

Dane A. Baumgardner, Secretary

- Business address: 221 W Philadelphia Street, Ste. 60W, York, PA 17401
- [redacted]

Jennifer F. Shugars, Assistant Secretary

- Business address: 221 W Philadelphia Street, Ste. 60W, York, PA 17401
- [redacted]

Beneficial Ownership of
DENTSPLY North America LLC Chart

DENTSPLY North America LLC is a wholly owned subsidiary of DENTSPLY SIRONA Inc.:



ALL OWNERSHIP PERCENTAGES 100%
CONFIDENTIAL AND PROPRIETARY

List of DENTSPLY SIRONA Inc. Section 16 Officers (NOT OWNERS)

Business address for Corporation and Section 16 Officers:
DENTSPLY SIRONA Inc.
13320-B Ballantyne Corporate Place
Charlotte, NC 28277
Phone: 704-587-0453

Executive Vice President, Corporate Development	Rosenzweig, Richard
General Counsel	Rosenzweig, Richard
Secretary	Rosenzweig, Richard
Chief Human Resources Officer	Frohning, Andrea
Senior Vice President	Frohning, Andrea
Interim Chief Financial Officer	Cueto, Herman V.
Chief Executive Officer	Campion, Simon D.
President	Campion, Simon D.
Senior Vice President	Johnson, Robert Anthony
Chief Supply Chain Officer	Johnson, Robert Anthony

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "DENTSPLY NORTH AMERICA LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "DENTSPLY NORTH AMERICA LLC" WAS FORMED ON THE FOURTH DAY OF MAY, A.D. 2000.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203236204

Date: 03-21-25

3223012 8300

SR# 20251172264

You may verify this certificate online at corp.delaware.gov/authver.shtml

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF AUTHORIZATION
(Limited Liability Company)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

DENTSPLY NORTH AMERICA LLC

is a limited liability company formed under the laws of Delaware as Dentsply North America LLC and was authorized to transact business in the State of North Carolina by issuance of a certificate of authority on 27th day of July, 2018.

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company has not withdrawn from the State of North Carolina, (ii) the said limited liability company's certificate of authority has not been suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively revoked for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial revocation, withdrawal, articles of merger, or articles of conversion for said limited liability company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 9th day of February, 2024.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 118509896-1 Reference# 20776166- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification

NC Dept. of Agriculture & Consumer Services

Food & Drug Protection Division

Firm Name: DENTSPLY NORTH AMERICA LLC

Address: 13320 - B Ballantyne CORPORATE PLACE CHARLOTTE, NC 28277

License Type: Distributor

License Number: 570

Status: ActiveInGoodStanding

Discipline: No

Issue Date: 12/20/2024

Original Issue: 5/1/2023

Expiration Date: 12/31/2025

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 05/08/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com
INSURED Dentsply Sirona Inc. Susquehanna Commerce Center Attn: Jake Rappoldt 221 West Philadelphia Street Suite 60W York, PA 17401	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Insurance Company of the State of Pennsylv — 19429 INSURER B: Allianz Global Corporate & Specialty SE (U — B5244 INSURER C: Zurich Insurance Europe AG — D2213 INSURER D: Great American Assurance Company — 26344 INSURER E: QBE Insurance Corporation — 39217 INSURER F: Endurance Worldwide Insurance Ltd — C2202

COVERAGES **CERTIFICATE NUMBER:** W38967585 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT LOC OTHER:			800280514	05/01/2025	05/01/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 5,000,000 $ 2,000,000 $ 100,000 $ 1,000,000 $ 10,000,000 $ 10,000,000
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			B080117605U25	05/01/2025	05/01/2026	EACH OCCURRENCE AGGREGATE	$ 15,000,000 $ 15,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
C	Excess Liability - 1st Layer			B080124879U25	05/01/2025	05/01/2026	Limit	$10M X $15M

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SEE ATTACHED

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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The ACORD name and logo are registered marks of ACORD

AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		Dentsply Sirona Inc. Susquehanna Commerce Center Attn: Jake Rappoldt 221 West Philadelphia Street Suite 60W York, PA 17401
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

INSURER AFFORDING COVERAGE: Great American Assurance Company NAIC#: 26344
POLICY NUMBER: EXC 5867144 EFF DATE: 05/01/2025 EXP DATE: 05/01/2026

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 2nd Layer	Limit	$15M X $25M

INSURER AFFORDING COVERAGE: QBE Insurance Corporation NAIC#: 39217
POLICY NUMBER: B080124929U25 EFF DATE: 05/01/2025 EXP DATE: 05/01/2026

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 3rd Layer	Limit	$10M X $40M

INSURER AFFORDING COVERAGE: Zurich Insurance Europe AG NAIC#: D2213
POLICY NUMBER: B080117627U25 EFF DATE: 05/01/2025 EXP DATE: 05/01/2026

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 4th Layer	Limit	$40M X $50M

INSURER AFFORDING COVERAGE: QBE Insurance Corporation NAIC#: 39217
POLICY NUMBER: B080123402U25 EFF DATE: 05/01/2025 EXP DATE: 05/01/2026

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 5th Layer	Limit	$25M X $90M

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AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
Willis Towers Watson Southeast, Inc.		Dentsply Sirona Inc. Susquehanna Commerce Center Attn: Jake Rappoldt 221 West Philadelphia Street Suite 60W York, PA 17401
POLICY NUMBER See Page 1		
CARRIER See Page 1	NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

INSURER AFFORDING COVERAGE: Endurance Worldwide Insurance Ltd NAIC#: C2202

POLICY NUMBER: B080126142U25 EFF DATE: 05/01/2025 EXP DATE: 05/01/2026

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 6th Layer	Limit	$10M X $115M

INSURER AFFORDING COVERAGE: ProAssurance Specialty Insurance Company NAIC#: 17400

POLICY NUMBER: N25PA380013 EFF DATE: 05/01/2025 EXP DATE: 05/01/2026

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Products Liability	Each Occurrence	$10,000,000

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SR ID: 27741427 BATCH: 3955670 CERT: W38967585

Subsidiaries of DENTSPLY SIRONA Inc. (the "Company") – December 31, 2024

1. Augma Bio Materials Ltd. (Israel, 20%)
2. Barracuda Partners, L.P. (Delaware, 25%)
3. Byte AU Pty. Ltd. (Australia)
4. Byte AU Unit Trust (Australia)
5. Clear Blue Smiles, Inc. (Delaware, 15%)
6. Datum Biotech Ltd. (Israel)
7. Datum Dental Ltd. (Israel)
8. DeguDent GmbH (Germany)
9. Dentsply - Sirona Poland SP.z.o.o (Poland)
10. Dentsply (Tianjin) International Trading Co. Ltd. (China)
11. Dentsply Argentina S.A.C.e.I. (Argentina)
12. Dentsply BX Sarl (Luxembourg)
13. Dentsply Canada Ltd. (Canada)
14. Dentsply CH Sarl (Luxembourg)
15. Dentsply Chile Comercial Limitada (Chile)
16. Dentsply De Trey GmbH (Germany)
17. Dentsply Dental (Tianjin) Co. Ltd. (China)
18. Dentsply Dental B.V. (Netherlands)
19. Dentsply Dental S.a.r.l. (Luxembourg)
20. Dentsply Europe S.a.r.l. (Luxembourg)
21. DENTSPLY Finance Co. LLC (Delaware)
22. Dentsply GAC Europe SAS (France)
23. Dentsply Germany Investments GmbH (Germany)
24. Dentsply IH A/S (Denmark)
25. Dentsply IH AB (Sweden)
26. Dentsply IH AS (Norway)
27. Dentsply IH GmbH (Germany)
28. Dentsply IH Holdings GmbH (Germany)
29. Dentsply IH Inc. (Delaware)
30. Dentsply IH Ltd (United Kingdom)
31. Dentsply IH Oy (Finland)
32. DENTSPLY Implants (HK) Co. Limited (Hong Kong)
33. Dentsply Implants Manufacturing GmbH (Germany)
34. Dentsply Implants NV (Belgium)
35. Dentsply India Pvt. Ltd. (India)
36. Dentsply Industria e Comercio Ltda. (Brazil)
37. Dentsply Israel Ltd. (Israel)
38. Dentsply Limited (Cayman Islands)
39. Dentsply LLC (Delaware)
40. Dentsply Mexico, S.A. de C.V. (Mexico)
41. Dentsply Nordics AB (Sweden)
42. DENTSPLY North America LLC (Delaware)
43. Dentsply Portugal, Unipessoal. Lda. (Portugal)
44. Dentsply Russia Limited (United Kingdom)
45. Dentsply Sirona (N.Z.) Limited (New Zealand)
46. DENTSPLY SIRONA (PHILS.), INC. (Philippines, 99.999%)
47. Dentsply Sirona (Thailand) Co., Ltd. (Thailand)
48. Dentsply Sirona Arabia Regional Headquarter (Saudi Arabia)
49. Dentsply Sirona Austria GmbH (Austria)
50. Dentsply Sirona Benelux B.V. (Netherlands)

51. Dentsply Sirona Dental Solutions (Shanghai) Co. Ltd. (China)
52. Dentsply Sirona Deutschland GmbH (Germany)
53. Dentsply Sirona Europe GmbH (Austria)
54. Dentsply Sirona France S.A.S. (France)
55. Dentsply Sirona Holdings Inc. (Delaware)
56. Dentsply Sirona Iberia S.A. (Spain)
57. Dentsply Sirona Italia SrL (Italy)
58. DENTSPLY Sirona K.K. (Japan)
59. DENTSPLY Sirona Korea Limited (Korea)
60. Dentsply Sirona Limited Liability Company (Russia)
61. Dentsply Sirona Malaysia Sdn Bhd (Malaysia)
62. Dentsply Sirona Orthodontics Inc. (Delaware)
63. Dentsply Sirona Pty. Ltd. (Australia)
64. Dentsply Sirona Real Estate GmbH (Germany)
65. Dentsply Sirona Reinsurance Limited (Bermuda)
66. Dentsply Sirona Repair Centre (UK) Limited (United Kingdom)
67. Dentsply Sirona Schweiz AG (Switzerland)
68. Dentsply Sirona Singapore Pte. Ltd. (Singapore)
69. Dentsply Sirona Slovakia s.r.o. (Slovakia)
70. Dentsply Sirona South Africa (Proprietary) Limited (South Africa)
71. Dentsply Sirona Switzerland Sarl (Switzerland)
72. Dentsply Sirona SZ I GmbH (Switzerland)
73. Dentsply Sirona SZ II GmbH (Switzerland)
74. Dentsply Sirona US LLC (Delaware)
75. Dentsply Sirona Vietnam Company Limited (Vietnam)
76. Dentsply South Africa (Pty.) Ltd. (South Africa)
77. Dentsply Sweden AB (Sweden)
78. Dentsply Turkey Diş Hekimliği Ürünleri A.Ş (Turkey)
79. Dentsply Ukraine LLC (Ukraine)
80. Dentsply US Inc. (Delaware)
81. DS Dental Instruments SRL (Barbados)
82. DS International Services Inc. (Delaware)
83. DS Rep B.V. (Netherlands)
84. E.S. Healthcare NV (Belgium)
85. E.S. Tooling NV (Belgium)
86. GAC Deutschland GmbH (Germany)
87. JCM International Inc. (Delaware)
88. Maillefer Instruments Holding S.a.r.l. (Switzerland)
89. Maillefer Instruments Plus Sarl (Switzerland)
90. Megalopolis Dental S.A. de C.V. (Mexico)
91. MHT Optic Research AG (Switzerland)
92. Minnesota Medical Technologies Corporation (Minnesota – 10.71%)
93. MIS Implants Technologies Ltd. (Israel)
94. New Britain Medical Supplies, Inc. (Connecticut)
95. Ohio IC Company (Delaware)
96. OraMetrix GmbH (Germany)
97. OraMetrix S.R.L. (Costa Rica)
98. Ortho Concept Sarl (France)
99. Orthodental, S.A. de C.V. (Mexico)
100. Prident (Shanghai) Dental Medical Devices Co., Ltd. (China)
101. Prident International, Inc. (California)
102. PT Dentsply Indonesia (Indonesia)
103. SCI 2R (France)

104. Sirona Dental Comércio de Produtos e Sistemas Odontológicos Ltda. (Brazil)
105. Sirona Dental GmbH (Austria)
106. Sirona Dental Mexico, S. de R.L. de C.V. (Mexico)
107. Sirona Dental Services GmbH (Germany)
108. Sirona Dental Systems Co., Ltd (Thailand)
109. SIRONA Dental Systems GmbH (Germany)
110. Sirona Dental Systems O.O.O. (Russia)
111. Sirona Dental Systems Private Ltd. (India)
112. Sirona Dental Systems Trading, LLC (United Arab Emirates, 49%)
113. Sirona Dental, Inc. (Delaware)
114. SIRONA Immobilien GmbH (Germany)
115. Sirona Technologie GmbH & Co. KG (Germany)
116. SIRONA Verwaltungs GmbH (Germany)
117. Societe de Recherche Techniques Dentaires SAS (France)
118. Straight Smile Limitada (Costa Rica)
119. Straight Smile PEO LLC (Delaware)
120. Straight Smile, LLC (Delaware)
121. The Dental Trading Co., Ltd. (Thailand)
122. Tulsa Dental Products LLC (Delaware)
123. Tuzodent S.A. de C.V. (Mexico)
124. VDW GmbH (Germany)
125. VIPI Indústria, Comércio, Exportação e Importação de Produtos Odontológicos Ltda. (Brazil)
126. Wellspect AB (Sweden)
127. Wellspect AG (Switzerland)
128. Wellspect ApS (Denmark)
129. Wellspect AS (Norway)
130. Wellspect B.V. (Netherlands)
131. Wellspect GmbH (Germany)
132. Wellspect Healthcare GmbH (Austria)
133. Wellspect Inc. (Delaware)
134. Wellspect Ltd. (United Kingdom)
135. Wellspect Medikal Urunler Kimya Turizm Sanayi Ve Ticaret Anonim Sirketi (Turkey)
136. Wellspect Oy (Finland)
137. Wellspect S.A.S. (France)
138. Wellspect S.L. (Spain)
139. Wellspect Srl (Italy)
140. Zetta Digital Healthcare Technology (Suzhou) Ltd. (China)
141. Zetta25 AG (Switzerland)
142. Zhermack GmbH Deutschland (Germany)
143. Zhermack SpA (Italy)
144. ZST Holdings Inc. (Canada, 16.2%)

All ownership percentages are 100% unless otherwise noted

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 07/02/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Southeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: WTW Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@wtwco.com
INSURED Dentsply Sirona Inc. Susquehanna Commerce Center Attn: Jake Rappoldt 221 West Philadelphia Street Suite 60W York, PA 17401	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Insurance Company of the State of Pennsylv — 19429 INSURER B: Allianz Global Corporate & Specialty SE (U — B5244 INSURER C: Zurich Insurance PLC UK Branch — D2213 INSURER D: Great American Assurance Company — 26344 INSURER E: QBE Insurance Corporation — 39217 INSURER F: XL Insurance America Inc — 24554

COVERAGES **CERTIFICATE NUMBER:** W34214198 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY PRO-JECT LOC OTHER:			800279989	05/01/2024	05/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 5,000,000 $ 2,000,000 $ 100,000 $ 1,000,000 $ 10,000,000 $ 10,000,000
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $			B080117605024	05/01/2024	05/01/2025	EACH OCCURRENCE AGGREGATE	$ 15,000,000 $ 15,000,000
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
C	Excess Liability - 1st Layer			B080124879024	05/01/2024	05/01/2025	Limit	$10M X $15M

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

SEE ATTACHED

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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AGENCY CUSTOMER ID: _____

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Willis Towers Watson Southeast, Inc.	Dentsply Sirona Inc. Susquehanna Commerce Center Attn: Jake Rappoldt 221 West Philadelphia Street Suite 60W York, PA 17401
POLICY NUMBER See Page 1	
CARRIER: See Page 1 / NAIC CODE: See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

INSURER AFFORDING COVERAGE: Great American Assurance Company NAIC#: 26344
POLICY NUMBER: EXC 5610445 EFF DATE: 05/01/2024 EXP DATE: 05/01/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 2nd Layer	Limit	$15M X $25M

INSURER AFFORDING COVERAGE: QBE Insurance Corporation NAIC#: 39217
POLICY NUMBER: B080124929U24 EFF DATE: 05/01/2024 EXP DATE: 05/01/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 3rd Layer	Limit	$10M X $40M

INSURER AFFORDING COVERAGE: Zurich Insurance PLC UK Branch NAIC#: D2213
POLICY NUMBER: B080117627U24 EFF DATE: 05/01/2024 EXP DATE: 05/01/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 4th Layer	Limit	$40M X $50M

INSURER AFFORDING COVERAGE: QBE Insurance Corporation NAIC#: 39217
POLICY NUMBER: B080123402U24 EFF DATE: 05/01/2024 EXP DATE: 05/01/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 5th Layer	Limit	$25M X $90M

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SR ID: 26120552 BATCH: 3525514 CERT: W34214198

AGENCY CUSTOMER ID: _____

LOC #: _____

ACORD® ADDITIONAL REMARKS SCHEDULE

AGENCY Willis Towers Watson Southeast, Inc.	NAMED INSURED Dentsply Sirona Inc. Susquehanna Commerce Center Attn: Jake Rappoldt 221 West Philadelphia Street Suite 60W York, PA 17401
POLICY NUMBER See Page 1	
CARRIER See Page 1 / NAIC CODE See Page 1	EFFECTIVE DATE: See Page 1

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

INSURER AFFORDING COVERAGE: XL Insurance America Inc NAIC#: 24554

POLICY NUMBER: US00139769LI24A EFF DATE: 05/01/2024 EXP DATE: 05/01/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Excess Liability - 6th Layer	Limit	$10M X $115M

INSURER AFFORDING COVERAGE: ProAssurance Specialty Insurance Company NAIC#: 17400

POLICY NUMBER: N24PA380009 EFF DATE: 05/01/2024 EXP DATE: 05/01/2025

TYPE OF INSURANCE:	LIMIT DESCRIPTION:	LIMIT AMOUNT:
Products Liability	Each Occurrence	$10,000,000
	MED EXP(Any one pers)	$10,000
	PRODUCTS-COMP/OP AGG	$10,000,000

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SR ID: 26120552 BATCH: 3525514 CERT: W34214198

Subsidiaries of DENTSPLY SIRONA Inc. (the "Company") – December 31, 2023

1. Augma Bio Materials Ltd. (Israel, 20%)
2. Barracuda Partners, L.P. (Delaware, 25%)
3. Byte AU Pty. Ltd. (Australia)
4. Byte AU Unit Trust (Australia)
5. Byteme Aligners Limited (United Kingdom)
6. Clear Blue Smiles, Inc. (Delaware, 15%)
7. Datum Biotech Ltd. (Israel)
8. Datum Dental Ltd. (Israel)
9. DeguDent GmbH (Germany)
10. Dentsply - Sirona Poland SP.z.o.o (Poland)
11. Dentsply (Tianjin) International Trading Co. Ltd. (China)
12. Dentsply Argentina S.A.C.e.I. (Argentina)
13. Dentsply BX Sarl (Luxembourg)
14. Dentsply Canada Ltd. (Canada)
15. Dentsply CH Sarl (Luxembourg)
16. Dentsply Chile Comercial Limitada (Chile)
17. Dentsply De Trey GmbH (Germany)
18. Dentsply Dental (Tianjin) Co. Ltd. (China)
19. Dentsply Dental B.V. (Netherlands)
20. Dentsply Dental S.a.r.l. (Luxembourg)
21. Dentsply Europe S.a.r.l. (Luxembourg)
22. DENTSPLY Finance Co. LLC (Delaware)
23. Dentsply GAC Europe SAS (France)
24. Dentsply Germany Investments GmbH (Germany)
25. Dentsply IH A/S (Denmark)
26. Dentsply IH AB (Sweden)
27. Dentsply IH AS (Norway)
28. Dentsply IH GmbH (Germany)
29. Dentsply IH Holdings GmbH (Germany)
30. Dentsply IH Inc. (Delaware)
31. Dentsply IH Ltd (United Kingdom)
32. Dentsply IH Oy (Finland)
33. DENTSPLY Implants (HK) Co. Limited (Hong Kong)
34. Dentsply Implants Manufacturing GmbH (Germany)
35. Dentsply Implants NV (Belgium)
36. Dentsply India Pvt. Ltd. (India)
37. Dentsply Industria e Comercio Ltda. (Brazil)
38. Dentsply Israel Ltd. (Israel)
39. Dentsply Limited (Cayman Islands)
40. Dentsply LLC (Delaware)
41. Dentsply Mexico, S.A. de C.V. (Mexico)
42. Dentsply Nordics AB (Sweden)
43. DENTSPLY North America LLC (Delaware)
44. Dentsply Portugal, Unipessoal. Lda. (Portugal)
45. Dentsply Russia Limited (United Kingdom)
46. Dentsply Sirona (N.Z.) Limited (New Zealand)
47. DENTSPLY SIRONA (PHILS.), INC. (Philippines)
48. Dentsply Sirona (Thailand) Co., Ltd. (Thailand)
49. Dentsply Sirona Austria GmbH (Austria)
50. Dentsply Sirona Benelux B.V. (Netherlands)

51. Dentsply Sirona Dental Solutions (Shanghai) Co. Ltd. (China)
52. Dentsply Sirona Deutschland GmbH (Germany)
53. Dentsply Sirona Europe GmbH (Austria)
54. Dentsply Sirona France S.A.S. (France)
55. Dentsply Sirona Holdings Inc. (Delaware)
56. Dentsply Sirona Iberia S.A. (Spain)
57. Dentsply Sirona Italia SrL (Italy)
58. DENTSPLY Sirona K.K. (Japan)
59. DENTSPLY Sirona Korea Limited (Korea)
60. Dentsply Sirona Malaysia Sdn Bhd (Malaysia)
61. Dentsply Sirona Limited Liability Company (Russia)
62. Dentsply Sirona Orthodontics Inc. (Delaware)
63. Dentsply Sirona Pty. Ltd. (Australia)
64. Dentsply Sirona Real Estate GmbH (Germany)
65. Dentsply Sirona Schweiz AG (Switzerland)
66. Dentsply Sirona Singapore Pte. Ltd. (Singapore)
67. Dentsply Sirona Slovakia s.r.o. (Slovakia)
68. Dentsply Sirona South Africa (Proprietary) Limited (South Africa)
69. Dentsply Sirona Switzerland Sarl (Switzerland)
70. Dentsply Sirona SZ I GmbH (Switzerland)
71. Dentsply Sirona SZ II GmbH (Switzerland)
72. Dentsply Sirona US LLC (Delaware)
73. Dentsply Sirona Vietnam Company Limited (Vietnam)
74. Dentsply South Africa (Pty.) Ltd. (South Africa)
75. Dentsply Sweden AB (Sweden)
76. Dentsply Turkey Diş Hekimliği Ürünleri A.Ş (Turkey)
77. Dentsply Ukraine LLC (Ukraine)
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79. DS Dental Instruments SRL (Barbados)
80. DS International Services Inc. (Delaware)
81. DS Rep B.V. (Netherlands)
82. E.S. Healthcare NV (Belgium)
83. E.S. Tooling NV (Belgium)
84. GAC Deutschland GmbH (Germany)
85. JCM International Inc. (Delaware)
86. Maillefer Instruments Holding S.a.r.l. (Switzerland)
87. Maillefer Instruments Plus Sarl (Switzerland)
88. Megalopolis Dental S.A. de C.V. (Mexico)
89. MHT Optic Research AG (Switzerland)
90. Minnesota Medical Technologies Corporation (Minnesota – 10.71%)
91. MIS Implants Technologies HK Limited (Hong Kong)
92. MIS Implants Technologies Ltd. (Israel)
93. MİSDENT Implants Diş Ürünleri Sanayi Ticaret Anonim Şirketi (Turkey)
94. New Britain Medical Supplies, Inc. (Connecticut)
95. Oasis Medikal Urunler Kimya Turizm Sanayi Ve Ticaret Anonim Sirketi (Turkey)
96. Ohio IC Company (Delaware)
97. OraMetrix GmbH (Germany)
98. OraMetrix S.R.L. (Costa Rica)
99. Ortho Concept Sarl (France)
100. Orthodental, S.A. de C.V. (Mexico)
101. Prident (Shanghai) Dental Medical Devices Co., Ltd. (China)
102. Prident International, Inc. (California)
103. PT Dedent Supply (Indonesia)

104. PT Dentsply Indonesia (Indonesia)
105. SCI 2R (France)
106. Sirona Dental Comércio de Produtos e Sistemas Odontológicos Ltda. (Brazil)
107. Sirona Dental GmbH (Austria)
108. Sirona Dental Limited Sirketi (Turkey)
109. Sirona Dental Mexico, S. de R.L. de C.V. (Mexico)
110. Sirona Dental Services GmbH (Germany)
111. Sirona Dental Systems Co., Ltd (Thailand, 74.649%)
112. SIRONA Dental Systems GmbH (Germany)
113. Sirona Dental Systems O.O.O. (Russia)
114. Sirona Dental Systems Private Ltd. (India)
115. Sirona Dental Systems Trading, LLC (United Arab Emirates, 49%)
116. Sirona Dental, Inc. (Delaware)
117. SIRONA Immobilien GmbH (Germany)
118. Sirona Technologie GmbH & Co. KG (Germany)
119. SIRONA Verwaltungs GmbH (Germany)
120. Societe de Recherche Techniques Dentaires SAS (France)
121. Straight Smile Limitada (Costa Rica)
122. Straight Smile, LLC (Delaware)
123. Teeth Network Limited (United Kingdom)
124. The Dental Trading Co., Ltd. (Thailand, 100%)
125. Tulsa Dental Products LLC (Delaware)
126. Tuzodent S.A. de C.V. (Mexico)
127. VDW GmbH (Germany)
128. VIPI Indústria, Comércio, Exportação e Importação de Produtos Odontológicos Ltda. (Brazil)
129. Wellspect AB (Sweden)
130. Wellspect AG (Switzerland)
131. Wellspect ApS (Denmark)
132. Wellspect AS (Norway)
133. Wellspect B.V. (Netherlands)
134. Wellspect GmbH (Germany)
135. Wellspect Healthcare GmbH (Austria)
136. Wellspect Inc. (Delaware)
137. Wellspect Ltd. (United Kingdom)
138. Wellspect Oy (Finland)
139. Wellspect S.A.S. (France)
140. Wellspect S.L. (Spain)
141. Wellspect Srl (Italy)
142. Zetta Digital Healthcare Technology (Suzhou) Ltd. (China)
143. Zetta25 AG (Switzerland)
144. Zhermack GmbH Deutschland (Germany)
145. Zhermack SpA (Italy)
146. ZST Holdings Inc. (Canada, 16.2%)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Dentsply North America LLC MDEG License # (if applicable) _____

Physical Address 13320-B Ballantyne Corporate Place

City Charlotte State NC Zip 28277

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 910-988-7937 Website www.dentsplysirona.com

Licensing Company Email dsstatelic@dentsplysirona.com

Section 2: Personal Information

First Mandrell Middle _____ Last McGill

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ☑ M ☐ F ☐ X

Mailing Address 13320-B Ballantyne Corporate Place

City Charlotte State NC Zip 28277

Telephone 910-988-7937 Email dsstatelic@dentsplysirona.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		11/12 - 07/16	
Address	**City**	**State**	**Zip**
4025 Riverpoint PKwy	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Bachelor of Science in Business			

School Name		From - To (MM/YY – MM/YY)	
Terrell High School		08/89 - 06/92	
Address	**City**	**State**	**Zip**
201 Greenwave Blvd	Dawson	GA	39842
Diploma/Degree obtained, if any			
General			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/22 - Pres	[redacted]	York	SC	[redacted]
10/21 - 07/22		Fort Mill	SC	
12/16 - 10/21		Fort Mill	SC	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Dentsply Sirona		10/20 – 12/24	
Business Address	**City**	**State**	**Zip**
13320 Ballantyne Corp Pl.	Charlotte	NC	28277
Phone	**Title**	**Number of Employed Hours**	
704-754-6302	Sr. Facilities Manager	8320 hours	
Description of Duties			
Responsible for the day-to-day operations and maintenance of the Corp HQ.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Madell McH

Original Signature (electronic, copies or stamps not accepted)

12/17/24

Date

I, Mandrell McGill, **certify that as the MDEG Administrator for** Dentsply Sirona,

that I (initial that you have read and meet the following requirements):

1. MM Have a high school diploma or its equivalent;
2. MM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mandrell McGill
Print Name (First, Last)

Mandrell McGill
Original Signature (electronic, copies or stamps not accepted)

12/17/24
Date

Board Use Only	Date Received: 1115725

User ID	Country	First Name	Last Name	Location
2002492	United States	Anthony	Garrison	CharlotteNC (0361)
2002510	United States	Brittany	Jacobs	CharlotteNC (0361)
2002682	United States	Jeremy	Christenberry	CharlotteNC (0361)
2003011	United States	Lindi	Barton-Brobst	CharlotteNC (0361)
2004487	United States	Arjan	de Roy	CharlotteNC (0361)
2007416	United States	Srinivasan	Masilamani	CharlotteNC (0361)
2011002	United States	Eric	Aluise	CharlotteNC (0361)
2011421	United States	Shivanand	Ramlogan	CharlotteNC (0361)
2011708	United States	Bridget	Foor	CharlotteNC (0361)
2012662	United States	James	Miller	CharlotteNC (0361)
2013368	United States	Madeline	Albarran	CharlotteNC (0361)
2013419	United States	Noe	Henriquez	CharlotteNC (0361)
2013434	United States	Rinardo	Henderson	CharlotteNC (0361)
2013445	United States	Stephen	Carrothers	CharlotteNC (0361)
2013449	United States	Talia	Nastacio	CharlotteNC (0361)
2013464	United States	Thomas	Sidey	CharlotteNC (0361)
2013466	United States	Zack	Bowman	CharlotteNC (0361)
2013509	United States	Carol	Cowles	CharlotteNC (0361)
2013511	United States	Chad	Williams	CharlotteNC (0361)
2013517	United States	Christopher	Law	CharlotteNC (0361)
2013542	United States	Harpreet	Rathore	CharlotteNC (0361)
2013556	United States	Jeffery	Lanier	CharlotteNC (0361)
2013565	United States	Johnny	Walker	CharlotteNC (0361)
2013571	United States	Karena	Lanier	CharlotteNC (0361)
2013586	United States	Maria	Hadley	CharlotteNC (0361)
2013587	United States	Marilyn	Baxter	CharlotteNC (0361)
2013707	United States	Bernadette	Ambrosio	CharlotteNC (0361)
2014218	United States	Pradhyoth	Duggirala	CharlotteNC (0361)
2015587	United States	Bethany	Graybill	CharlotteNC (0361)
2017496	United States	LeShundra	Nathan	CharlotteNC (0361)
2018624	United States	Brian	Janko	CharlotteNC (0361)
2018868	United States	Jason	Holmberg	CharlotteNC (0361)
2019047	United States	Sheryl	Norton	CharlotteNC (0361)
2019093	United States	Daniyal	Khusro	CharlotteNC (0361)
2019171	United States	Kristin	Paris	CharlotteNC (0361)
2019811	United States	Phillip	Antoline	CharlotteNC (0361)
2020766	United States	Darren	Morrow	CharlotteNC (0361)
2020767	United States	Chelsea	DePetro	CharlotteNC (0361)
2020939	United States	Constance	Short	CharlotteNC (0361)
2020954	United States	Lori	Schneider	CharlotteNC (0361)
2020981	United States	Joshua	Humphrey	CharlotteNC (0361)
2021346	United States	Steven	Biles	CharlotteNC (0361)
2021368	United States	Thibaut	Taquet	CharlotteNC (0361)

2021694	United States	Ryan	Niccolls	CharlotteNC (0361)
2022075	United States	Melanie	Jenkins	CharlotteNC (0361)
2022130	United States	Daniel	Workinger	CharlotteNC (0361)
2022150	United States	Tiffany	Brook	CharlotteNC (0361)
2022151	United States	Alvaro	Montenegro Valls	CharlotteNC (0361)
2022349	United States	Leah	Chriss	CharlotteNC (0361)
2022469	United States	Patricio	Aycinena	CharlotteNC (0361)
2022481	United States	Marissa	Goodall	CharlotteNC (0361)
2022574	United States	Jinal	Butani	CharlotteNC (0361)
2022630	United States	Pooja	Patel	CharlotteNC (0361)
2022631	United States	Malcolm	Bingham	CharlotteNC (0361)
2022710	United States	Jon	Girardot	CharlotteNC (0361)
2022797	United States	Eneida	Gonzalez	CharlotteNC (0361)
2022846	United States	Ryan	Vitek	CharlotteNC (0361)
2022848	United States	Paige	Miller	CharlotteNC (0361)
2022896	United States	Mandrell	McGill	CharlotteNC (0361)
2022912	United States	Kamran	Tariq	CharlotteNC (0361)
2022936	United States	Hedyeh	Hashemi	CharlotteNC (0361)
2023091	United States	Jean Francois	Aphing-Kouassi	CharlotteNC (0361)
2023148	United States	Adam	Bergan	CharlotteNC (0361)
2023151	United States	Sinclair	Lee	CharlotteNC (0361)
2023243	United States	Anthony	Mondi	CharlotteNC (0361)
2023283	United States	Andrew	Haug	CharlotteNC (0361)
2023300	United States	Christopher	Sergeant	CharlotteNC (0361)
2023442	United States	Brian	Gorman	CharlotteNC (0361)
2023443	United States	Cynthia	Ayscue	CharlotteNC (0361)
2023453	United States	Patrick	Barry	CharlotteNC (0361)
2023470	United States	Courtney	Shanklin	CharlotteNC (0361)
2023574	United States	Magesh	Udayakumar	CharlotteNC (0361)
2023604	United States	Edith	Diaz	CharlotteNC (0361)
2023679	United States	Victoria	Hain	CharlotteNC (0361)
2023820	United States	Joseph	Troublefield	CharlotteNC (0361)
2023886	United States	Davina	Booth	CharlotteNC (0361)
2023898	United States	Adam	Doepel	CharlotteNC (0361)
2023914	United States	Shevella	Riwdy	CharlotteNC (0361)
2023952	United States	Nitin	Dubey	CharlotteNC (0361)
2023953	United States	Brendan	Roberts	CharlotteNC (0361)
2024019	United States	Stephanie	Dingle	CharlotteNC (0361)
2024038	United States	Eric	Vines	CharlotteNC (0361)
2024039	United States	Taylor	Stone	CharlotteNC (0361)
2024120	United States	Michelle	Olsen	CharlotteNC (0361)
2024133	United States	Elena	Matthews	CharlotteNC (0361)
2024187	United States	Joshua	Meute	CharlotteNC (0361)
2024193	United States	Amanda	Cargain	CharlotteNC (0361)

2024261	United States	Brandon	DiStefano	CharlotteNC (0361)
2024342	United States	Won-Joo	Kim	CharlotteNC (0361)
2024392	United States	Jacquelyn	Gildea	CharlotteNC (0361)
2024405	United States	Adam	Quay	CharlotteNC (0361)
2024406	United States	Alexia	Carmichael	CharlotteNC (0361)
2024504	United States	Megan	Garruto	CharlotteNC (0361)
2024505	United States	Marc	Settin	CharlotteNC (0361)
2024559	United States	Matthew	Mickle	CharlotteNC (0361)
2024635	United States	Andrea	Daley	CharlotteNC (0361)
2024862	United States	Bharath	Panyadahundi	CharlotteNC (0361)
2024953	United States	Kyle	Condie	CharlotteNC (0361)
2025077	United States	Graham	Harris	CharlotteNC (0361)
2025082	United States	Jasmine	Moore	CharlotteNC (0361)
2025083	United States	Eric	Lopez	CharlotteNC (0361)
2025086	United States	Grant	Peters	CharlotteNC (0361)
2025087	United States	Noah	Haislip	CharlotteNC (0361)
2025090	United States	Franz	Schmid	CharlotteNC (0361)
2025097	United States	Adelina	Rios Lopez	CharlotteNC (0361)
2025185	United States	Amy	Shook	CharlotteNC (0361)
2025186	United States	Robert	Moody	CharlotteNC (0361)
2025240	United States	Michelle	Rodriguez	CharlotteNC (0361)
2025265	United States	Richard	Hynes	CharlotteNC (0361)
2025348	United States	Emily	Clark	CharlotteNC (0361)
2025606	United States	Avantika	Garg	CharlotteNC (0361)
2025641	United States	Kelley	Ciotti	CharlotteNC (0361)
2025645	United States	Amanda	Elsherif	CharlotteNC (0361)
2025714	United States	Brian	Finley	CharlotteNC (0361)
2025764	United States	Heather	Nelson	CharlotteNC (0361)
2025851	United States	Richa	Agnihotri	CharlotteNC (0361)
2025931	United States	Peter	Nemeth	CharlotteNC (0361)
2025934	United States	Adria	Fabre de Roussac	CharlotteNC (0361)
2025937	United States	Aishwarya	Prakash	CharlotteNC (0361)
2026269	United States	Michelle	Thompson	CharlotteNC (0361)
2026298	United States	Barbra	Beaulieu	CharlotteNC (0361)
2027233	United States	Hanh	Tu	CharlotteNC (0361)
2027296	United States	Jenna	Pinchook	CharlotteNC (0361)
2027299	United States	Alexia	Romero	CharlotteNC (0361)
2027652	United States	Hideyoshi	Johnson	CharlotteNC (0361)
2027702	United States	Jasmin	Rios Lopez	CharlotteNC (0361)
2027953	United States	Salvatore	Pistone	CharlotteNC (0361)
2028063	United States	Casey	Cummings	CharlotteNC (0361)
2028447	United States	Luciano	Bengardino	CharlotteNC (0361)
2028557	United States	Patrick	Siebel	CharlotteNC (0361)
2028575	United States	Kevin	Czerney	CharlotteNC (0361)

2028901	United States	Jodi	Seader	CharlotteNC (0361)
2029161	United States	Rocio Jennifer	Baeza	CharlotteNC (0361)
2029167	United States	Jennifer	Cook	CharlotteNC (0361)
2029510	United States	Shawn	Suber	CharlotteNC (0361)
2029668	United States	Andrea	Terry	CharlotteNC (0361)
2029807	United States	Malique	Williams	CharlotteNC (0361)
2029808	United States	Meredith	West	CharlotteNC (0361)
2029812	United States	Katherine	Sanniota	CharlotteNC (0361)
2029813	United States	Alexandra	Turner	CharlotteNC (0361)
2029814	United States	Brandon	O'Laughlin	CharlotteNC (0361)
2029839	United States	Darryn	Byler	CharlotteNC (0361)
2029907	United States	Alisha	Fligg	CharlotteNC (0361)
2030152	United States	Cynthia	Dew	CharlotteNC (0361)
2030229	United States	Dena	Hudson	CharlotteNC (0361)
2030455	United States	Daniel	Moyer	CharlotteNC (0361)
2030519	United States	Shareen	Knapik	CharlotteNC (0361)
2030571	United States	Eric	Nebel	CharlotteNC (0361)
2030602	United States	William	Benjaminsen	CharlotteNC (0361)
2030708	United States	Zachary	Taylor	CharlotteNC (0361)
2030734	United States	Lauren	Benson	CharlotteNC (0361)
2030740	United States	Stacy	Kotowski	CharlotteNC (0361)
2030890	United States	Bindu Madhavi	Paladugu	CharlotteNC (0361)
2033433	United States	Simon	Campion	CharlotteNC (0361)
2033571	United States	Gabrielle	Mancini	CharlotteNC (0361)
2033572	United States	Logan	Hamilton	CharlotteNC (0361)
2033640	United States	Cara	Vice	CharlotteNC (0361)
2033702	United States	Jean	Lagraba	CharlotteNC (0361)
2033789	United States	Bradley	O'Kelly	CharlotteNC (0361)
2033987	United States	Christian	Beasley	CharlotteNC (0361)
2034038	United States	Rachael	Idakwo	CharlotteNC (0361)
2034267	United States	Jane	Brewster	CharlotteNC (0361)
2034296	United States	Camilo	Agrado	CharlotteNC (0361)
2034359	United States	Jon	Parenteau	CharlotteNC (0361)
2034417	United States	Darlene	Ledbetter	CharlotteNC (0361)
2035037	United States	Bruce	Peatey	CharlotteNC (0361)
2035040	United States	Lindsay	Jackson	CharlotteNC (0361)
2035076	United States	Beatrix	Sipos-Nagy	CharlotteNC (0361)
2035107	United States	Adriane	Shilmover	CharlotteNC (0361)
2035646	United States	Carlton	Austin	CharlotteNC (0361)
2035992	United States	Carly	Hancock	CharlotteNC (0361)
2036950	United States	Nathaniel	Josifovski	CharlotteNC (0361)
2037067	United States	Nicole	Ziefert	CharlotteNC (0361)
2037290	United States	Katherine	Walker	CharlotteNC (0361)
2037854	United States	LUIS	Carrillo	CharlotteNC (0361)

2037855	United States	Luciano	Dellosa	CharlotteNC (0361)
2037856	United States	Samuel	Westmoreland	CharlotteNC (0361)
2037859	United States	Grant	Greenstein	CharlotteNC (0361)
2038052	United States	BRYANT	Boswell	CharlotteNC (0361)
2038487	United States	Andrea	Frohning	CharlotteNC (0361)
2038524	United States	Gary	Foster	CharlotteNC (0361)
2038628	United States	Kimberly	Owens	CharlotteNC (0361)
2038641	United States	David	Porter	CharlotteNC (0361)
2039537	United States	Christopher	Andrews	CharlotteNC (0361)
2039604	United States	Veronica	Dean	CharlotteNC (0361)
2040145	United States	Robert	Kearley	CharlotteNC (0361)
2040515	United States	Marie-Noel	Mukum	CharlotteNC (0361)
2040726	United States	Caitlin	Barnhouse	CharlotteNC (0361)
2041278	United States	Prosper	Mbongue-Muna	CharlotteNC (0361)
2041402	United States	Meera	Ogale	CharlotteNC (0361)
2041678	United States	Annalyn	Monson	CharlotteNC (0361)
2041700	United States	Anthony	Hunter	CharlotteNC (0361)
2041702	United States	Alexandra	Goeddel	CharlotteNC (0361)
2041860	United States	Christie	Forte	CharlotteNC (0361)
2042071	United States	DeMario	Harris	CharlotteNC (0361)
2042893	United States	Alexander	Moreno	CharlotteNC (0361)
2042894	United States	Ella	Mascaro	CharlotteNC (0361)
2042895	United States	Hunter	Jones	CharlotteNC (0361)
2042896	United States	Madeline	Rawls	CharlotteNC (0361)
2042897	United States	Samuel	McNeil	CharlotteNC (0361)
2042898	United States	Spencer	Healey	CharlotteNC (0361)
2042900	United States	Thomas	Serrano	CharlotteNC (0361)
2043037	United States	Sheetal	Soni	CharlotteNC (0361)
2043288	United States	Vikram	Pande	CharlotteNC (0361)
2043498	United States	Katherine	Williams	CharlotteNC (0361)
2043873	United States	Adam	Schmitt	CharlotteNC (0361)
2044048	United States	Sriya	Kakarala	CharlotteNC (0361)
2044073	United States	Qikun	Feng	CharlotteNC (0361)
2044233	United States	Mirjalol	Nugmanov	CharlotteNC (0361)
2044351	United States	Cassandra	Leeper	CharlotteNC (0361)
2044388	United States	Jeremy	Yetter	CharlotteNC (0361)
2044444	United States	Patrick	Morgison	CharlotteNC (0361)
2044445	United States	Jackson	Leavitt	CharlotteNC (0361)
2044446	United States	Annabeth	Sanders	CharlotteNC (0361)
2044469	United States	Jacob	Baldwin	CharlotteNC (0361)
2044470	United States	Desmond	Trogdon	CharlotteNC (0361)
2044471	United States	Cali	Konek	CharlotteNC (0361)
2044498	United States	Noah	Futch	CharlotteNC (0361)
2044581	United States	Devki	Patel	CharlotteNC (0361)

2044583	United States	Jadon	Wooten	CharlotteNC (0361)
2044584	United States	Willow	Abrunza	CharlotteNC (0361)
2044585	United States	Cornell	Dorsey	CharlotteNC (0361)
2044586	United States	Elizabeth	Keyster	CharlotteNC (0361)
2044626	United States	Meredith	Woodard	CharlotteNC (0361)
2044649	United States	Weston	Miller	CharlotteNC (0361)
2044665	United States	Faith	Faircloth	CharlotteNC (0361)
2044668	United States	Madison	Michaud	CharlotteNC (0361)
2044701	United States	Kristin	Jackson	CharlotteNC (0361)
2044750	United States	Helen	Ulrich	CharlotteNC (0361)
2044768	United States	Denzel	Washington	CharlotteNC (0361)
2044769	United States	Corinthia	Bostic	CharlotteNC (0361)
2044796	United States	Bailey	VonSeemann	CharlotteNC (0361)
2044816	United States	Brian	Ranson	CharlotteNC (0361)
2044817	United States	Carsey	Wilder	CharlotteNC (0361)
2044838	United States	Evan	Campbell	CharlotteNC (0361)
2044844	United States	Eric	Grogg	CharlotteNC (0361)
2044847	United States	Morgan	Matthews	CharlotteNC (0361)
2044859	United States	Brianna	Rao	CharlotteNC (0361)
2044860	United States	Douglas	Champagne	CharlotteNC (0361)
2044903	United States	Michael	Schroering	CharlotteNC (0361)
2044904	United States	Christian	Nanna	CharlotteNC (0361)
2044909	United States	Anesia	Cherry	CharlotteNC (0361)
2044945	United States	Reagan	Sands	CharlotteNC (0361)
2044946	United States	Nicholas	Voit	CharlotteNC (0361)
2044955	United States	Tommy	Dawkins	CharlotteNC (0361)
2044956	United States	Conor	Mangan	CharlotteNC (0361)
2044964	United States	Jonathan	Watson	CharlotteNC (0361)
2044985	United States	Hannah	Rugelis	CharlotteNC (0361)
2044994	United States	Marlon	Ubeda	CharlotteNC (0361)
2044995	United States	Ryan	McSorley	CharlotteNC (0361)
2045034	United States	Kristian	Kauserud	CharlotteNC (0361)
2045035	United States	Pearce	DeChamplain	CharlotteNC (0361)
2045036	United States	ShaCoya	Price	CharlotteNC (0361)
2045037	United States	Eric	McLeod	CharlotteNC (0361)
2045038	United States	William	Athanas	CharlotteNC (0361)
2045096	United States	Carsyn	Bolin	CharlotteNC (0361)
2045097	United States	Camryn	Dean	CharlotteNC (0361)
2045098	United States	Kyle	Phillips	CharlotteNC (0361)
2045114	United States	Kailah	Jones	CharlotteNC (0361)
2045130	United States	Sydney	Webb	CharlotteNC (0361)
2045131	United States	Desmond	Curry	CharlotteNC (0361)
2045132	United States	Katherine	Schuh	CharlotteNC (0361)
2045134	United States	Makayla	Gosnell	CharlotteNC (0361)

2045135	United States	Colby	Bruce	CharlotteNC (0361)
2045136	United States	Kristopher	Brucker	CharlotteNC (0361)
2045140	United States	Adam	Baker	CharlotteNC (0361)
2045141	United States	John	Pereira	CharlotteNC (0361)
2045142	United States	Jenna	Galanti	CharlotteNC (0361)
2045147	United States	Hinal	Patel	CharlotteNC (0361)
2045148	United States	Elijah	Weber	CharlotteNC (0361)
2045174	United States	Kathleen	Carpenter	CharlotteNC (0361)
2045224	United States	Addison	Partin	CharlotteNC (0361)
2045225	United States	AliReza	Hamdoon	CharlotteNC (0361)
2045226	United States	Chase	Smith	CharlotteNC (0361)
2045253	United States	Timothy	Funderburk	CharlotteNC (0361)
2045257	United States	Trevor	Moore	CharlotteNC (0361)
2045258	United States	Chloe	Jernigan	CharlotteNC (0361)
2045300	United States	Sara	White	CharlotteNC (0361)
2045301	United States	Olivia	Pollina	CharlotteNC (0361)
2045302	United States	McAulay	Maddox	CharlotteNC (0361)
2045303	United States	Travis	Ziefert	CharlotteNC (0361)
2045352	United States	Hannah	Gwydir	CharlotteNC (0361)
2045407	United States	Katherine	Knowlton	CharlotteNC (0361)
2045442	United States	Taylor	Cosgrove	CharlotteNC (0361)
2045446	United States	Margaret	Bellina	CharlotteNC (0361)
2045479	United States	Noah	Stowman	CharlotteNC (0361)
2045546	United States	Dorothy	Stroupe	CharlotteNC (0361)
2045560	United States	William	Samuel	CharlotteNC (0361)
2045561	United States	Brandon	Catherman	CharlotteNC (0361)
2045562	United States	Quentin	Allison	CharlotteNC (0361)
2045670	United States	Alexandra	Guarini	CharlotteNC (0361)
2045675	United States	Abigail	Erckman	CharlotteNC (0361)
2045676	United States	Adrienne	Rodriguez	CharlotteNC (0361)
2045714	United States	Brynn	Demma	CharlotteNC (0361)
2045719	United States	Megan	Cassidy	CharlotteNC (0361)
2045794	United States	Kimberly	Escobar	CharlotteNC (0361)
2045795	United States	Elizabeth	Kramer	CharlotteNC (0361)
2045796	United States	Matthew	Cummings	CharlotteNC (0361)
2045859	United States	Jonah	Troup	CharlotteNC (0361)
2045881	United States	Alexa	Loscher	CharlotteNC (0361)
2045932	United States	Anne	Kinzler	CharlotteNC (0361)
2045941	United States	Sara	Harrelson	CharlotteNC (0361)
2045942	United States	Colton	Williams	CharlotteNC (0361)
2045943	United States	Nayan	Malhotra	CharlotteNC (0361)
2046014	United States	Grace	Cooley	CharlotteNC (0361)
2046057	United States	Sophia	Mckenzie	CharlotteNC (0361)
2046116	United States	Grant	Thompson	CharlotteNC (0361)

2046117	United States	Elizabeth	Davis	CharlotteNC (0361)
2046231	United States	John	Sheldon	CharlotteNC (0361)
2046346	United States	Michael	Stevenson	CharlotteNC (0361)
2046393	United States	Anna Helena	Teixeira	CharlotteNC (0361)
2046484	United States	Manoj	Pammina	CharlotteNC (0361)
2046612	United States	Johanna	Umberger	CharlotteNC (0361)
2046635	United States	Alfred	Wims	CharlotteNC (0361)
2046668	United States	David	Ferguson	CharlotteNC (0361)
cckxm028	United States	Kathleen	Muller	CharlotteNC (0361)
ccmxp028	United States	Mari	Phelan	CharlotteNC (0361)
cfsjl058	United States	Steven	Lee	CharlotteNC (0361)
dilpp920	United States	David	Zdurne	CharlotteNC (0361)
dimjk050	United States	Matthew	Kozak	CharlotteNC (0361)
divdm965	United States	Jeanne	Ricciardi	CharlotteNC (0361)
dixyi168	United States	Luiz	Ribeiro	CharlotteNC (0361)
mwdxh114	United States	David	Hernandez	CharlotteNC (0361)
tlcfm017	United States	Christine	Mullen	CharlotteNC (0361)
2031356	United States	Ramyaa	Paul	CharlotteNC (0361)
2031366	United States	Kalyan	Kompella	CharlotteNC (0361)
2031369	United States	Vindo Kumar	Koda	CharlotteNC (0361)
2031433	United States	Shanniqua	Alexander	CharlotteNC (0361)
2031438	United States	Wess	Galdamez	CharlotteNC (0361)
2031477	United States	Chandu	Tokala	CharlotteNC (0361)
2031641	United States	Sanjana	Bedral	CharlotteNC (0361)
2031650	United States	Annu	Priya	CharlotteNC (0361)
2031656	United States	Manikanta	Gattigorla	CharlotteNC (0361)
2031752	United States	Ladonya	Ward	CharlotteNC (0361)
2032157	United States	Emily	Reeves	CharlotteNC (0361)
2032158	United States	Jennifer	Bouchard	CharlotteNC (0361)
2032160	United States	Rebecca	DeMeyer	CharlotteNC (0361)
2032322	United States	Koushik	Gowda	CharlotteNC (0361)
2033086	United States	Sayan	Kar	CharlotteNC (0361)
2033358	United States	Eleisa	Barbour	CharlotteNC (0361)
2033440	United States	Pranav Chhaganlal	Nimje	CharlotteNC (0361)
2033843	United States	Satya	Soumya	CharlotteNC (0361)
2033852	United States	Thiriveedi	Venkata Lakshmi Bhargavi	CharlotteNC (0361)
2034010	United States	Anil kumar	Benny	CharlotteNC (0361)
2035337	United States	Nicole	Terry	CharlotteNC (0361)
2037231	United States	Brad	Schatz	CharlotteNC (0361)
2037252	United States	Loganayaki	Kathirvel	CharlotteNC (0361)
2037296	United States	Sudha Suman	Kallamadi	CharlotteNC (0361)
2037305	United States	Geetha-Sree	Nagam	CharlotteNC (0361)
2037307	United States	Ankush	Jain	CharlotteNC (0361)
2037733	United States	Rakesh	Kumar	CharlotteNC (0361)

2037740	United States	Agnibha	Sanyal	CharlotteNC (0361)
2037741	United States	Danny	Krueger	CharlotteNC (0361)
2037742	United States	LUIS	Trejo	CharlotteNC (0361)
2037746	United States	Logan	Jordan	CharlotteNC (0361)
2037775	United States	Jennifer	Davis-Webb	CharlotteNC (0361)
2037972	United States	Brian	Dunkel	CharlotteNC (0361)
2037977	United States	Sanjeev	Deora	CharlotteNC (0361)
2037979	United States	Gia	Kim	CharlotteNC (0361)
2037980	United States	Louise	Brown	CharlotteNC (0361)
2037981	United States	Samantha	Tonda	CharlotteNC (0361)
2037986	United States	Rob	Dewberry	CharlotteNC (0361)
2038042	United States	Nidhi	Singh	CharlotteNC (0361)
2038066	United States	Jason	Murner	CharlotteNC (0361)
2038162	United States	Talatam	Sri Viswa Santosh	CharlotteNC (0361)
2038235	United States	Vishnu	Devan	CharlotteNC (0361)
2038342	United States	Greg	Reeves	CharlotteNC (0361)
2038345	United States	Saskia	Feldman	CharlotteNC (0361)
2038350	United States	Stephanie	Sheldon	CharlotteNC (0361)
2038549	United States	Sean	Sawyer	CharlotteNC (0361)
2038550	United States	Shubhanjali	Agarwal	CharlotteNC (0361)
2038580	United States	Dattatreya	Munshi	CharlotteNC (0361)
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2038648	United States	Rathod	Vikas	CharlotteNC (0361)
2038730	United States	Luke	Mennen	CharlotteNC (0361)
2039107	United States	Gurru	Mukesh Kumar	CharlotteNC (0361)
2039108	United States	Vijay	Kumar Gundla	CharlotteNC (0361)
2039109	United States	Utsav	Tyagi	CharlotteNC (0361)
2039388	United States	Rawa	Osman	CharlotteNC (0361)
2039499	United States	Niladri	Shekhar Rout	CharlotteNC (0361)
2039665	United States	Unnikrishnan	P	CharlotteNC (0361)
2039670	United States	Madhuri	Srinivas Kanagoda	CharlotteNC (0361)
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2039692	United States	Poorni	S	CharlotteNC (0361)
2039724	United States	Shone	Thomas	CharlotteNC (0361)
2039731	United States	Arunvenkatesh	R	CharlotteNC (0361)
2039733	United States	Koppireddy	Lakshmi	CharlotteNC (0361)
2039735	United States	BrahmanandaReddy	Narala	CharlotteNC (0361)
2039790	United States	Jalagam	Sireesha	CharlotteNC (0361)
2039876	United States	Sowmya	T S	CharlotteNC (0361)
2039934	United States	Suresh	Harikrishnan	CharlotteNC (0361)
2039983	United States	Jaisimha	Vakati	CharlotteNC (0361)
2039984	United States	John	Witemire	CharlotteNC (0361)
2039986	United States	Innara	Merchant	CharlotteNC (0361)
2039988	United States	Chris	Stuart	CharlotteNC (0361)

2039989	United States	Arundeep	Thota	CharlotteNC (0361)
2040106	United States	Sudha	Murugesan	CharlotteNC (0361)
2040110	United States	Geetha	Balakrishnan	CharlotteNC (0361)
2040123	United States	Ramesh	Akula	CharlotteNC (0361)
2040283	United States	Hiram	Cruz	CharlotteNC (0361)
2040286	United States	Mark	Eddins	CharlotteNC (0361)
2040392	United States	Pratik	Mane	CharlotteNC (0361)
2040433	United States	Philip	Abba	CharlotteNC (0361)
2040445	United States	Josh	Haddad	CharlotteNC (0361)
2040590	United States	Partha	Kundu	CharlotteNC (0361)
2040636	United States	Gustavo	Reyes	CharlotteNC (0361)
2040638	United States	Aman	Hota	CharlotteNC (0361)
2040639	United States	Anil	Panda	CharlotteNC (0361)
2040665	United States	Rebecca	Vanderbeek	CharlotteNC (0361)
2040709	United States	Iti	Puri	CharlotteNC (0361)
2040713	United States	Craig	Engle	CharlotteNC (0361)
2040715	United States	John	Manza	CharlotteNC (0361)
2040997	United States	Geetha	G	CharlotteNC (0361)
2041242	United States	Harin	Babu	CharlotteNC (0361)
2041363	United States	Vina	Zhang	CharlotteNC (0361)
2041365	United States	Sijo	Sarah	CharlotteNC (0361)
2041437	United States	Neetu	Rani	CharlotteNC (0361)
2041493	United States	Yuriy	Pavlish	CharlotteNC (0361)
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2041593	United States	Dhanush	Kundapura	CharlotteNC (0361)
2041594	United States	Sand	Lopez	CharlotteNC (0361)
2041620	United States	Rosalind	Miller	CharlotteNC (0361)
2041774	United States	Monika	Dsouza	CharlotteNC (0361)
2041840	United States	Nikitha	K S	CharlotteNC (0361)
2041879	United States	Santosh	Sai	CharlotteNC (0361)
2041914	United States	Stephanie	Rua	CharlotteNC (0361)
2041999	United States	Mark	Cagle	CharlotteNC (0361)
2042000	United States	Agen	Pan	CharlotteNC (0361)
2042100	United States	Drew	Rodack	CharlotteNC (0361)
2042105	United States	Jagjot	Singh	CharlotteNC (0361)
2042106	United States	Sreedhar	Kadiyala	CharlotteNC (0361)
2042108	United States	Janet	Bilbao	CharlotteNC (0361)
2042158	United States	Derek	Nicholson	CharlotteNC (0361)
2042165	United States	Ujjawal	Anand	CharlotteNC (0361)
2042262	United States	David	Marks	CharlotteNC (0361)
2042325	United States	Douglas	Rowell	CharlotteNC (0361)
2042466	United States	Karan	Raval	CharlotteNC (0361)
2042576	United States	Vinod	Reddy	CharlotteNC (0361)
2042579	United States	Debbie	Vigil	CharlotteNC (0361)

2042589	United States	Bonnie	Seaton	CharlotteNC (0361)
2042598	United States	Hans	Dudeck	CharlotteNC (0361)
2042646	United States	Diego Armando	Calvo	CharlotteNC (0361)
2042715	United States	Devdutta	Chatterjee	CharlotteNC (0361)
2042880	United States	Kirshna	Gogulapaty	CharlotteNC (0361)
2042883	United States	Alex	Mamone	CharlotteNC (0361)
2043019	United States	Amanda	Moore	CharlotteNC (0361)
2043104	United States	Shirley	Gomez	CharlotteNC (0361)
2043105	United States	Jose	Truque	CharlotteNC (0361)
2043300	United States	Jerry	Wilson	CharlotteNC (0361)
2043368	United States	Bryan	Montes	CharlotteNC (0361)
2043369	United States	Jorge	Soto	CharlotteNC (0361)
2043370	United States	Hilbeberto	Perez	CharlotteNC (0361)
2043494	United States	Sreedhar	CS	CharlotteNC (0361)
2043518	United States	Guggilla	Mounika	CharlotteNC (0361)
2043591	United States	Minhaj	Latif	CharlotteNC (0361)
2043593	United States	Hrishikesh	Deka	CharlotteNC (0361)
2043595	United States	Michaela	Francisco	CharlotteNC (0361)
2043729	United States	Victoria	Lam	CharlotteNC (0361)
2043731	United States	Emilio	Bermudez	CharlotteNC (0361)
2043804	United States	sudeepa	Chowdhury	CharlotteNC (0361)
2043817	United States	Prathyusha	Kukala	CharlotteNC (0361)
2043818	United States	Mahesh	Onteru	CharlotteNC (0361)
2043843	United States	Sander	Volkering	CharlotteNC (0361)
2043985	United States	Yi	Zou	CharlotteNC (0361)
2044013	United States	Tracey	Kramer	CharlotteNC (0361)
2044042	United States	Tingting	Wang	CharlotteNC (0361)
2044060	United States	Ryan	Burnett	CharlotteNC (0361)
2044085	United States	Lemuel	Montana	CharlotteNC (0361)
2044111	United States	Jerri	Zhou	CharlotteNC (0361)
2044131	United States	Morgan	Wilke	CharlotteNC (0361)
2044132	United States	Gabbie	Hoang	CharlotteNC (0361)
2044133	United States	Jack	Fox	CharlotteNC (0361)
2044210	United States	Luke	Champ	CharlotteNC (0361)
2044336	United States	Adam	Marks	CharlotteNC (0361)
2044369	United States	DJ	Levy	CharlotteNC (0361)
2044376	United States	Jessica	Dugan	CharlotteNC (0361)
2044392	United States	Uday	Dodda	CharlotteNC (0361)
2044396	United States	Maria	RAMIREZ	CharlotteNC (0361)
2044417	United States	Khanjan	Saraiya	CharlotteNC (0361)
2044419	United States	Mohana	Kodali	CharlotteNC (0361)
2044420	United States	Sreenivas	Reddy	CharlotteNC (0361)
2044421	United States	Prashanth	KR	CharlotteNC (0361)
2044422	United States	Mohammed	PEPS	CharlotteNC (0361)

2044423	United States	Rajat	GL	CharlotteNC (0361)
2044426	United States	Supreeth	hv	CharlotteNC (0361)
2044436	United States	Joe	Daoud	CharlotteNC (0361)
2044473	United States	Sudha	Dafouti	CharlotteNC (0361)
2044474	United States	Apoorva	Bansal	CharlotteNC (0361)
2044533	United States	Venkat	Soma	CharlotteNC (0361)
2044537	United States	Eric	Balasanyan	CharlotteNC (0361)
2044553	United States	Rohini	NCap	CharlotteNC (0361)
2044681	United States	Sireesh	Maganti	CharlotteNC (0361)
2044710	United States	Malin	Maurice	CharlotteNC (0361)
2044711	United States	Mingku	Lin	CharlotteNC (0361)
2044712	United States	Stalin	Krupanandam	CharlotteNC (0361)
2044713	United States	Ethel	Mbanya	CharlotteNC (0361)
2044714	United States	Elizabeth	Bejarano	CharlotteNC (0361)
2044715	United States	Deborah	Kardash	CharlotteNC (0361)
2044716	United States	Gerre	Bryant	CharlotteNC (0361)
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2044718	United States	David	Elish	CharlotteNC (0361)
2044719	United States	Alejandro	Meneses	CharlotteNC (0361)
2044720	United States	Wesley	Hayden	CharlotteNC (0361)
2044722	United States	Nanda	Kadukuntla	CharlotteNC (0361)
2044724	United States	Srinivas	Pulkaram	CharlotteNC (0361)
2044725	United States	Victor	Rojas	CharlotteNC (0361)
2044726	United States	Franklin	Gerardo Fernandez	CharlotteNC (0361)
2044742	United States	Kelly	Fanning	CharlotteNC (0361)
2044765	United States	Alan	Gorman	CharlotteNC (0361)
2044766	United States	Hamdi	Ayadi	CharlotteNC (0361)
2044770	United States	Rakhi	Garg	CharlotteNC (0361)
2044925	United States	Rajesh	Kumar	CharlotteNC (0361)
2044943	United States	Yang	Yun	CharlotteNC (0361)
2044952	United States	Kavitha	VCap	CharlotteNC (0361)
2044953	United States	Rudrajit	Das	CharlotteNC (0361)
2045031	United States	Bhargav	Somisetty	CharlotteNC (0361)
2045032	United States	Vishwanathan	Krishnamurthy	CharlotteNC (0361)
2045033	United States	Suyash	Agarwal	CharlotteNC (0361)
2045041	United States	Sudheer	Chennamsetty	CharlotteNC (0361)
2045059	United States	Alona	Malynovska	CharlotteNC (0361)
2045060	United States	Cody	Eddins	CharlotteNC (0361)
2045117	United States	Adi	Chinta	CharlotteNC (0361)
2045118	United States	Luke	Russo	CharlotteNC (0361)
2045128	United States	Jesus	Coto	CharlotteNC (0361)
2045133	United States	Ismail	Lewis	CharlotteNC (0361)
2045157	United States	Boobalan	Veerapathiran	CharlotteNC (0361)
2045169	United States	Megan	Harris	CharlotteNC (0361)

2045171	United States	Fadi	Abaid	CharlotteNC (0361)
2045215	United States	Klea	Garcia	CharlotteNC (0361)
2045237	United States	Mariana	Steelsmith	CharlotteNC (0361)
2045273	United States	Rajesh	D-Rajesh	CharlotteNC (0361)
2045274	United States	Roger	Alvarado	CharlotteNC (0361)
2045305	United States	Maria	Barroso	CharlotteNC (0361)
2045366	United States	Jayesh	Talreja	CharlotteNC (0361)
2045368	United States	Girishkumar	Chevuru	CharlotteNC (0361)
2045369	United States	Herman	Cueto	CharlotteNC (0361)
2045432	United States	Vijay	Rex	CharlotteNC (0361)
2045503	United States	JP	Kirch	CharlotteNC (0361)
2045515	United States	George	Delsignore	CharlotteNC (0361)
2045533	United States	Andrew	Lechner	CharlotteNC (0361)
2045534	United States	Saravanan	KEPS	CharlotteNC (0361)
2045535	United States	Poornima	BES	CharlotteNC (0361)
2045536	United States	Raghavendra	SES	CharlotteNC (0361)
2045537	United States	Avinash	Kempi	CharlotteNC (0361)
2045552	United States	Joel	Melkersson Dalen	CharlotteNC (0361)
2045565	United States	Max	Haggard	CharlotteNC (0361)
2045566	United States	Laxman	Sankhala	CharlotteNC (0361)
2045677	United States	Sena	Reddy Jangari	CharlotteNC (0361)
2045711	United States	Riya	Singharoy	CharlotteNC (0361)
2045720	United States	Bishal	Dutta	CharlotteNC (0361)
2045721	United States	Gomathi	Srinilaya	CharlotteNC (0361)
2045722	United States	Ayush	Watnani	CharlotteNC (0361)
2045746	United States	Premnath	Jesudhas	CharlotteNC (0361)
2045747	United States	Praveen	Sampathkumar	CharlotteNC (0361)
2045748	United States	Jonathan	Hales	CharlotteNC (0361)
2045761	United States	Vrushali	Kashinath	CharlotteNC (0361)
2045762	United States	Meghana	hv	CharlotteNC (0361)
2045763	United States	Sreemoyee	Majumder	CharlotteNC (0361)
2045764	United States	Anup	Sinha	CharlotteNC (0361)
2045765	United States	Praveen	Raj	CharlotteNC (0361)
2045766	United States	Naindeep	Kaur	CharlotteNC (0361)
2045767	United States	Neha	Kumari	CharlotteNC (0361)
2045783	United States	Sabhita	MCap	CharlotteNC (0361)
2045813	United States	Balaji	Lakshmanan	CharlotteNC (0361)
2045826	United States	Rakesh	Kimar	CharlotteNC (0361)
2045855	United States	Tejshree	Dalvi	CharlotteNC (0361)
2045861	United States	Satya	Yaamini	CharlotteNC (0361)
2045880	United States	David	Anello	CharlotteNC (0361)
2045888	United States	Caroline	Ford	CharlotteNC (0361)
2045890	United States	Mukesha	Kumara	CharlotteNC (0361)
2045946	United States	Akhilesh	Agnihotri	CharlotteNC (0361)

2045948	United States	Jagdeep	Singh	CharlotteNC (0361)
2045965	United States	Aarti	Kumari	CharlotteNC (0361)
2045982	United States	Tanya	Hores	CharlotteNC (0361)
2045984	United States	Lukas	Hrina	CharlotteNC (0361)
2045986	United States	Derek	Poon	CharlotteNC (0361)
2046135	United States	Agnes	Sahaya Rani	CharlotteNC (0361)
2046148	United States	Anna	Gazova	CharlotteNC (0361)
2046182	United States	Syed	Husain	CharlotteNC (0361)
2046184	United States	Gaurang	Desai	CharlotteNC (0361)
2046194	United States	Grant	Robinson	CharlotteNC (0361)
2046198	United States	Etty	Torrentes	CharlotteNC (0361)
2046264	United States	Carles	Boixadera	CharlotteNC (0361)
2046267	United States	Lars	Loren	CharlotteNC (0361)
2046269	United States	Tamara	Salman	CharlotteNC (0361)
2046340	United States	Harsh	Bhosale	CharlotteNC (0361)
2046362	United States	V Swetha	Sarvani	CharlotteNC (0361)
2046363	United States	Akanksha	Yadav	CharlotteNC (0361)
2046365	United States	Kashish	Chandra	CharlotteNC (0361)
2046366	United States	Jatin	Acharya	CharlotteNC (0361)
2046367	United States	Tae	Park	CharlotteNC (0361)
2046432	United States	Pushpendra	Makwane	CharlotteNC (0361)
2046440	United States	Vikas	Singh	CharlotteNC (0361)
2046453	United States	Bea	Monton	CharlotteNC (0361)
2046454	United States	Matt	Patel	CharlotteNC (0361)
2046455	United States	Fabienne	Azoulay	CharlotteNC (0361)
2046456	United States	Michael	Atienza	CharlotteNC (0361)
2046560	United States	Kelsey	Riner	CharlotteNC (0361)
2046600	United States	Jared	Stevens	CharlotteNC (0361)
2046605	United States	Naveen	Jayaprakash	CharlotteNC (0361)
2046615	United States	Spencer	Meiner	CharlotteNC (0361)
2046636	United States	Souvik	Tah	CharlotteNC (0361)
2046655	United States	Nick	Adams	CharlotteNC (0361)
2046656	United States	Mohit	Gupta	CharlotteNC (0361)
2046751	United States	Rupama	Pal	CharlotteNC (0361)
2046752	United States	Ravi	Chopra	CharlotteNC (0361)
2046846	United States	Michelle	Medina	CharlotteNC (0361)
2046847	United States	Pritika	Bhattacharya	CharlotteNC (0361)
2046898	United States	Mahak	Jain	CharlotteNC (0361)
2046899	United States	Mahadevi	Chetla	CharlotteNC (0361)
2046900	United States	Ilona	Farion	CharlotteNC (0361)
2046904	United States	Ranabir	Raha	CharlotteNC (0361)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended **December 31, 2022**

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

Commission File Number **0-16211**

DENTSPLY SIRONA Inc.

(Exact name of registrant as specified in its charter)

Delaware	**39-1434669**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
13320 Ballantyne Corporate Place, Charlotte, North Carolina	**28277-3607**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code: **(844) 848-0137**

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol	Name of each exchange on which registered
Common Stock, par value $.01 per share	**XRAY**	**The Nasdaq Stock Market LLC**

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.
Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.
Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.
Yes ☒ No ☐

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).
Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company" and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☒ Accelerated Filer ☐ Non-Accelerated Filer ☐ Smaller Reporting Company ☐
Emerging Growth Company ☐ If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C.7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act) Yes ☐ No ☒

The aggregate market value of the voting common stock held by non-affiliates of the registrant computed by reference to the closing price as of the last business day of the registrant's most recently completed second quarter ended June 30, 2022, was $7,664,602,549. Based on the closing price on June 30, 2022. For purpose of this calculation only, without determining whether the following are affiliates of the registrant, the registrant has assumed that (i) its directors and executive officers are affiliates, and (ii) no party who has filed a Schedule 13D or 13G is an affiliate.

The number of shares of the registrant's common stock outstanding as of the close of business on February 16, 2023 was 215,361,909.

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the definitive Proxy Statement of DENTSPLY SIRONA Inc. (the "Proxy Statement") to be used in connection with the 2023 Annual Meeting of Stockholders are incorporated by reference into Part III of this Form 10-K to the extent provided herein. Except as specifically incorporated by reference herein the Proxy Statement is not deemed to be filed as part of this Form 10-K.

DENTSPLY SIRONA Inc.
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PART I

FORWARD-LOOKING STATEMENTS

Information included in or incorporated by reference in this Form 10-K, and other filings with the U.S. Securities and Exchange Commission (the "SEC") and the Company's press releases or other public statements, contains or may contain forward-looking statements. Please refer to a discussion of our forward-looking statements and associated risks in Item 1 "Business- Forward-Looking Statements and Associated Risks" and Item 1A "Risk Factors" of this Form 10-K.

GENERAL

Unless otherwise stated herein or the context otherwise indicates, reference throughout this Form 10-K to "Dentsply Sirona", or the "Company," "we," "us" or "our" refers to financial information and transactions of DENTSPLY SIRONA Inc., together with its subsidiaries on a consolidated basis.

INDUSTRY AND MARKET DATA

Unless indicated otherwise, the information concerning our industry contained in this Form 10-K is based on our general knowledge of and expectations concerning the industry. The Company's market position, market share and industry market size are based on data from various industry analyses, our internal research and data, and adjustments and assumptions we believe to be reasonable. The Company has not independently verified data from industry analyses and cannot guarantee their accuracy or completeness. In addition, we believe that data regarding the industry, market size and its market position and market share within such industry provide general guidance but are inherently imprecise. Further, the Company's estimates and assumptions involve risks and uncertainties and are subject to change based on various factors, including those discussed in Item 1A "Risk Factors" of this Form 10-K. These and other factors could cause results to differ materially from those expressed in the estimates and assumptions.

Item 1. Business

Overview

DENTSPLY SIRONA Inc. ("Dentsply Sirona" or the "Company") is the world's largest manufacturer of professional dental products and technologies, with a 136-year history of innovation and service to the dental industry and patients worldwide. Dentsply Sirona develops, manufactures, and markets comprehensive solutions including technologically-advanced dental equipment as well as dental and healthcare consumable products under a strong portfolio of world class brands. Dentsply Sirona's products provide innovative, high-quality and effective solutions to advance patient care and deliver better, safer and faster dentistry. The Company introduced the first dental electric drill over 131 years ago, the first dental X-ray unit approximately 100 years ago, the first dental computer-aided design/computer-aided manufacturing ("CAD/CAM") system approximately 30 years ago, and numerous other significant innovations including pioneering ultrasonic scaling to increase the speed, effectiveness and comfort of cleaning and revolutionizing both file and apex locater technology to make root canal procedures easier and safer. Dentsply Sirona continues to make significant investments in research and development ("R&D"), and its track record of innovative and profitable new products continues today. Dentsply Sirona's worldwide headquarters is located in Charlotte, North Carolina and its shares of common stock are listed in the United States on Nasdaq under the symbol XRAY.

The Company conducts its business through two reportable segments: (1) Technologies & Equipment ("T&E") and (2) Consumables. For the year ended December 31, 2022, T&E net revenues represented approximately 59.1% of worldwide net revenues, while Consumables net revenues represented the remaining 40.9% of worldwide net revenues.

The business is conducted in the United States of America ("U.S." or "United States"), as well as in over 150 foreign countries, principally through its foreign subsidiaries. Dentsply Sirona has a long-established presence in the European market, particularly in Germany, Sweden, France, the United Kingdom ("UK"), Switzerland and Italy. The Company also has a significant market presence in the Asia-Pacific region, Central and South America, the Middle-East region, and Canada.

Principal Products and Product Categories

The worldwide professional dental industry encompasses the diagnosis, treatment and prevention of disease and ailments of the teeth, gums and supporting bone. The Company offers a broad suite of products which together provide digital workflows for dental practitioners to make the highest use of technological advancements throughout each stage of patient care. Dentsply Sirona's principal product categories are dental technology and equipment products and dental consumable products. Additionally, the Company manufactures and sells healthcare consumable products for urological applications. As part of its technology and equipment solutions, the Company also offers an open, cloud-based platform for digital services. These products and solutions are produced by the Company globally and are distributed throughout the world under some of the most well-established brand names and trademarks in these industries, including but not limited to: AH PLUS, ANKYLOS, AQUASIL ULTRA, ARTICADENT, ASTRA TECH, ATLANTIS, AXANO, AXEOS, BYTE, CALIBRA CEMENTS, CAULK, CAVITRON, CELTRA, CERAMCO, CERCON, CEREC, CEREC MCX, CITANEST, CONFORM FIT, DAC, DELTON, DENTSPLY, DETREY, DS CORE, DYRACT, ESTHET.X, FRIOS, IMPLANT EV, INLAB, INTEGO, IPN, LOFRIC, LUCITONE, MAILLEFER, MIDWEST, MIS, MTM, NAVINA, NUPRO, OMNICAM, OMNITAPER EV, ORAQIX, ORIGO, ORTHOPHOS, OSSEOSPEED, OSSIX, PALODENT, PRIME & BOND, PROFILE, PRIMEMILL, PRIMEPRINT, PRIMESCAN, PRIMETAPER EV, PROGLIDER, PROTAPER ULTIMATE, RECIPROC, PUREVAC, SANI-TIP, SCHICK, SIDEXIS, SIMPLANT, SINIUS, SIROLASER, SIRONA, SLIMLINE, SMARTLITE PRO, SPECTRA ST, STYLUS, SULTAN, SUREFIL, SURESMILE, SYMBIOS, T1, T2, T3, T4, TENEO, THERMAFIL, TRIODENT, TRUBYTE, TRUNATOMY, VDW, VIPI, WAVEONE, WELLSPECT, XENO, XIVE, XYLOCAINE and ZHERMACK.

Technologies & Equipment Segment

Equipment & Instruments

The Equipment & Instruments product category consists of basic and high-tech dental equipment such as treatment centers, imaging equipment, motorized dental handpieces, and other instruments for dental practitioners and specialists. Imaging equipment serves as the starting point for the Company's digital workflow offerings and consists of a broad range of diagnostic imaging systems for 2D or 3D, panoramic, and intra-oral applications. Treatment centers comprise a broad range of products from basic dental chairs to sophisticated chair-based units with integrated diagnostic, hygiene and ergonomic functionalities, as well as specialist centers used in preventive treatment and for training purposes. This product group also includes other lab equipment such as amalgamators, mixing machines and porcelain furnaces.

Implants

The Implants product offering includes technology to support signature digital workflows for implant systems, a portfolio of innovative dental implant products, bone regenerative and restorative solutions, and educational programs, all of which provide dental professionals with a completely new way of practicing implantology. The Implants business is supported by key technologies including custom abutments, advanced tapered immediate load screws and regenerative bone growth factor.

CAD/CAM

Dental CAD/CAM technologies are products designed for dental offices to support numerous digital dental procedures including dental restorations. This product category includes a full-chairside economical restoration of esthetic ceramic dentistry offering called CEREC, as well as stand-alone CAD/CAM, digital impressions ("DI") intra-oral scanners, mills, and services. The full-chairside offering enables dentists to practice same day or single visit dentistry.

Orthodontics

The Company's Orthodontics product category primarily includes a dentist-directed aligner solution, SureSmile, and a direct-to-consumer aligner solution, Byte. The Orthodontics product category also includes a High Frequency Vibration ("HFV") technology device known as VPro or as HyperByte within Byte's product offering. The aligner offerings include software technology that enables aligner treatment planning and for SureSmile seamless connectivity of a digital workflow from diagnostics through treatment delivery.

Healthcare

This category consists mainly of urology catheters and other healthcare-related consumable products.

Consumables Segment

Dental consumable products consist of value-added dental supplies and small equipment used in dental offices for the treatment of patients. It also includes specialized treatment products used within the dental office and laboratory settings including products used in the preparation of dental appliances by dental laboratories.

Endodontic & Restorative Products

The Company's Endodontic & Restorative products frequently work together to provide a tandem solution in high-tech dental procedures. The Endodontic products include drills, filers, sealers, irrigation needles and other tools or single-use solutions which support root canal procedures. Restorative products include dental prosthetics, such as artificial teeth, dental ceramics, digital dentures, precious metal dental alloys, and crown and bridge porcelain products.

Other Consumables

The remaining consumables products include small equipment products such as intraoral curing light systems, dental diagnostic systems and ultrasonic scalers and polishers, as well as other dental supplies including dental anesthetics, prophylaxis paste, dental sealants, impression materials, teeth whiteners and topical fluoride.

Net sales for each product category as a percentage of the Company's total net sales for the year ended December 31, 2022, were as follows:

	% of Net Sales
Equipment & Instruments	17.3 %
Implants	14.5 %
CAD/CAM	12.8 %
Orthodontics	7.6 %
Healthcare	6.9 %
Technology & Equipment segment revenue	59.1 %
Endodontic & Restorative	29.8 %
Other consumables	11.1 %
Consumables segment revenue	40.9 %
Total net sales	100.0 %

Dental Industry, Sales and Distribution

The Company believes that the dental industry is attractive and will grow over the long-term based on the following factors:

- Increasing worldwide population, including a shift towards aging demographics, which will require greater dental care.
- Natural teeth are being retained longer - individuals with natural teeth are much more likely to visit a dentist than those without any natural teeth.
- Increasing demand for aesthetic dentistry and the use of aligners as an orthodontic treatment.
- Continued opportunities in emerging markets related to the rise in discretionary incomes making dental services an increasing priority.
- Increasing demand for single visit dentistry versus historical multi-visit procedure requirements, and for higher quality of patient care in terms of comfort and ease of product use and handling.
- Increasing demand for earlier preventive care - dentistry has evolved from a profession primarily dealing with pain, infections, and tooth decay to one with increased emphasis on earlier diagnosis, preventive care, and the role oral health plays in overall health.

- Increasing opportunity for digital collaboration between General Practitioners ("GPs"), specialists, labs, and patients is creating widening demand for fully integrated solutions such as cloud-based platforms and services facilitated by GPs.
- Increasing demand for more efficiency and better workflow in the dental office, including digital tools such as the enhanced power of diagnostic equipment through 3D imaging. The rapid pace of digital technology adoption including the digitization of clinical workflows is becoming a category standard versus traditional manual processes.

The Company is able to navigate macroeconomic challenges and is well positioned to execute on its strategy of enabling dentists to have superior integrated workflows through its robust market offerings in all key areas of dental procedures (implants, endodontic, restorative and aligners) as well as digital infrastructure (CAD/CAM and imaging) utilized in dental practices around the globe.

As of December 31, 2022, Dentsply Sirona employed approximately 5,000 highly-trained, sales and technical staff specialized in each of our various products and solutions to provide comprehensive marketing, sales, and technical support services to meet the needs of our distributors, dealers and end-users.

Sales and Distribution

Dentsply Sirona distributes approximately two-thirds of its dental consumable and technology and equipment products through third-party distributors. Certain highly technical products such as dental technology equipment, dental ceramics, crown and bridge porcelain products, endodontic instruments and materials, orthodontic aligners and appliances, and dental implants are often sold directly to the dental laboratory or dental professionals in some markets. Additionally, the Company's Byte business produces aligners which are sold direct to consumers under doctor-directed, personalized treatment plans.

For the year ended December 31, 2021, no customer accounted for 10% or more of consolidated net sales or consolidated accounts receivable balance. Customers that accounted for 10% or more of net sales and accounts receivable for the years ended December 31, 2022 and 2020 were as follows:

	2022		2020	
	% of net sales	% of accounts receivable	% of net sales	% of accounts receivable
Henry Schein, Inc.	11 %	15 %	14 %	N/A
Patterson Companies, Inc.	N/A	12 %	10 %	18 %

Although a significant portion of the Company's sales are made to distributors, dealers and importers, Dentsply Sirona focuses much of its marketing efforts on the dentists, dental hygienists, dental assistants, dental laboratories and dental schools which are the end-users of its products. As part of this end-user "pull through" marketing approach, the Company conducts extensive distributor, dealer and end-user marketing programs. Additionally, the Company trains laboratory technicians, dental hygienists, dental assistants and dentists in the proper use of its products and introduces them to the latest technological developments at its educational courses conducted throughout the world. The Company also maintains ongoing consulting and educational relationships with various dental associations and recognized worldwide opinion leaders in the dental field.

Operating Principles

The Company's focus includes the creation of more meaningful solutions for dentists built around the following five key operating principles:

- *Approach customers as one:* Put the customer at the center of how Dentsply Sirona is organized. The Company has an integrated approach to customer service, direct and indirect selling, and clinical education to strengthen the relationship with the customer and better serve the customers' needs.
- *Create innovative solutions that customers love to use:* A comprehensive R&D program that prioritizes strategic spending building the next generation of digital workflow technologies and service offerings, resulting in more impactful innovations each year.
- *Think and act with positive intent and the highest integrity:* Execute the business in a way that empowers our people, respects the communities in which we do business, and establishes trust with our partners and stakeholders.

- *Operate sustainably in everything we do:* Take a thoughtful, proactive approach to creating a sustainable company through investments in our employees, customers, and the environment.
- *Use size and global breadth to our advantage:* The Company is focused on integrating its dental product portfolios to unlock operational efficiencies, including performance improvements in procurement, logistics, manufacturing, sales force and marketing programs; and at the same time simplifying the business on a worldwide scale. In combination, these initiatives will improve organizational efficiency and better leverage the Company's selling, general and administrative infrastructure.

Product Development

While the Company enjoys market leadership in several of its product categories, continuous innovation and product development are critical for it to continue to grow its share in markets it serves. Many of Dentsply Sirona's existing products are undergoing brand extensions, and the Company also continues to focus efforts on successfully launching innovative products that have a more significant impact on how dental and clinical professionals treat their patients. In particular, the Company has continued to prioritize investments supporting digitally enhanced workflows through each stage of patient care, including imaging and scanning technologies used in diagnosis, treatment planning software, and customized products to deliver treatment. During 2022, the Company unveiled its cloud solution DS Core, an open platform developed in collaboration with Google Cloud that integrates digital dentistry workflows across its devices, services, and technologies. The DS Core digital platform is designed to enable more precise and simplified cloud storage, optimize diagnostic capabilities, and streamline existing workflows and collaboration with laboratory partners and specialists. Through R&D investments, the Company has accelerated a number of other new product developments during the year which enhance the digital dentistry offering for both equipment and consumables products. Innovations include the Company's Primeprint Solution to provide medical-grade 3D printing, Primescan Connect which offers a laptop-based version of Primescan, the SmartLite Pro EndoActivator which serves as a new irrigation solution for root canal procedures, and the Axano treatment center combining smart design with efficient workflows. During the year, the Company also introduced its premium EV Implants System for providing implants that are harmonized, simplified and digitally enabled, as well as its enhanced orthodontic offering SureSmile Solutions that includes the addition of a whitening kit, retainers, and the VPro orthodontic device which uses high-frequency vibration to reduce discomfort in aligner treatment.

During 2021, product launches included software upgrades for CEREC and SureSmile introduction of PrimeTaper, a self-tapping implant with a tapered design; and ProTaper Ultimate, the next generation of endodontic files. The Company also acquired key supporting technologies in OSSIX bone regenerative collagen through the purchase of Datum Dental, and the new VPro aligner treatment devices through the acquisition of substantially all of the assets of Propel Orthodontics LLC ("Propel"). During 2020, the Company introduced Axeos, a new digital imaging product with a 3D wide field of view and Primemill, a time saving grinding and milling restoration machine. New products introduced within the past three years accounted for approximately 14% of 2022 sales.

R&D investments include activities to accelerate product and clinical innovation and discipline, and develop potential improvements to the manufacturing process. These investments also support engineering efforts that incorporate customer feedback into continuous improvement for current and next-generation products, with an objective to achieve more frequent development and release cycles. The Company also undertakes pre-commercialization trials and testing of technological improvements prior to inception of the manufacturing process. As is true across its other functions, the Company is continually transforming how R&D is conducted by identifying best practices, driving efficiencies, and optimizing cost structure to enable a more effective development process with a strategic focus on innovation process discipline. We are also looking to increasingly utilize an enterprise approach to funding that employs a returns-based mindset and allocates R&D spend towards those areas with the highest return.

In addition to internal product development, the Company also pursues external R&D opportunities, including acquisitions, licensing, or other arrangements with third parties. Initiatives to support technological development also include collaborations with research institutions and dental and medical schools. The Company annually supports the achievements of dental students conducting innovative research through its *Student Competition for Advancing Dental Research and its Application Awards* program. The Company is also committed to participation in clinical research demonstrating the efficacy of our products prior to market introduction, and in supporting the clinical education and technical training of dental professionals. Dentsply Sirona has 55 academies and education centers that are home to state-of-the-art training facilities for dental professionals who seek a comprehensive variety of clinical and technical continuing education curriculum. The academies offering hands-on teaching, live lectures, and on-demand webinars and courses which are taught by a diverse range of internationally known experts in all fields of dentistry. The Company provides over 7,000 training courses through our DS Academy annually, with approximately 300,000 dental professionals participating.

Through our internal research centers as well as through our collaborations with external research institutions, dental and medical schools, the Company directly invests in the development of new products, improvement of existing products and advances in technology. These investments include an emphasis on research in digital data sharing technology, including the incorporation of long-term artificial intelligence and machine learning. The continued development of these areas is a critical step in meeting the Company's strategic goal as a leader in defining the future of dentistry. The Company's long-term plans for investment in product development include an objective to maintain a level of R&D spend that is at least 4% of annual net sales with a focus on innovation and expansion of digital, software, services, and other platform offerings.

Acquisition Activities

Dentsply Sirona believes that the dental technology and consumable products industries continue to experience consolidation with respect to both product manufacturing and distribution, although they remain fragmented thereby creating a number of acquisition opportunities.

The Company views acquisitions as a key part of its long-term growth strategy. These acquisition activities are intended to supplement the Company's organic growth and assure ongoing expansion of its business to capitalize on significant growth drivers, including new technologies, additional products, organizational strength and geographic breadth. During the first quarter of the year ended December 31, 2021, the Company purchased Datum Dental, Ltd., a producer and distributor of specialized regenerative dental material based in Israel, which provided the Company with a key technology to serve the implants markets. The Company followed in the second quarter of the year ended December 31, 2021 with the purchase of substantially all of the assets of Propel, a U.S. based company which manufactures and sells orthodontic devices and provides in-office and at-home orthodontic accessory devices, this investment is expected to further accelerate the growth and profitability of the Company's combined aligners business. In the third quarter of the year ended December 31, 2021, the Company completed its acquisition of a partially owned affiliate based in Switzerland that primarily develops highly specialized software, which is expected to further accelerate the development of the Company's specialized software related to CAD/CAM systems. During the year ended December 31, 2020, the Company made various investments, including the acquisition of Byte, a direct-to-consumer aligners business, which complements the Company's existing aligner product by adding a digital component and is expected to enhance scale and accelerate the growth of the Company's combined aligners business going forward. This acquisition was representative of the Company's strategy of matching technological advancement in digital dentistry with innovative marketing and delivery in order to reach areas of high-growth potential for customer demand. For more information regarding the Company's acquisition activity, refer to Note 6, Business Combinations, in the Notes to the Consolidated Financial Statements in Part II, Item 8 of this Form 10-K.

Operating and Technical Expertise

Dentsply Sirona believes that its manufacturing capabilities are important to its success. The manufacturing processes of the Company's products require substantial and varied technical expertise. Complex materials technology and processes are necessary to manufacture the Company's products. Where the Company can improve quality and customer service and lower costs, we endeavor to automate our global manufacturing operations.

Financing

Information about Dentsply Sirona's working capital, liquidity and capital resources is provided in Part II, Item 7 "Management's Discussion and Analysis of Financial Condition and Results of Operations" of this Form 10-K.

Competition

The Company conducts its operations, both domestic and foreign, under highly competitive market conditions. Competition in the dental and healthcare consumable products and dental technology and equipment products industries is based primarily upon product performance, quality, safety and ease of use, as well as price, customer service, innovation and acceptance by clinicians, technicians and patients. Dentsply Sirona believes that its principal strengths include its well-established brand names, its reputation for high quality and innovative products, its leadership in product development and manufacturing, its global sales force, the breadth of its product line and distribution network, its commitment to customer satisfaction and support of the Company's products by dental and medical professionals.

The size and number of the Company's competitors vary by product line and from region to region. There are many companies that produce some, but no competitor produces all of the same types of products as those produced by the Company.

Regulation

The development, manufacture, sale and distribution of the Company's products are subject to comprehensive governmental regulation both within and outside the U.S. The following sections describe certain, but not all, of the significant regulations that apply to the Company. For a description of the risks related to the regulations that the Company is subject to, please refer to Item 1A. "Risk Factors" of this Form 10-K.

The majority of the Company's products are classified as medical devices and are subject to restrictions under domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders, including, but not limited to, the U.S. Food, Drug, and Cosmetic Act (the "FDCA"), Council Directive 93/42/EEC on Medical Devices ("MDD") (1993) in the European Union ("EU"), which will be updated to the EU Medical Device Regulation ("MDR") in 2021 (and implementing and local measures adopted thereunder) and similar international laws and regulations. The FDCA requires these products, when sold in the U.S., to be safe and effective for their intended use and to comply with the regulations administered by the U.S. Food and Drug Administration ("FDA"). Certain medical device products are also regulated by comparable agencies in non-U.S. countries in which they are produced or sold.

Dental and medical devices sold by the Company in the U.S. are generally classified by the FDA into a category that renders them subject to the same controls that apply to all medical devices, including regulations regarding alteration, misbranding, notification, record-keeping and good manufacturing practices. In the EU, the Company's products are subject to the medical device laws of the various member states, which are based on a Directive of the European Commission. Such laws generally regulate the safety of the products in a similar way to the FDA regulations. The Company products in Europe bear the CE mark showing that such products comply with European regulations. The Company's products classified by EU MDD were mandated to be certified under the new MDR. These regulations also applied to all medical device manufacturers who market their medical devices in the EU and all such manufacturers had to perform significant upgrades to quality systems and processes including technical documentation and subject them to new certification under EU MDR in order to continue to sell those products in the EU. Although all medical device manufacturers were required to certify their Class I (as defined in the EU MDR regulations) products by May 2021, the EU MDR regulations for additional Classes of medical devices is mandated to be fully enforceable by May 2024. This also includes completion of certified quality management systems to manufacturers quality management systems. The Company remains focused on ensuring that all its products that are considered to be medical devices will be fully certified as required by the EU MDR dates and timelines.

Recently, the Chinese government launched a national program for volume-based, centralized medical device and consumables procurement with minimum quantity commitments in an attempt to negotiate lower prices from drug manufacturers and reduce the price of medical devices and other products. Under the program, the government will award contracts to the lowest bidders who are able to satisfy the quality and quantity requirements. The successful bidders will be guaranteed a sale volume for at least a year, giving the winner an opportunity to gain or increase market share. The volume guarantee is intended to make manufacturers more willing to cut their prices in order to win a bid and may also enable successful bidders to lower their distribution and commercial costs. Many types of drugs are covered under the program, including drugs made by international pharmaceutical companies and generics made by domestic Chinese manufacturers. The program, which is anticipated to take effect in the first half of 2023, could in the future result in reduced margins on covered devices and products, required renegotiation of distributor arrangements, and incurrence of inventory-related charges. The Company currently expects that sales of our Implants products in China will be negatively affected by price reductions.

The Company is also subject to domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders regarding anti-bribery and anti-corruption, including, but not limited to, the U.S. Foreign Corrupt Practices Act ("FCPA"), the U.S. Federal Anti-Kickback Statute ("AKS"), the UK's Bribery Act 2010 (c.23), Brazil's Clean Company Act 2014 (Law No. 12,846) China's National Health and Family Planning Commission ("NHFPC") circulars No. 40 and No. 50, and similar international laws and regulations. The FCPA and similar anti-bribery and anti-corruption laws applicable in non-U.S. jurisdictions generally prohibit companies and their intermediaries from improperly offering or paying anything of value to foreign government officials for the purpose of obtaining or retaining business. Some of the Company's customer relationships are with governmental entities and therefore may be subject to such anti-bribery laws. The AKS and similar fraud and abuse laws applicable in non-U.S. jurisdictions prohibit persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in exchange for or to induce either the referral of an individual, or the furnishing or arranging for a good or service, for which payment may be made under a health care program, such as, in the U.S., Medicare or Medicaid.

The Company's production and sale of products is further subject to regulations concerning the supply of conflict minerals, various environmental regulations such as the Federal Water Pollution Control Act (the "Clean Water Act") and others enforced by the Environmental Protection Agency ("EPA") or equivalent state agencies, and the Patient Protection and Affordable Care Act as amended by the Health Care and Education Reconciliation Act (the "Health Care Reform Law"). In the sale, delivery and servicing of the Company's products to other countries, it must also comply with various domestic and foreign export control and trade embargo laws and regulations, including those administered by the Department of Treasury's Office of Foreign Assets Control ("OFAC"), the Department of Commerce's Bureau of Industry and Security ("BIS") and similar international governmental agencies, which may require licenses or other authorizations for transactions relating to certain countries and/or with certain individuals identified by the respective government. Despite the Company's internal compliance program, policies and procedures may not always protect it from reckless or criminal acts committed by its employees or agents. Violations of these requirements are punishable by criminal or civil sanctions, including substantial fines and imprisonment. Due in part to its direct-to-consumer model, the Company's Byte aligner business in the U.S. is subject to various state laws, rules and policies which govern the practice of dentistry within such state. Byte contracts with an expansive nationwide network of independent licensed dentists and orthodontists for the provision of clinical services, including the oversight and control of each customer's clinical treatment in order to comply with these regulations and ensure that the business does not violate rules pertaining to the corporate practice of dentistry.

The Company is subject to domestic and foreign laws, rules, regulations, self-regulatory codes, circulars and orders governing data privacy and transparency, including, but not limited to, the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 (the "HITECH Act"), the California Consumer Privacy Act, the European General Data Protection Regulation (the "GDPR"), China's Personal Information Protection Law, the Physician Payments Sunshine Provisions of the Patient Protection and Affordable Care Act, the EU Directive 2002/58/EC (and implementing and local measures adopted thereunder), France's Data Protection Act of 1978 (rev. 2004) and France's Loi Bertrand, certain rules issued by Denmark's Health and Medicines Authority, and similar international laws and regulations. HIPAA, as amended by the HITECH Act, the GDPR and similar data-privacy laws applicable in non-U.S. jurisdictions, restrict the use and disclosure of personal health information, mandate the adoption of standards relating to the privacy and security of individually identifiable health information and require us to report certain breaches of unsecured, individually identifiable health information. The Physician Payments Sunshine Provisions of the Patient Protection and Affordable Care Act require the Company to record all transfers of value to physicians and teaching hospitals and to report this data to the Centers for Medicare and Medicaid Services for public disclosure. Similar reporting requirements have also been enacted in several states, and an increasing number of countries worldwide either have adopted or are considering similar laws requiring transparency of interactions with health care professionals.

The Company believes it is in substantial compliance with the laws and regulations that regulate its business. There are, however, significant uncertainties involving the application of various legal requirements, the violation of which could result in, among other things, sanctions. See Item 1A, "Risk Factors" of this Form 10-K for additional detail.

Sources and Supply of Raw Materials and Finished Goods

The Company manufactures the majority of the products that it sells. The Company sources the necessary raw materials from various suppliers, and no single supplier accounts for more than 10% of our supply requirements.

Intellectual Property

Products manufactured by Dentsply Sirona are sold primarily under its own tradenames and trademarks. Dentsply Sirona also owns and maintains more than 5,000 patents throughout the world and has also licensed a number of patents owned by others.

Our policy is to protect its products and technology through patents and trademark registrations both in the U.S. and in significant international markets. The Company monitors trademark use worldwide and promotes enforcement of its patents and trademarks in a manner that is designed to balance the cost of such protection against obtaining the greatest value for the Company. Dentsply Sirona believes its patents and trademark properties are important and contribute to the Company's marketing position but it does not consider its overall business to be materially dependent upon any individual patent or trademark. Additional information regarding certain risks related to our intellectual property is included in Item 1A "Risk Factors" of this Form 10-K and is incorporated herein by reference.

Human Capital

Our employees are core to our Company, and their contributions enable the success of our business. As of December 31, 2022, our organization and its subsidiaries employed over 15,000 employees across the globe. Of these employees, approximately 3,600 were employed in the U.S. Some employees outside of the U.S. and particularly in Europe are covered by collective bargaining, union contracts, worker councils or other similar programs. Our talent strategy prioritizes attracting, engaging, developing, and retaining talent to support our business strategy. We strive to foster a diverse and inclusive environment where every employee can grow and perform at their best.

Attract, Engage, Develop & Retain

In 2022, we continued to evolve our talent strategy to support business priorities. We continued deployment of our Emerging Talent program focused on attracting early-career employees through strategic partnerships with Historically Black Colleges and Universities and local trade schools. The comprehensive program provides rotational assignments, on-the-job experiences, networking events, development sessions and executive interactions. We offer global learning and development opportunities including a partnership with LinkedIn Learning which offers thousands of on-demand learning modules in multiple languages and our custom leadership development framework to assess, develop and coach leaders at multiple levels. Our robust set of tools for goal setting and development planning is designed to support future-focused growth including our employee-led career mapping and global mentor matching programs. We also offer regular performance feedback, development planning and talent review processes in an automated format for our professional employees.

To keep employees connected, engaged and informed, we continued to hold virtual town halls and live video chats. These events provide multiple opportunities for our global workforce to submit questions to our executive leadership team. Employee feedback is an important element of our culture. We launch global engagement surveys at least every 18 months and strategically deploy pulse and lifecycle surveys throughout the year. We leverage insights from these surveys to drive actions that improve the employee experience, supporting talent attraction, engagement, and retention.

Compensation and Benefits

As part of the our total rewards philosophy, we offer competitive compensation and benefit programs designed to attract and retain top talent. We are committed to providing and administering these programs in a way that treats our employees at all levels fairly and equitably. Our total rewards offerings vary by country and include an array of programs that support our employees' financial, physical, and mental well-being, including annual performance incentive opportunities, pension and retirement savings programs, health and welfare benefits, paid time off (including for charitable actions), leave programs, flexible work schedules and employee assistance programs.

Diversity, Equity & Inclusion

Diversity in our organization is a source of great strength. We provide opportunities for all employees to bring their perspective, experience, and lens to the workplace. Our commitment to a diverse workforce helps us create robust solutions to our customers' challenges and drive innovation. We strive to foster an environment in which our teams feel inspired and empowered to do their best work and bring new ideas to the table. We have a Diversity, Equity & Inclusion strategy focused on embedding diversity, equity & inclusion into our culture.

As part of our sustainability program, BEYOND-Taking Action for a Brighter World, we are striving to achieve global gender pay equity and global gender parity by 2025. We are members of the Paradigm for Parity cross-sector diversity commitment – a coalition of more than 130 CEOs, executives, board members, founders and experts dedicated to providing women and men equal opportunity and power and achieving gender parity by 2030.

Diversity, Equity & Inclusion Council

Our Diversity, Equity & Inclusion Council is a group of demographically and functionally diverse employees from across the world dedicated to enabling our diversity, equity & inclusion efforts and championing initiatives that support the organization internally and externally. A top priority of the Diversity, Equity & Inclusion Council is to equip leaders to discuss and be accountable for driving sustained diversity, equity, and inclusion progress.

Employee Resource Groups

The purpose of our employee resource groups is to foster a diverse, equitable, and inclusive environment enabling employees to bring their best to work as they participate in successfully executing our strategy. As of December 31, 2022, our employees have led the successful establishment of seven employee resource groups consisting of approximately 2,000 members from across the globe. Our employee resource groups focus on developing talent, increasing employee engagement, and creating awareness through allyship. We consistently recognize high participation in employee resource group-led events.

Training and Awareness

We offer a catalog of on-demand diversity, equity & inclusion training options aimed at strengthening awareness. A standout offering is our ongoing "Conversations of Understanding" sessions. Employees are invited to register for these small group discussions where internal volunteers share experiences on varying diversity, equity, & inclusion topics to generate healthy discussion and awareness.

Talent Acquisition

Our organization has talent sourcing guidelines requiring diverse and internal candidate interview slates for Director-level and above roles. To increase internal mobility, we offer career development options and utilize our talent review processes to highlight diverse talent. We educate our hiring managers on inclusive hiring practices.

Measuring Progress

Our executive leadership team regularly monitors and actions on diversity metrics, including attraction, engagement, advancement, and retention of diverse talent. We actively partner with an external consultancy to identify available talent pools in all our geographic markets and establish benchmarks for diverse representation across function, geography and level. All executive leaders create annual action plans and progress is reviewed quarterly.

Employee Health & Safety Matters

The health and safety of our employees are of utmost importance to us. We have a dedicated Employee Health & Safety ("EHS") program that provides global processes and trainings and monitors our progress against set goals. Our actions are in line with EHS frameworks and certifications such as OHSAS 18001 and ISO 45001. We also have a Corporate Crisis Management Team, prepared to respond to crisis situations we may be confronted on a global scale with in a prompt and efficient manner.

Other Factors Affecting the Business

The Company's business is subject to quarterly fluctuations in demand due to price changes, marketing and promotional programs, management of inventory levels by distributors, and implementation of strategic initiatives which may impact sales levels in any given period. Demand can also fluctuate based on the timing of dental tradeshows where promotions are offered, major new product introductions, and variability in dental patient traffic, which can be exacerbated by seasonal or severe weather patterns, or other demographic disruptions such as the recent COVID-19 pandemic. Some dental practices in certain countries may also delay purchasing equipment and restocking consumables until year-end due to tax planning which can impact the timing of our consolidated net sales, net income and cash flows. Sales for the industry and the Company are generally strongest in the second and fourth quarters and weaker in the first and third quarters, due to the effects of the items noted above and due to the impact of holidays and vacations, particularly throughout Europe.

Although the backlog on products is generally not material to the financial statements due in part to the Company's efforts to maintain short lead times within its manufacturing, levels can fluctuate and affect sales in certain periods due to supply chain disruption and unavailability of required inputs.

Securities Exchange Act Reports

The SEC maintains a website that contains reports, proxy and information statements, and other information regarding issuers, including the Company, that file electronically with the SEC. The public can obtain any documents that the Company files with the SEC at http://www.sec.gov. The Company files annual reports, quarterly reports, proxy statements and other documents with the SEC under the Securities Exchange Act of 1934, as amended ("Exchange Act").

Dentsply Sirona also makes available free of charge through the investor section of its website at www.dentsplysirona.com its annual report on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K and amendments to these reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act as soon as reasonably practicable after such materials are filed with or furnished to the SEC. The information contained on, or that may be accessed through, the Company's website is not incorporated by reference into, and is not a part of, this report.

Forward-Looking Statements and Associated Risks

All statements in this Form 10-K that do not directly and exclusively relate to historical facts constitute "forward-looking statements." These statements represent current expectations and beliefs, and no assurance can be given that the results described in such statements will be achieved. Such statements are subject to numerous assumptions, risks, uncertainties and other factors that could cause actual results to differ materially from those described in such statements, many of which are outside of our control. No assurance can be given that any expectation, belief, goal or plan set forth in any forward-looking statement can or will be achieved, and readers are cautioned not to place undue reliance on such statements which speak only as of the date they are made. We do not undertake any obligation to update or release any revisions to any forward-looking statement or to report any events or circumstances after the date of this Form 10-K or to reflect the occurrence of unanticipated events.

You should carefully consider these and other relevant factors, including those risk factors in Item 1A, "Risk Factors" of this Form 10-K and any other information included or incorporated by reference in this report, and information which may be contained in the Company's other filings with the SEC, when reviewing any forward-looking statement. Investors should understand it is impossible to predict or identify all such factors or risks. As such, you should not consider either the foregoing lists, or the risks identified in the Company's SEC filings, to be a complete discussion of all potential risks or uncertainties associated with an investment in the Company.

Item 1A. Risk Factors

Summary

The following is a summary of the significant risk factors that could materially impact our business, financial condition or future results, including risks related to our businesses, our international operations, our regulatory environments, ownership of our common stock, COVID-19, and other general risks:

- Management identified material weaknesses in our internal control over financial reporting that resulted in errors in previously issued financial statements. If we fail to remediate these material weaknesses or experiences additional material weaknesses in the future, we may be unable to accurately and timely report financial results or comply with the requirements of being a public company, which could cause the price of our common stock to decline and harm our business.
- We restated certain of our previously issued consolidated financial statements, which resulted in unanticipated costs and may affect investor confidence and raise reputational issues.
- We may be subject to litigation and regulatory examinations, investigations, proceedings or court orders as a result of or relating to our internal investigation and if any of these items are resolved adversely against us, it could harm our business, financial condition and results of operations.
- Our failure to timely file our periodic reports with the SEC limits our access to the public markets to raise debt or equity capital, and restricts our ability to issue equity securities.
- Lack of global standardized processes, centralization of transaction management and/or execution could result in control deficiencies and impact management's assertions and financial reporting.
- We rely heavily on information and technology to operate both our businesses and our technology dependent product solutions portfolios, and any continued cyber incidents with respect to our supporting information and technology infrastructure, whether by deliberate attacks or unintentional events, could harm our operations.
- Privacy concerns and laws, evolving regulation of cross-border data transfer restrictions and other regulations may adversely affect our business.
- We may be unable to develop innovative products and solutions or stimulate customer demand.
- Our ongoing business operations may be disrupted for a significant period of time, resulting in material operating costs and financial losses.
- We may be unable to execute key strategic initiatives due to competing priorities and strategies of our distribution partners and other factors, which may result in financial losses and operational inefficiencies.
- The success of our business depends in part on achieving our strategic objectives, including through acquisitions, dispositions, and strategic investments and initiatives.
- We may fail to realize the expected benefits of our strategic initiatives, including announced or potential future restructuring and transformation efforts.
- We have recognized substantial goodwill and indefinite-lived intangible asset impairment charges, most recently in Q3 and Q4 2022, and may be required to recognize additional goodwill and indefinite-lived intangible asset impairment charges in the future.
- Our failure to obtain patents and, consequently, to protect our proprietary technology could have an adverse impact on our competitive position.
- Our profitability could suffer if third parties infringe upon our intellectual property rights or if our products are found to infringe upon the intellectual property rights of others.
- Changes in our credit ratings or macroeconomic impacts on credit markets may increase our cost of capital and limit financing options.
- A breach of the covenants under our debt instruments outstanding from time to time could result in an event of default under the applicable agreement.
- We may not be able to repay our outstanding debt in the event that we do not generate sufficient cash flow to service our debts and cross default provisions may be triggered due to a breach of covenants under our existing indebtedness.
- Our foreign currency hedging and cash management transactions may be ineffective or only partially mitigate the impact, exposing us to unexpected interest rate volatility.
- Due to the international nature of our business, including increasing exposure to markets outside of the U.S., political or economic changes or other factors could harm our business and financial performance.
- Due to our international operations, we are exposed to the risk of changes in foreign exchange rates.
- Changes in or interpretations of tax rules, operating structures, transfer pricing regulations, country profitability mix and regulations may adversely affect our effective tax rate.
- We may be unable to obtain necessary product approvals and marketing clearances.
- Inadequate levels of reimbursement from governmental or other third-party payers for procedures using our products may cause our revenue to decline.

- Challenges may be asserted against our products due to real or perceived quality, health or environmental issues.
- If we fail to comply with laws and regulations relating to health care fraud, we could suffer penalties or be required to make significant changes to our operations, which could adversely affect our business.
- Our business is subject to extensive, complex and changing domestic and foreign laws, rules, regulations, self-regulatory codes, directives, circulars and orders that failure to comply with which, if not complied with, could subject us to civil or criminal penalties or other liabilities.
- Our quarterly operating results and market price for our common stock may continue to be volatile.
- Certain provisions in our governing documents, and of Delaware law, may make it more difficult for a third party to acquire us.
- Our revenue, results of operations, cash flow, and liquidity may be materially adversely impacted by the ongoing COVID-19 outbreak.
- Our business may be adversely affected by changes in global economic conditions, including inflation, rising interest rates, and supply chain shortages.
- The loss of members of our senior management and the resulting management transition might have an adverse impact on our future operating results.
- Talent gaps and failure to manage and retain top talent may impact our ability to grow the business.
- We face the inherent risk of litigation and claims.
- Climate change and related natural disasters could negatively impact our business and financial results.
- Expectations relating to environmental, social and governance considerations may expose us to potential liabilities, increased costs, reputational harm, and other adverse effects on our business.

Below is a full description of each of such significant risk factors.

RISKS RELATED TO OUR RESTATEMENT AND INTERNAL CONTROLS

Management identified material weaknesses in our internal control over financial reporting that resulted in errors in previously issued financial statements. If we fail to remediate these material weaknesses or experiences additional material weaknesses in the future, we may be unable to accurately and timely report financial results or comply with the requirements of being a public company, which could cause the price of our common stock to decline and harm our business.

Management identified material weaknesses in internal controls over financial reporting in conjunction with the Audit and Finance Committee's investigation as described in the Explanatory Note of Amendment No. 1 to the Annual Report on Form 10-K for the fiscal year ended December 31, 2021 (the "2021 Form 10-K/A"). The description of the material weaknesses that were determined to exist as of December 31, 2021 is included under Item 8 of this Form 10-K. Management began implementing the remediation efforts in 2022; however, as of December 31, 2022, the material weaknesses previously identified have not yet been remediated.

A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting such that there is a reasonable possibility that a material misstatement of our annual or interim financial statements will not be prevented or detected in a timely basis.

While we are devoting substantial resources to the planning and ongoing implementation of remediation efforts to address the identified material weaknesses and prevent additional material weaknesses from occurring, it cannot be assured that the measures we have taken to date, and are continuing to implement, will be sufficient to remediate these material weaknesses or to avoid potential future material weaknesses. We cannot estimate how long the remediation process will take at this time, and may identify deficiencies or other material weaknesses, in addition to the ones already identified, that we may not be able to remediate in a timely manner. Accordingly, there is a reasonable possibility that the material weaknesses identified, or other material weaknesses or deficiencies identified in the future, could result in a misstatement of accounts or disclosures that would result in a material misstatement of our financial statements that would not be prevented or detected on a timely basis or cause us to fail to meet our obligations under securities laws, stock exchange listing rules, or debt instrument covenants to file periodic financial reports on a timely basis.

Further, because of its inherent limitations, including the possibility of human error, the circumvention or overriding of controls, or fraud, even our remediated and effective internal control over financial reporting may not prevent or detect all misstatements and may not provide reasonable assurances with respect to the preparation and presentation of financial statements. In addition, projections of any evaluation of effectiveness of internal control over financial reporting to future periods are subject to the risk that the control may become either obsolete or inadequate as a result of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

4T

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02642	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Intra-Cellular Therapies, Inc.

Physical Address: 100 West Road, Suite 400

City: Towson State: MD Zip: 21204

Mailing Address (if different from physical address): 135 Route 202/206, Suite 6

City: Bedminster State: NJ Zip: 07921

Telephone: 410-842-1030 Website: https://www.intracellulartherapies.com

Name of Designated Representative (DR): Betsy Otranto

Licensing Company Email: statelicensing@intracellulartherapies.c DR Email: botranto@itci-inc.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Military		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attached

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): Johnson & Johnson

Corporation Name: Intra-Cellular Therapies, Inc.

Mailing Address: 135 Route 202/206, Suite 6

City: Bedminster State: NJ Zip: 07921

Telephone: 866-565-2873 Email: ra-psgus_jom_cus_ser@its.jnj.com

Contact Person Name: Marc Larkins

Date of SEC Registration: 9/24/1944	SEC Registration Number: 0000200406	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	NA ✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	NA ✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	NA ✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Intra-Cellular Therapies, Inc.
Facility Name

John Condon
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

4/10/25
Date

Board Use Only	Date Received: 4/21/25	Amount: $1000 ck 3598

An official website of the United States government Here's how you know

FDA

Current through April 16, 2025

You have searched Finished drug products

Search Results: *'intra-cellular'*

Back to Search Page

Showing 1 to 7 of 7 entries Show 50 entries

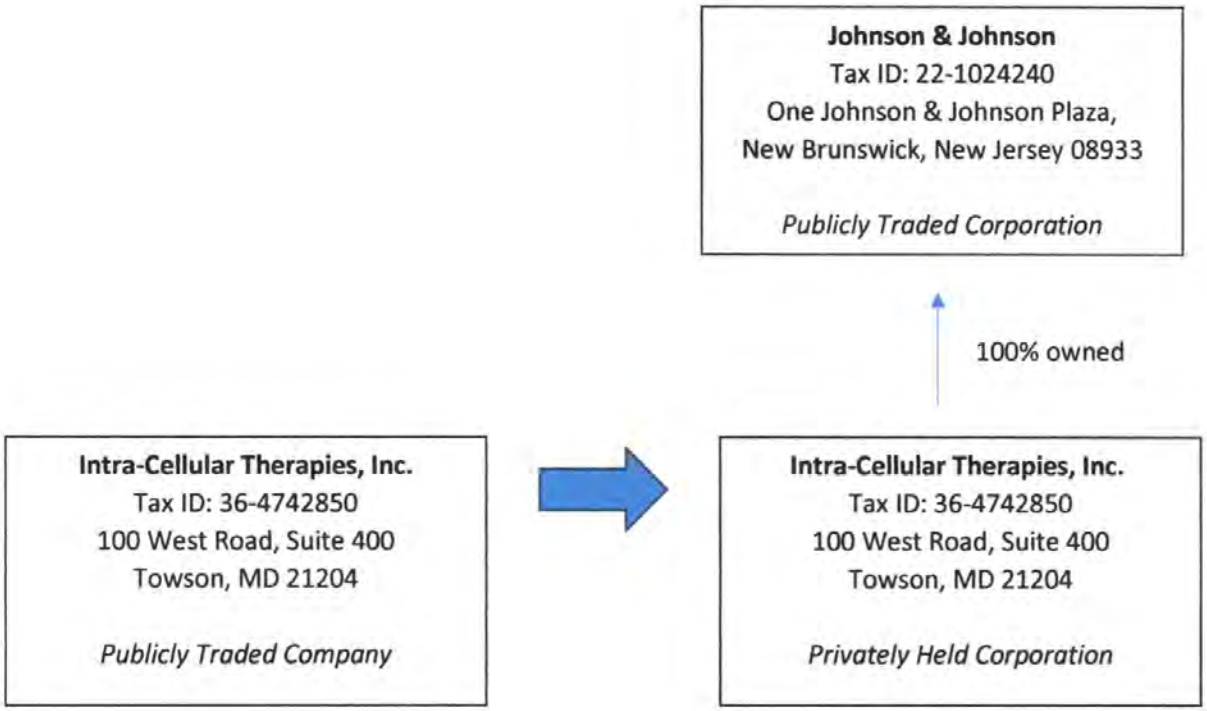
Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Produ
CAPLYTA	72060-110-07	10.5mg/1	CAPSULE	ORAL	NDA209500	Intra-Cellular Therapies, Inc	72060-
CAPLYTA	72060-110-40	10.5mg/1	CAPSULE	ORAL	NDA209500	Intra-Cellular Therapies, Inc	72060-
CAPLYTA	72060-121-07	21mg/1	CAPSULE	ORAL	NDA209500	Intra-Cellular Therapies, Inc	72060-

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Produ
CAPLYTA	72060-121-40	21mg/1	CAPSULE	ORAL	NDA209500	Intra-Cellular Therapies, Inc	72060-
CAPLYTA	72060-142-07	42mg/1	CAPSULE	ORAL	NDA209500	Intra-Cellular Therapies, Inc	72060-
CAPLYTA	72060-142-30	42mg/1	CAPSULE	ORAL	NDA209500	Intra-Cellular Therapies, Inc	72060-
CAPLYTA	72060-142-40	42mg/1	CAPSULE	ORAL	NDA209500	Intra-Cellular Therapies, Inc	72060-

Previous 1 Next

Exhibit A

Pre and Post Org Charts





COMPANY INFORMATION

Intra-Cellular Therapies, Inc.
100 West Road, Suite 400
Towson, Maryland 21204
Phone: (410) 842-1030
Website: https://www.intracellulartherapies.com
Email: statelicensing@intracellulartherapies.com

FEIN: 36-4742850
State of Formation: Delaware
Date Incorporated: 8/29/2012
File Number: 5205371

Ownership Information

Intra-Cellular Therapies, Inc. is 100% owned by Johnson & Johnson.

Parent Company: Johnson & Johnson
Parent Company Address: One Johnson and Johnson Plaza, New Brunswick, NJ 08933
Parent Company Phone: 1 (866) 565-2873
Parent Company FEIN: 22-1024240

CORPORATE OFFICERS

Melissa Joyce Magee, President
Business Address: 135 Route 202/206 Suite 6, Bedminster, NJ 07921
Business Phone: (267) 257-2988

John P Condon, SVP, General Counsel and Assistant Secretary
Business Address: 135 Route 202/206 Suite 6, Bedminster, NJ 07921
Business Phone: (646) 984-1649

Mohit Vatsa, Head of Finance
Business Address: 135 Route 202/206 Suite 6, Bedminster, NJ 07921
Phone: (646) 984-1649

Randall Lamar Nixon, Secretary
Business Address: 1125 Trenton-Harbourton Rd, Titusville, NJ 08560
Business Phone: (908) 347-2977

DESCRIPTION OF OPERATIONS

Intra-Cellular Therapies, Inc. ("Intra-Cellular") is virtual manufacturer of prescription drugs. Intra-Cellular's products are NOT Controlled Substances. As a virtual manufacturer, Intra-Cellular does not manufacture, distribute, or store drug product. Intra-Cellular's products are manufactured by a contract manufacturer and distributed to customers by a Third-Party Logistics Provider.

Intra-Cellular's has approximately 20 employees working on site during normal business hours with hours of operations are 8:00 a.m. – 5:00 p.m. (Eastern Time), Monday through Friday. Intra-Cellular's square footage is 3164 sq. ft.

Intra-Cellular's Labeler code is: 72060
Intra-Cellular's records are stored by the 3pl at their location.

CONTRACT MANUFACTURERS

Gregory Pharmaceutical Holdings, Inc. dba UPM Pharmaceuticals
501 5th Street
Bristol, TN 37620
FEIN: 1000208638

Patheon, Inc.
111 Consumers Drive
Whitby Ontario
Canada L1N 5Z5
FEIN: 3003516812

A+ Secure Packaging LLC dba Cardinal Health Packaging Solutions
339 Mason Rd.
La Vergne, TN 37086
FEIN: 3008816891

THIRD-PARTY LOGISTICS PROVIDERS

Intra-Cellular's Third Party Logistics (3PL) providers manage the storage and distribution of Intra-Cellular's product into the commercial supply chain.

Cardinal Health dba Specialty Pharmaceutical Services
501 Mason Road Ste. 200
La Vergne, TN 37086
Contact: Joel Wayment
Contact Phone: (615) 287-5312

Cardinal Health dba Specialty Pharmaceutical Services
6640 Echo Avenue Suite D
Reno, NV 89506
Contact: Joel Wayment
Contact Phone: (615) 287-5312

PAGE

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "INTRA-CELLULAR THERAPIES, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF APRIL, A.D. 2025.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5205371 8300

SR# 20251425896

Authentication: 203371858

Date: 04-07-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

DISTRIBUTOR REGISTRATION

STATE OF MARYLAND
DEPARTMENT OF HEALTH

183778

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Intra-Cellular Therapies, Inc.
100 West Road
Suite 400
Towson MD 21204

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Intra-Cellular Therapies, Inc.
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2027)

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
D06534	05/31/2027

SIGNATURE OF BEARER

183777

183778

State of Maryland

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Intra-Cellular Therapies, Inc.
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2027)

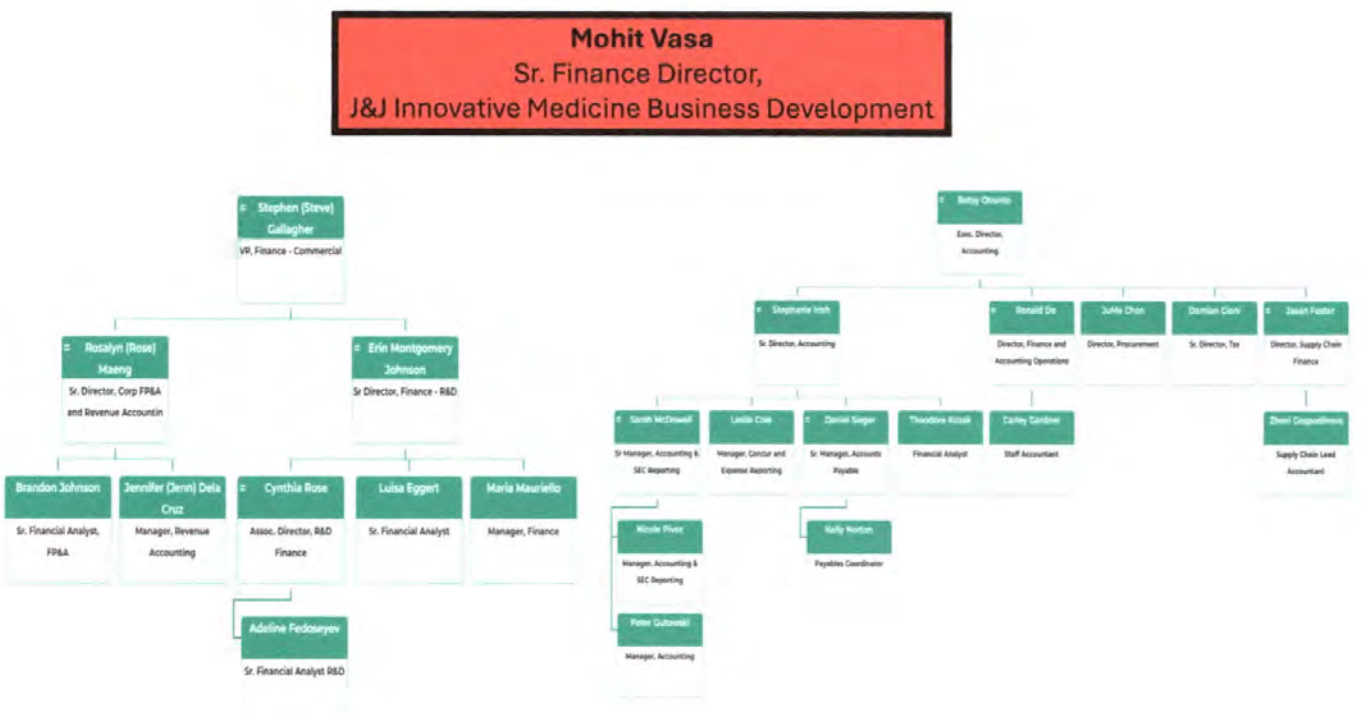
SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D06534	05/31/2027

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES


Mohit Vasa
Sr. Finance Director,
J&J Innovative Medicine Business Development
Stephen (Steve) Gallagher
VP, Finance - Commercial
Rosalyn (Rose) Maeng
Sr. Director, Corp FP&A and Revenue Accountin
Erin Montgomery Johnson
Sr Director, Finance - R&D
Brandon Johnson
Sr. Financial Analyst, FP&A
Jennifer (Jenn) Dela Cruz
Manager, Revenue Accounting
Cynthia Rose
Assoc. Director, R&D Finance
Luisa Eggert
Sr. Financial Analyst
Maria Mauriello
Manager, Finance
Adeline Fedoseyev
Sr. Financial Analyst R&D
Betsy Chiarito
Exec. Director, Accounting
Stephanie Irish
Sr. Director, Accounting
Ronald De
Director, Finance and Accounting Operations
JuMe Chon
Director, Procurement
Damian Cieri
Sr. Director, Tax
Jason Foster
Director, Supply Chain Finance
Sarah McDowell
Sr Manager, Accounting & SEC Reporting
Leslie Cole
Manager, Concur and Expense Reporting
Daniel Sieger
Sr. Manager, Accounts Payable
Theodore Kozak
Financial Analyst
Carley Cardone
Staff Accountant
Zheni Cooperdimova
Supply Chain Lead Accountant
Nicole Piver
Manager, Accounting & SEC Reporting
Peter Gutowski
Manager, Accounting
Nelly Norton
Payables Coordinator

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, DC 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of The Securities Exchange Act of 1934

Date of report (Date of earliest event reported): April 15, 2025

Johnson & Johnson

(Exact name of registrant as specified in its charter)

New Jersey	1-3215	22-1024240
(State or Other Jurisdiction of Incorporation)	(Commission File Number)	(IRS Employer Identification No.)

One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933
(Address of Principal Executive Offices)
(Zip Code)
Registrant's telephone number, including area code:

732-524-0400

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

SECURITIES REGISTERED PURSUANT TO SECTION 12(b) OF THE ACT

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, Par Value $1.00	JNJ	New York Stock Exchange
1.150% Notes Due November 2028	JNJ28	New York Stock Exchange
2.700% Notes due February 2029	JNJ29B	New York Stock Exchange
3.200% Notes Due June 2032	JNJ32	New York Stock Exchange
3.050% Notes due February 2033	JNJ33B	New York Stock Exchange
1.650% Notes Due May 2035	JNJ35	New York Stock Exchange
3.350% Notes Due June 2036	JNJ36A	New York Stock Exchange
3.350% Notes due February 2037	JNJ37B	New York Stock Exchange
3.550% Notes Due June 2044	JNJ44	New York Stock Exchange
3.600% Notes due February 2045	JNJ45	New York Stock Exchange
3.700% Notes due February 2055	JNJ55	New York Stock Exchange

Item 2.02 Results of operations and financial condition

On April 15, 2025, Johnson & Johnson issued the attached press release (Exhibit 99.1) announcing its sales and earnings for the first quarter ended March 30, 2025.

Item 8.01 Other Events

On April 15, 2025, Johnson & Johnson issued the attached press release (Exhibit 99.3) announcing that its Board of Directors declared a 4.8% increase in the quarterly dividend, from $1.24 per share to $1.30 per share, marking the 63rd year of consecutive increases. At the new rate, the indicated dividend on an annual basis is $5.20 per share compared to the previous rate of $4.96 per share. The next quarterly dividend is payable on June 10, 2025 to shareholders of record at the close of business on May 27, 2025. The ex-dividend date is May 27, 2025.

Item 9.01 Financial statements and exhibits

(d) Exhibits.

Exhibit No.	Description of Exhibit
99.1	Press Release dated April 15, 2025 for the period ended March 30, 2025
99.2	Unaudited Comparative Supplementary Sales Data and Condensed Consolidated Statement of Earnings for the fiscal first quarter
99.3	Press Release dated April 15, 2025
104	The cover page from this Current Report on Form 8-K, formatted in Inline XBRL.

Signatures

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

JOHNSON & JOHNSON
(Registrant)

Date: April 15, 2025

By: /s/ Robert J. Decker, Jr.

Robert J. Decker, Jr.
Controller
(Principal Accounting Officer)

Exhibit 99.1

Johnson&Johnson

Media contact:
media-relations@its.jnj.com

Investor contact:
investor-relations@its.jnj.com

For immediate release

Johnson & Johnson reports Q1 2025 results

- *2025 First-Quarter reported sales growth of 2.4% to $21.9 Billion with operational growth of 4.2%* and adjusted operational growth of 3.3%**
- *2025 First-Quarter earnings per share (EPS) increased to $4.54 which includes the reversal of special charges and adjusted EPS increased to $2.77 or 2.2%**
- *Significant new product pipeline progress including approval of TREMFYA in Crohn's disease, data for RYBREVANT/LAZCLUZE overall survival in non-small cell lung cancer and icotrokinra in plaque psoriasis, and initiation of the clinical trial for a general surgery robotic system, OTTAVA*
- *Company increases Full-Year 2025 operational sales[2,5] guidance to reflect the addition of CAPLYTA following the completion of the Intra-Cellular Therapies acquisition*
- *Including tariff costs, dilution from the Intra-Cellular Therapies acquisition, and updated foreign exchange, Company maintains Full-Year 2025 adjusted reported EPS[4] outlook of 6.2%* growth at the mid-point*

New Brunswick, N.J. (April 15, 2025) – Johnson & Johnson (NYSE: JNJ) today announced results for first-quarter 2025. "The power of Johnson & Johnson's uniquely diversified portfolio was on full display this quarter, with strong operational sales growth reinforcing our confidence in 2025 guidance," said Joaquin Duato, Chairman and Chief Executive Officer, Johnson & Johnson. "During the quarter, we fortified our position as an innovation powerhouse with major advancements across our pipeline, including TREMFYA in IBD, RYBREVANT plus LAZCLUZE in non-small-cell lung cancer, and OTTAVA, our soft tissue surgical robotic system, and further enhanced our leading neuroscience portfolio with the completion of the Intra-Cellular Therapies acquisition."

Overall financial results

	Q1		
($ in Millions, expect EPS)	**2025**	**2024**	**% Change**
Reported Sales	$21,893	$ 21,383	2.4%
Net Earnings	$10,999	$3,255	237.9%
EPS (diluted)	$4.54	$1.34	238.8%

	Q1		
Non-GAAP* ($ in Millions, except EPS)	**2025**	**2024**	**% Change**
Operational Sales[1,2]			4.2%
Adjusted Operational Sales[1,3]			3.3%
Adjusted Net Earnings[1,4]	$6,706	$6,580	1.9%
Adjusted EPS (diluted)[1,4]	$2.77	$2.71	2.2%
Free Cash Flow[6,7]	~$3,400	$2,850	

i Non-GAAP financial measure; refer to reconciliations of non-GAAP financial measures included in accompanying schedules

[2] Excludes the impact of translational currency

[3] Excludes the net impact of acquisitions and divestitures and translational currency

[4] Excludes intangible amortization expense and special items

[5] Excludes COVID-19 Vaccine

[6] Non-GAAP measure; defined as cash flow from operating activities, less additions to property, plant and equipment. Cash flow from operations, the most directly comparable GAAP financial measure, will be included in subsequent SEC filings.

[7] First-quarter 2025 is estimated as of April 15, 2025

Note: values may have been rounded

Regional sales results

Q1			% Change			
($ in Millions)	2025	2024	Reported	Operational[1,2]	Currency	Adjusted Operational[1,3]
U.S.	$12,305	$11,620	5.9%	5.9	-	4.4
International	9,588	9,763	(1.8)	2.1	(3.9)	1.9
Worldwide	$21,893	$21,383	2.4%	4.2	(1.8)	3.3

[1] Non-GAAP financial measure; refer to reconciliations of non-GAAP financial measures included in accompanying schedules

[2] Excludes the impact of translational currency

[3] Excludes the net impact of acquisitions and divestitures and translational currency

Note: values may have been rounded

Segment sales results

Q1			% Change			
($ in Millions)	2025	2024	Reported	Operational[1,2]	Currency	Adjusted Operational[1,3]
Innovative Medicine	$13,873	$13,562	2.3%	4.2	(1.9)	4.4
MedTech	8,020	7,821	2.5	4.1	(1.6)	1.3
Worldwide	$21,893	$21,383	2.4%	4.2	(1.8)	3.3

[1] Non-GAAP financial measure; refer to reconciliations of non-GAAP financial measures included in accompanying schedules

[2] Excludes the impact of translational currency

[3] Excludes the net impact of acquisitions and divestitures and translational currency

Note: values may have been rounded

First-Quarter 2025 segment commentary:

Operational sales* reflected below excludes the impact of translational currency.

Innovative Medicine

Innovative Medicine worldwide operational sales grew 4.2%* driven primarily by DARZALEX, CARVYKTI, ERLEADA, and RYBREVANT/LAZCLUZE in Oncology, TREMFYA and SIMPONI/SIMPONI ARIA in Immunology, SPRAVATO in Neuroscience, and XARELTO in Cardiovascular/Metabolism/Other. Growth was partially offset by an approximate (810) basis points impact from STELARA in Immunology.

MedTech

MedTech worldwide operational sales grew 4.1%*, with net acquisitions and divestitures positively impacting growth by 2.8%. Growth was driven primarily by Abiomed in Cardiovascular and wound closure products in General Surgery. Growth was partially offset by Spine, Sports & Other in Orthopaedics.

Full-year 2025 guidance:

Johnson & Johnson does not provide GAAP financial measures on a forward-looking basis because the company is unable to predict with reasonable certainty the ultimate outcome of legal proceedings, unusual gains and losses, acquisition-related expenses, and purchase accounting fair value adjustments without unreasonable effort. These items are uncertain, depend on various factors, and could be material to Johnson & Johnson's results computed in accordance with GAAP.

($ in Billions, except EPS)	April 2025	January 2025
Adjusted Operational Sales[1,2,5] Change vs. Prior Year / Mid-point	2.0% – 3.0% / 2.5%	2.0% – 3.0% / 2.5%
Operational Sales[2,5] / Mid-point Change vs. Prior Year / Mid-point	$91.6B – $92.4B / $92.0B 3.3% – 4.3% / 3.8%	$90.9B – $91.7B / $91.3B 2.5% – 3.5% / 3.0%
Estimated Reported Sales[3,5]/ Mid-point Change vs. Prior Year / Mid-point	$91.0B – $91.8B / $91.4B 2.6% – 3.6% / 3.1%	$89.2B – $90.0B / $89.6B 0.5% – 1.5% / 1.0%
Adjusted Operational EPS (Diluted)[2,4] / Mid-point Change vs. Prior Year / Mid-point	$10.50 – $10.70 / $10.60 5.2% – 7.2% / 6.2%	$10.75 – $10.95 / $10.85 7.7% – 9.7% / 8.7%
Adjusted EPS (Diluted)[3,4] / Mid-point Change vs. Prior Year / Mid-point	$10.50 – $10.70 / $10.60 5.2% – 7.2% / 6.2%	$10.50 – $10.70 / $10.60 5.2% – 7.2% / 6.2%

1 Non-GAAP financial measure; excludes the net impact of acquisitions and divestitures
2 Non-GAAP financial measure; excludes the impact of translational currency
3 Calculated using Euro Average Rate: April 2025 = $1.10 and January 2025 = $1.04 (Illustrative purposes only)
4 Non-GAAP financial measure; excludes intangible amortization expense and special items
5 Excludes COVID-19 Vaccine

Note: percentages may have been rounded

Other modeling considerations will be provided on the webcast

Notable announcements in the quarter:

The information contained in this section should be read together with Johnson & Johnson's other disclosures filed with the Securities and Exchange Commission, including its Current Reports on Form 8-K, Quarterly Reports on Form 10-Q and Annual Reports on Form 10-K. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. The reader is also encouraged to review all other news releases and information available in the Investor Relations section of the company's website at News Releases, as well as Innovative Medicine News Center, MedTech News & Events, and www.factsaboutjnjc.com.

Regulatory	European Commission approves subcutaneous RYBREVANT (amivantamab) for the treatment of patients with advanced EGFR-mutated non-small cell lung cancer[1]	Press Release
	European Commission approves Johnson & Johnson's subcutaneous DARZALEX (daratumumab)-based quadruplet regimen for the treatment of patients with newly diagnosed multiple myeloma, regardless of transplant eligibility[1]	Press Release

	U.S. FDA approves TREMFYA (guselkumab), the first and only IL-23 inhibitor offering both subcutaneous and intravenous induction options, for adult patients with moderately to severely active Crohn's disease	Press Release
	Nipocalimab, the first and only investigational treatment to be granted U.S. FDA Breakthrough Therapy designation for the treatment of adults with moderate-to-severe Sjögren's disease, has now received Fast Track designation	Press Release
Data Releases	Johnson & Johnson MedTech Announces Completion of First Cases with OTTAVA Robotic Surgical System[1]	Press Release
	Icotrokinra results show 75% of adolescents with plaque psoriasis achieved completely clear skin and demonstrate favorable safety profile in a once daily pill[1]	Press Release
	Johnson & Johnson highlights new data that showcase the strength of nipocalimab, demonstrating long-term sustained disease control in adults living with generalized myasthenia gravis (gMG)[1]	Press Release
	TREMFYA (guselkumab) is the first and only IL-23 inhibitor to significantly reduce both the signs and symptoms and the progression of structural damage in adults living with active psoriatic arthritis[1]	Press Release
	Johnson & Johnson MedTech to Highlight Latest Advancements in Heart Disease Treatment with Impella at ACC.25	Press Release
	RYBREVANT (amivantamab-vmjw) plus LAZCLUZE (lazertinib) outperforms osimertinib with a significant and unprecedented overall survival benefit in patients with EGFR-mutated non-small cell lung cancer	Press Release
	New nipocalimab data and real-world research at AAN 2025 highlight positive Phase 3 results and commitment to people living with generalized myasthenia gravis (gMG)	Press Release
	RYBREVANT (amivantamab-vmjw) plus LAZCLUZE (lazertinib) significantly outperforms standard of care in first-line EGFR-mutated lung cancer with compelling new data at ELCC 2025	Press Release
	Johnson & Johnson MedTech Showcases New Era of Digital Orthopaedics at AAOS 2025	Press Release
	Icotrokinra meets primary endpoint of clinical response in ulcerative colitis study and shows potential to transform the treatment paradigm for patients	Press Release
	Icotrokinra results show potential to set a new standard of treatment in plaque psoriasis	Press Release
	TREMFYA (guselkumab) subcutaneous (SC) induction data support potential to be the first and only in its class to offer the option of both intravenous and SC induction therapy in ulcerative colitis	Press Release
	New nipocalimab data published in mAbs journal details differentiated molecular design, clinical profile and potential of nipocalimab to treat IgG-driven alloantibody and autoantibody diseases	Press Release
	Findings from pivotal nipocalimab Phase 3 study in a broad antibody positive population of people living with generalized myasthenia gravis (gMG) published in The Lancet Neurology	Press Release
Product Launch	Shockwave Medical Launches Novel Forward Intravascular Lithotripsy Platform in U.S. to Transform Treatment of Difficult-to-Cross Calcified Lesions	Press Release

Other	Johnson & Johnson Closes Landmark Intra-Cellular Therapies, Inc. Acquisition to Solidify Neuroscience Leadership[1]	Press Release
	Johnson & Johnson to Return to Tort System to Defeat Meritless Talc Claims[1]	Press Release
	Johnson & Johnson Increases U.S. Investment to More than $55 Billion Over the Next Four Years	Press Release
	Johnson & Johnson Announces Darren Snellgrove as Vice President, Investor Relations	Press Release

[1] Subsequent to the quarter

Webcast information:

Johnson & Johnson will conduct a conference call with investors to discuss this earnings release today at 8:30 a.m., Eastern Time. A simultaneous webcast of the call for investors and other interested parties may be accessed by visiting the Johnson & Johnson website. A replay and podcast will be available approximately two hours after the live webcast in the Investor Relations section of the company's website at events-and-presentations.

About Johnson & Johnson:

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity. Learn more at www.jnj.com.

Non-GAAP financial measures:

* "Operational sales growth" excluding the impact of translational currency, "adjusted operational sales growth" excluding the net impact of acquisitions and divestitures and translational currency, as well as "adjusted net earnings", "adjusted diluted earnings per share" and "adjusted operational diluted earnings per share" excluding after-tax intangible amortization expense and special items, are non-GAAP financial measures and should not be considered replacements for, and should be read together with, the most comparable GAAP financial measures. Except for guidance measures, reconciliations of these non-GAAP financial measures to the most directly comparable GAAP financial measures can be found in the accompanying financial schedules of the earnings release and the Investor Relations section of the company's website at quarterly results.

Copies of the financial schedules accompanying this earnings release are available on the company's website at quarterly results. These schedules include supplementary sales data, a condensed consolidated statement of earnings, reconciliations of non-GAAP financial measures, and sales of key products/franchises. Additional information on Johnson & Johnson, including adjusted income before tax by segment, an Innovative Medicine pipeline of selected compounds in late stage development and a copy of today's earnings call presentation can also be found in the Investor Relations section of the company's website at quarterly results.

Note to investors concerning forward-looking statements:

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding, among other things: future operating and financial performance, product development, and market position and business strategy. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties

materialize, actual results could vary materially from the expectations and projections of Johnson & Johnson. Risks and uncertainties include, but are not limited to: economic factors, such as interest rate and currency exchange rate fluctuations or changes to applicable laws and regulations; competition, including technological advances, new products and patents attained by competitors; challenges inherent in new product research and development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success for new and existing products; challenges to patents; the impact of patent expirations; the ability of the Company to successfully execute strategic plans, including restructuring plans; the impact of business combinations and divestitures; manufacturing difficulties or delays, internally or within the supply chain; product efficacy or safety concerns resulting in product recalls or regulatory action; significant adverse litigation or government action, including related to product liability claims; changes to applicable laws and regulations, including tax laws and global health care reforms; trends toward health care cost containment; changes in behavior and spending patterns of purchasers of health care products and services; financial instability of international economies and legal systems and sovereign risk; and increased scrutiny of the health care industry by government agencies. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's most recent Annual Report on Form 10-K, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. Any forward-looking statement made in this release speaks only as of the date of this release. Johnson & Johnson does not undertake to update any forward-looking statement as a result of new information or future events or developments.

Exhibit 99.2

Johnson & Johnson and subsidiaries
Supplementary sales data

(Unaudited; Dollars in Millions)

	FIRST QUARTER				
			Percent Change		
Sales to customers by geographic area	**2025**	**2024**	**Total**	**Operations**	**Currency**
U.S.	**$12,305**	**11,620**	5.9 %	5.9	—
Europe	**5,110**	**5,163**	(1.0)	2.2	(3.2)
Western Hemisphere excluding U.S.	**1,167**	**1,194**	(2.3)	9.2	(11.5)
Asia-Pacific, Africa	**3,311**	**3,406**	(2.8)	(0.6)	(2.2)
International	**9,588**	**9,763**	(1.8)	2.1	(3.9)
Worldwide	**$21,893**	**21,383**	2.4 %	4.2	(1.8)

Note: Percentages have been calculated using actual, non-rounded figures and, therefore, may not recalculate precisely.

Johnson & Johnson and subsidiaries
Supplementary sales data

(Unaudited; Dollars in Millions)	FIRST QUARTER				
			Percent Change		
Sales to customers by segment of business	**2025**	**2024**	**Total**	**Operations**	**Currency**
Innovative Medicine					
U.S.	**$ 8,092**	**7,612**	6.3 %	6.3	—
International	**5,781**	**5,950**	(2.9)	1.5	(4.4)
	13,873	**13,562**	2.3	4.2	(1.9)
MedTech					
U.S.	**4,213**	**4,008**	5.1	5.1	—
International	**3,807**	**3,813**	(0.2)	3.0	(3.2)
	8,020	**7,821**	2.5	4.1	(1.6)
U.S.	**12,305**	**11,620**	5.9	5.9	—
International	**9,588**	**9,763**	(1.8)	2.1	(3.9)
Worldwide	**$ 21,893**	**21,383**	2.4 %	4.2	(1.8)

Note: Percentages have been calculated using actual, non-rounded figures and, therefore, may not recalculate precisely.

Johnson & Johnson and subsidiaries
Condensed consolidated statement of earnings

(Unaudited; in Millions Except Per Share Figures)

	FIRST QUARTER				
	2025		2024		Percent Increase (Decrease)
	Amount	Percent to Sales	Amount	Percent to Sales	
Sales to customers	$ 21,893	100.0	$ 21,383	100.0	2.4
Cost of products sold	7,357	33.6	6,511	30.4	13.0
Gross Profit	14,536	66.4	14,872	69.6	(2.3)
Selling, marketing and administrative expenses	5,112	23.3	5,257	24.6	(2.8)
Research and development expense	3,225	14.7	3,542	16.6	(8.9)
Interest (income) expense, net	(128)	(0.6)	(209)	(1.0)	
Other (income) expense, net	(7,321)	(33.4)	2,404	11.2	
Restructuring	17	0.1	164	0.8	
Earnings before provision for taxes on income	13,631	62.3	3,714	17.4	267.0
Provision for taxes on income	2,632	12.1	459	2.2	473.4
Net earnings	$ 10,999	50.2	$ 3,255	15.2	237.9
Net earnings per share (Diluted)	$ 4.54		$ 1.34		238.8
Average shares outstanding (Diluted)	2,423.8		2,430.1		
Effective tax rate	19.3 %		12.4 %		
Adjusted earnings before provision for taxes and net earnings [1] [A]					
Earnings before provision for taxes on income	$ 8,011	36.6	$ 7,877	36.8	1.7
Net earnings	$ 6,706	30.6	$ 6,580	30.8	1.9
Net earnings per share (Diluted)	$ 2.77		$ 2.71		2.2
Effective tax rate	16.3 %		16.5 %		

[1] See Reconciliation of Non-GAAP Financial Measures.

[A] NON-GAAP FINANCIAL MEASURES "Adjusted earnings before provision for taxes on income," "adjusted net earnings," "adjusted net earnings per share (diluted)," and "adjusted effective tax rate" are non-GAAP financial measures and should not be considered replacements for GAAP results. The Company provides earnings before provision for taxes on income, net earnings, net earnings per share (diluted), and effective tax rate on an adjusted basis because management believes that these measures provide useful information to investors. Among other things, these measures may assist investors in evaluating the Company's results of operations period over period. In various periods, these measures may exclude such items as intangible asset amortization expense, significant gains from divestitures, significant costs associated with acquisitions, restructuring, litigation, and changes in applicable laws and regulations (including significant accounting or tax matters). Special items may be highly variable, difficult to predict, and of a size that sometimes has substantial impact on the Company's reported results of operations for a period. Management uses these measures internally for planning, forecasting and evaluating the performances of the Company's businesses, including allocating resources and evaluating results relative to employee performance compensation targets. Unlike earnings before provision for taxes on income, net earnings, net earnings per share (diluted), and effective tax rate prepared in accordance with GAAP, adjusted earnings before provision for taxes on income, adjusted net earnings, adjusted net earnings per share (diluted), and adjusted effective tax rate may not be comparable with the calculation of similar measures for other companies. The limitations of using these non-GAAP financial measures as performance measures are that they provide a view of the Company's results of operations without including all events during a period, such as intangible asset amortization expense, significant gains from divestitures, the effects of an acquisition, restructuring, litigation, and changes in applicable laws and regulations (including significant accounting or tax matters) and do not provide a comparable view of the Company's performance to other companies in the health care industry. Investors should consider non-GAAP financial measures in addition to, and not as replacements for, or superior to, measures of financial performance prepared in accordance with GAAP.

Johnson & Johnson and subsidiaries
Reconciliation of non-GAAP financial measures

(Dollars in Millions Except Per Share Data)	First Quarter 2025	2024
Net Earnings, after tax- as reported	**$10,999**	**$3,255**
Pre-tax Adjustments		
Litigation related	(6,966)	2,726
Intangible Asset Amortization expense	1,120	1,078
Restructuring related [1]	55	171
Acquisition, integration and divestiture related	132	148
(Gains)/losses on securities	39	(20)
Medical Device Regulation	—	51
COVID-19 Vaccine related costs	—	9
Tax Adjustments		
Tax impact on special item adjustments [2]	1,315	(856)
Tax legislation and other tax related	12	18
Adjusted Net Earnings, after tax	**$6,706**	**$6,580**
Average shares outstanding (Diluted)	2,423.8	2,430.1
Adjusted net earnings per share (Diluted)	**$2.77**	**$2.71**
Operational adjusted net earnings per share (Diluted)	**$2.81**	

Notes:

[1] In fiscal 2023, the company completed a prioritization of its research and development (R&D) investment within the Innovative Medicine segment to focus on the most promising medicines with the greatest benefit to patients. This resulted in the exit of certain programs within therapeutic areas. The R&D program exits are primarily in infectious diseases and vaccines including the discontinuation of its respiratory syncytial virus (RSV) adult vaccine program, hepatitis and HIV development. The restructuring expenses of $144 million in the fiscal first quarter of 2024 include the termination of partnered and non-partnered program costs and asset impairments. This program was completed in Q4 2024.

In fiscal 2023, the company initiated a restructuring program of its Orthopaedics franchise within the MedTech segment to streamline operations by exiting certain markets, product lines and distribution network arrangements. The restructuring expenses of $55 million in the fiscal first quarter of 2025 and $27 million in the fiscal first quarter of 2024 primarily includes costs related to market and product exits.

[2] The tax impact related to special item adjustments reflects the current and deferred income taxes associated with the above pre-tax special items in arriving at adjusted earnings.

Johnson & Johnson and subsidiaries
Reconciliation of non-GAAP financial measures

Adjusted operational sales growth[A]
First quarter 2025 actual vs. 2024 actual

	Segments		
	Innovative Medicine	MedTech	Total
WW As Reported	**2.3 %**	**2.5 %**	**2.4 %**
U.S.	6.3 %	5.1 %	5.9 %
International	(2.9 %)	(0.2 %)	(1.8 %)
WW Currency	**(1.9)**	**(1.6)**	**(1.8)**
U.S.	—	—	—
International	(4.4)	(3.2)	(3.9)
WW Operational	**4.2 %**	**4.1 %**	**4.2 %**
U.S.	6.3 %	5.1 %	5.9 %
International	1.5 %	3.0 %	2.1 %
Shockwave		**(3.3)**	**(1.2)**
U.S.		(5.1)	(1.8)
International		(1.4)	(0.5)
All Other Acquisitions and Divestitures (A&D)	**0.2**	**0.5**	**0.3**
U.S.	0.0	0.9	0.3
International	0.4	0.2	0.3
WW Adjusted Operational Ex A&D	**4.4 %**	**1.3 %**	**3.3 %**
U.S.	6.3 %	0.9 %	4.4 %
International	1.9 %	1.8 %	1.9 %

Note: Percentages are based on actual, non-rounded figures and may not sum

[A] NON-GAAP FINANCIAL MEASURE "Adjusted operational sales growth" excludes acquisitions, divestitures and translational currency and is a non-GAAP financial measure. Investors should consider non-GAAP financial measures in addition to, and not as replacements for, or superior to, measures of financial performance prepared in accordance with GAAP. Due to the variable nature of acquisitions and divestitures, and the impact they may have on the analysis of underlying business performance and trends, management believes that providing this measure enhances an investor's understanding of the Company's performance and may assist in the evaluation of ongoing business operations period over period. This non-GAAP financial measure is presented to permit investors to more fully understand how management assesses the performance of the Company, including for internal evaluation of the performance of the Company's businesses and planning and forecasting for future periods. The use of this non-GAAP financial measure as a performance measure is limited in that it provides a view of the Company's results of operations without including all events during a period and may not provide a comparable view of the Company's performance to that of other companies in the health care industry.

Johnson & Johnson
Segment sales
(Dollars in Millions)

	FIRST QUARTER				
			% Change		
	2025	2024	Reported	Operational[1]	Currency
INNOVATIVE MEDICINE SEGMENT[2]					
ONCOLOGY					
US	**$3,013**	**2,383**	26.4 %	26.4 %	— %
Intl	**2,664**	**2,430**	9.6	14.4	(4.8)
WW	**5,678**	**4,814**	17.9	20.4	(2.5)
CARVYKTI					
US	**318**	**140**	*	*	—
Intl	**51**	**16**	*	*	*
WW	**369**	**157**	*	*	*
DARZALEX					
US	**1,829**	**1,464**	24.9	24.9	—
Intl	**1,409**	**1,228**	14.7	19.8	(5.1)
WW	**3,237**	**2,692**	20.3	22.5	(2.2)
ERLEADA					
US	**292**	**285**	2.5	2.5	—
Intl	**479**	**404**	18.5	23.1	(4.6)
WW	**771**	**689**	11.9	14.6	(2.7)
IMBRUVICA					
US	**235**	**265**	(11.5)	(11.5)	—
Intl	**474**	**518**	(8.5)	(4.2)	(4.3)
WW	**709**	**784**	(9.5)	(6.7)	(2.8)
RYBREVANT / LAZCLUZE[3]					
US	**113**	**36**	*	*	—
Intl	**28**	**11**	*	*	*
WW	**141**	**47**	*	*	*
TALVEY[3]					
US	**68**	**50**	35.2	35.2	—
Intl	**18**	**8**	*	*	*
WW	**86**	**58**	48.4	50.2	(1.8)
TECVAYLI					
US	**105**	**101**	4.9	4.9	—
Intl	**46**	**33**	38.8	45.9	(7.1)
WW	**151**	**133**	13.3	15.0	(1.7)
ZYTIGA / abiraterone acetate					
US	**7**	**9**	(24.3)	(24.3)	—
Intl	**118**	**172**	(31.3)	(28.5)	(2.8)
WW	**125**	**181**	(30.9)	(28.3)	(2.6)
OTHER ONCOLOGY[3]					
US	**47**	**33**	42.9	42.9	—
Intl	**42**	**41**	4.6	10.1	(5.5)
WW	**89**	**73**	21.7	24.7	(3.0)

See footnotes at end of schedule

4U

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Ionis Pharmaceuticals, Inc

Physical Address: 2855 Gazelle Court

City: Carlsbad State: CA Zip: 92010

Mailing Address (if different from physical address): 2855 Gazelle Court

City: Carlsbad State: CA Zip: 92010

Telephone: 760-931-9200 Website: www.ionispharma.com

Name of Designated Representative (DR): Sheetal Patel

Licensing Company Email: pharmalicensing@ionis.com DR Email: skpatel@ionis.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies and Specialty Distributors		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed with-in last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): _____

Corporation Name: Ionis Pharmaceuticals, Inc.

Mailing Address: 2855 Gazelle Court

City: Carlsbad State: CA Zip: 92010

Telephone: 760-931-9200 Email: pharmalicensing@ionis.com

Contact Person Name: Kyle Brian Jenne

Date of SEC Registration: 12/18/2015	SEC Registration Number: 0000874015	Stock Exchange Symbol: IONS

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. **Access form at** http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

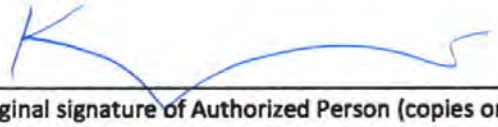
I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Ionis Pharmaceuticals, Inc

Facility Name

Kyle Jenne

Print Name of Authorized Person Submitting Application



Original signature of Authorized Person (copies or stamps not accepted)

2-11-25

Date

Board Use Only	Date Received: 3/24/25	Amount: $1000-ck 3339

An official website of the United States government Here's how you know

FDA

Current through March 5, 2025

You have searched Finished drug products

Search Results: *'ionis'*

Back to Search Page

Showing 1 to 1 of 1 entries Show entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
TRYNGOLZA	71860-101-01	80mg/.8mL	INJECTION, SOLUTION	SUBCUTANEOUS	NDA218814	Ionis Pharmaceuticals, Inc.	71860-101	olezarsen sodium	OLEZARSEN SODIUM	HUMAN PRESCRIPTION DRUG	12/19/2024	N/A	NDA	1 SYRINGE, GLASS in 1 CARTON (71860-101-01) / .8 mL in 1 SYRINGE, GLASS

Previous 1 Next

IONIS

Description of Operations

Ionis Pharmaceuticals, Inc is a VirtualManufacturer. Ionis Pharmaceuticals, Inc's products are manufactured by Contract Manufacturers and will be distributed to Specialty Pharmaceuticals and Specialty Distributors by their Third-Party Logistics Provider, Cardinal Health 105, LLC , who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Vetter Pharma Fertigung GmBH & Co
Schuelzenstrasse 87, 99-101
Ravensburg, Germany 88212
FDA Establishment Number: 3002270322

Contact Person: Brid Murphy
Contact Number: + 353 (87) 6067760

Almac Pharma Services LLC
2661 Audobon Road
Audobon, PA 19403
FDA Establishment Number: 3000214934

Contact Person: Amber Zaleski
Contact Number: 215-660-8503

Vetter manufactures Ionis Pharmaceuticals, Inc's product and Almac packages the finished product. At no time does Vetter own the product, contract with Ionis Pharmaceuticals, Inc's customers, invoice, nor sell a Ionis Pharmaceuticals, Inc product. Ionis Pharmaceuticals, Inc's products are not Controlled Substances.

Labeler Code:
71860

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal Health 105, LLC acts as Ionis Pharmaceuticals, Inc's Third Party Logistics (3PL) provider to manage the storage and distribution of Ionis Pharmaceuticals, Inc's product throughout the United States. Cardinal Health 105, LLC's address is:

Cardinal Health 105, LLC
501 Mason Road, Ste 200
LaVergne, TN 37086
Contact: Kevin Hansen & Phone Number: 615-793-1757

Ionis Pharmaceuticals, Inc's has 930 employees working on site during normal business hours of operation which are 8:30 am – 5:00 pm Monday through Friday.

Ionis Pharmaceuticals, Inc's sales records are stored at Ionis Pharmaceuticals, Inc.

Ionis Pharmaceuticals, Inc's facility square footage is 250.



Company Information

Company Name:	Ionis Pharmaceuticals, Inc
Address:	2855 Gazelle Court
City, State, Zip:	Carlsbad, CA 92010
Phone:	760-931-9200
Website:	Ionispharma.com
E-mail:	pharmalicensing@ionisph.com

FEIN:	33-0336973
State of Formation:	Delaware
Date Incorporated:	03/25/1991
File Number:	2258177

Ownership Information

Ionis Pharmaceuticals, Inc is a Publicly Traded company on the NASDAQ stock exchange under the symbol IONS. There is no parent company.

Officers

Kyle Jenne, EVP, Chief Global Product Strategy and Operations Officer
Business Address: 2855 Gazelle Court, Carlsbad, CA 92010
Business Phone: 760-931-9200

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Elizabeth Lynn Hougen, EVP, CFO
Business Address: 2855 Gazelle Court, Carlsbad, CA 92010
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Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "IONIS PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTEENTH DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

2258177 8300

SR# 20242238089

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203503752

Date: 05-17-24

BOARD OF PHARMACY

LICENSING DETAILS FOR: WLS 8382

NAME: IONIS PHARMACEUTICALS INC

LICENSE TYPE: WHOLESALER

LICENSE STATUS: CLEAR

ADDRESS

2855 GAZELLE COURT
CARLSBAD CA 92010
SAN DIEGO COUNTY

ISSUANCE DATE

JUNE 6, 2024

EXPIRATION DATE

JUNE 1, 2025

CURRENT DATE / TIME

MAY 5, 2025
9:55:53 AM

LICENSE RELATIONSHIPS

NAME: PATEL, SHEETAL KIRAN

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: DESIGNATED REPRESENTATIVE (WHOLESALER)

LICENSE NUMBER: 26445 **PRIMARY STATUS:** CLEAR

CALIFORNIA DEPARTMENT OF CONSUMER AFFAIRS

Board of Pharmacy

ORIGINAL CERTIFICATE

Wholesale Drug Permit

LICENSE NO. WLS 8382

ISSUE DATE 6/6/2024

IONIS PHARMACEUTICALS INC
2855 GAZELLE COURT
CARLSBAD, CA 92010

The above is licensed with the State Board of Pharmacy as a Corporation

The official status of this license can be verified at www.pharmacy.ca.gov

PLACE RENEWAL LICENSE HERE

VALID UNTIL 6/1/2025

RECEIPT NUMBER 00754485

This original license must be kept for the life of the license and posted in public view.

In accordance with section 4060 of the Business and Professions Code, the business named above is hereby licensed at the above address, and is subject to the rules and regulations of the California State Board of Pharmacy.

This permit is NONTRANSFERABLE and must be renewed annually on or before the indicated date. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, shareholder (more than 10 percent share change), designated representative-in-charge, manager or vice president of operations. If you are planning to change location or designated representative-in-charge, the approval must be in advance of the change.

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

----- POST IN PUBLIC VIEW -----

OPHWS1 09/30/19 WLS

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 01/09/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

Holder Identifier :

PRODUCER	CONTACT NAME:	
Aon Risk Insurance Services West, Inc. Los Angeles CA Office 707 Wilshire Boulevard Suite 2600 Los Angeles CA 90017-0460 USA	PHONE (A/C. No. Ext): (866) 283-7122	FAX (A/C. No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	Illinois Union Insurance Company	27960
INSURER B:	Atlantic Specialty Insurance Company	27154
INSURER C:		
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Ionis Pharmaceuticals, Inc.
2855 Gazelle Court
Carlsbad CA 92010-6670 USA

COVERAGES **CERTIFICATE NUMBER:** 570110442454 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE / X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: POLICY / PRO-JECT / X LOC OTHER:			711-01-71-66-0004 International GL	07/01/2024	07/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000 $1,000,000 $15,000 $1,000,000 $2,000,000 Excluded
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY / SCHEDULED AUTOS HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB / OCCUR EXCESS LIAB / CLAIMS-MADE DED / RETENTION						EACH OCCURRENCE AGGREGATE	
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER (Mandatory in NH) Y/N N/A If yes, describe under DESCRIPTION OF OPERATIONS below						PER STATUTE / OTH-ER E.L. EACH ACCIDENT E.L. DISEASE-EA EMPLOYEE E.L. DISEASE-POLICY LIMIT	
A	Products Liability			G24400591012 Claims Made	07/01/2024	07/01/2025	Each Occ Limit Agg Limit Each Occ Ded	$15,000,000 $15,000,000 $25,000

Certificate No : 570110442454

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Coverage.

CERTIFICATE HOLDER

Ionis Pharmaceuticals, Inc.
2855 Gazelle Court
Carlsbad CA 92010-6670 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Insurance Services West, Inc.

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Bai, Dong
Castenada, Kayla D.
Chen, Jana
Chong, Ling Wa
Crosby, Jeffrey R.
Donner, Aaron J.
Grigg, Wendy M.
Guo, Shuling
Hettrick, Lisa A.
Holland, Christie J.
Hsueh, Ying-Chang
Huang, Lulu
Kubli, Dieter A.
Lai, Chen-Yen
Liu, Mingxia
Low, Audrey K.
Maazi, Hadi
Mullick, Adam E.
Murray, Susan F.
Peng, Danni
Penke, Loka Raghu Kumar
Perelis, Mark
Pirie, Elaine C.
Revenko, Alexey S.
Riney Jr., Stanley J.
Sanderlin III, Edward J.
Suanico, Kenneth D.
Tolentino, Angelica P.
Wei, Ying
Wijesekara, Nadeeja T.
Yeh, Ting Yuan
Zhao, Chenguang

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Carlborg, Emma
Crutchfield, Amanda
Davis, Scott E.
Diago, Oscar
Donovan, Scott M.
dos Santos Chaves, Rodrigo
Dung, Ashley P.
Freier, Susan M.
Hilton, Jacqueline M.
Medina, Gisel E.
Moss, Richard A.
Phillips, Naomi R.

Quirk, Clare
Raus, Jordan
Swayze, Grant S.
Thomas, Antony
Watt, Andrew
Webb, Chiu Ho T.
Zhao, Luyi

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Clemente, Melvin A.
Delio, Alena M.
Klein, Stephanie K.
Lacson, Ernani E.
Ramirez, Jasmine
Toth, Beatrice I.
Watson, Marion J.

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Anderson, Patrick E.
Astore, Courtney A.
Bose, Arijit
Capitanio, Juliana S.
Damle Ph.D., Sagar S.
Dobbyn Ph.D., Amanda L.
Gutierrez, Michael A.
Hodonsky, Chani J.
Lavender, Christopher A.
Longchamps, Ryan J.
Ogawa, Yuya
Pak, Travis
Ponte, Rui A.
Praveen, Kavita
Relic Ph.D., Dorde
Rigo Nusser, Frank
Zhang, Shengsheng
Zhang, Yuhang

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Benevides, Darrion C.
Berlin, Shanon R.
Collup, Kenton C.
Cox, Jennifer
Dan, Amy
Fazio, Michael J.
Gattis, Danielle L.
Gilmore, Deanna M.

Jordan, Tyrel S.
Migawa, Michael T.
Ruiz, Daniel L.
Ruiz, Maria C.
Simpson, Amanda R.
Wan, William B.
Watson, Christopher J.

Employee Name
Anderson, Brooke A.
Berdeja, Andres R.
Chappell, Alfred E.
Cummins, Lendell L.
Galindo-Murillo, Rodrigo
Gaus, Hans
Holguin, Bret
Horiya, Satoru
Huggins, Ian J.
Jadhav, Satish
Nikan, Mehran
Phi, Steven H.
Prakash, Thazha P.
Schaefer, Rebecca J.
Tanowitz, Michael B.
Warren, Hunter T.
Wilczynski, Andre
Wilson, Amber L.
Yu, Jinghua
Zhang, Geping

Employee Name
Afetian, Megan E.
Afshar Bakooshli, Mohsen
Bachmann, Gemma L.
Booten, Sheri L.
Bravo Hernandez, Mariana
Bruening, Dona R.
Carrer, Michele
da Paz Ferreira Pinto Duarte, Antonio A.
DuGal, Jordan A.
Ford, Brittany T.
Hong, Christine C.
Hunyara, John L.
Jafar-nejad, Paymaan
Kamme, Fredrik C.
Kelly, Mackenzie
Kordasiewicz, Holly B.

Li, Shuzhen
Ling, Kar Yun Karen
Lombardo, Nicole G.
Lopez Ortega Ph.D., Elena
Lopez, Deborah F.
McCauley, Madelyn E.
Noble, Briana N.
O'Rourke, Jacqueline G.
Powers, Berit E.
Rustenburg, Chelsea T.
Santos, Anne Jinro A.
Tian, Mengnan
Trinh, Kaitlyn A.
Zhao, Hien T.

Employee Name
Lee, Nara
Murray, Heather M.
Nichols, Joshua G.
Pollak, Adam J.
Tian, Jun

Employee Name
Black, Pamela R.
Sipe, Donna R.
Swayze, Eric

Employee Name
Behling, Alexander B.
Cowling, Belinda S.
Doherty, Shane
Dorow, Steven W.
Li, Yang
Mathews, Joel A.
Pappas, Ioannis
Prikhodko, Olga
Qi, Jinfeng
Sasaki, Shruti
Smith, Chelsey N.
Soriano, Armand T.
Tewalt, Eric F.

Employee Name
Arva, Akshaya
Bennett, Clarence F.

Bustos, Lynette
Courtney, Margo F.
Hakanson, Angie M.
Huang, Rui
Jackson, Michaela R.
Munier, Joseph J.
Pontarelli, Alexander
Reid, Dylan A.
Tosat Bitrian, Carlota
Wang, Xizi

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Ecker, David J.
Ferragamo, Erin C.
McMahon, Moira A.

Employee Name
Bui, Huynh-Hoa T.
Chien, Lauren E.
Coldren, Bret A.
de Carvalho Rodrigues, Deivid
Dutta, Arijit
Freestone, Graeme C.
Fu, Wuxia
Geisert, David L.
Hafez, Ismail
Huang, Pin-Yao
Kandell, Rebecca M.
Ladd Effio, Christopher
Li, Zheng
Mikhaylova, Veronika
Morton, Stephen W.
Murdock, Karissa
Oestergaard, Michael E.
Pasek-Allen, Jacqueline
Sasmor, Henri M.
Solan, Qingxia
Vasquez, Guillermo
Zhao, Jing

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Bujanover, Shay
Eddy, Ginger
Householder Ph.D., Kyle T.

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Narayan Ph.D., Veena M.

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Baker, Brenda
DeYoung, Mary B.
Elfman, Lauren M.
Hannan, Lisa A.
Madsen, Sarah K.
Partridge, Wesley D.
Sanathara, Nayna M.

Employee Name
Drum, Monica
Villa, Kathleen F.

Employee Name
Brumfield, Tiffany M.
Golias, Johanna L.
Korwek, Kelly J.
Lyons, Heather M.
Oliphant, Carrie S.
Schaefer, Melanie L.
Shardonofsky, Jana D.

Employee Name
Berger, Robert A.
Bianchi, Pauline A.
Chianta, Maria F.
Dalley, Sarah I.
Hines, Stephanie J.
Hurst, James E.
Jackson, George E.
Melo Nazareno, Rita R.
Nemec, Jamison D.
Slawny, Nicole A.
Sperl, Pamela L.
Williams, Vicki D.

Employee Name
Bedford, Bethany G.
Blauth, Kevin R.
Boylan, Erin M.
Dieme, Barthelemy

Ruggles, James A.
Schnabel, Catherine A.
Tung, Norint

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Conrad, Kelly L.
Edwards, Michael
Ouellette, Michelle R.
Snell, Clayton W.

Employee Name
Keene, Neil T.
Londono Fajardo, Leonardo A.
Trent, Stacy A.
Williams, Madeleine

Employee Name
Beatman, Jennifer L.
Bruhl, Rebecca E.
Dion, James
Green, Connor
Lufkin, Jaclyn K.
Nguyen, Annette T.
Ochoa, Cristal
Oubre, Elizabeth A.
Turner, Karyn G.
Varney, Cory
Zhou, Ying

Employee Name
Biehl, Shannon P.
Christensen, Alexa D.
Goldstein, Ida H.
Pamplin, James B.
Regan, Esther
Schupp, Eric M.

Employee Name
Buczek, Paulann
Burgh, Denise C.
Eckhart, Prabhdeep K.
Hurley, Sean P.
Lynch, Frances D.
Mergenthaler-Hagan, Reneka

Mihalczo, Carol P.
Patel, Sheetal K.
Ripley, Todd A.
Schippers, Neil
Vigliarolo, Dominique
Woodworth, Krista D.

Employee Name
Birchall, Jonathan J.
Fritz, Victoria C.
Graham, Ashley M.
Proctor, Kelly J.
Tiu, Patricia M.

Employee Name
Fox, Monica J.
Gawlik, Robin M.
Jaimes, Marcelina
Keegan, Marianna D.
Link, Laura L.
O'Meara, Alison J.
Scott, Michelle R.

Employee Name
Bradhurst, Amanda L.
Choate, Adam A.
Davis, Amanda M.
Fraser, Michelle L.
Fuller, Jennifer M.
Pettibone, Anne

Employee Name
Classen, Kelly J.

Employee Name
McIlwain, Aaron G.

Employee Name
Adial, Prem C.
Dressler, Erika L.
Glover, Alexander J.
Jordan, Katherine E.
Zwerner, Jason P.

Employee Name
Blake, Hezekiah
Choi, Wing Yi
Dewing, Caroline
Drowns, Matthew D.
Kim, Myron S.
Klaeser, Hannah E.
Kramer, Christopher D.
MacPherson, Ian
Niphadkar, Utkarsha Vinayak
Park, Kenneth J.
Pham, Eric K.
Thomas, Alexander W.

Employee Name
Bodker, Jessica M.
Henson Hannough, Dawn
Kolatkar, Orly
Smith, Todd E.

Employee Name
Alvarez, Alejandro D.
Carroll, Angela M.
Cerminara, Keelann L.
Chespak, Lauren Y.
Garczynski, Brett J.
Haarala, Heather
Hayden, Elise A.
Jensen, John K.
Keegan, Christopher T.
Kulp, Alana M.
Lazarus, Denise M.
Leonard, Mica G.
Lowe, Kelly M.
Moore, Meghan L.
Nolan, Jamie M.
Parton, Julie J.
Perrone, Jeffrey J.
Rogers, Amy M.
Smith, Adrian D.
Walega, Allison C.
Wynalek, Christa C.

Employee Name

Claxton, Ami J.
Kymes, Steven M.
Sikora Kessler, Joanna E.
Vera Llonch, Montserrat
Yarlas, Aaron S.

Employee Name
Joshi, Samin R.
Macdonald, Juan P.
Peter, Anil

Employee Name
Adams, Treca L.
Evans, Lise L.
Hennessy, David G.
Irwin, Peggy P.
Matthews, Timoli H.
Schwab, Donald M.
Wiebking, Katherine M.

Employee Name
Malewicz, Kara
Mizer, Kelly C.
Reeves, Tricia M.
Sze, David

Employee Name
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Employee Name
Monia, Brett P.
Smith, Heather R.

Employee Name
Jenne, Kyle B.
Salazar, Charlaine M.
Tucker, Alana A.

Employee Name
Daly, Carmel

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DeCore, Megan B.
Fitzsimmons, Bethany L.
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Walke, Daniel W.

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Binder, Daria R.
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Nehrbas, George E.
Papp, Emily E.
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Employee Name
Brewer, Katharine L.
Hartin, Gail

Employee Name
Hougen, Elizabeth L.
Ianni, Chae C.

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Bakkal, Oguz G.

Burinskas, Kathleen K.
Chavez, Monica J.
Dowdy, Clayton T.
Han, Xiao
Homa, Nellie
Hughes, Alice P.
Lewis, David A.
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Dutra, Mariana Antunes
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Frazier, Angela L.
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Hrycko, Piotr R.
Johnson, Terry D.
Kim, Tae H.
Koo, Evan K.
Medeiros, Casey
Morgan, Jennifer V.
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Redd, Jennifer M.
Reed, Theresa A.
Schramm, Theresa C.
Sell, Michael A.
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Tran, Ngoctuyet T.
Truong, Benjamin D.
Vasconcelos, Renato
Westling, Jennifer A.

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Caruso, Jenica E.
Cruz, Jasmine C.
Defernez, Tracy E.
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Horning, Karen K.
Kiss, Kitti
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Macario, Clariza
Mitchell, Rosa R.
Perez, Maria
Quintos, Diane S.
Rickert, Mayra
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Shrader, Matthew C.
Sitt, Alison J.
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Warren Swift, Brieanna

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Blessing, Sara E.
Buck, Eric
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Griffin, Sharonda L.
Henry, Michael T.
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Cassidy, Mae M.
Dwinell, Ruxandra
Ferragamo, Madison D.
Jhung, Heidi
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Klemens, Mallorie P.
Krebs, Richard A.
Melhouse, Nicole A.
Morgan, Jamie L.
Motohashi, Nancy M.
Mullvain Esq., Alexander P.
Murphy, Michael
Nunez, Maria
O'Neil, Patrick R.
Owen, Ryan M.
Strickland, Stephanie A.

Villanueva, Venita J.
Yoon, Melissa M.

Employee Name
Amstadter, Anjanette M.
Aneksirikul, Suphitsara
Bock, Brandon R.
Bradley, Kym M.
Capaldi, Daniel C.
Chan, Jonathan C.
Feltch, Alayna M.
Flanagan, Althia L.
Garcia, Theodore H.
Giles, Ella M.
Hong, James
Koch, Charles A.
Kolkey, Kimmy A.
Lakshmanan, Rajeswari
Lee, Tae H.
MacInnis, Ceara Y.
Mai, Bao V.
Mazzitelli, Carolyn L.
McCarthy, Brian D.
Medina, Karina A.
Okada, Bethany K.
Olsen, Philip D.
Rentel, Claus A.
Rhodes, Dennis W.
Rice, Stephen J.
Roussis, Stilianos G.
Runas, Sheena Q.
Soni, Brijinder S.
Susanto, Christina G.
Torres, Christina L.
Vasko, Nicholas J.
Wang, Ellison
Wang, Yen-Chih
Yu, Irene R.

Employee Name
Aguayo, Moises
Anderson, Christa D.
Beuligmann, Caroline E.
Cedillo, Isaiah E.
Chan, Gabriella
Chreng, Dana S.
Clemons, Gregory E.

Coffin, Christopher C.
Coleman, Melissa L.
Cooperman, Carter
Diamond, Matthew L.
Donnelley, Joseph P.
Erpelding, Dusten R.
Fullman, Jonathan R.
Gbur, Randi K.
Gorman, Dennis P.
Gueta, Adriana
Hedrick, Dwayne M.
High, Christopher S.
Hope, Liam E.
Hutchinson, Reid A.
Jones, Aaron F.
Kang, Helena H.
Kinshofer, Audrey M.
Klopchin, Patrick
Lee, Christopher
Lopez Jr., Jorge A.
Moore, Max N.
Nguyen, Kristine A.
Nowak, Trent D.
Ring, Francis J.
Santos, Evan C.
Schwier, Todd A.
Scozzari, Anthony N.
Sima, Jerome
Smith, Justin W.
Spate, Joshua G.
Tat, Timothy C.
Troche Ortiz, Ero J.
Valenzuela, Arthur

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Basu, Sujit K.
Berdeja, Valentin M.
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Cholkar, Kishore
Cummings, Brendan C.
Davalos, Ashley
Demirkiran, Hande
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Fradkin, Linda
Golec, Brent L.
Jacob, Christine V.
Joe, Terence W.

Kabingue, Ranjee Kenn R.
Khatri, Hetal J.
Li, Tinghui
Lietzow, Michael A.
Lim, Marc A.
Ma, Julie C.
Mathai, Jacob
Occena, Tomsil M.
Padilla, Angeliqueo E.
Pechulis, Christopher W.
Phung, Binh S.
Robledo, Margaret E.
Schiess, Theodore W.
Searcy, Justin D.
Watt, Russell P.
Wollenberg, Alexander L.
Yin, Haiqing

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Chen, Lijian
Flores, Daniel M.
Kim, Joseph T.
McPherson, Andrew K.
Quinones, Ryan E.
Rodriguez, Andrew A.

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Powers, Eric

Employee Name
Devlin, Joseph
Erro Garcia, Maria E.
Williams, Sinead

Employee Name
Hubner, Fernanda

Employee Name
Alex, Tasha K.
Bondarenko, Kaitlyn I.
Carlile, Lexi A.
Carter, Dawn D.
Cruz-Scheckner, Catherynne B.
Fernandez, Eduardo F.

Hernandez, Leigh A.
Kellogg, Mark R.
Lucero, Jasmin C.
Pourbovali, Aida
Sheehan, Deanna L.
Tunnell, Linda F.
Vanderpool, Maria Celeste R.
Wohl, Evan L.

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Chen, Chen
Chen, Doreen Y.
Chen, Mei
Deng, Yiwen
Jung Ph.D., Shiangtung W.
Li, Dan
Li, Lu
Lin, Tao
Lyu, Fan
Ren, Daren
Schulz, Daniel J.
Su, John Q.
Wang, Xiongfei
Xia, Shuting
Yang, Qingqing
Yin, Lixuan
Yu, Di
Zeigler, Haoyue L.

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Banijamali, Alireza
Berman-Booty, Lisa D.
Burel, Sebastien A.
Chen, Hao
Colabucci, Angela Y.
Diep, John K.
Dixon, Jeremy D.
Dudek, Laura L.
Gao, Xiang
Greenlee, Sarah M.
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Hall, Shannon I.
Hannah, Amy L.
Heller, Colleen
Henry, Scott
Hoffmaster, Christine M.
Holmes, Tamika M.

Hsiao, Jill A.
Huffman, Janel L.
Jalali, Kayvon
Jensen, Brianne
Khalili, Samira
Khan, Shabana E.
Kim, Tae-Won
Lance, Kaylee A.
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Li, Hongda
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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, DC 20549

FORM 10-K

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2023

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission file number 000-19125

Ionis Pharmaceuticals, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**33-0336973**
(State or other jurisdiction of incorporation or organization)	(IRS Employer Identification No.)
2855 Gazelle Court, Carlsbad, CA	**92010**
(Address of Principal Executive Offices)	(Zip Code)

760-931-9200

(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol	Name of each exchange on which registered
Common Stock, $.001 Par Value	"IONS"	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☒ No ☐

Indicate by check if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company, or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer ☒	Accelerated Filer ☐
Non-accelerated Filer ☐	Smaller Reporting Company ☐
	Emerging Growth Company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management assessment of the effectiveness of its internal controls over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the Registrant is a shell company (as defined in Rule 12b-2 of the Act). Yes ☐ No ☒

The approximate aggregate market value of the voting common stock held by non-affiliates of the Registrant, based upon the last sale price of the common stock reported on The Nasdaq Global Select Market was $4,243,321,410 as of June 30, 2023.*

The number of shares of voting common stock outstanding as of February 15, 2024 was 145,751,797.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed on or about April 25, 2024 with the Securities and Exchange Commission in connection with the Registrant's annual meeting of stockholders to be held on June 6, 2024 are incorporated by reference into Part III of this Report.

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* Excludes 39,747,443 shares of common stock held by directors and officers and by stockholders whose beneficial ownership is known by the Registrant to exceed 10 percent of the common stock outstanding at June 30, 2023. Exclusion of shares held by any person should not be construed to indicate that such person possesses the power, direct or indirect, to direct or cause the direction of the management or policies of the Registrant, or that such person is controlled by or under common control with the Registrant.

FORWARD-LOOKING STATEMENTS

This report on Form 10-K and the information incorporated herein by reference includes forward-looking statements regarding our business and the therapeutic and commercial potential of our commercial medicines, additional medicines in development and technologies. Any statement describing our goals, expectations, financial or other projections, intentions or beliefs, is a forward-looking statement and should be considered an at-risk statement. Such statements are subject to certain risks and uncertainties and particularly those inherent in the process of discovering, developing and commercializing medicines that are safe and effective for use as human therapeutics, and in the endeavor of building a business around such medicines. Our forward-looking statements also involve assumptions that, if they never materialize or prove correct, could cause our results to differ materially from those expressed or implied by such forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those discussed in this report on Form 10-K, including those identified in Item 1A entitled "Risk Factors". Although our forward-looking statements reflect the good faith judgment of our management, these statements are based only on facts and factors currently known by us. Except as required by law, we undertake no obligation to update any forward-looking statements for any reason. As a result, you are cautioned not to rely on these forward-looking statements.

In this report, unless the context requires otherwise, "Ionis," "Company," "we," "our," and "us" refers to Ionis Pharmaceuticals, Inc. and its subsidiaries.

Summary of Risk Factors

There are a number of risks related to our business and our securities. Below is a summary of material factors that make an investment in our securities speculative or risky. Importantly, this summary does not address all of the risks that we face. Additional discussion of the risks summarized in this risk factor summary, as well as other risks that we face, can be found in this report on Form 10-K in Item 1A entitled "Risk Factors":

- Our ability to generate substantial revenue from the sale of our medicines;
- The availability of adequate coverage and payment rates for our medicines;
- Our and our partners' ability to compete effectively;
- Our ability to successfully manufacture our medicines;
- Our ability to successfully develop and obtain marketing approvals for our medicines;
- Our ability to secure and maintain effective corporate partnerships;
- Our ability to sustain cash flows and achieve consistent profitability;
- Our ability to protect our intellectual property;
- Our ability to maintain the effectiveness of our personnel; and
- The impacts of pandemics, climate change, wars and other global events.

TRADEMARKS

"Ionis," the Ionis logo, and other trademarks or service marks of Ionis Pharmaceuticals, Inc. appearing in this report are the property of Ionis Pharmaceuticals, Inc. "Akcea," the Akcea logo, and other trademarks or service marks of Akcea Therapeutics, Inc. appearing in this report are the property of Akcea Therapeutics, Inc., Ionis' wholly owned subsidiary. This report contains additional trade names, trademarks and service marks of others, which are the property of their respective owners. Solely for convenience, trademarks and trade names referred to in this report may appear without the ® or TM symbols.

CORPORATE INFORMATION

We incorporated in California in 1989 and in January 1991 we changed our state of incorporation to Delaware. In December 2015, we changed our name to Ionis Pharmaceuticals, Inc. from Isis Pharmaceuticals, Inc. Our principal offices are in Carlsbad, California.

We make available, free of charge, on our website, *www.ionispharma.com*, our reports on Forms 10-K, 10-Q, 8-K and amendments thereto, as soon as reasonably practicable after we file such materials with, or furnish such materials to, the Securities and Exchange Commission, or SEC. Periodically, we provide updates about the company in the Newsroom section of the Investors & Media page of our website. Any information that we include on or link to our website is not a part of this report or any registration statement that incorporates this report by reference. The SEC maintains an internet site, *www.sec.gov*, that contains reports, proxy and information statements, and other information that we file electronically with the SEC.

IONIS PHARMACEUTICALS, INC.
FORM 10-K
For the Fiscal Year Ended December 31, 2023
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PART I
Item 1. Business

Overview

For three decades as a pioneer in RNA-targeted medicines, we have focused on bringing better futures to people with serious diseases. Today, we continue to drive innovation in RNA therapies. A deep understanding of disease biology and an industry-leading drug discovery technology propels our work, coupled with a passion and urgency to deliver better futures for patients.

We currently have five marketed medicines to treat serious diseases: SPINRAZA (nusinersen), QALSODY (tofersen), WAINUA (eplontersen), TEGSEDI (inotersen) and WAYLIVRA (volanesorsen). We also have a rich innovative late- and mid-stage pipeline in neurology, cardiology and other areas of high patient need. We currently have nine medicines in Phase 3 development and multiple additional medicines in early and mid-stage development.

Over the past year, we made important progress executing on our vision to bring next-level value to patients and all stakeholders. We achieved this progress by focusing on a clear vision to prioritize and expand the Ionis wholly owned pipeline, deliver Ionis medicines directly to patients and enhance our technology leadership, all underscored by continued financial strength and responsibility. The United States, or U.S., Food and Drug Administration, or FDA, approved two Ionis-discovered medicines, QALSODY and WAINUA. We delivered positive Phase 3 data readouts for WAINUA, olezarsen and donidalorsen. Our Phase 3 pipeline expanded with study starts for bepirovirsen, IONIS-FB-L_{Rx} and zilganersen and we reported five additional positive data readouts from our mid- and late-stage pipeline. Our recent achievements position us to continue to deliver a steady cadence of potentially transformational medicines to patients in need in the near and mid-term. We also advanced our go-to-market plans for our near-term commercial opportunities, WAINUA, olezarsen and donidalorsen. And we expanded and diversified our technology when we advanced our first cardiac myocyte targeting medicine and medicines using our mesyl phosphoramidate, or MsPA, backbone into preclinical development.

We accomplished all of this while earning revenues of $788 million for 2023 and ending the year with a cash and short-term investment balance of $2.3 billion. Our multiple sources of revenue and capital structure enable us to continue investing in our commercial readiness efforts for multiple late-stage programs, our innovative pipeline and our technology. By continuing to focus on these priorities, we believe we are well positioned to drive future growth and to bring next-level value to patients and shareholders.

Marketed Medicines

SPINRAZA is the global market leader for the treatment of patients with spinal muscular atrophy, or SMA, a progressive, debilitating and often fatal genetic disease. Our partner, Biogen, is responsible for commercializing SPINRAZA worldwide. From inception through December 31, 2023, we have earned more than $2.1 billion in revenues from our SPINRAZA collaboration, including more than $1.6 billion in royalties on sales of SPINRAZA.

QALSODY is an antisense medicine that received accelerated approval in April 2023 from the FDA for the treatment of adult patients with superoxide dismutase 1 amyotrophic lateral sclerosis, or SOD1-ALS, a rare, neurodegenerative disorder that causes progressive loss of motor neurons leading to death. Our partner, Biogen, is responsible for commercializing QALSODY worldwide. The European Medicines Agency, or EMA, is currently reviewing QALSODY for approval in the European Union, or EU.

WAINUA is a once monthly, self-administered subcutaneous LIgand-Conjugated Antisense, or LICA, medicine that received FDA approval in December 2023 for the treatment of adults with polyneuropathy of hereditary transthyretin-mediated amyloidosis, or ATTRv-PN, a debilitating, progressive, and fatal disease. WAINUA is the only approved medicine for the treatment of ATTRv-PN that can be self-administered via an auto-injector. We and AstraZeneca are commercializing WAINUA in the U.S. with the launch having commenced in January 2024. We and AstraZeneca are seeking regulatory approval for WAINUA in Europe and other parts of the world. AstraZeneca has exclusive rights to commercialize WAINUA outside of the U.S.

TEGSEDI is a once weekly, self-administered subcutaneous medicine approved in the U.S., Europe, Canada and Brazil for the treatment of patients with ATTRv-PN. We sell TEGSEDI in the U.S. and Canada (collectively, North America) and Europe through our distribution agreement with Swedish Orphan Biovitrum AB, or Sobi. In October 2023, our agreement for TEGSEDI in North America was terminated. As a result, Sobi is transitioning responsibilities to us. In February 2024, we began the process to withdraw the TEGSEDI New Drug Application, or NDA. In Latin America, PTC Therapeutics International Limited, or PTC, is commercializing TEGSEDI in Brazil and is pursuing access in additional Latin American countries through its exclusive license agreement with us.

WAYLIVRA is a once weekly, self-administered, subcutaneous medicine approved in Europe and Brazil as an adjunct to diet in adult patients with genetically confirmed familial chylomicronemia syndrome, or FCS, and at high risk for pancreatitis. We sell WAYLIVRA in Europe through our distribution agreement with Sobi. In Latin America, PTC is commercializing WAYLIVRA in Brazil for two indications, FCS and familial partial lipodystrophy, or FPL, and is pursuing access in additional Latin American countries through its exclusive license agreement with us.

Medicines in Registration and Phase 3 Studies

We currently have nine medicines in registration or Phase 3 studies for eleven indications, which are:

WAINUA (eplontersen) is our medicine to treat patients with transthyretin amyloidosis, or ATTR, that is approved in the U.S. for the treatment of adults with ATTRv-PN, under regulatory review in other countries for ATTRv-PN and in development for ATTR cardiomyopathy, or ATTR-CM. In September 2023, *The Journal of the American Medical Association*, or *JAMA*, published positive results from the Phase 3 NEURO-TTRansform study in patients with ATTRv-PN showing WAINUA halted disease progression and continuously improved quality of life at 35-, 66- and 85-week analyses. In July 2023, we completed enrollment of the Phase 3 CARDIO-TTRansform study of WAINUA in patients with ATTR-CM with data planned for as early as 2025. In February 2024, the FDA granted Fast Track designation to WAINUA for the treatment of patients with ATTR-CM. Additionally, in January 2022 and October 2023, the FDA and EMA, respectively, granted orphan drug designation to WAINUA for the treatment of ATTR.

Olezarsen is our medicine in development for FCS, an ultra-rare indication and severe hypertriglyceridemia, or SHTG, a much broader indication. In September 2023, we reported positive results from the Phase 3 Balance study in patients with FCS showing statistically significant triglyceride lowering and a substantial reduction in acute pancreatitis events in addition to a favorable safety and tolerability profile. Based on our positive Phase 3 results in FCS patients we are preparing regulatory submissions to the FDA and EMA. In January 2023, the FDA granted fast track designation to olezarsen for the treatment of patients with FCS. Additionally, we are currently conducting a broad Phase 3 development program for olezarsen for the treatment of SHTG including three Phase 3 studies supporting development (CORE, CORE2 and ESSENCE). In February 2024, the FDA granted Breakthrough Therapy designation and orphan drug designation to olezarsen for the treatment of FCS. Additionally, in January 2023, the FDA granted olezarsen Fast Track designation for the treatment of patients with FCS.

Donidalorsen is our medicine in development for hereditary angioedema, or HAE. In January 2024, we reported positive data from the Phase 3 OASIS-HAE study in patients treated every four weeks or patients treated every eight weeks. We are currently conducting OASIS-Plus, our open-label study in patients who were either previously treated with other prophylactic therapies or who have completed OASIS-HAE. Throughout 2022 and 2023, we reported positive data from the Phase 2 study and Phase 2 open-label extension, or OLE, study, including two-year OLE data. In December 2023, we licensed European commercialization rights of donidalorsen to Otsuka Pharmaceutical Co., Ltd., or Otsuka. We are preparing to submit an NDA to the FDA. Otsuka is preparing to submit a Marketing Authorization Application, or MAA, to the EMA. In September 2023 and February 2024, the FDA and EMA, respectively, granted orphan drug designation to donidalorsen.

Zilganersen is our medicine in development for Alexander disease, or AxD. In September 2023, we advanced zilganersen into the Phase 3 portion of its ongoing study for patients with AxD. In September 2020 and October 2019, the FDA and EMA, respectively, granted orphan drug designation to zilganersen. Additionally in August 2020, the FDA granted rare pediatric designation to zilganersen.

Ulefnersen is our medicine in development for amyotrophic lateral sclerosis, or ALS, with mutations in the fused in sarcoma gene, or *FUS*. We are currently conducting a Phase 3 study of ulefnersen in juvenile and adult patients with FUS-ALS. In August 2023 and September 2023, the FDA and EMA, respectively, granted orphan drug designation to ulefnersen.

QALSODY (tofersen) is our medicine to treat patients with SOD1-ALS. In April 2023, the FDA granted Biogen accelerated approval of QALSODY for patients with SOD1-ALS. QALSODY is currently under regulatory review in the EU. Additionally, Biogen is developing QALSODY to treat presymptomatic SOD1-ALS patients in the ongoing ATLAS study. In September 2016 and August 2016, the FDA and EMA, respectively, granted orphan drug designation to QALSODY.

Pelacarsen is our medicine in development to treat patients with elevated lipoprotein(a), or Lp(a)-driven cardiovascular disease, or CVD. Novartis is developing pelacarsen, including conducting the ongoing Lp(a) HORIZON Phase 3 cardiovascular outcome study in patients with elevated Lp(a)-driven CVD, which achieved full enrollment in July 2022 with more than 8,000 patients. In April 2020, the FDA granted Fast Track designation to pelacarsen.

Bepirovirsen is our medicine in development for chronic hepatitis B virus, or HBV. GSK is developing bepirovirsen, including conducting the ongoing B-Well Phase 3 program in patients with HBV. GSK reported positive results from Phase 2 studies in 2023, including durable response data from the Phase 2 B-Sure long-term follow-up study of bepirovirsen in complete responder patients from the Phase 2b B-Clear study of patients with HBV. In February 2024, the FDA granted Fast Track designation to bepirovirsen.

IONIS-FB-L_{Rx} is our medicine in development for immunoglobulin A, or IgA, nephropathy, or IgAN, and geographic atrophy, or GA. In the second quarter of 2023, Roche advanced IONIS-FB-L_{Rx} into Phase 3 development in patients with IgAN. In October 2023, we reported positive interim data from the ongoing Phase 2 study of IONIS-FB-L_{Rx} in patients with IgAN. Additionally, IONIS-FB-L_{Rx} is in an ongoing Phase 2 study in patients with GA, refer to the IONIS-FB-L_{Rx} description below for further details.

Our Marketed Medicines –Bringing Value to Patients Today

SPINRAZA – SPINRAZA (nusinersen) injection for intrathecal use is a survival motor neuron-2, or SMN2, directed antisense medicine indicated for the treatment of SMA in pediatric and adult patients.

SPINRAZA is the global market leader for the treatment of patients with SMA, a progressive, debilitating and often fatal genetic disease. Our partner, Biogen, is responsible for commercializing SPINRAZA worldwide.

SMA is characterized by loss of motor neurons in the spinal cord and lower brain stem. People with SMA have a deletion or defect in their *SMN1* gene and rely on their *SMN2* gene to produce functional SMN protein, which motor neurons need to maintain motor function and muscle strength. However, in untreated people the *SMN2* gene can only produce approximately 10% of the SMN protein critical for motor neurons, resulting in severe and progressive loss of motor function and strength.

The rate and severity of degeneration varies depending on the amount of functional SMN protein a patient can produce. Type 1, or infantile-onset, SMA is the most severe form of the disease. Type 1 SMA patients produce very little SMN protein and often progress to death or permanent ventilation by the age of 2. Patients with Type 2 or Type 3, or later-onset, SMA produce more SMN protein, but also suffer from a progressive loss of muscle strength and function and a reduced life expectancy.

Biogen continues to expand the body of evidence supporting SPINRAZA's durable efficacy and well-established safety profile to address the remaining needs of SMA patients of all ages. This includes the following ongoing studies:

- DEVOTE: In the Phase 2/3 DEVOTE study, Biogen is evaluating the safety and potential to achieve increased efficacy with a higher dose of SPINRAZA compared to the currently approved dose. In 2022, Biogen reported final data from Part A of the ongoing, three-part DEVOTE study. Results from Part A, an open-label safety evaluation period in children and teens with later-onset SMA, suggest that the higher dosing regimen of SPINRAZA leads to higher levels of the drug in the cerebrospinal fluid, or CSF, supporting further development of a higher dose of SPINRAZA. Additionally, the results indicated that SPINRAZA was generally well-tolerated.
- RESPOND: In the Phase 4 RESPOND study, Biogen is evaluating the benefit of SPINRAZA in infants and children with a suboptimal clinical response to the gene therapy, onasemnogene abeparvovec. In 2023, Biogen presented interim results from the RESPOND study that showed improved motor function in most participants treated with SPINRAZA following treatment with onasemnogene abeparvovec.
- ASCEND: In the Phase 3b ASCEND study, Biogen is evaluating the clinical outcomes and assessing the safety of a higher dose of SPINRAZA in children, teens and adults with later-onset SMA following treatment with risdiplam.

Additionally, Biogen continues to conduct the Phase 2 NURTURE study, an open-label study investigating the benefit of SPINRAZA when administered before symptom onset in patients genetically diagnosed with SMA, and likely to develop Type 1 or Type 2 SMA. NURTURE was the first study to investigate the potential to slow or stop SMA disease progression in presymptomatic SMA patients. In 2022, Biogen reported new NURTURE study data, showing that early and sustained treatment with SPINRAZA helped participants to maintain and/or make progressive gains in motor function. These data showed that after 11 months of additional follow-up since the 2020 interim analysis, all children who were able to walk alone maintained this ability and one child gained the ability to walk alone, increasing the total percentage of study participants able to walk from 92% to 96%. Further, most children achieved motor milestones within age-appropriate timelines and no major motor milestones were lost. The safety of SPINRAZA over this extended follow-up period was consistent with previously reported findings.

The approval of SPINRAZA was based on efficacy and safety data from multiple clinical studies, including two randomized, placebo-controlled Phase 3 studies, ENDEAR, in patients with infantile-onset SMA, and CHERISH, in patients with later-onset SMA as well as from SHINE, an OLE study for patients with SMA who participated in prior SPINRAZA studies.

QALSODY – QALSODY (tofersen) is an antisense medicine used to treat ALS in adults who have a mutation in the superoxide dismutase 1, or SOD1, gene, or SOD1-ALS. The FDA granted QALSODY accelerated approval based on reduction in plasma neurofilament light chain, or Nfl., observed in patients treated with QALSODY. Continued approval for this indication may be contingent upon verification of clinical benefit in confirmatory trial(s).

SOD1-ALS is a rare, fatal, neurodegenerative disorder caused by a mutation in the *SOD1* gene leading to a progressive loss of motor neurons. As a result, people with SOD1-ALS experience increasing muscle weakness, loss of movement, difficulty breathing and swallowing and eventually succumb to the disease. Current treatment options for people with SOD1-ALS are extremely limited. It is estimated that there are approximately 1,400 patients with SOD1-ALS in the G7 countries (comprised of Canada, France, Germany, Italy, Japan, the United Kingdom and the U.S.).

Biogen is also evaluating QALSODY for treatment of presymptomatic individuals who have a SOD1 genetic mutation. See the "Tofersen" description under "Our Phase 3 Pipeline" section below for further information on the development program for presymptomatic individuals. Tofersen is one of three medicines we have in development to treat ALS.

QALSODY received accelerated approval from the U.S. FDA in April 2023 and is currently under regulatory review in the EU. The QALSODY NDA and MAA included results from a Phase 1 study in healthy volunteers, a Phase 1/2 study evaluating ascending dose levels, the Phase 3 VALOR study, and the Phase 3 OLE study, as well as 12-month integrated results from the Phase 3 VALOR study and the Phase 3 OLE study. The 12-month integrated data show that earlier initiation of QALSODY, compared to delayed initiation, slowed declines in clinical function, respiratory function, muscle strength and quality of life and build on the results previously observed in the initial readout. The 12-month data compare patients with early initiation of QALSODY (at the start of VALOR) to those who had a delayed initiation of QALSODY (six months later, in the OLE).

At the time of the 12-month analysis, because the majority of participants survived without permanent ventilation, the median time to death or permanent ventilation, could not be estimated. However, early survival data suggest a lower risk of death or permanent ventilation with earlier initiation of QALSODY. Additionally, the latest 12-month results showed that reductions in total SOD1 protein (a marker of target engagement) and neurofilament (a marker of axonal injury and neurodegeneration) were sustained over time. QALSODY reduced total CSF SOD1 protein and plasma neurofilament levels in both early- and delayed-start groups as follows:

- 33% and 21% reduction in SOD1 protein, the intended target for QALSODY, respectively
- 51% and 41% reduction in plasma neurofilament, a marker of neuron injury, respectively

QALSODY had a favorable safety and tolerability profile.

The FDA and EMA granted QALSODY orphan drug designation for the treatment of ALS in September 2016 and August 2016, respectively.

In December 2018, Biogen exercised its option to license QALSODY. As a result, Biogen is responsible for global development, regulatory and commercialization activities, and costs for QALSODY.

WAINUA – WAINUA (eplontersen) injection is a LICA medicine indicated for the treatment of adults with ATTRv-PN. WAINUA prevents the production of TTR protein, reducing the amount of amyloid buildup that damages organs and tissues. WAINUA was approved by the FDA in December 2023.

ATTR amyloidosis is a systemic, progressive and fatal disease in which patients experience multiple overlapping clinical manifestations caused by the inappropriate formation and aggregation of TTR amyloid deposits in various tissues and organs, including peripheral nerves, heart, intestinal tract, eyes, kidneys, central nervous system, thyroid and bone marrow. The progressive accumulation of TTR amyloid deposits in these tissues and organs leads to organ failure and eventually death.

ATTRv-PN is caused by the accumulation of misfolded mutated TTR protein in the peripheral nerves. Patients with ATTRv-PN experience ongoing debilitating nerve damage throughout their body resulting in the progressive loss of motor functions, such as walking. These patients also accumulate TTR in other major organs, which progressively compromises their function and eventually leads to death within five to fifteen years of disease onset. There are an estimated 40,000 addressable patients, which includes those with ATTRv-PN and those with ATTRv- mixed phenotype worldwide.

Often, patients with ATTRv-PN will have TTR build up in the heart and experience cardiomyopathy symptoms. Similarly, patients with ATTR-CM may often have TTR build up in their peripheral nerves and experience nerve damage and a variety of symptoms, including progressive difficulty with motor functions. As a result, we are developing WAINUA to treat all types of ATTR. See the "WAINUA" description under "Our Phase 3 Pipeline" section below for further information on our development program for ATTR-CM.

FDA approval was based on the interim analysis of the Phase 3 NEURO-TTRansform study in patients with ATTRv-PN. NEURO-TTRansform was a global, multi-center, randomized, open-label study designed to evaluate the efficacy, safety and tolerability of WAINUA. The study compared WAINUA to the historical placebo arm from the TEGSEDI (inotersen) NEURO-TTR Phase 3 study. In the interim analysis, WAINUA demonstrated a statistically significant and clinically meaningful change from baseline for the co-primary and secondary endpoints at 35 weeks compared to the external placebo group. In the study, WAINUA achieved an 81% ($p<0.0001$) least squares, or LS, mean reduction in the co-primary endpoint of serum TTR concentration compared to baseline, demonstrating reduced TTR protein production. WAINUA also demonstrated a significant treatment effect on the co-primary endpoint of modified Neuropathy Impairment Score +7, or mNIS+7, a measure of neuropathic disease progression, with a statistically significant difference in mean change from baseline versus the external placebo group ($p<0.0001$). The study also met its key secondary endpoint of change from baseline in the Norfolk Quality of Life Questionnaire-Diabetic Neuropathy, or Norfolk QoL-DN, showing that treatment with WAINUA significantly improved patient-reported quality of life compared to the external placebo group ($p<0.0001$). In September 2023, The *Journal of American Medical Association, or JAMA*, published the Phase 3 NEURO-TTRansform study results.

Additionally, in April 2023, we presented positive data that WAINUA met all co-primary and secondary endpoints in the NEURO-TTRansform study at the final analysis at week 66. At week 66:

- WAINUA achieved a LS mean reduction of 82% in serum TTR concentration from baseline, compared to an 11% reduction from baseline in the external placebo group ($p<0.0001$).
- WAINUA stopped disease progression as measured by mNIS+7 resulting in a 0.28 point LS mean increase compared to a 25.06 point increase for the external placebo group from baseline (24.8 point LS mean improvement; $p<0.0001$).
- WAINUA improved quality of life demonstrating a 5.5 point LS mean decrease (improvement) on the Norfolk QoL-DN, compared to a 14.2 point increase (worsening) in the external placebo group (19.7 point LS mean improvement; $p<0.0001$).

And in July 2023, we reported that WAINUA continued to halt neuropathy disease progression and improve quality of life in patients with ATTRv-PN through the end of treatment analysis at week 85.

WAINUA is currently under regulatory review in the EU and other countries for the treatment of patients with ATTRv-PN.

In January 2022 and October 2023, the FDA and EMA, respectively, granted orphan drug designation to WAINUA for the treatment of ATTR.

In December 2021, we entered into an agreement with AstraZeneca to jointly develop and commercialize WAINUA in the U.S. We initially granted AstraZeneca exclusive rights to commercialize WAINUA outside the U.S., except for certain Latin American countries. In July 2023, we expanded those rights to include Latin America.

TEGSEDI – TEGSEDI (inotersen) injection is an antisense medicine indicated for the treatment of ATTRv-PN in adults. TEGSEDI prevents the production of TTR protein, reducing the amount of amyloid buildup that damages organs and tissues.

TEGSEDI is commercially available in numerous countries, including the U.S., many European countries, Canada, and Latin America. We launched TEGSEDI in the U.S. and EU in late 2018. In 2021, we began selling TEGSEDI in the U.S., Canada and Europe through our distribution agreement with Sobi. Refer to the section titled, *Overview*, for further details on our distribution agreement with Sobi. In Latin America, PTC is commercializing TEGSEDI in Brazil and is pursuing access in additional Latin American countries through its exclusive license agreement with us.

The approvals of TEGSEDI were based on efficacy and safety data from the Phase 3 NEURO-TTR study in patients with ATTRv-PN.

WAYLIVRA – WAYLIVRA (volanesorsen) is an antisense medicine indicated as an adjunct to diet in adult patients with genetically confirmed FCS and at high risk for acute, potentially fatal pancreatitis, in whom response to diet and triglyceride lowering therapy has been inadequate. WAYLIVRA reduces triglyceride levels by inhibiting the production of apolipoprotein C-III, or apoC-III, a protein that is a key regulator of triglyceride levels.

FCS is a rare, genetic disease estimated to affect one to two individuals per million and characterized by extremely elevated triglyceride levels, typically greater than 1,000 mg/dl. FCS can lead to many chronic health issues including severe, recurrent abdominal pain, fatigue, high risk of life-threatening pancreatitis and abnormal enlargement of the liver or spleen. In addition, people with FCS are often unable to work, adding to their disease burden. In severe cases, patients can have bleeding into the pancreas, serious tissue damage, infection, and cyst formation, as well as damage to other vital organs such as the heart, lungs, and kidneys.

WAYLIVRA received conditional marketing authorization in May 2019 from the European Commission, or EC. WAYLIVRA is commercially available in multiple European countries and in Latin America. We launched WAYLIVRA in the EU in the third quarter of 2019. In 2021, we began selling WAYLIVRA in Europe through our distribution agreement with Sobi. In Latin America, WAYLIVRA is approved for two indications, FCS and FPL. PTC is commercializing WAYLIVRA in Brazil and is pursuing access in additional Latin American countries through its exclusive license agreement with us. In the fourth quarter of 2022, WAYLIVRA was approved in Brazil for a second indication, FPL.

WAYLIVRA's conditional marketing authorization in the EU for FCS and approval in Brazil for FCS were based on efficacy and safety data from the Phase 3 APPROACH study and supported by results from the Phase 3 COMPASS study. WAYLIVRA's approval in Brazil for FPL was based on efficacy and safety data from the Phase 3 BROADEN study in patients with FPL.

Our Innovative Pipeline of Investigational Medicines

As a pioneer in RNA-targeted therapeutics, we continue to drive innovation with a leading pipeline in neurology, cardiology and other areas of high patient need.

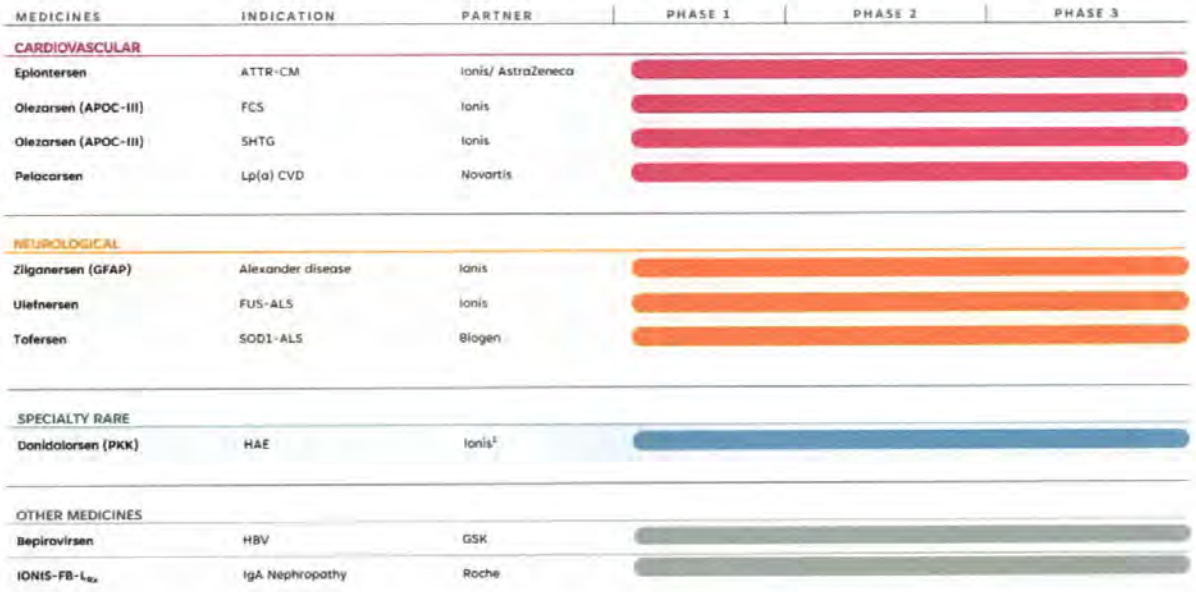
The table below lists the medicines in our clinical pipeline and includes the disease indication, the partner (if the medicine is partnered), and the development status of each medicine. We categorize first-in-patient studies to establish a medicine's safety profile as Phase 1/2 and in the table below these are listed in the Phase 2 column. Studies in patients that are designed to establish an investigational medicine's proof of concept and additional safety profile are also listed in Phase 2. Pivotal studies designed to enable registrational filing for marketing authorization are listed in Phase 3. We have included descriptions for each of our medicines in Phase 2 and Phase 3 development below.



1 Granted Otsuka exclusive rights to commercialize donidalorsen in Europe.

Our Phase 3 Pipeline

We currently have nine medicines in our Phase 3 pipeline:



1 Granted Otsuka exclusive rights to commercialize donidalorsen in Europe.

Eplontersen (TTR) – Eplontersen (TTR) – Eplontersen (formerly IONIS-TTR-L_{Rx}) is an investigational LICA medicine we designed to inhibit the production of TTR protein. As discussed above under "WAINUA" in our "Marketed Medicines" section, we are developing eplontersen as a monthly self-administered subcutaneous injection to treat all types of ATTR, including ATTR-CM.

ATTR-CM is caused by the accumulation of misfolded TTR protein in the cardiac muscle. Patients experience ongoing debilitating heart damage resulting in progressive heart failure, which results in death within three to five years from disease onset. ATTR-CM includes both the genetic and wild-type form of the disease. There are an estimated 300,000 to 500,000 patients with ATTR-CM worldwide.

Often, patients with ATTRv-PN will have TTR build up in the heart and experience cardiomyopathy symptoms. Similarly, patients with ATTR-CM may often have TTR build up in their peripheral nerves and experience nerve damage and a variety of symptoms, including progressive difficulty with motor functions.

In January 2020, we initiated the CARDIO-TTRansform Phase 3 cardiovascular outcome study of eplontersen in patients with ATTR-CM. CARDIO-TTRansform is a global, multi-center, randomized, double-blind, placebo-controlled study in approximately 1,400 patients with ATTR-CM. We designed the study to evaluate the efficacy, safety and tolerability of eplontersen in patients with ATTR-CM. The primary endpoint in the CARDIO-TTRansform study is a composite outcome of cardiovascular mortality and recurrent cardiovascular clinical events up to Week 140. In July 2023, we announced that the CARDIO-TTRansform study had completed enrollment.

In January 2022 and October 2023, the FDA and EMA, respectively, granted orphan drug designation to WAINUA for the treatment of ATTR.

Olezarsen (ApoC-III) – Olezarsen (formerly IONIS-APOCIII-L_{Rx}) is an investigational LICA medicine we designed to inhibit the production of apoC-III for patients who are at risk of disease due to elevated triglyceride levels. ApoC-III is a protein produced in the liver that regulates triglyceride metabolism in the blood. People with severely elevated triglycerides, such as people with FCS, are at high risk for acute pancreatitis and an increased risk of cardiovascular disease, or CVD. It is estimated that FCS affects one to two individuals per million worldwide and more than three million patients have SHTG in the U.S.

We are currently conducting a broad development program for olezarsen that includes the Phase 3 Balance study in patients with FCS and three Phase 3 studies supporting development for the treatment of SHTG: CORE, CORE2 and ESSENCE.

In September 2023, we reported positive topline data from the Phase 3 Balance study in patients with FCS. The study met its primary efficacy endpoint with a statistically significant reduction in triglyceride (TG) levels with the olezarsen 80 mg monthly dose at six months compared to placebo (p=0.0009); triglyceride lowering continued to improve at 12 months. In addition, olezarsen 80 mg showed a substantial reduction in acute pancreatitis events compared to placebo, a key secondary endpoint. Treatment with olezarsen 80 mg resulted in a >75% reduction in apoC-III, a protein produced in the liver that regulates TG metabolism in the blood. In addition to the 80 mg monthly dose, the study also evaluated a 50 mg monthly dose. Olezarsen demonstrated a dose-dependent effect, with both study doses showing a substantial reduction in acute pancreatitis compared to placebo. The 50 mg dose did not reach statistical significance at six months on the primary endpoint of triglyceride lowering (p=0.0775). Olezarsen demonstrated a favorable safety and tolerability profile in the study. Based on the positive results, we plan to file a New Drug Application, or NDA, in 2024 with the U.S. FDA in addition to EU regulatory filings for patients with FCS.

We are also conducting ongoing Phase 3 studies for the expanded SHTG patient population. CORE and CORE2 are global, multi-center, randomized, double-blind, placebo-controlled studies enrolling approximately 540 and 390 patients, respectively, designed to assess the efficacy, safety and tolerability of olezarsen in patients with SHTG. The CORE and CORE2 studies compare olezarsen to placebo in patients with triglyceride levels equal to or greater than 500 mg/dL who are on currently available therapies for elevated triglycerides. The primary endpoint of the studies is the percent change in fasting triglycerides from baseline at month six. Additionally, in November 2022, we initiated ESSENCE, a global, multi-center, randomized, double-blind, placebo-controlled study enrolling approximately 1,300 patients to provide a robust safety database. The primary endpoint of the study is the percent change in fasting triglycerides from baseline at month six.

In January 2020, we reported positive results from a Phase 2 clinical study in patients with hypertriglyceridemia and at high risk of or with established CVD. Olezarsen achieved statistically significant, dose-dependent reductions in fasting triglycerides compared to placebo at all dose levels. Olezarsen also achieved statistical significance in numerous key secondary endpoints, including significant reductions in apoC-III. Olezarsen had a favorable safety and tolerability profile supportive of continued development.

In February 2024, the FDA granted Breakthrough Therapy designation and orphan drug designation to olezarsen for the treatment of FCS. Additionally, in January 2023, the FDA granted olezarsen Fast Track designation for the treatment of patients with FCS.

Donidalorsen (PKK) – Donidalorsen (formerly IONIS-PKK-L_{Rx}) is an investigational LICA medicine we designed to inhibit the production of prekallikrein, or PKK. HAE is a rare genetic disease that is characterized by severe and potentially fatal swelling of the arms, legs, face and throat. PKK plays an important role in the activation of inflammatory mediators associated with acute attacks of HAE. By inhibiting the production of PKK, donidalorsen could be an effective prophylactic approach to preventing HAE attacks. It is estimated that there are more than 20,000 patients with HAE in the U.S. and Europe.

In January 2024, we reported positive topline data from the Phase 3 OASIS-HAE study in patients with HAE. The study met its primary efficacy endpoint with a statistically significant reduction in the rate of HAE attacks in patients treated with 80 mg of donidalorsen via subcutaneous injection dosed every four weeks, or Q4W, (p<0.001) or every eight weeks, or Q8W, (p=0.004) compared to placebo. In addition, the trial showed donidalorsen achieved statistical significance on all secondary endpoints in the Q4W group and key secondary endpoints in the Q8W group. Donidalorsen demonstrated a favorable safety and tolerability profile in the study. Based on the positive results, we plan to file a NDA in 2024 with the U.S. FDA. Otsuka, which has exclusive rights to commercialize donidalorsen in Europe, is preparing to submit a Marketing Authorization Application to the European Medicines Agency, or EMA.

In May 2022, we initiated OASIS-Plus, a multi-center, open-label, global study in approximately 110 patients who were either previously treated with other prophylactic therapies or who have completed OASIS-HAE.

In 2021 and 2022 we reported positive results from the Phase 2 clinical study of donidalorsen in patients with HAE. And in 2022 and 2023, we presented positive results from the Phase 2 OLE study of donidalorsen in patients with HAE. Following the 13-week blinded, placebo-controlled Phase 2 study with a fixed 13-week dosing period where they received donidalorsen 80 mg every four weeks, patients were eligible for enrollment in the OLE study. Of the 20 Phase 2 study participants, 17 entered the OLE study and were on a fixed 13-week dosing period where they received 80 mg every four weeks. From week 17 through two years, patients entered a flexible dosing period where they either received donidalorsen 80 mg every four weeks, 80 mg every eight weeks, or 100 mg every four weeks. Over the two years, patients treated with donidalorsen via subcutaneous injection showed an overall sustained mean reduction in HAE attack rates of 96% from baseline, from 2.70 to 0.06 attacks per month, across all dosing groups. Furthermore, all patients treated with donidalorsen reported a clinically meaningful improvement in quality of life as measured by the Angioedema Quality of Life Questionnaire (AE-QoL) over two years. Donidalorsen had a favorable safety and tolerability profile in the study.

In September 2023 and February 2024, the FDA and EMA granted orphan drug designation to donidalorsen.

In December 2023, we granted Otsuka exclusive rights to commercialize donidalorsen in Europe.

Pelacarsen (Apo(a)) (TQJ230) – Pelacarsen (formerly IONIS-APO(a)-L_{Rx}) is an investigational LICA antisense medicine we designed to inhibit the production of apolipoprotein(a), or Apo(a), in the liver to offer a direct approach for reducing Lp(a). Elevated Lp(a) is recognized as an independent, genetic cause of CVD. Lp(a) levels are determined at birth and lifestyle modification, including diet and exercise, do not impact Lp(a) levels. Inhibiting the production of Apo(a) in the liver reduces the level of Lp(a) in blood, potentially slowing down or reversing CVD in people with hyperlipoproteinemia(a), a condition in which individuals have levels of Lp(a) greater than 50 mg/dL, the recognized threshold for risk of CVD. We believe antisense technology is well suited to address hyperlipoproteinemia(a) because it specifically targets the RNA that codes for all forms of the Apo(a) molecule. It is estimated that there are more than eight million people living with CVD and elevated levels of Lp(a).

In December 2019, Novartis initiated the Phase 3 study of pelacarsen, Lp(a) HORIZON, in patients with elevated Lp(a) levels and a prior cardiovascular event. Lp(a) HORIZON is a global, multi-center, randomized, double-blind, placebo-controlled cardiovascular outcomes study in more than 8,000 patients designed to assess the efficacy, safety and tolerability of pelacarsen. Patients are treated with 80 mg of pelacarsen administered monthly by subcutaneous injection. The primary endpoint in Lp(a) HORIZON is the time to occurrence of first major adverse cardiovascular event, or MACE. In July 2022, we announced that the Lp(a) HORIZON study had completed enrollment.

In November 2018, at the American Heart Association, or AHA, annual meeting, we reported results of the Phase 2 study of pelacarsen in patients with hyperlipoproteinemia(a). In the Phase 2 study, we observed statistically significant and dose dependent reductions from baseline in Lp(a) levels. Approximately 98% of patients who received the highest dose in the study demonstrated a reduction in Lp(a) levels to below the recommended threshold for CVD events (<50 mg/dL). Pelacarsen had a favorable safety and tolerability profile supportive of continued development.

In February 2019, Novartis exercised its option to license pelacarsen. As a result, Novartis is responsible for global development, regulatory and commercialization activities, and costs for pelacarsen.

In April 2020, the FDA granted pelacarsen Fast Track designation for the treatment of patients with elevated Lp(a) and CVD. In December 2020, the Center for Drug Evaluation, or CDE, of China National Medical Products Administration granted breakthrough therapy designation to pelacarsen.

Zilganersen – Zilganersen (formerly ION373) is an investigational antisense medicine we designed to inhibit the production of glial fibrillary acidic protein, or GFAP. We are developing zilganersen as a potential therapy for AxD, a rare, progressive and fatal neurological disease that affects the myelin sheath which protects nerve fibers. AxD is caused by a gain-of-function mutation in the *GFAP* gene and is characterized by progressive deterioration, including loss of skills and independence, generally leading to death in childhood or early adulthood.

Two major types of AxD have been defined. Type I onset typically occurs before four years of age and patients can experience head enlargement, seizures, limb stiffness, delayed or declining cognition, and lack of growth. Type II onset typically occurs after the age of four and symptoms can include difficulty speaking, swallowing, and making coordinated movements. AxD is most often fatal. There are treatments that can relieve symptoms, but there is no disease modifying therapy yet available to patients.

In April 2021, we initiated a pivotal study of zilganersen in patients with AxD and in September 2023, we advanced zilganersen into the Phase 3 portion of the pivotal study. The pivotal study of zilganersen is a multi-center, double-blind, placebo-controlled, multiple-ascending dose study in approximately 55 patients with AxD designed to assess the efficacy, safety and tolerability of zilganersen. Patients will receive zilganersen or placebo for a 60-week period, after which all patients in the study will receive zilganersen for a 60-week open-label treatment period. The primary endpoint is the change from baseline in the 10-Meter Walk Test, or 10MWT.

In September 2020 and October 2019, the FDA and EMA, respectively, granted orphan drug designation to zilganersen. Additionally in August 2020, the FDA granted rare pediatric designation to zilganersen.

Ulefnersen (FUS) – Ulefnersen (formerly ION363) is an investigational antisense medicine we designed to reduce the production of the FUS protein to treat people with ALS caused by mutations in the *FUS* gene. Because antisense-mediated reduction of mutant FUS protein in a FUS-ALS mouse model demonstrated the ability to prevent motor neuron loss, it is hypothesized that reduction of FUS protein will reverse or prevent disease progression in FUS-ALS patients. It is estimated that there are approximately 350 patients with FUS-ALS in G7 countries.

In April 2021, we initiated a Phase 3 study of ulefnersen in patients with FUS-ALS. The Phase 3 trial of ulefnersen is a global, multi-center, randomized, double-blind, placebo-controlled study in approximately 75 patients designed to assess the efficacy, safety and tolerability of ulefnersen. Part 1 of the trial consists of patients randomized to receive a loading regimen of ulefnersen or placebo for days one, 28 and 85 after which patients are dosed quarterly for a total of 61 weeks, followed by a 12 week follow up for participants entering Part 2 or 40 week follow up for participants not entering Part 2. Part 2 is an open-label period in which all patients in the trial will receive ulefnersen or placebo loading regimen at week four followed by one dose every 12 weeks for 85 weeks. The primary endpoint is the change from baseline as measured by joint rank analysis of the combined assessment of the Revised Amyotrophic Lateral Sclerosis Functional Rating Scale, or ALSFRS-R, Total Score, time of rescue or discontinuation from Part 1 and entering Part 2 due to a deterioration in function, and Ventilation Assistance-free survival, or VAFS.

In August 2023 and September 2023, the FDA and EMA, respectively, granted orphan drug designation to ulefnersen.

Tofersen (SOD1) (BIIB067) – Tofersen (formerly IONIS-SOD1$_{Rx}$) is an investigational antisense medicine we designed to inhibit the production of SOD1 protein, which is a well understood genetic cause of ALS. As discussed above under the "QALSODY" section in our "Marketed Medicines" section, Biogen is also evaluating tofersen for treatment of presymptomatic individuals who have a SOD1 genetic mutation.

In April 2021, Biogen initiated a Phase 3 study of tofersen, called ATLAS, in presymptomatic individuals with a SOD1 genetic mutation. ATLAS is a multi-center, randomized, double-blind, placebo-controlled study enrolling approximately 150 subjects designed to assess the efficacy, safety and tolerability of tofersen. Patients are only given tofersen if they meet a defined biomarker threshold or progress to develop clinically manifest SOD1-ALS.

In September 2016 and August 2016, the FDA and EMA, respectively, granted orphan drug designation to tofersen.

In December 2018, Biogen exercised its option to license tofersen. As a result, Biogen is responsible for global development, regulatory and commercialization activities, and costs for tofersen.

Bepirovirsen (HBV) (GSK3228836) – Bepirovirsen (formerly IONIS-HBV$_{Rx}$) is an investigational antisense medicine we designed to inhibit the production of viral proteins associated with HBV. These include proteins associated with infection and replication, including the hepatitis B surface antigen, or HBsAg, which is present in both acute and chronic infections and is associated with a poor prognosis in people with chronic HBV infection.

HBV infection is a serious health problem that can lead to significant and potentially fatal health conditions, including cirrhosis, liver failure and liver cancer. Chronic HBV infection is one of the most common persistent viral infections in the world, affecting nearly 300 million people and resulting in approximately 900,000 deaths annually. Currently available therapies, although effective in reducing circulating HBV in the blood, do not effectively inhibit HBV antigen production and secretion, which are associated with poor prognosis and increased risk of liver cancer.

In January 2023, GSK initiated the Phase 3 program of bepirovirsen, B-Well, in patients with chronic HBV. B-Well 1 and B-Well 2 are global, multi-center, randomized, double-blind, placebo-controlled studies enrolling more than 500 patients each. GSK designed these studies to assess the efficacy, safety and tolerability of bepirovirsen. The arms will be stratified based on HBsAg levels at screening. The primary endpoint is the number of patients achieving functional cure with baseline HBsAg ≤ 1,000 IU/mL. Functional cure is defined as a sustained suppression (24 weeks or longer) of HBV DNA (< Lower Limit of Quantification, or LLOQ) while off all HBV treatments with HBsAg loss (<0.05 IU/mL) with or without HBsAg after a finite duration of therapy.

In June 2022, GSK presented positive results from the Phase 2b B-CLEAR study of bepirovirsen in patients with chronic HBV infection. The end of study results showed that treatment with bepirovirsen in some patients resulted in sustained clearance of HBsAg and HBV DNA for 24 weeks after end of bepirovirsen treatment in people with chronic HBV infection. Treatment with bepirovirsen that was administered weekly at a dose of 300 mg per week for 24 weeks, with loading doses administered on day four and 11 (treatment arm 1), resulted in 9% of patients on NA treatment and 10% of patients not on NA treatment both achieving the primary outcome of HBsAg levels and HBV DNA levels below the LLOQ. This is defined as a sustained response and was observed for 24 weeks post last dose. Patients with low baseline HBsAg levels responded best to treatment with bepirovirsen with 16% and 25% of patients achieving the primary outcome in treatment arm one of the on NA and not on NA cohorts, respectively. Additionally in June 2023, GSK presented durable response data from the Phase 2 B-Sure long-term follow-up study of bepirovirsen in complete responder patients from the Phase 2b B-Clear study of patients with HBV. Bepirovirsen had a favorable safety and tolerability profile supportive of continued development.

In October 2023, GSK reported data from the B-Together Phase 2b study of bepirovirsen in patients with chronic HBV infection at the AASLD Liver Meeting. The data showed that between 9-15% of patients attained the primary outcome of HBsAg and HBV DNA below the LLOQ for 24 weeks after planned end of sequential treatment with pegylated interferon, in the absence of newly initiated antiviral therapy. Additionally, all patients who achieved the primary endpoint had a baseline HBsAg ≤3000 IU/mL. Bepirovirsen had a favorable safety and tolerability profile supportive of continued development.

In August 2019, GSK exercised its option to license our HBV program following the positive results of the Phase 2a study of bepirovirsen in patients with chronic HBV infection. As a result, GSK is responsible for global development, regulatory and commercialization activities, and costs for the HBV program.

In February 2024, the FDA granted bepirovirsen Fast Track designation for the treatment of patients with chronic HBV infection.

IONIS-FB-L$_{Rx}$ (IgAN) (RG6299) – IONIS-FB-L$_{Rx}$ is an investigational LICA medicine we designed to inhibit the production of complement factor B, or FB, and the alternative complement pathway. Genetic association studies have shown that overaction of the alternative complement pathway has been associated with the development of several complement-mediated diseases, including IgAN. As discussed below under the "IONIS-FB-L$_{Rx}$" section in our "Other Medicines in Development" section, we are also developing IONIS-FB-L$_{Rx}$ for GA, secondary to age-related macular degeneration, or AMD.

IgAN is one of the most common causes of inflammation that impairs the filtering ability of kidneys and is an important cause of chronic kidney disease and kidney failure. Also known as Berger's disease, IgAN is characterized by deposits of IgA in the kidneys, resulting in inflammation and tissue damage.

In April 2023, Roche initiated a Phase 3 study of IONIS-FB-L$_{Rx}$, called IMAGINATION, in patients with IgAN. IMAGINATION is a multi-center, randomized, double-blind, placebo-controlled study enrolling approximately 430 patients designed to assess the efficacy, safety and tolerability of IONIS-FB-L$_{Rx}$. The primary endpoint is the change from baseline in the urine protein-to-creatinine ratio, or UPCR, at week 37.

In November 2022, we presented positive results from the Phase 2 open-label study of IONIS-FB-L$_{Rx}$ in patients with IgAN at the American Society of Nephrology's, or ASN, Kidney Week. In the Phase 2 study, which included results from the first 10 patients treated with IONIS-FB-L$_{Rx}$, IONIS-FB-L$_{Rx}$ met its primary endpoint of change in 24-hour urinary protein, demonstrating a 44% mean reduction in proteinuria from baseline to week 29. Kidney function, as measured by estimated glomerular filtration rate, or eGFR, was maintained in all patients in the study. The results from the Phase 2 study provided proof-of-concept for the potential of IONIS-FB-L$_{Rx}$ to treat patients with IgAN by inhibiting complement FB and the alternative complement pathway. Additionally, in November 2023 at ASN Kidney Week, we presented new positive interim results from the ongoing Phase 2 study, which included results from 13 patients. The results showed that IONIS-FB-L$_{Rx}$ effectively and selectively reduced circulating FB, Alternate Pathway Activity, or AH50 and urinary complement Ba. Additionally, IONIS-FB-L$_{Rx}$ reduced established proteinuria in patients with IgAN after six-months of treatment. The Phase 2 open-label study remains ongoing and will evaluate IONIS-FB-L$_{Rx}$ in approximately 25 patients with IgAN. IONIS-FB-L$_{Rx}$ had a favorable safety and tolerability profile supportive of continued development.

4V

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Precigen, Inc

Physical Address: 20358 Seneca Meadows Parkway

City: Germantown State: MD Zip: 20876

Mailing Address (if different from physical address): 20374 Seneca Meadows Parkway

City: Germantown State: MD Zip: 20876

Telephone: 301-556-2982 Website: https://precigen.com/

Name of Designated Representative (DR): David Sokoloff

Licensing Company Email: statelicensing@precigen.com DR Email: dsokoloff@precigen.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies, Specialty Distributors		☒ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed within the last year.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: VA

Parent Company (if any): N/A

Corporation Name: Precigen, Inc.

Mailing Address: 20374 Seneca Meadows Parkway

City: Germantown State: MD Zip: 20876

Telephone: 301-556-2982 Email: statelicensing@precigen.com

Contact Person Name: David Sokoloff

Date of SEC Registration:	SEC Registration Number: 001-36042	Stock Exchange Symbol: PGEN

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Precigen, Inc

Facility Name

Rutul Shah

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

18 MAR 2025

Date

Board Use Only	Date Received: 4/15/25	Amount: $1000 cc #499

PRECIGEN

Description of Operations

Precigen, Inc. is a Virtrual Manufacturer. Precigen's products are manufactured by a Contract Manufacturer and will be distributed to Specialty Distributors by their Third-Party Logistics Provider, Integrated Commercialization Services, Inc., who is licensed to ship pharmaceutical products into your state.

Contract Manufacturer Information:
We are using the following contract manufacturer to produce our product:

Catalent Maryland, Inc.
801 W. Baltimore Street, Suite 302
Baltimore, MD 21201
FDA Establishment Number: 3015558590

Contact Person:
Contact Number:

Catalent manufactures Precigen's product and packages finished product. At no time does Catalent own the product, contract with Precigen's customers, invoice, nor sell a Precigen product. Precigen's products are not Controlled Substances.

Labeler Code: 84768

Third Party Logistic information:
For distribution into the commercial supply channels, Integrated Commercialization Services, Inc. acts as Precigen's Third Party Logistics (3PL) provider to manage the storage and distribution of Precigen's product-throughout the United States. Integrated Commercialization Services, Inc.'s address is:

Integrated Commercialization Services, Inc.
420 International Blvd., Suite #500
Brooks, KY 40109

Precigen has 150 employees working on site during normal business hours.
Precigen's hours of operation are 8:00 am – 5:00pm Monday through Friday.

Precigen's records are stored at Integrated Commercialization Services, Inc.

eDRLS - Electronic Drug Registration & Listing System

Current Date: 18-SEP-2024
Labeler DUNS: 191027528
Labeler Name: Precigen, Inc.
Labeler Code Assigned: 84768

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).



Company Information

Company Name: Precigen, Inc
Address: 20358 Seneca Meadows Parkway
City, State, Zip: Germantown, MD 20876
Phone: 760-505-9942
Website: https://precigen.com/
E-mail:

FEIN: 26-0084895
State of Formation: Virginia
Date Incorporated:
File Number:

Ownership Information

Precigen, Inc. is a Publicly Traded company on the NASDAQ stock exchange under the symbol [PGEN].

Officers

Harry Thomasian Jr., CFO
Business Address: 20358 Seneca Meadows Parkway, Germantown, MD 20876

Rutul Shah, COO
Business Address: 20358 Seneca Meadows Parkway, Germantown, MD 20876

Donald Lehr, Chief Legal Officer
Business Address: 20358 Seneca Meadows Parkway, Germantown, MD 20876

Helen Sabzevari, CEO
Business Address: 20358 Seneca Meadows Parkway, Germantown, MD 20876

Phil Tennant, CCO
Business Address: 20358 Seneca Meadows Parkway, Germantown, MD 20876

B0351-2744 03/03/2025 8:46PM Rec'd by SD SOS

Commonwealth of Virginia

State Corporation Commission

CERTIFICATE OF GOOD STANDING

I Certify the Following from the Records of the Commission:

That Precigen, Inc. is duly incorporated under the law of the Commonwealth of Virginia;

That the corporation was incorporated on April 19, 2004;

That the corporation's period of duration is perpetual; and

That the corporation is in existence and in good standing in the Commonwealth of Virginia as of the date set forth below.

Nothing more is hereby certified.

Signed and Sealed at Richmond on this Date:

February 26, 2025

Bernard J. Logan, Clerk of the Commission

CERTIFICATE NUMBER : 202502261063211

DISTRIBUTOR REGISTRATION

183506

STATE OF MARYLAND
DEPARTMENT OF HEALTH

Maryland Board of Pharmacy

4201 Patterson Avenue
Baltimore, Maryland 21215

Precigen Inc
20358 Seneca Meadows Parkway
Germantown MD 20876

THE MARYLAND STATE BOARD OF PHARMACY CERTIFIES THAT
Precigen Inc
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2025)

In accordance with the Health Occupations Article of the Annotated Code of Maryland

LIC. REG. PERM. NO.	EXPIRATION DATE
D07646	05/31/2025

SIGNATURE OF BEARER

183506

183506

State of Maryland

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT **Precigen Inc**
IS A REGISTERED **Active**
Distributor (exp.: 05/31/2025)

SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D07646	05/31/2025

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

Employee list confidential:
Ezerski, Connie
Sabzevari, Helen
Sarni, Lisa Renee
Thomasian , Harry
Baghestani, Homeyra
Bailor, Georgia N
Garcia, Natalia
Kennedy, Gina
Pineda, Paola Ghazarian
Reardon, Jeremy M
Zheng, Xiuming
Gatto, Peter
Lehr, Donald P.
Pellegrino, Christina Leanne
Rakhman, Alexandra
Burr, Jemellin
Mintzer, Samuel D
Miracle, Eric
ODonnell, Jason Todd
Shah, Rutul
Davis, Jelani N
Neupane, Tripti
Mader, Teresa Ann
Bonifacio, Gaetano
Cappuccio, Jeffrey
Merkert, Joseph
Tennant, Phillip James
Butman, Bryan T
Balasubramanian, Anuradha
Boakye-Yiadom, Dennis
Chen, Yun-Chu
Deleon, Sean
Deriquito, Chris Edison Cortes
Katzer, Morgan
Pattasseril, Jacob
Pinto, Crecilla Roshani
Sahin, Derek M
Schwichtenberg, Matthew
Sweatmon, Joseph C
Ahmad, Syed
Liu, Luman
Slone, Robert D.
Coe, Michelle
Harris, Daniel
Hsu, Joseph
Keene, Allison M
Newman, Robert
Pal, Srabani
Patel, Henil J
Reyes, Denis
Smith, Abigail
Sunil, Sushma J
Wong, James
Franco, Julio C
Harwell, Brett Alexander

Marsteller, Daniel
Bartlett, Mariane Cristina
Cocavessis, Christopher
Sokoloff, David
Zaidi, Syed
Anayannis, Nicole V
Chakiath, Marion
Misse, Amalea E
Nikoopour Dailami, Enayatollah
Shepard, Lindsey
Tolouei Semnani, Roshanak
Ward, Elizabeth K
Brough, Douglas E
Epstein, Benjamin Ezra
Ettyreddy, Damodar R
Gnanadurai, Clement
Santos Lopez, Jaime J
Taimassov, Anton
Ahmad, Shamim
Chauhan, Pooja
Cosby, Tahnia
Granados, Rene A
Johnson, Rahim
Plummer, Jacques
Sailor, Carlos
Sayed, Afreen Asif Ali
Velez, Jose
Adeel, Sana
Bishop, Felecia
Bommireddipalli, Sreedeepthi
Challa, Shiva
Chun, Alfred
Robinson, Gina Denise
Romano, Andrew R.
Seboka, Mosis Adugna
Vasantharaj, Yajna
Ziegler, Judson
Bolinger, Cheryl
Dadon, Tikva
Potter, Gregory B.
Ross, Holly M
Woessner, David
Joo, Woo S
Wang, Aifen
Dauphin, Cory M
Lankford, Amy
Tan, Tasha
Vummidi Giridhar, Premkumar
Chan, Tim
Poortman, Carolyn M
Bachy, Christine
Stephens, Sarah Holly
Triplett, Sherry
Kaligotla Ghosh, Shanti
Kelley, Priscilla J
Shah, Khyati

Surapaneni, Ramya Sree
Lucas, Debra Sue
Rogers, Alexandria E
Russell, Robert Sheldon
Diamond, Caroline

The content of this document is confidential and is not to be used beyond its intended use.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Precigen, Inc

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 20358 Seneca Meadows Parkway

City Germantown State MD Zip 20876

Mailing Address (if different from physical address) 20374 Seneca Meadows Parkway

City Germantown State MD Zip 20876

Telephone 301-556-2982 Website https://precigen.com/

Licensing Company Email statelicensing@precigen.com

Section 2: Personal Information

First David Middle Lawrence Last Sokoloff

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 20358 Seneca Meadows Pkwy

City Germantown State MD Zip 20876

Telephone [redacted] Email dsokoloff@precigen.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: Montgomery High School		From - To (MM/YY – MM/YY): 09/91 – 06/95	
Address: 1066 Rt. 601, Skillman, NJ	City: Skillman	State: NJ	Zip: 08558
Diploma/Degree obtained, if any: High School Diploma			
School Name: Gettysburg College		From - To (MM/YY – MM/YY): 08/95 – 05/99	
Address: 300 N. Washington St.	City: Gettysburg	State: PA	Zip: 17325
Diploma/Degree obtained, if any: Bachelor of Arts in Economics			
School Name:		From - To (MM/YY – MM/YY):	
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			
School Name: George Washington University Elliott School of Internal Affairs		From - To (MM/YY – MM/YY): 08/07 – 05/09	
Address: 1957 E St. NW	City: Washington	State: DC	Zip: 20052
Diploma/Degree obtained, if any: Masters of Arts in International Development Studies			
School Name: Massachusetts Institute of Technology		From - To (MM/YY – MM/YY): 03/18 – 05/20	
Address: 77 Massachusetts Avenue	City: Cambridge	State: MA	Zip: 02139
Diploma/Degree obtained, if any: Masters of Applied Science in Supply Chain Mgmt			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/16 – current	[redacted]	Washington	DC	[redacted]
07/13 – 03/16		Washington	DC	

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
See attached resume			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

DAVID L. SOKOLOFF

[redacted]

Senior Executive and Supply Chain Leader

EXECUTIVE SUMMARY

Results driven executive leader with over 20 years of experience building effective and high performing teams. Successful record of developing new business through value-add propositions, customer-centric approach, and operational expertise. Proven driver of change management, leading programs in complex and fast-paced environments. Strong data science and financial background as well as skilled in negotiation and stakeholder alignment.

CORE COMPETENCIES

Executive Leadership | Supply Chain Management | Distribution | Sales & Operations Planning
Trade Compliance | Change Management | Inventory Management | VMI | Network Optimization
QA/cGMP/Validation | Cold Chain Management | Capacity Planning | Operational Excellence
KPI & Analytics Program Development | Strategic Sourcing | Supplier & Customer Relationship Management

EDUCATION

Massachusetts Institute of Technology, Cambridge, MA
Master of Applied Science in Supply Chain Management (5.0/5.0 GPA) **Class of 2020**

George Washington University, Washington, DC
Master of Arts in International Development Studies, Management Concentration (3.8/4.0 GPA) **Class of 2009**

Gettysburg College, Gettysburg, PA
Bachelor of Arts in Economics **Class of 1999**

Certifications & Skills: APICS Certified Supply Chain Professional (CSCP), cGMP, SAP S4HANA, MS Office Suite, PowerBI, JMP, Vensim, AnyLogic, Gretl, Python, SQL, SAS, US Gov. Contract & Agreement Officer Representative.

Languages: English (native), French (advanced), Gilbertese (advanced), Spanish (beginner).

HIGHLIGHTED ACCOMPLISHMENTS

- Established logistics network and strategic partnerships in <9 months for Novavax's global CoVID vaccine launch.
- Built S&OP program, GMP Materials Management department, and world-wide distribution with 99.5% OTIF.
- US government certified sourcing representative. Managed over $25M in federal contracts and provided technical guidance on more than $300M in federal grants.
- Led supply chain campaigns for the US government in 10+ international humanitarian responses.
- Transformed USG inventory management increasing accuracy, compliance, and processing hours by 75%.
- Formed a team of 22 distributors for Phoenix Container achieving $13M in sales and servicing over 1K clients throughout N. America. Additionally, served on the Board of Directors advising the firm's senior management team.

PROFESSIONAL EXPERIENCE

Precigen, Inc., Germantown, MD
Executive Director of Supply Chain **March 2024 – Present**
Biopharmaceutical company advancing the next generation of gene and cell therapies to target intractable diseases in areas of immuno-oncology, autoimmune disorders, and infectious diseases. Recruited to develop the Supply Chain organization for the company's first Commercial Product Launch.

- Lead strategic design and development of the Precigen Supply Chain organization to meet business needs.
- Launched the S&OP program to support strategic vision execution, stakeholder alignment, and supply and demand modelling.
- Responsible for GxP compliance with material handling, transportation, and storage throughout the network.
- Initiated ERP & Serialization project to evaluate, select and implement a compliant validated system within 6 months.
- Establishing strategic partners for a global commercial organization, ensuring compliance, performance, risk mitigation, and competitive rates.
- Subject Matter Expert supporting Commercial, R&D, Clinical operations and validation, quality, regulatory, tax and distribution programming.

Novavax, Inc., Gaithersburg, MD

Senior Director of Global Logistics and Materials Management **May 2020 – March 2024**

Biotechnology company addressing infectious diseases through the discovery, development, and delivery of vaccines to patients around the world, including a commercialized protein-based vaccine targeting COVID-19. Hired to build the Supply Chain division, which rapidly grew to a 70-person team supporting Novavax's first commercial product with global market licensing and distribution.

- Manage a $42M annual budget supporting 28 sites on 3 continents with <6% budget vs actual variance.
- Built network of strategic partners ensuring supply chain resiliency and reduced third party provider rates by 15%.
- Launched company's trade compliance department supporting subsidiaries as well as 20 CMO partners throughout US, Europe, and Asia. $2M in savings from Duty Mitigation program and eliminated import/export irregularities.
- Instituted analytical program reducing risk (<0.01% product loss), improving product delivery (99.5% OTIF), achieving department savings (>$4.6M). Led expansion of the program to other departments in the organization.
- Established S&OP program, Cold Chain Management portfolio, lane Risk and Security profiles, Warehousing & Transportation SOPs, and Strategic Sourcing team.
- Expert speaker for LogiPharma (US & EU), Clinical Trial Supply, HPCLC, LNS Global, and MIT University.

USAID Bureau for Humanitarian Assistance (BHA), Washington, DC

Logistics Specialist, Acting Team Lead, *Secret Level US Security Clearance* **April 2014 – May 2020**

BHA is the US government's lead agency for providing life-saving humanitarian assistance — including emergency healthcare, critical nutrition services, shelter, and sanitation — to the world's most vulnerable people. I provided supply chain expertise on programming and led global operations for humanitarian interventions.

- Served as Acting Lead of the Logistics team overseeing all operations, staff, and $200M budget.
- Led the logistics and operations in over 10 international humanitarian responses.
- Supply Chain Subject Matter Expert (SME) on over 300 proposals for government funding, managing $25M spend.
- Designed a global prepositioning strategy reducing OpEx by 20% through stochastic demand forecasting model and mixed integer linear programming.
- Developed a new supply chain for the Yemen response, reducing transit time of relief cargo by 20 days. This model was later adopted by the United Nations World Food Program (WFP) and the World Health Organization (WHO).
- Invented load planner for emergency shipments, decreasing processing time by 80%.
- Established training program & audit protocols; chaired staff & product selection committees; and represented the US Government with agencies, international partners, the United Nations, and foreign governments.

For Granted, Inc., Washington, DC

Founder and CEO **Jan. 2006 – Present**

Founded and incorporated this 501(c)(3) nonprofit following my Peace Corps service in the Republic of Kiribati. For Granted is committed to improving lives in underserved communities around the world.

- Lead strategic planning, marketing, fundraising, program design, monitoring and evaluation, regulatory compliance, and financial reporting.
- Established programs with diverse partners including the private sector, international NGOs, the US Government, and the governments of Kiribati, Taiwan, St. Kitts and Nevis, and Dominica.
- Cross-functional projects include Microfinance in Burkina Faso, Child Health Initiative in Madagascar, and Educational programming in the Caribbean, Pacific, S. Asia and Africa.

Doctors Without Borders / Médecins Sans Frontières, Haiti, Chad, S. Sudan

National Coordinator of Logistics, Manager of Logistics Operations **Jan. 2010 – Mar. 2013**

Doctors Without Borders cares for people affected by conflict, disease outbreaks, natural and human-made disasters, and exclusion from health care in over 70 countries. I managed end-to-end Operations for humanitarian crises.

- Oversaw country logistical budget and build resilient strategic partnership programming.
- Director of operations for 100-bed Cholera Treatment Center, 180-bed trauma hospital, inventory & asset management equities, site and staff security, external public relations, and strategic sourcing.
- Managed import/export program for medical & logistical material, improving clearance time by 75%.
- Ran activities for a 98-member team of contracted staff as well as 30 daily workers.
- Restructured HR footprint with a 10% Reduction in Staff while maintaining patient care level.

CARE USA, Washington, DC, Nairobi and Kilifi, Kenya

Consultant **Dec. 2008 – May 2009**

CARE is an international organization addressing poverty and social justice. I led the Program Evaluation for a youth program in Kenya.

- Led team to review CARE's Sport for Social Change Initiative (SSCI) and 30+ member organizations.
- Built strategic alliance framework for Community Based Organizations (CBOs) to advance their movement.
- Wrote comprehensive research report, supporting increased inclusion, impact, and business continuity.

Phoenix Container, Inc.

Director of Sales and Marketing **Jan. 2001 - Sept. 2003 & Jan. 2006 – June 2007**

Served on the board as well as managed sales and distribution for this $40M US based steel container manufacturing company with N. American distribution.

- Increased sales by 16% in a highly competitive market.
- Supervised a team of 22 distributors throughout U.S. serving ~1K clients.
- Negotiated contracts with carriers and 3PLs to optimize N. American transportation strategy yielding 25% savings.

United States Peace Corps, Republic of Kiribati

Education Specialist **Oct. 2003 – Dec. 2005**

Mathematics professor and led several community initiatives during my service.

- Solicited funding from Australian government for rain catchment system, providing water to 1,500+ villagers.
- Built library with over 2,500 in-kind books and in-kind shipping solicited from international donors.
- Designed corporal punishment workshop implemented in over 20 Kiribati schools, counseling 175 Kiribati teachers on alternative forms of discipline.
- Wrote a 7,000-word Kiribati/English Dictionary adopted by Ministry of Education and the US Peace Corps.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, David Sokoloff, **certify that as the designated representative for**

Precigen, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DS I am at least 21 years of age;
3. DS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Sokoloff

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

18 Mar 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Sokoloff

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

18 Mar 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Maryland, ss. County of Montgomery

I, David Sokoloff, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

18 Mar 2025

Date

Subscribed and Sworn to before me this 18th day of March.

Connie Dalton Ezell

Notary Public Signature

(Seal)

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): August 28, 2024

PRECIGEN, INC.

(Exact name of registrant as specified in its charter)

Virginia	001-36042	26-0084895
(State or other jurisdiction of incorporation)	(Commission File Number)	(I.R.S. Employer Identification No.)

20374 Seneca Meadows Parkway, Germantown, Maryland 20876
(Address of principal executive offices) (Zip Code)

(301) 556-9900
(Registrant's telephone number, including area code)

N/A
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, No Par Value	**PGEN**	**Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Item 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 28, 2024, the Compensation and Human Capital Management Committee (the "Compensation Committee") of the Board of Directors of Precigen, Inc. (the "Company") approved the grant of performance stock units ("PSUs") under the Company's 2023 Omnibus Incentive Plan, as amended (the "Plan"), to certain key employees of the Company, including the Company's named executive officers set forth in the table below. The Compensation Committee believes that the incorporation of the PSUs as a component of long-term equity incentive compensation provided to the executive officers will enhance the alignment of executive compensation with long-term shareholder value creation, because the vesting of the PSUs is conditioned upon the Company's achievement of certain key operational milestones important to its growth and success.

The PSUs will vest in two equal 50% installments based upon the achievement of two specified operational milestones relating to (i) the Company's good faith submission to the U.S. Food and Drug Administration (the "FDA") of a complete Biologics License Application ("BLA") for the Company's PRGN-2012 investigational product and (ii) the approval of the BLA by the FDA, in each case during the period from the grant date through December 31, 2026 (the "Performance Period"). The performance milestones may be achieved (and the PSUs earned) at any time during the Performance Period, and the PSUs will vest and be settled in shares of the Company's common stock at such time as the Compensation Committee certifies that an applicable performance milestone has been achieved, subject to the executive's continued employment through the applicable achievement date (except as described below). Any PSUs for which a performance milestone has not been achieved by the end of the Performance Period will be cancelled and forfeited.

Upon an executive's termination of employment by the Company without "cause", by the executive for "good reason" or due to the executive's death and disability (each as defined in the applicable award agreement), the PSUs will remain outstanding and eligible to vest upon the earlier of the achievement of a milestone or a "change in control" (as defined in the Plan), *provided*, that, if the termination is by the Company without "cause" or by the executive for "good reason", then the PSUs would only vest pro-rata based on the executive's service with the Company from March 1, 2024 through the termination date. In the event of a change in control in which the PSUs are not assumed or continued by the successor or surviving entity, the PSUs will vest in full at target levels, subject to the executive's continued employment through the date of the change in control (except as described in the preceding sentence). Upon a termination of employment for any reason other than as described above, any portion of the PSUs that is unvested and unearned as of the termination date will be forfeited.

The following table sets forth the target PSUs granted to the Company's named executive officers:

Name	Target PSUs (#)
Dr. Helen Sabzevari	1,650,000
Harry Thomasian	250,000
Rutul Shah	250,000
Donald Lehr	108,000

The foregoing description of the PSUs is qualified in its entirety by reference to the full text of the form of Performance Stock Unit Agreement, a copy of which will be filed as an exhibit to the Company's Quarterly Report on Form 10-Q for the fiscal quarter ended September 30, 2024.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Precigen, Inc.

By: /s/ Donald P. Lehr
Donald P. Lehr
Chief Legal Officer

Dated: August 30, 2024

4W

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☒ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Scholar Rock, Inc.

Physical Address: 301 Binney Street, 3rd Floor

City: Cambridge State: MA Zip: 02142

Mailing Address (if different from physical address): 301 Binney Street, 3rd Floor

City: Cambridge State: MA Zip: 02142

Telephone: 8572593860 Website: www.scholarrock.com

Name of Designated Representative (DR): Tracey Sacco

Licensing Company Email: trade@scholarrock.com DR Email: tsacco@scholarrock.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☒ Others: Biologic	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies/ Distributors		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: DE

Parent Company (if any): _____

Corporation Name: Scholar Rock, Inc.

Mailing Address: 301 Binney Street, 3rd Floor

City: Cambridge State: MA Zip: 02142

Telephone: 8572593860 Email: trade@scholarrock.com

Contact Person Name: Tracey M Sacco

Date of SEC Registration: 05/01/2015	SEC Registration Number: 0001662455	Stock Exchange Symbol: SRRK

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• **[a]Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Scholar Rock, Inc.
Facility Name

Jay Backstrom
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

05MAR2025
Date

Board Use Only	Date Received: 3/24/25	Amount: $1000-ck 3428

Erin Vorisek

From: Michael Wolfe
Sent: Monday, November 25, 2024 11:40 AM
To: Collin Breslin
Subject: FW: Labeler Code Request Approved

From: Jamie McEntee <jmcentee@scholarrock.com>
Sent: Friday, September 6, 2024 7:11 AM
To: Bronte Woodlan <Bronte.Woodlan@twolabs.com>; Michael Wolfe <mwolfe@scholarrock.com>
Subject: FW: Labeler Code Request Approved

Hi Bronte,

See the email below for the approved labeler code information we received. Let me know if you need anything else to proceed with the next steps.

Thanks,
Jamie

From: Neda Memar <nmemar@scholarrock.com>
Sent: Thursday, September 5, 2024 8:35 PM
To: Jamie McEntee <jmcentee@scholarrock.com>
Cc: Scott Adamczyk <sadamczyk@scholarrock.com>
Subject: Fwd: Labeler Code Request Approved

FYI

Get Outlook for iOS

From: edrls@fda.hhs.gov <edrls@fda.hhs.gov>
Sent: Thursday, September 5, 2024 1:38:53 PM
To: Neda Memar <nmemar@scholarrock.com>
Subject: Labeler Code Request Approved

This message originated from outside of Scholar Rock.

eDRLS - Electronic Drug Registration & Listing System

Current Date: 05-SEP-2024
Labeler DUNS: 117776824
Labeler Name: Scholar Rock, Inc.
Labeler Code Assigned: 84717

The Food and Drug Administration (FDA) has assigned the above Labeler Code to your firm. **The number cannot be used until you have confirmed the assignment. Please revise and resubmit your Labeler Code Request SPL to include the assigned number above to complete the process. To do this, open the previous Labeler Code Request SPL file and fill in the new information (your assigned Labeler Code) without changing the other existing information. Fill in a new root id and new version number with the original set id and the appropriate effective time.**

For CDER Direct Users: Open the previously submitted and accepted Labeler Code Request, click Create New Version, enter the Labeler Code assigned in the field for "Labeler Code", and Submit SPL.

This Labeler Code should be used to create the NDC (National Drug Code) assigned to all drugs you manufacture or distribute for U.S. commercial distribution. The assignment of NDC is extensively discussed in Title 21 of Code of Federal Regulations (CFR) 207.35. The NDC for each drug must be submitted as part of drug listing information submitted to FDA. Per 21 CFR Part 207, owners or operators of an establishment entering into the manufacture or processing of a drug or drugs shall drug list, every drug in commercial distribution within 5 days after the beginning of operation. Labeler Codes are assigned by FDA and may be inactivated at any time upon violation of the Federal Food, Drug and Cosmetic Act.

Note that receipt of this letter is not to be construed as Federal Government endorsement or approval of the establishment or its products.

For additional information please visit Drug Registration and Listing System or reply back to this email (edrls@fda.hhs.gov).

Company Information

Scholar Rock, Inc.
301 Binney Street, 3rd Floor
Cambridge, MA 02142
857-259-3860
www.scholarrock.com
info@scholarrock.com

FEIN: 46-4197530
State of Formation: Delaware
Date Incorporated: 5/1/2015

Ownership Information

Scholar Rock, Inc. is a wholly owned subsidiary of Scholar Rock Holding Corporation.

Scholar Rock Holding Corporation
Address: 301 Binney Street, 3rd Floor
Cambridge, MA 02142
Phone: (857) 259-3860
EIN: 82-3750435

DESCRIPTION OF OPERATIONS

Scholar Rock, Inc. is a biopharmaceutical Virtual Manufacturer that discovers, develops, and delivers life-changing therapies for people with serious diseases that have high unmet need. As a global leader in the biology of the transforming growth factor beta (TGFβ) superfamily of cell proteins and named for the visual resemblance of a scholar rock to protein structures, the clinical-stage company is focused on advancing innovative treatments where protein growth factors are fundamental.

THIRD-PARTY LOGISTICS

For distribution into the commercial supply channels, Cardinal Health acts as Scholar Rock's Third Party Logistics (3PL) provider to manage the storage and distribution of Scholar Rock's product to an exclusive network including one specialty distributor and one specialty pharmacy. Cardinal's address is:

Cardinal Health
15 Ingram Blvd
LaVergne, TN 37086

CONTRACT MANUFACTURERS

Scholar Rock, Inc uses the following contract manufacturers to produce product:

Catalent Indiana, LLC
1300 S Patterson Dr
Bloomington, Indiana 47403
FEIN: 3005949964



Almac Pharma Services, LLC
2661 Audobon Rd
Audobon, PA 19403
FEIN: 3000214934

PRODUCTS

As a virtual manufacturer, Scholar Rock, Inc. does not manufacture, distribute, or store product at their Massachusetts facility. At no time do contact manufacturers own Scholar Rock, Inc. products, contract with Scholar Rock, Inc. customers, invoice or sell Scholar Rock, Inc. products.

Labeler Code: 84717

Scholar Rock has 182 employees working during normal business hours.

Scholar Rock's hours of operation are 9:00 am – 5:00pm Monday through Friday.

Scholar Rock, Inc.

Ownership Information

Scholar Rock, Inc.is a Publicly Traded (NASDAQ : SRRK), Massachusetts based company that plans to commercialize pharmaceutical drugs across the United States.

Company Information

Scholar Rock, Inc.
301 Binney Street, 3rd Floor
Cambridge, MA 02142
857-259-3860
www.scholarrock.com
info@scholarrock.com

FEIN: 46-4197530
State of Formation: Delaware
Date Incorporated: 5/1/2015

Officers

Tracey Sacco, Chief Commercial Officer
Business Address: 301 Binney Street, 3rd Floor Cambridge, MA 02142
Business Phone: 9179743286
Email: tsacco@scholarrock.com

Junlin Ho, General Counsel & Corporate Secretary
Business Address: 301 Binney Street, 3rd Floor Cambridge, MA 02142
Business Phone: 857-259-3792
Email: jho@scholarrock.com

Jay Backstrom, President and CEO
Business Address: 301 Binney Street, 3rd Floor Cambridge, MA 02142
Business Phone: 857-259-3860
Email: jbackstrom@scholarrock.com

Designated Representative

Tracey Sacco, Chief Commercial Officer

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SCHOLAR ROCK, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF JUNE, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

5438799 8300

SR# 20242832798

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 203676478

Date: 06-11-24

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Scholar Rock, Inc.
301 Binney Street, 3rd Floor
Cambridge, MA 02142

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200115

Type: Virtual Manufacturer

Issue Date: 01/28/2025

Expiration Date: 01/28/2026

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

Employee Name
Adamczyk, Scott
Aghajani Memar, Neda
Alsuraih, Mohammed
Ambrose, Judann
Backstrom, Jay
Baez, Jerry
Baffa, Alessandra
Ballard, Jillian
Barnes, Jennifer
Barnobi, Erin
Barrett, Doreen
Bates, Linda
Bauer, Christine
Bernard, Emily
Bertonassi, Ashley
Bitel, Darlene
Blandino, Peter
Boston, Christopher
Breslin, Collin
Brown, Joanna
Brown, Tom
Bundschuh, Kimberly
Calagione, Bethany
Caliri, Kim
Cameron, Sean
Canonico, Kaleigh
Capocelli, Kelley
Chang, Martin
Chapron, Christopher
Chen, David
Cherubino, Christabella
Clark, George
Cortes, Leslie
Costello, Kerry
Cote, Shaun
Crippen, Tara
Crossin, Jeremy
D'Allesantro, Corrine
Damadio, Diane
Danehy, Francis

Daudt, Donald
Davis, Marleyna
Davis, Kristin
DeWall, Stephen
Dixon, Ewa
Donnelly, Jason
Falvo, Marie
Falzone, Salvatore
Finigan, Patrick
Finnegan, Chris
Flores, Sam
Fogel, Adam
Frankiewicz, Christopher
Frieler, Ryan
Fulham, Melissa
Fuller, Christopher
Gan, Lu
Garrido, Tiago
Giansiracusa, Andrew
Granville, Karen
Gueye, Mouhamed
Haley-Boyer, Michelle
Hamm, Jon
Henry, Susan
Hirai, Satoko
Ho, Junlin
Hong, Janet
Horst, Lianzi
Houston, Melissa
Howard, Stephanie
Huang, Yan
Huang, Jui-Fu
Jackson, Justin
Ju, Yawen
Kataev Roitman, Inna
Kavosi, Mania
Kennedy, Martha
Kirwan, Brian
Kondabolu, Aravind
Kuchi, Meghana
Kurbanov, Mourad

LaCortiglia, Debbie
LaJeunesse, Liz
Larson, Matthew
Laskarzewski, Seth
Leisgang, Mary
Leneus, Ashley
Leonard, TJ
Lesh, Sabrina
Liang, Brian
Liu, Hongcheng
Liu, Lan
Liu, Wei
Long, Tammy
Longwell, Nicole
Lopez, Erin
Luther, Matthew
MacLeod, Molly
Malavasi, Jeff
Marantz, Jing
Marich, Andrej
Martin, Joseph
McEntee, Jamie
McGarrigle, DJ
McGratty, Rachel
McLaughlin, Peter
Medina, Jennifer
Meshulam, Deborah
Miller, Paul
Mohamed, Omar
Moore, Erin
Morin, Elizabeth
Myles, Ted
Nicholls, Samantha
Nofsinger, Rushmie
O'Neil, Janet
Osborne, Gina
Pacardo, Dennis
Pal, Ajai
Parlavecchio, Caryn
Patel, Bhargavi
Pedersen, Hilary

Petersen, Derek
Pham, Elizabeth
Pittenger, Jessica
Polzin, Atsuko
Price, Ann
Qatanani, Mo
Reed, Alex
Regmi, Bimal
Reynolds, Kristina
Roberts, Lara
Robotham, Mariellen
Rossello Urgell, Jose
Rosti, Robert
Roy, Sucharita
Sacco, Tracey
Sadanowicz, Mara
Sahtout, Mohammad
Samuel, Sebastian
Sanft, Todd
Schnare, Ron
Sell, Karen
Shafer, Beth
Shah, Jayni
Shannon, Chuck
Sidoni, Jenny
Simard, Chris
Simkins, Elissa
Sims, John
Song, Guochen
Steinriede, Kent
Sterling, Kelly
Streich, Frederick
Su, Allen
Talat, Asif
Tetta, Chet
Tirucherai, Giri
Tran, Kathy
Trolli, Giulia
Umans, Kim
Vosseller, Denise
Wakefield, Sam

Wang, Jenny
Warne, Desiree
Watkins, Rita
Wilkins, Clare
Williams, Eva
Wolfe, Michael
Worley, Tanya
Xu, Tiina
Xu, Yang
Yao, Bert
Yarra, Jessica
Yu, Yi
Yu, Dongzi
Yurkovetskaya, Anna
Zawadzka, Agatha
Zhang, Jim
Zhao, Guolin
Zhou, Donghui

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UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Fiscal Year Ended December 31, 2023

OR

☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the Transition Period from to

Commission File Number: 001-38501

SCHOLAR ROCK HOLDING CORPORATION
(Exact name of Registrant as specified in its charter)

Delaware	82-3750435
(State or Other Jurisdiction of Incorporation or Organization)	(I.R.S. Employer Identification Number)

301 Binney Street, 3rd Floor
Cambridge, MA 02142
(857) 259-3860
(Address, Including Zip Code, and Telephone Number, Including Area Code, of Registrant's Principal Executive Offices)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.001 per share	SRRK	The Nasdaq Global Select Market

Securities registered pursuant to Section 12(g) of the Act: None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, a smaller reporting company or an emerging growth company. See the definitions of "large accelerated filer," "accelerated filer," "smaller reporting company," and "emerging growth company" in Rule 12b-2 of the Exchange Act.

Large Accelerated Filer	☐	Accelerated Filer	☐
Non-accelerated Filer	☒	Smaller Reporting Company	☒
		Emerging growth company	☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act.) Yes ☐ No ☒

As of June 30, 2023, the last day of the registrant's most recently completed second fiscal quarter, the aggregate market value of the Common Stock held by non-affiliates of the registrant was approximately $158.3 million based on the closing price of the registrant's common stock on June 30, 2023. The calculation excludes shares of the registrant's common stock held by current executive officers, directors and stockholders that the registrant has concluded are affiliates of the registrant. This determination of affiliate status is not a determination for other purposes.

As of March 14, 2024, there were 77,866,281 shares of common stock outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's definitive proxy statement for its 2023 Annual Meeting of Stockholders, which the registrant intends to file pursuant to Regulation 14A with the Securities and Exchange Commission not later than 120 days after the registrant's fiscal year ended December 31, 2023, are incorporated by reference into Part III of this Annual Report on Form 10-K.

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SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K ("Annual Report"), including the documents incorporated by reference, contains forward-looking statements within the meaning of the federal securities laws, Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended. We intend these forward-looking statements to be covered by the safe harbor provisions for forward-looking statements contained in the Private Securities Litigation Reform Act of 1995 and are including this statement for purposes of complying with those safe harbor provisions. All statements other than statements of historical facts contained in this Annual Report on Form 10-K are forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may", "will", "should", "expects", "intends", "plans", "anticipates", "believes", "estimates", "predicts", "potential", "continue" or the negative of these terms or other comparable terminology. Some of the risks and uncertainties that may cause our actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements include, among others, the following:

- the success, cost and timing of clinical trials for apitegromab (such as our Phase 3 SAPPHIRE clinical trial) and SRK-181, including the progress, completion, timing of results, and actual results of our clinical trials;
- the timing, scope, or likelihood of our ability to obtain and maintain regulatory approval from the U.S. Food and Drug Administration ("FDA"), the European Commission ("EC") and other regulatory authorities for apitegromab following completion of our Phase 3 SAPPHIRE clinical trial, and any related restrictions, limitations or warnings in the label of any approval for apitegromab;
- our success in identifying and executing a development program for our preclinical product candidates, including SRK-439 and identifying additional product candidates from our preclinical programs and research pipeline;
- our success in identifying and executing development programs for additional indications for apitegromab and SRK-181;
- the clinical utility of our product candidates and their potential advantages over other therapeutic options;
- our ability to obtain, generally or on terms acceptable to us, funding for our operations, including funding necessary to complete further development and, upon successful development, if approved, commercialization of apitegromab, SRK-181, SRK-439 or any of our future product candidates;
- our ability to retain our executives and highly skilled technical and managerial personnel, which could be affected due to any transition in management, or if we fail to recruit additional highly skilled personnel;
- our expectations regarding our ability to obtain and maintain intellectual property protection for our product candidates and the duration of such protection and our ability to operate our business without infringing on the intellectual property rights of others;
- our ability, through third party manufacturers to successfully manufacture our product candidates for clinical trials and for commercial use, if approved;
- our ability to successfully build a commercial infrastructure to launch and market apitegromab, or otherwise provide access to apitegromab, if and when it is approved or receives pricing or reimbursement approval;
- our ability to establish or maintain collaborations or strategic relationships;
- our expectations relating to the potential of our proprietary platform technology;
- the size and growth potential of the markets for our product candidates, and our ability to serve those markets, either alone or in combination with others;

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- the impact of new laws and regulations or amendments to existing laws and regulations in the United States and foreign countries;
- risks associated with the impact of global economic and political developments on our business, including rising inflation and capital market disruptions, economic sanctions and economic slowdowns or recessions or public health pandemics;
- developments and projections relating to our competitors and our industry;
- our estimates and expectations regarding cash, cash reserves, and expense levels, future revenues, capital requirements and needs for additional financing, including our expected use of proceeds from our public offerings, and liquidity sources;
- our expectations regarding the period during which we qualify as a "smaller reporting company" as defined by Rule 12b-2 of the Securities Exchange Act of 1934; and
- other risks and uncertainties, including those listed under the caption Part II, Item 1A "Risk Factors".

The risks set forth above are not exhaustive. Other sections of this report may include additional factors that could adversely affect our business and financial performance. Moreover, we operate in a very competitive and rapidly changing environment. New risk factors emerge from time to time and it is not possible for management to predict all risk factors, nor can we assess the impact of all risk factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. Given these risks and uncertainties, investors should not place undue reliance on forward-looking statements as a prediction of actual results. Investors should also refer to our most recent Annual Report on Form 10-K and our Quarterly Reports on Form 10-Q for future periods and Current Reports on Form 8-K as we file them with the SEC, and to other materials we may furnish to the public from time to time through Current Reports on Form 8-K or otherwise, for a discussion of risks and uncertainties that may cause actual results, performance or achievements to differ materially from those expressed or implied by forward-looking statements. We expressly disclaim any responsibility to update any forward-looking statements to reflect changes in underlying assumptions or factors, new information, future events, or otherwise, and you should not rely upon these forward-looking statements after the date of this report.

We may from time to time provide estimates, projections and other information concerning our industry, the general business environment, and the markets for certain diseases, including estimates regarding the potential size of those markets and the estimated incidence and prevalence of certain medical conditions. Information that is based on estimates, forecasts, projections, market research or similar methodologies is inherently subject to uncertainties, and actual events, circumstances or numbers, including actual disease prevalence rates and market size, may differ materially from the information reflected in this Annual Report. Unless otherwise expressly stated, we obtained this industry data, business information, market data, prevalence information and other data from reports, research surveys, studies and similar data prepared by market research firms and other third parties, industry, medical and general publications, government data, and similar sources, in some cases applying our own assumptions and analysis that may, in the future, prove not to have been accurate.

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PART I

Item 1. Business

I. Overview

We are a late-stage biopharmaceutical company focused on the discovery, development and delivery of innovative medicines for the treatment of serious diseases in which signaling by protein growth factors plays a fundamental role. As a global leader in transforming growth factor beta ("TGFβ") superfamily biology, our novel understanding of the molecular mechanisms of growth factor activation enabled us to develop a proprietary platform for the discovery and development of monoclonal antibodies that locally and selectively target the precursor, or latent, forms of growth factors. By targeting the signaling proteins at the cellular level and acting in the disease microenvironment, we believe we may avoid the historical dose-limiting safety challenges associated with inhibiting growth factors for therapeutic effect. We believe our focus on biologically validated growth factors may facilitate a more efficient development path.

Based on this proprietary and scalable technology platform, we are building a growing portfolio of novel product candidates with the aim of transforming the lives of patients suffering from a wide range of serious diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis and iron-restricted anemia. We have discovered and progressed the development of:

- Apitegromab, an investigational, fully human monoclonal antibody that inhibits myostatin activation by selectively binding the pro- and latent forms of myostatin in skeletal muscle and is being developed for the treatment of spinal muscular atrophy ("SMA"). We also believe apitegromab could have potential in the treatment of other neuromuscular disorders where the inhibition of myostatin may be beneficial.

- SRK-439, a novel, preclinical, investigational myostatin inhibitor that has high invitro affinity for pro- and latent myostatin and maintains myostatin specificity and is being developed for the treatment of cardiometabolic disorders.

- SRK-181, an inhibitor of the activation of latent transforming growth factor beta-1 ("TGFβ1"), that is being developed for the treatment of cancers that are resistant to anti-PD-(L)1 antibody therapies.

- Potent and selective inhibitors of the activation of TGFβ for the treatment of fibrotic diseases. We are advancing multiple antibody profiles toward product candidate selection including antibodies that selectively inhibit the activation of latent TGFβ1 in the context of fibrotic extracellular matrix and that avoid perturbing TGFβ1 presented by cells of the immune system.

- Additional discovery and early preclinical programs related to the selective modulation of growth factor signaling including bone morphogenetic protein 6 ("BMP6") and other growth factors.

Our first product candidate, apitegromab, is a highly selective, fully human, monoclonal antibody, with a unique mechanism of action that results in inhibition of the activation of the growth factor, myostatin, in skeletal muscle. Apitegromab is being developed as a potential first muscle-targeted therapy for the treatment of SMA. We are conducting SAPPHIRE, a pivotal Phase 3 clinical trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA (which is estimated to represent the majority of the current prevalent SMA patient population in the U.S. and Europe). We completed enrollment of SAPPHIRE in 2023, with the top-line data readout expected in the fourth quarter of 2024. If successful and if apitegromab is approved, we expect to initiate a commercial product launch in 2025.

Apitegromab was evaluated in our Phase 2 TOPAZ proof-of-concept clinical trial for the treatment of patients with Type 2 and Type 3 SMA. Positive 12-month top-line results were initially announced in April 2021. We have subsequently presented data from the TOPAZ trial over 24-months (June 2022) and 36-months (July 2023), which showed that continued treatment with apitegromab over the extended period was associated with substantial and sustained improvement in motor function and patient-reported outcomes (via caregiver proxy)in patients with nonambulatory

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Types 2 and 3 SMA receiving an SMN therapy (see "Phase 2 TOPAZ Trial Analysis" below). Additionally, we have a long-term extension study, ONYX, for patients from both the TOPAZ and SAPPHIRE studies, who are receiving apitegromab in conjunction with an approved SMN therapy. The FDA granted fast track designation, rare pediatric disease designation and orphan drug designation to apitegromab for the treatment of SMA in May 2021, August 2020 and March 2018, respectively. The European Medicines Agency ("EMA") granted Priority Medicines ("PRIME") designation in March 2021 and the EC granted orphan medicinal product designation in December 2018 to apitegromab for the treatment of SMA.

In October 2023, we announced an expansion of our therapeutic focus into cardiometabolic disorders by advancing our anti-myostatin program with SRK-439, a novel, fully human anti-myostatin monoclonal antibody, for evaluation in cardiometabolic disorders, including obesity. We are developing SRK-439 towards a potential investigational new drug application ("IND") submission in 2025. To inform the development of SRK-439, we plan to initiate a Phase 2 proof-of-concept trial of apitegromab in combination with GLP-1 receptor agonist (GLP-1 RA) in 2024 with data expected in mid-2025.

Our second product candidate, SRK-181, a highly selective inhibitor of the activation of latent TGFβ, is being developed for the treatment of cancers that are resistant to checkpoint inhibitor therapies ("CPI therapies"), such as anti-PD-1 or anti-PD-L1 antibody therapies (referred to together as anti-PD-(L)1 antibody therapies). SRK-181 was evaluated in our Phase 1 DRAGON proof-of-concept clinical trial in patients with locally advanced or metastatic solid tumors that exhibit resistance to anti-PD-(L)1 antibody therapies. We completed enrollment of the DRAGON trial in December 2023. This two-part clinical trial consists of a dose escalation portion (Part A) and a dose expansion portion evaluating SRK-181 in combination with an approved anti-PD-(L)1 antibody therapy (Part B). Part B commenced in 2021 and includes the following active cohorts: urothelial carcinoma, cutaneous melanoma, non-small cell lung cancer, clear cell renal cell carcinoma ("ccRCC") and head and neck squamous cell carcinoma ("HNSCC"). Safety, efficacy and biomarker data were presented in November 2023 at the Society for Immunotherapy of Cancer ("SITC") 38th Annual Meeting. We believe that the DRAGON trial achieved its study objectives by showing objective, durable clinical responses in patients with ccRCC resistant to PD-1 therapy above what is expected from continuing PD-1 alone. We expect to present emerging data from the DRAGON trial at medical meetings in the future.

Beyond these programs, we continue to discover and develop highly specific monoclonal antibodies to selectively modulate growth factor signaling. Growth factors are naturally occurring proteins that typically act as signaling molecules between cells and play a fundamental role in regulating a variety of normal cellular processes, including cell growth and differentiation. Current therapeutic approaches to treating diseases in which growth factors play a fundamental role involve directly targeting the active form of the growth factor or its receptor systemically throughout the body. These approaches have suffered from a variety of shortcomings, including lack of pathway selectivity, lack of target selectivity, and non-localized target inhibition.

Our innovative approach is rooted in our structural biology insights into the mechanism by which certain growth factors are activated in close proximity to the cell surface. We integrate these insights with sophisticated protein expression, monoclonal antibody discovery capabilities, and assay development to test the characteristics of our monoclonal antibodies. We believe our proprietary platform can address the challenges of treating diseases in which growth factors play a fundamental role by:

- targeting the natural activation mechanism to prevent activation of the growth factor rather than attempting to inhibit the growth factor after activation;
- achieving heightened specificity for the targeted growth factor while minimizing interactions with structurally similar and related growth factors, thereby potentially reducing the risk of unintended systemic adverse events; and
- targeting the disease microenvironment, where we believe we can interfere with the disease process while minimizing the effects on the normal physiological processes mediated by the same growth factors.

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Our structural insights and unique antibody discovery capabilities can be applied to other protein classes beyond growth factors, with an aim of generating differentiated candidates targeting cell surface receptors such as immune cell receptors or G-protein coupled receptors, where selectivity remains challenging.

II. Our Approach and Proprietary Platform

Our innovative approach is rooted in our novel understanding of the molecular mechanisms of growth factor activation and signaling and is designed to discover and develop monoclonal antibody product candidates that can inhibit the activation of a growth factor with an unprecedented degree of selectivity. Our proprietary platform is designed to generate product candidates that target the growth factor's latent precursor form prior to its activation within the disease microenvironment, or tissue where it is localized.

Growth factors are naturally occurring proteins that typically act as signaling molecules between cells and play a fundamental role in regulating a variety of normal cellular processes. Members of the TGFβ superfamily of growth factors, for example, can mediate diverse biological functions, including cell growth and differentiation, tissue homeostasis, immune modulation and extracellular matrix remodeling. Growth factors have also been shown to play a fundamental role in a variety of disease processes. Because of the importance of growth factors in multiple diseases, the pharmaceutical industry has made many attempts to inhibit growth factors in a variety of therapeutic settings. However, products utilizing conventional approaches have seen only limited success. Current therapeutic approaches to treating diseases in which growth factors play a fundamental role involve directly targeting an activated growth factor or its receptor systemically throughout the body and have suffered from a variety of shortcomings:

- Lack of pathway selectivity—multiple growth factors often signal through the same or overlapping sets of related receptors, making it difficult to specifically modulate one pathway over another;
- Lack of target selectivity—members of the same growth factor superfamily share considerable structural similarities, making it difficult to achieve specific inhibition of the targeted growth factor; this can result in broad systemic inhibition that can cause undesirable, and in many cases toxic, side effects; and
- Lack of disease microenvironment localization—systemic and non-selective inhibition of a growth factor can block the growth factor's role in the disease process, but can also simultaneously interfere with its other normal physiological roles.

Our approach to the discovery and development of growth factor targeted drugs is new and different from traditional approaches. Our approach of targeting the precursor, or latent forms of growth factors is based on the breakthrough discovery by the laboratory of our cofounder, Timothy A. Springer, Ph.D. of Harvard Medical School and Boston Children's Hospital.

Unlike many other proteins that are produced and secreted by cells in a mature, or active, form, many growth factors are expressed by cells in a latent form. For example, TGFβ1 is produced by cells as a single protein which is then enzymatically processed by the cells into two distinct and physically separated domains — the mature growth factor and the remaining portion of the original protein, referred to as the prodomain — which remain associated as part of a complex. This secreted complex is latent, or inactive, and must first be activated to carry out its normal function in a highly localized tissue or disease microenvironment. In a seminal peer-reviewed publication in 2011, Dr. Springer elucidated a new understanding of the mechanism of activation of the latent growth factor complex among members of the TGFβ superfamily by solving a high-resolution x-ray crystal structure of this latent form of TGFβ1 (as illustrated in the graphic below).

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Graphic

Structural representation of the latent form of TGFβ1 wherein the prodomain wraps around the active growth factor

This research explained at a molecular level why the secreted form of TGFβ1 is inactive. The prodomain, though physically separated from the mature growth factor domain, forms a "cage" around the active form of TGFβ1, blocking the growth factor from signaling through its receptor. Only when the cage is "unlocked" by a precursor activation event can the growth factor be released and mediate its effects in the local microenvironment. Dr. Springer further hypothesized that this phenomenon likely holds true for most members of the TGFβ superfamily, though the exact nature of the activation event, such as integrin binding or enzymatic cleavage, may differ among members of the superfamily. Importantly, while many growth factors are structurally very similar, their cages are structurally diverse, and this provides the basis for our approach to improved selectivity.

We believe that there are several important advantages to our approach of targeting the precursor, or latent, forms of growth factors over conventional therapeutic approaches, which inhibit mature growth factors or their receptors systemically throughout the body:

- targeting the latent precursor allows intervention at the site of action, within the microenvironment of the diseased tissue. Because our antibodies specifically bind the latent forms of the growth factors, we can prevent the activation of the growth factors. Given that many growth factors act primarily within the microenvironment where they are activated, as opposed to exerting their effects systemically, we believe that prevention of activation is a preferred mode of action for achieving improved outcomes. In contrast, traditional approaches to targeting growth factor signaling are focused on inhibiting the growth factor after it has been activated and released systemically;

- targeting the latent precursor allows heightened selectivity among structurally related growth factors, which we believe could limit off target effects. For example, two members of the TGFβ superfamily, myostatin and GDF11, are 90% identical in their growth factor domains. Therefore, many of the traditional inhibitors that target myostatin also inadvertently inhibit GDF11. Similarly, most of the known inhibitors of TGFβ are paninhibitors, meaning that they do not distinguish among the three isoforms of TGFβ, namely, TGFβ1, TGFβ 2 and TGFβ3. Despite the sequence similarities of the active forms of these growth factors, their cages are structurally diverse. We have been able to harness this diversity to generate antibodies that specifically bind the

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inactive growth factor precursors and inhibit activation of a particular growth factor of interest, but not others that are closely related; and

- targeting these precursor forms in the disease microenvironment, we believe we can interfere with the disease process while minimizing the effects on the normal physiological processes mediated by growth factors.

To enable our novel approach, we have built a proprietary platform that is rooted in our structural biology insights into activation of latent growth factor precursors. We integrate these insights with sophisticated protein expression, monoclonal antibody discovery capabilities, and assay development to test the characteristics of our monoclonal antibodies. In addition to this know-how, our proprietary platform is covered by patents projected to expire well into the 2030s, excluding any patent term adjustments or extensions. The key elements of our proprietary platform include the following:

- focusing on growth factor targets with a high degree of evidence implicating them in a disease process or processes;

- utilizing structural biology insights to generate recombinant versions of the latent forms of targeted growth factors, as well as versions of closely related growth factors utilizing proprietary technology and in-house expertise;

- developing proprietary assays in which we are able to recapitulate the natural activation mechanism that these growth factors undergo in the human body;

- designing sophisticated selection strategies utilizing recombinant antibody libraries such as phage and yeast display that allow us to identify monoclonal antibodies, a well-established therapeutic modality, that can modulate the activation of these growth factors without having an effect on the activation of other closely related growth factors; and

- optimizing the output of such selections to ensure that our product candidates have the appropriate characteristics for manufacturability and further development.

Using our innovative approach and proprietary platform, we are creating a pipeline of novel product candidates that selectively modulate the activation of growth factors implicated in a variety of serious diseases. Our structural insights and unique antibody discovery capabilities can also be applied to other protein classes beyond growth factors, with an aim of generating differentiated candidates targeting cell surface receptors such as immune cell receptors or G-protein coupled receptors, where selectivity remains challenging.

III. Our Expertise

We have assembled an experienced management team, board of directors, and scientific founders who bring extensive industry experience to our company. The members of our team have deep experience in discovering, developing and commercializing therapeutics, having worked at companies such as: Acceleron Pharma, Inc.; Alnylam Pharmaceuticals, Inc.; AMAG Pharmaceuticals, Inc.; Celgene Corporation; Foundation Medicine, Inc.; and Novartis Pharmaceuticals. We were founded by internationally respected scientists, Drs. Timothy A. Springer and Leonard I. Zon of Harvard Medical School and Boston Children's Hospital.

IV. Our Strategy

Using our proprietary platform to unlock the therapeutic potential of targeting growth factor signaling in the disease microenvironment, our goal is to deliver novel therapies to underserved patients suffering from a wide range of serious diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis and iron-restricted anemia. To achieve this goal, we plan to:

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- ***Continue advancing apitegromab in SMA to characterize its potential to offer meaningful benefit to patients.*** We are developing our first product candidate, apitegromab, for the treatment of patients with SMA. By targeting the latent form of myostatin and specifically inhibiting its activation in muscle, we believe apitegromab holds considerable promise in improving motor function in patients with SMA. We are conducting SAPPHIRE, a pivotal Phase 3 trial to evaluate the efficacy and safety of apitegromab in patients with nonambulatory Type 2 and Type 3 SMA being treated with survival motor neuron ("SMN") therapy (e.g., therapies that upregulate the expression of SMN, such as SMN splicing modulators).

- ***Identify the next indication(s) for apitegromab.*** Our goal is to maximize the value of apitegromab by exploring its potential across SMA types and in other myostatin-related indications. We believe that the role of apitegromab as a muscle-targeted therapy could have broad potential beyond SMA, spanning multiple muscle disorders in which fast-twitch fibers may play an important role in motor function. There is also increasing recognition of the important role of skeletal muscle in modulating metabolic physiology, highlighting a potential therapeutic opportunity for myostatin blockade. We have efforts underway to evaluate these opportunities, including preclinical and translational research, development path assessments, and commercial evaluations.

- ***Leverage anti-myostatin expertise to expand into cardiometabolic disorders.*** Muscle plays a key role in metabolic functions and energy homeostasis. Leveraging the effect of anti-myostatin on increasing muscle mass and our expertise in selectively targeting anti-myostatin, we have been developing myostatin-selective inhibitors to address cardiometabolic disorders, including obesity. Our platform has generated multiple anti-myostatin antibodies, including apitegromab, that selectively target pro- and latent forms of myostatin. SRK-439, a novel anti-myostatin antibody in preclinical development by us, has attractive properties, including high in vitro affinity for pro- and latent myostatin, maintenance of myostatin specificity (i.e., no GDF11 or Activin-A binding), and robust in vivo efficacy in preclinical models. We believe the selectivity of these product candidates enables a favorable risk-benefit profile for patients with cardiometabolic disorders.

- ***Advance our TGFβ1 product candidate, SRK-181, through clinical proof-of-concept.*** Our second antibody program is focused on the discovery and development of potent and selective inhibitors of the activation of latent TGFβ1. We believe that the selectivity of SRK-181, as observed in preclinical studies, is a significant differentiator in our efforts to address the historical dose-limiting safety challenges resulting from non-selectively inhibiting multiple isoforms that activate the TGFβ signaling pathway. We have completed enrollment of the Phase 1 proof-of-concept clinical trial of SRK-181 in patients with locally advanced or metastatic solid tumors that are experiencing resistance to anti-PD-(L)1 antibody therapy. Data from the DRAGON trial supports proof-of-concept for SRK-181 in heavily pre-treated patients with ccRCC resistant to anti-PD-(L)1 therapy. Additionally, we believe that SRK-181 has the potential to address unmet medical needs in other oncology indications, and we will endeavor to maximize the value of this product candidate.

- ***Continue to leverage our proprietary platform to expand our pipeline beyond current lead programs.*** We will continue to leverage and expand our proprietary platform to selectively target the activation of additional growth factors, both within and beyond the TGFβ superfamily. Given the established role of signaling by protein growth factors in numerous diseases, we believe that these efforts could result in new opportunities to treat diseases with unmet medical need. In order to support our pipeline expansion and intention to be the leader in the field of growth factor-targeted drug development, we are investing in the technologies supporting our proprietary platform. We have designed a proprietary, state of the art, antibody display library to more efficiently identify differentiated candidate antibodies. Furthermore, we believe that our structural insights have applicability beyond growth factor activation to include other cell signaling mechanisms.

  We believe that additional product candidates in the TGFβ portfolio have the potential to address other disorders associated with increased TGFβ signaling, including tissue and organ fibrosis. To advance the discovery and development of selected inhibitors originating from our TGFβ program that we believe have the potential to address unmet medical needs in non-oncology indications, we entered into a three-year fibrosis-focused collaboration with Gilead Sciences, Inc. ("Gilead") in 2018. At the conclusion of the agreement in

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January 2022, the rights to the respective antibodies reverted to us. We have identified a suite of anti-fibrotic antibodies with novel selectivity profiles that were discovered over the course of the collaboration including those which may have therapeutic potential for the treatment of organ fibrosis by inhibiting TGFβ1 function in connective tissue while having no impact on the activation or signaling of TGFβ1 in the immune system. We plan to continue the advancement of these assets as part of our growing preclinical pipeline.

In addition, using our structural insight, we have identified modulators of BMP 6 (a TGFβ superfamily growth factor) by selectively inhibiting its co-receptor RGMc or hemojuvelin which is required for activation. BMP6 functions as a critical control point in iron modulation via regulation of hepcidin. Traditional approaches to inhibiting the signaling of BMP6 systemically would likely perturb the numerous different physiological processes in which BMP6 is involved. Our approach could provide the potential for tissue specific modulation of BMP signaling and iron regulation.

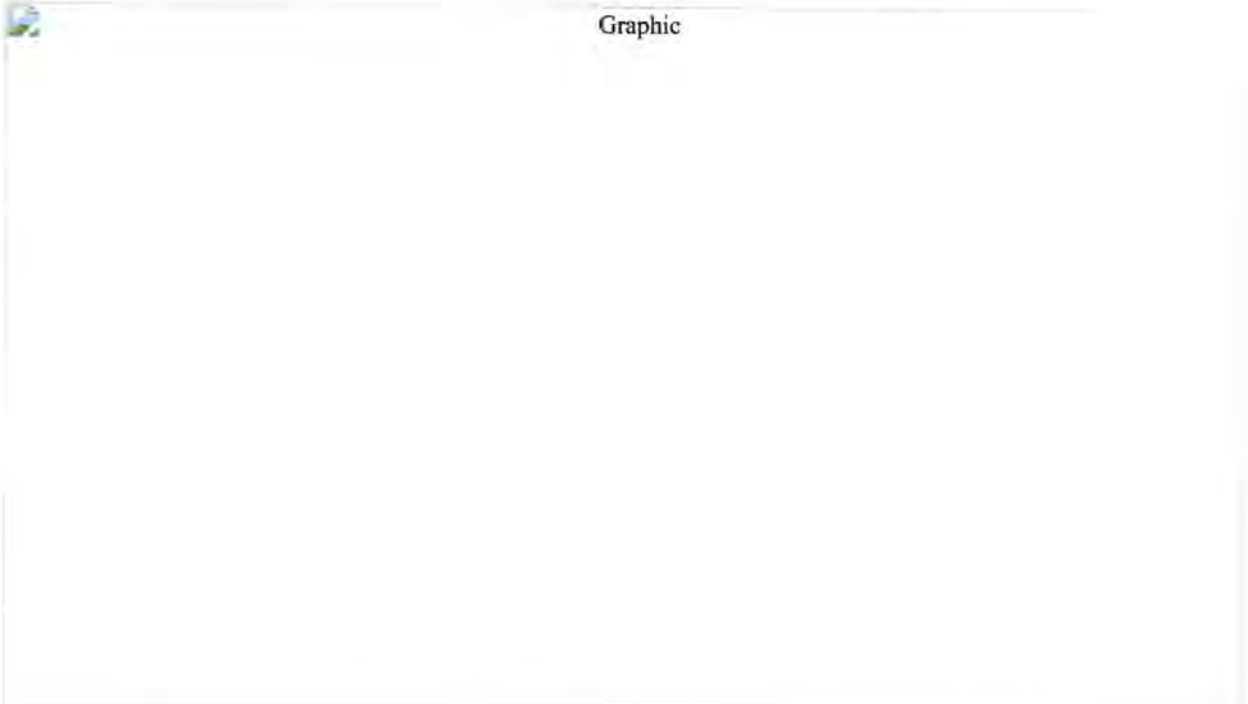
- ***Selectively seek strategic collaborations to maximize the value of our proprietary platform and pipeline.*** Given the potential of our proprietary platform to generate novel product candidates that could treat a wide variety of diseases, we believe that we can maintain in-house discipline with respect to our key development and commercialization efforts, while at the same time maximizing the full potential of our proprietary platform for other disease areas and indications. As a result, we may seek additional strategic collaborations around certain targets, product candidates or disease areas that we believe could benefit from the resources of either larger biopharmaceutical companies or those specialized in a particular area of relevance.

V. Our Pipeline

Using our innovative approach and proprietary platform, we are creating a differentiated pipeline of novel product candidates that selectively inhibit the activation of latent growth factors believed to be important drivers in a variety of diseases, including neuromuscular disorders, cardiometabolic disorders, cancer, fibrosis, and iron-restricted anemia. Our proprietary platform includes (i) our know-how enabling expression and purification of latent protein growth factor complexes in quantity and quality sufficient to enable antibody discovery; (ii) strategies to identify rare antibodies that selectively bind targeted latent protein growth factor complexes; and (iii) assays developed by us to test the highly selective antibodies' ability to modulate the activation of specific latent growth factors. We have worldwide rights to our proprietary platform and all of our product candidates.

The following summarizes our pipeline programs:

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VI. Our Product Candidates

a. Latent Myostatin

Utilizing our proprietary platform, we targeted the precursor form of myostatin and generated two novel antibodies, each with a design tailored for specific patient populations: apitegromab for SMA and SRK-439 for obesity. Both antibodies are novel, highly selective inhibitors of the activation of myostatin from its inactive precursor in skeletal muscle, where myostatin resides and signals upon activation. While mature myostatin is 90% identical in the growth factor domain to its most closely related TGFβ superfamily member, GDF11, the prodomain that cages mature myostatin and keeps it in its latent precursor form is only 52% identical to the GDF11 prodomain.

In preclinical studies, we have shown that apitegromab selectively avoids interaction with other closely related growth factors that play distinct physiological roles. We observed multi-fold increases in serum latent myostatin levels in mouse models of both early and late SMN restoration and that apitegromab promoted increased strength (as measured by torque generation) in SMN-deficient mice. In a Phase 1 clinical trial designed to evaluate the safety, tolerability, and pharmacokinetic ("PK") /pharmacodynamic ("PD") profile of apitegromab in adult healthy volunteers, there were no dose-limiting toxicities and we observed robust and sustained target engagement following administration of apitegromab.

SRK-439 has also shown robust preclinical efficacy, as detailed in "Cardiometabolic Disorders – SRK-439 (inhibitor of latent myostatin)" section below. We believe that these results, from two diet-induced obesity ("DIO") mice models provide the scientific rationale and support the hypothesis that inhibition of myostatin in combination with GLP-1 receptor agonist ("RA")-driven weight loss may lead to retention of lean muscle.

i. Role of Myostatin

Myostatin, also known as growth differentiation factor 8 ("GDF8"), is a member of the TGFβ superfamily and is produced by skeletal muscle cells. As with other tissues and organs in the human body, healthy muscle homeostasis is maintained by a proper balance of growth signals, or anabolic stimuli, and breakdown signals, or catabolic stimuli. In

4X

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	■ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: APOZEAL PHARMACEUTICALS INC

Physical Address: 2091 HARTEL STREET

City: LEVITTOWN State: PA Zip: 19057

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 215-949-0809 Website: APOZEALPHARMA.COM

Name of Designated Representative (DR): SADATHULLA SHAREEF

Licensing Company Email: FACILITY@APOZEALPHARMA.C DR Email: SSHAREEF@APOZEALPHARMA.COM

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	■ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: SADATHULLA SHAREEF

Business Name: APOZEAL PHARMACEUTICAL INC

Business Address: 2091 HARTEL STREET

City: LEVITTOWN State: PA Zip: 19057

Telephone: 215-949-0809 Email: FACILITY@APOZEALPHARMA.COM

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

APOZEAL PHARMACEUTICALS INC

Facility Name

SADATHULLA SHAREEF

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

01/06/2025

Date

Board Use Only	Date Received: 1/13/25	Amount: $1000-CK#2947

An official website of the United States government Here's how you know

Drug Establishments Current Registration Site

New Search

Search Results for *Apozeal Pharmaceuticals*

Showing 1 to 1 of 1 entries

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
APOZEAL PHARMACEUTICALS INC	3004536846	119101193	ANALYSIS; MANUFACTURE; PACK	2091 Hartel St, Levittown, Pennsylvania (PA) 19057, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Friday, Jan 17, 2025

New Search

Verified M.H 3/25/25

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	APOZEAL PHARMACEUTICALS INC		
Request Type:	Subsistence Certificate	**Issuance Date:**	August 06, 2024
Request No.:	040600920	**File No.:**	0013564878
Receipt No.:	001164456		
Filing Type:	Domestic Business Corporation		
Filing Subtype:	Business		
Initial Filing Date:	August 29, 2023		
Status:	Active		

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

APOZEAL PHARMACEUTICALS INC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

Certificate of Registration

Certificate No. 1000004426
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Manufacturer (Prescription)
Manufacturer (Non-Prescription)
Distributor (Prescription)
Distributor (Non-Prescription)

Drug & Device Registration
2525 N. 7th ST.
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

APOZEAL PHARMACEUTICALS INC.
2091 HARTEL STREET
LEVITTOWN, PA 19057

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: October 30, 2023
Expiration Date: The Last Day of November, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Pennsylvania
Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

APOZEAL PHARMACEUTICALS INC. 2091 Hartel Street; Levittown, PA 19057
Certificate(s): **1000004426** issued: 10/30/2023 expires: 11/30/2025; **8000003163** issued: 10/30/2023 expires: 11/30/2025

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version

Database Version

Certificate of Licensure

Certificate No. 8000003163
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
2525 N. 7th ST.
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:

Wholesaler/Distributor

APOZEAL PHARMACEUTICALS INC.
2091 HARTEL STREET
LEVITTOWN, PA 19057

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: October 30, 2023
Expiration Date: The Last Day of November, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 7901199220

Application/License No. _____

Apozeal Pharmaceuticals Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2091 Hartel St , Levittown, PA 19057 (Address of Applicant/Principal), as PRINCIPAL, and Nationwide Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of OH (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1100 Locust Street, Department 2006, Des Moines, IA 50391 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on July 12, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 17th day of July, 2024.

APPLICANT/PRINCIPAL
Apozeal Pharmaceuticals Inc.

Authorized Representative

SURETY COMPANY
Nationwide Mutual Insurance Company

Surety Company's Representative

VALERIE ANN ABER, Attorney-in-fact
print name

SEAL

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Power of Attorney

Bond Number: 7901199220

KNOW ALL MEN BY THESE PRESENTS THAT:

Nationwide Mutual Insurance Company, an Ohio corporation

hereinafter referred to severally as the "Company" and collectively as "the Companies" does hereby make, constitute and appoint:

VALERIE ANN ABER

each in their individual capacity, its true and lawful attorney-in-fact, with full power and authority to sign, seal, and execute on its behalf any and all bonds and undertakings, and other obligatory instruments of similar nature, in penalties not exceeding the sum of

Twenty Five Thousand and no/100 dollars ($25,000.00)

and to bind the Company thereby, as fully and to the same extent as if such instruments were signed by the duly authorized officers of the Company; and all acts of said Attorney pursuant to the authority given are hereby ratified and confirmed.

This power of attorney is made and executed pursuant to and by authority of the following resolution duly adopted by the board of directors of the Company:

"RESOLVED, that the president, or any vice president be, and each hereby is, authorized and empowered to appoint attorneys-in-fact of the Company, and to authorize them to execute and deliver on behalf of the Company any and all bonds, forms, applications, memorandums, undertakings, recognizances, transfers, contracts of indemnity, policies, contracts guaranteeing the fidelity of persons holding positions of public or private trust, and other writings obligatory in nature that the business of the Company may require; and to modify or revoke, with or without cause, any such appointment or authority; provided, however, that the authority granted hereby shall in no way limit the authority of other duly authorized agents to sign and countersign any of said documents on behalf of the Company."

"RESOLVED FURTHER, that such attorneys-in-fact shall have full power and authority to execute and deliver any and all such documents and to bind the Company subject to the terms and limitations of the power of attorney issued to them, and to affix the seal of the Company thereto; provided, however, that said seal shall not be necessary for the validity of any such documents."

This power of attorney is signed and sealed under and by the following bylaws duly adopted by the board of directors of the Company.

Execution of Instruments. Any vice president, any assistant secretary or any assistant treasurer shall have the power and authority to sign or attest all approved documents, instruments, contracts, or other papers in connection with the operation of the business of the company in addition to the chairman of the board, the chief executive officer, president, treasurer or secretary; provided, however, the signature of any of them may be printed, engraved, or stamped on any approved document, contract, instrument, or other papers of the Company.

IN WITNESS WHEREOF, the Company has caused this instrument to be sealed and duly attested by the signature of its officer the 1st day of April, 2024.

Antonio C. Albanese, **Vice President** of Nationwide Mutual Insurance Company

ACKNOWLEDGMENT

STATE OF NEW YORK COUNTY OF KINGS: ss

On this 1st day of April, 2024, before me came the above-named officer for the Company aforesaid, to me personally known to be the officer described in and who executed the preceding instrument, and he acknowledged the execution of the same, and being by me duly swom, deposes and says, that he is the officer of the Company aforesaid, that the seal affixed hereto is the corporate seal of said Company, and the said corporate seal and his signature were duly affixed and subscribed to said instrument by the authority and direction of said Company.

Sharon Laburda
Notary Public, State of New York
No. 01LA6427697
Qualified in Kings County
Commission Expires January 3, 2026

Notary Public
My Commission Expires
January 3, 2026

CERTIFICATE

I, Lezlie F. Chimienti, Assistant Secretary of the Company, do hereby certify that the foregoing is a full, true and correct copy of the original power of attorney issued by the Company; that the resolution included therein is a true and correct transcript from the minutes of the meetings of the boards of directors and the same has not been revoked or amended in any manner; that said Antonio C. Albanese was on the date of the execution of the foregoing power of attorney the duly elected officer of the Company, and the corporate seal and his signature as officer were duly affixed and subscribed to the said instrument by the authority of said board of directors; and the foregoing power of attorney is still in full force and effect.

IN WITNESS WHEREOF, I have hereunto subscribed my name as Assistant Secretary, and affixed the corporate seal of said Company this 17th day of July, 2024.

Assistant Secretary

BDJ 1(04-24)00

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler APOZEAL PHARMACEUTICALS INC

Pharmacy/Wholesaler License # (if applicable) WH #1000004426 MANUFACTURER #8000003163

Physical Address 2091 HARTEL STREET

City LEVITTOWN State PA Zip 19057

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 215-949-0809 Website APOZEALPHARMA.COM

Licensing Company Email FACILITY@APOZEALPHARMA.COM

Section 2: Personal Information

First SADATHULLA Middle _____ Last SHAREEF

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITI[redacted] Sex ■ M ☐ F ☐ X

Mailing Addre[redacted]

City HEWLETT State NY Zip[redacted]

Telephone[redacted] Email SSHAREEF@APOZEALPHARMA.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
KAKATIYA UNIVERSITY		1985-1989	
Address	**City**	**State**	**Zip**
WWarangal-506009, Telangana, India.	TELANGA	INDIA	506009
Diploma/Degree obtained, if any			
BACHELOR OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
1991- 1993 Jadavpur University, Calcutta, India		1991-1993	
Address	**City**	**State**	**Zip**
188, Raja Subodh Chandra Mallick Rd, Jadavpur, Kolkata, West	JADAVPUR, KOLKATA	INDIA	700032
Diploma/Degree obtained, if any			
MASTER OF TECHNOLOGY			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2001-PRESENT	[redacted]	HEWLETT	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
MAKS PHARMA AND DIAGNOSTICS			2012-~~PRESENT~~ 2023	
Business Address		City	State	Zip
2365 MILBURN AVE		BALDWIN	NY	11510
Phone	Title		Number of Employed Hours	
516-323-1255	PRESIDENT/CEO		25,000	
Description of Duties				
•Developing high quality business strategies and plans ensuring their alignment with short-term and long-term objectives •Leading and motivating subordinates to advance employee engagement develop a high performing managerial team				

Business Name			From - To (MM/YY – MM/YY)	
APOZEAL PHARMACEAUTICALS			2023-PRESENT	
Business Address		City	State	Zip
2091 HARTEL STREET		LEVITTOWN	PA	19057
Phone	Title		Number of Employed Hours	
215-949-0809	OWNER/DESIGNATED REP/CHAIRMAN		3000	
Description of Duties				
- Oversaw daily operations, ensuring alignment with regulatory requirements and quality standards. - Serve as a primary liason between Apozeal Pharmaceuticals and regulatory agencies				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

SADATHULLA SHAREEF

[redacted]

PROFESSIONAL EXPERIENCE

Apozeal Pharmaceuticals LEVITTOWN, PA 19057
AUGUST 2023- Present
CEO and Designated Representative

- Serve as the primary liaison between Apozeal Pharmaceuticals and regulatory agencies, ensuring compliance with state and federal laws.
- Oversee daily operations, ensuring alignment with regulatory requirements and quality standards.
  Lead a team of professionals, fostering a culture of collaboration and continuous improvement.
- Develop partnerships with healthcare providers and stakeholders, enhancing market presence and brand recognition.
- Train and mentor staff on compliance regulations and internal procedures, fostering a culture of accountability and excellence.
- Oversee the licensing and registration of pharmaceutical products, maintaining accurate records and documentation.

MAKS PHARMA AND DIAGNOSTICS INC. Baldwin, NY
October 2012 – December 2023
President/CEO

- Developing high quality business strategies and plans ensuring their alignment with short-term and long-term objectives
- Leading and motivating subordinates to advance employee engagement develop a high performing managerial team
- Overseeing all operations and business activities to ensure they produce the desired results and are consistent with the overall strategy and mission
- Make high-quality investing decisions to advance the business and increase profits
- Enforce adherence to legal guidelines and in-house policies to maintain the company's legality and business ethics
- Review financial and non-financial reports to devise solutions or improvements
- Build trust relations with key partners and stakeholders and act as a point of contact for important shareholders

AAA DRUGS INC. Rosedale, NY
April 2015- December 2018
Part-Time Pharmacist; Vice-President

- Prepare medications by reviewing and interpreting physician orders
- Detecting therapeutic incompatibilities
- Dispensing medications by compounding, packaging, and labeling pharmaceuticals
- Controlled medications by monitoring drug therapies; advising interventions
- Assist in managing the retail pharmacy business

STAYWELL PHARMACY CORP Palatine, IL |
August 2016-Current
President/CEO

- Developing high quality business strategies and plans ensuring their alignment with short-term and long-term objectives
- Leading and motivating subordinates to advance employee engagement develop a high performing managerial team
- Overseeing all operations and business activities to ensure they produce the desired results and are consistent with the overall strategy and mission
- Make high-quality investing decisions to advance the business and increase profits
- Enforce adherence to legal guidelines and in-house policies to maintain the company's legality and business ethics
- Review financial and non-financial reports to devise solutions or improvements
- Build trust relations with key partners and stakeholders and act as a point of contact for important shareholders

MEDICITI DRUGS INC. Ridgewood, NY
February 2010 -April 2015

Pharmacist

- Filling of prescriptions
- Instructing and advising patients

- Consult with doctors
- Worked with insurance companies
- Maintain records

Software knowledge: Micro Merchant

OLSHINS PHARMACY Newark, NJ **July 2007 – February 2010**

Pharmacist

- Fill prescriptions, verifying instructions from physicians on the proper amounts of medication to give to patient
- Check whether the prescription will interact negatively with other drugs that a patient is taking or any medical conditions the patient has
- Instruct patients on how and when to take a prescribed medicine and inform them about potential side effects they may experience from taking the medicine
- Oversee the work of pharmacy technicians and pharmacists in training
- Keep records and do other administrative tasks Software knowledge: OPUS

STANBIO LABORATORY (ISO 13485 CERTIFIED & FDA REGULATED) Boerne, TX | June 2003 – July 2006

Production Manager

- Supervision of day to day activities of various departments:
    - Packaging, Manufacturing, Warehouse, Purchasing, and Shipping/ Receiving.
- Production Planning and Scheduling
- Inventory Management and Stock Re-order Status check
- Purchase Planning
- Supplier Performance Evaluation.

Strong computer skills in MS Access, Word, Excel, Projects, Visio, Crystal Reports and Power Point

UNITED DIAGNOSTICS INDUSTRY (ISO 9001 CERTIFIED COMPANY) Dammam, KSA November 1993 – March 2003

Plant Manager

- Supervised day to day plant activities of various departments
    - Production, QC/QA, R&D, Warehouse, Customer Support and Biomedical
- Ensured implementation of quality management system in all the areas
- Involved in Method development and SOP writing, internal audits, non- conformance review, management review meetings, and corrective and preventive actions planning and follow up.
- Inventory management and stock reorder status check; purchase planning
- Supplier performance evaluation
- Production Planning and Scheduling
- Customer Orders Evaluation and Planning
- Organized Continuing Education and Technical Training

DP MEDICAL DIAGNOSTICS (SOLE DISTRIBUTORS FOR ABBOTT DIAGNOSTICS) Mumbai, India | April 1993 – October 1993

Diagnostics Sales Specialist TORCH DRUGS AND PHARMACEUTICALS Hyderabad, India | April 1990 – July 1991

Trainee Production Supervisor for Pharmaceutical Manufacturing

EDUCATION

MASTER OF TECHNOLOGY (BIOTECHNOLOGY) 1991- 1993 Jadavpur University, Calcutta, India
BACHELOR OF PHARMACY 1985- 1989 Kakatiya University, Warangal, A.P., India

PROFESSIONAL LICENCES

- Registered as Pharmacist in the State of NJ in May,2007.
- Registered as Pharmacist in the State of NY in Feb,2009

Trainings and Participation **Month Year**

- **EXCEL PARTERSHIPS, INC.; USA MAY05-MAY09, 2003. Accomplished Successfully RAB Accredited Lead Auditor Training ISO 9001:2000 with specific reference to FDA regulated Industries**

SKILLS

Computer software/ frameworks: Strong computer skills in MS Access, Word, Excel, Projects, Visio, Crystal Reports and Power Point

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, SADATHULLA SHAREEF, **certify that as the designated representative for**

APOZEAL PHARMACEUTICALS INC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. S.S I am at least 21 years of age;
3. S.S I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. S.S I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. S.S I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. S.S I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. S.S I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

SADATHULLA SHAREEF

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/06/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SADATHULLA SHAREEF

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/6/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Kings

I, Sadathulla Shareef, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/6/2025

Date

Subscribed and Sworn to before me this 6th day of January 2025

Notary Public Signature

UMMAY HABIBA KHAN
Notary Public - State of New York
No. 01KH6446540
Qualified in Kings County
My Commission Expires 01/23/27

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site APOZEAL PHARMACEUTICALS INC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) 1000004266

Physical Address 2091 HARTEL STREET

City LEVITTOWN State PA Zip 19057

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First SADATHULLA Middle _____ Last SHAREEF

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City HEWLETT State NY Zip [redacted]

Telephone [redacted] Email FACILITY@APOZEALPHARMA.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
KAKATIYA UNIVERSITY		1985-1989	
Address	**City**	**State**	**Zip**
WARANGAL-506009	TELANGA	INDIA	506009
Diploma/Degree obtained, if any			
BACHELOR OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
JADAVPUR UNIVERSITY		1991-1993	
Address	**City**	**State**	**Zip**
188 RAJA SUBODH CHANDRA MALLICK RD	JADAVPUR KOLKATA W. BE	INDIA	700032
Diploma/Degree obtained, if any			
MASTER OF TECHNOLOGY			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2001-PRESENT	[redacted]	HEWLETT	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
MAKS PHARMA AND DIAGNOSTICS INC			2012-PRESENT
Business Address	**City**	**State**	**Zip**
2365 MILBURN AVE BLDG #2	BALDWIN	NY	11510
Phone	**Title**		
516-323-1255	PRESIDENT		
Description of Duties			
Developing high quality business strategies and plans ensuring their alignment with short-term and long-term objectives •Leading and motivating subordinates to advance employee engagement develop a high performing managerial team			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SADATHULLA SHAREEF

Print Name (First, Last)

S.V.S

Original Signature (electronic, copies or stamps not accepted)

1/6/25

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Kings

I, Sadathulla Shareef, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

S.V.S

Original Signature

1/6/2025

Date

Subscribed and Sworn to before me this 6th day of January, 25

Notary Public Signature

UMMAY HABIBA KHAN
Notary Public - State of New York
No. 01KH6446540
Qualified in Kings County
My Commission Expires 01/23/27

(Seal)

LIST OF SALARIED EMPLOYESS IN APOZEAL

SL	NAME
1	AMRISH PATEL
2	ASEEMUDDIN MOHAMMED
3	ASHISHKUMAR PATEL
4	ASMA MUZAFFAR
5	BHAVINI PATEL
6	HARSESH DONDA
7	IMRAN UDDIN
8	JEFFREY BAISLEY
9	JIGNESH PATEL
10	KARAN NARESH ADVANI
11	KATE MCKEON
12	KIRAN KUMAR GANDE
13	NASHITH RAHAMAN SHAIK
14	NISHATH ANJUM SHAIK
15	RAJKUMAR PATEL
16	SADATHULLA SHAREEF
17	SHANE KUKLINSKI
18	SONDUS ELGAMSSY
19	SREENIVAS BHAT
20	TAREQ FAWZI

4Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Armas Pharmaceuticals Inc.

Physical Address: 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address): 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Telephone: 443-797-9457 Website: www.armaspharma.com

Name of Designated Representative (DR): Joseph A. Niemi

Licensing Company Email: armas@altalawgroup.com DR Email: armas@altalawgroup.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	■ Manufacturer (virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Micro Labs Ltd.
Address: 113-116, IV Phase, Jigani Link Road, KIA City: Bangalore, Karnataka State: India Zip: 560099

Name: Caplin Steriles Limited
Address: Beta Lactam Division, 152/6 & 154/16, Doresanipalya, Bilekahalli, Bannerghatta Road City: Bengaluru, Karnataka State: India Zip: 560076

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey
Parent Company (if any):
Corporation/Organization Name: Armas Pharmaceuticals Inc.
Mailing Address: 303 W. Main St., Ste 200
City: Freehold State: NJ Zip: 07728
Telephone: 443-797-9457 Email: armas@altalawgroup.com
Contact Person Name: Tanya Dobash

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Armas Pharmaceuticals Inc.

Facility Name

Joseph A. Niemi

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

8-16-2024

Date

Board Use Only	Date Received: 8/28/24	Amount: $1000-ck 2244 ✓

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Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name
Ampicillin	72485-421-10	1g/1	INJECTION, POWDER, FOR SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA201025	Armas Pharmaceuticals Inc.	72485-421	Ampicillin	AMPICILLIN SODIUM	HUMAN PRESCRIPTION DRUG
Ampicillin sodium	72485-422-10	2g/1	INJECTION, POWDER, FOR SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA201025	Armas Pharmaceuticals Inc.	72485-422	Ampicillin Sodium	AMPICILLIN SODIUM	HUMAN PRESCRIPTION DRUG
Ampicillin Sodium and Sulbactam Sodium	72485-416-10	1g/1, .5 g/1	INJECTION, POWDER, FOR SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA201024	Armas Pharmaceuticals Inc.	72485-416	ampicillin sodium, sulbactam sodium	AMPICILLIN SODIUM; SULBACTAM SODIUM	HUMAN PRESCRIPTION DRUG
Ampicillin Sodium and Sulbactam Sodium	72485-417-10	2g/1, 1 g/1	INJECTION, POWDER, FOR SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA201024	Armas Pharmaceuticals Inc.	72485-417	ampicillin sodium, sulbactam sodium	AMPICILLIN SODIUM; SULBACTAM SODIUM	HUMAN PRESCRIPTION DRUG
AZACITIDINE	72485-201-01	100mg/1	INJECTION, POWDER, LYOPHILIZED, FOR SOLUTION	INTRAVENOUS; SUBCUTANEOUS	ANDA207518	Armas Pharmaceuticals Inc.	72485-201	azacitidine	AZACITIDINE	HUMAN PRESCRIPTION DRUG
Brimonidine Tartrate/Timolol Maleate	72485-634-05	2mg/mL, 5 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA201949	ARMAS PHARMACEUTICALS INC	72485-634	Brimonidine Tartrate and Timolol Maleate	BRIMONIDINE TARTRATE; TIMOLOL MALEATE	HUMAN PRESCRIPTION DRUG
Brimonidine Tartrate/Timolol Maleate	72485-634-10	2mg/mL, 5 mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA201949	ARMAS PHARMACEUTICALS INC	72485-634	Brimonidine Tartrate and Timolol Maleate	BRIMONIDINE TARTRATE; TIMOLOL MALEATE	HUMAN PRESCRIPTION DRUG
Bromfenac	72485-649-71	1.035mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA203395	ARMAS PHARMACEUTICALS INC.	72485-649	Bromfenac	BROMFENAC SODIUM	HUMAN PRESCRIPTION DRUG
Busulfan	72485-210-08	6mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA210931	Armas Pharmaceuticals Inc.	72485-210	Busulfan	BUSULFAN	HUMAN PRESCRIPTION DRUG
CAFFEINE CITRATE	72485-104-01	60mg/3mL	INJECTION	INTRAVENOUS	ANDA207400	Armas Pharmaceuticals Inc.	72485-104	Caffeine Citrate	CAFFEINE CITRATE	HUMAN PRESCRIPTION DRUG
CAFFEINE CITRATE	72485-104-10	60mg/3mL	INJECTION	INTRAVENOUS	ANDA207400	Armas Pharmaceuticals Inc.	72485-104	Caffeine Citrate	CAFFEINE CITRATE	HUMAN PRESCRIPTION DRUG
Caffeine Citrate Oral Solution	72485-110-10	60mg/3mL	SOLUTION	ORAL	ANDA213202	Armas Pharmaceuticals Inc.	72485-110	Caffeine Citrate	CAFFEINE CITRATE	HUMAN PRESCRIPTION DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name
Capecitabine 150mg	72485-204-60	150mg/1	TABLET, FILM COATED	ORAL	ANDA207456	Armas Pharmaceuticals Inc.	72485-204	Capecitabine	CAPECITABINE	HUMAN PRESCRIPTION DRUG
Capecitabine 500mg	72485-205-12	500mg/1	TABLET, FILM COATED	ORAL	ANDA207456	Armas Pharmaceuticals Inc.	72485-205	Capecitabine	CAPECITABINE	HUMAN PRESCRIPTION DRUG
Ciprofloxacin and dexamethasone	72485-625-13	3mg/mL; 1 mg/mL	SUSPENSION/ DROPS	AURICULAR (OTIC)	ANDA215768	ARMAS PHARMACEUTICALS INC.	72485-625	Ciprofloxacin and dexamethasone	CIPROFLOXACIN HYDROCHLORIDE; DEXAMETHASONE	HUMAN PRESCRIPTION DRUG
Cisatracurium Besylate	72485-513-10	200mg/20mL	INJECTION	INTRAVENOUS	ANDA217725	Armas Pharmaceuticals	72485-513	Cisatracurium Besylate	CISATRACURIUM BESYLATE	HUMAN PRESCRIPTION DRUG
Dexamethasone Sodium Phosphate	72485-118-25	10mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA217797	Armas Pharmaceuticals	72485-118	Dexamethasone Sodium Phosphate	DEXAMETHASONE SODIUM PHOSPHATE	HUMAN PRESCRIPTION DRUG
Diphenhydramine Hydrochloride	72485-101-05	50mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA205723	Armas Pharmaceuticals Inc.	72485-101	Diphenhydramine Hydrochloride	DIPHENHYDRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Diphenhydramine Hydrochloride	72485-101-25	50mg/mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA205723	Armas Pharmaceuticals Inc.	72485-101	Diphenhydramine Hydrochloride	DIPHENHYDRAMINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Docetaxel	72485-214-01	20mg/mL	INJECTION	INTRAVENOUS	ANDA210327	Armas Pharmaceuticals Inc	72485-214	Docetaxel	DOCETAXEL	HUMAN PRESCRIPTION DRUG
Docetaxel	72485-215-04	80mg/4mL	INJECTION	INTRAVENOUS	ANDA210327	Armas Pharmaceuticals Inc.	72485-215	Docetaxel	DOCETAXEL	HUMAN PRESCRIPTION DRUG
Docetaxel	72485-216-08	160mg/8mL	INJECTION	INTRAVENOUS	ANDA210327	Armas Pharmaceuticals Inc.	72485-216	Docetaxel	DOCETAXEL	HUMAN PRESCRIPTION DRUG
Erlotinib	72485-217-30	25mg/1	TABLET, FILM COATED	ORAL	ANDA211960	Armas Pharmaceuticals Inc.	72485-217	Erlotinib hydrochloride	ERLOTINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Erlotinib	72485-218-30	100mg/1	TABLET, FILM COATED	ORAL	ANDA211960	Armas Pharmaceuticals Inc.	72485-218	Erlotinib hydrochloride	ERLOTINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Erlotinib	72485-219-30	150mg/1	TABLET, FILM COATED	ORAL	ANDA211960	Armas Pharmaceuticals Inc.	72485-219	Erlotinib hydrochloride	ERLOTINIB HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Erythromycin	72485-670-31	5mg/g	OINTMENT	OPHTHALMIC	ANDA064030	ARMAS PHARMACEUTICALS INC.	72485-670	Erythromycin	ERYTHROMYCIN	HUMAN PRESCRIPTION DRUG
Erythromycin	72485-670-35	5mg/g	OINTMENT	OPHTHALMIC	ANDA064030	ARMAS PHARMACEUTICALS INC.	72485-670	Erythromycin	ERYTHROMYCIN	HUMAN PRESCRIPTION DRUG
Etomidate	72485-508-10	2mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA215028	Armas Pharmaceuticals Inc.	72485-508	Etomidate	ETOMIDATE	HUMAN PRESCRIPTION DRUG
Etomidate	72485-509-10	2mg/mL	INJECTION, SOLUTION	INTRAVENOUS	ANDA215028	Armas Pharmaceuticals Inc.	72485-509	Etomidate	ETOMIDATE	HUMAN PRESCRIPTION DRUG
Gemcitabine	72485-221-02	200mg/5.26mL	INJECTION	INTRAVENOUS	ANDA210991	Armas Pharmaceuticals Inc.	72485-221	GEMCITABINE HYDROCHLORIDE	GEMCITABINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Gemcitabine	72485-222-10	1g/26.3mL	INJECTION	INTRAVENOUS	ANDA210991	Armas Pharmaceuticals Inc.	72485-222	GEMCITABINE HYDROCHLORIDE	GEMCITABINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name
Gemcitabine	72485-223-20	2g/52.6mL	INJECTION	INTRAVENOUS	ANDA210991	Armas Pharmaceuticals Inc.	72485-223	GEMCITABINE HYDROCHLORIDE	GEMCITABINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Imatinib mesylate	72485-202-90	100mg/1	TABLET, FILM COATED	ORAL	ANDA208302	Armas Pharmaceuticals Inc.	72485-202	imatinib mesylate	IMATINIB MESYLATE	HUMAN PRESCRIPTION DRUG
Imatinib mesylate	72485-203-30	400mg/1	TABLET, FILM COATED	ORAL	ANDA208302	Armas Pharmaceuticals Inc.	72485-203	imatinib mesylate	IMATINIB MESYLATE	HUMAN PRESCRIPTION DRUG
Irinotecan Hydrochloride	72485-211-02	20mg/mL	INJECTION	INTRAVENOUS	ANDA208718	Armas Pharmaceuticals Inc.	72485-211	Irinotecan Hydrochloride	IRINOTECAN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Irinotecan Hydrochloride	72485-212-05	20mg/mL	INJECTION	INTRAVENOUS	ANDA208718	Armas Pharmaceuticals Inc.	72485-212	Irinotecan Hydrochloride	IRINOTECAN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Irinotecan Hydrochloride	72485-213-15	20mg/mL	INJECTION	INTRAVENOUS	ANDA208718	Armas Pharmaceuticals Inc.	72485-213	Irinotecan Hydrochloride	IRINOTECAN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Isoproterenol Hydrochloride	72485-113-10	.2mg/mL	INJECTION	INTRACARDIAC; INTRAMUSCULAR; INTRAVENOUS; SUBCUTANEOUS	ANDA210845	Armas Pharmaceuticals Inc.	72485-113	Isoproterenol Hydrochloride	ISOPROTERENOL HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Ketotifen Fumarate Ophthalmic Solution	72485-617-10	.25mg/mL	SOLUTION/ DROPS	OPHTHALMIC	ANDA077958	Armas Pharmaceuticals Inc.	72485-617	Ketotifen Fumarate	KETOTIFEN FUMARATE	HUMAN OTC DRUG
LEVETIRACETAM	72485-106-10	100mg/mL	INJECTION	INTRAVENOUS	ANDA211954	Armas Pharmaceuticals Inc.	72485-106	LEVETIRACETAM	LEVETIRACETAM	HUMAN PRESCRIPTION DRUG
LEVETIRACETAM	72485-106-25	100mg/mL	INJECTION	INTRAVENOUS	ANDA211954	Armas Pharmaceuticals Inc.	72485-106	LEVETIRACETAM	LEVETIRACETAM	HUMAN PRESCRIPTION DRUG
Lidocaine	72485-611-10	20mg/mL	JELLY	TOPICAL	ANDA040433	ARMAS PHARMACEUTICALS INC.	72485-611	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Lidocaine	72485-611-30	20mg/mL	JELLY	TOPICAL	ANDA040433	ARMAS PHARMACEUTICALS INC.	72485-611	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Lidocaine	72485-611-31	20mg/mL	JELLY	TOPICAL	ANDA040433	ARMAS PHARMACEUTICALS INC.	72485-611	Lidocaine Hydrochloride	LIDOCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Lincomycin	72485-114-01	600mg/2mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA215082	Armas Pharmaceuticals Inc.	72485-114	Lincomycin	LINCOMYCIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Lincomycin	72485-115-10	3000mg/10mL	INJECTION, SOLUTION	INTRAMUSCULAR; INTRAVENOUS	ANDA215082	Armas Pharmaceuticals Inc.	72485-115	Lincomycin	LINCOMYCIN HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG
Loteprednol Etabonate	72485-630-05	5mg/g	GEL	OPHTHALMIC	ANDA212080	ARMAS PHARMACEUTICALS INC.	72485-630	Loteprednol Etabonate	LOTEPREDNOL ETABONATE	HUMAN PRESCRIPTION DRUG
Loteprednol Etabonate	72485-653-05	2mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	ANDA215933	ARMAS PHARMACEUTICALS INC.	72485-653	Loteprednol Etabonate	LOTEPREDNOL ETABONATE	HUMAN PRESCRIPTION DRUG
Loteprednol Etabonate	72485-653-10	2mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	ANDA215933	ARMAS PHARMACEUTICALS INC.	72485-653	Loteprednol Etabonate	LOTEPREDNOL ETABONATE	HUMAN PRESCRIPTION DRUG

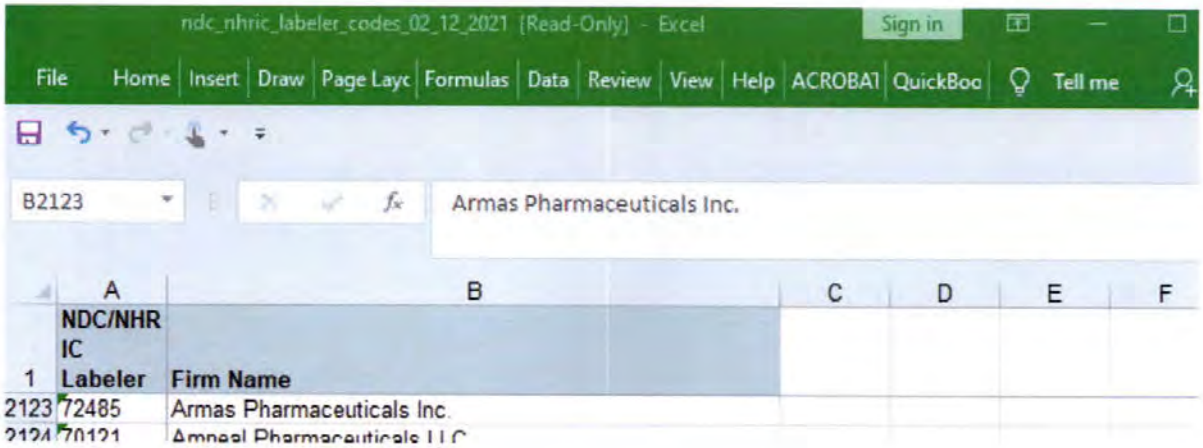
Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name
- Loteprednol Etabonate	72485-665-05	5mg/mL	SUSPENSION/ DROPS	OPHTHALMIC	ANDA207609	ARMAS PHARMACEUTICALS INC.	72485-665	Loteprednol Etabonate	LOTEPREDNOL ETABONATE	HUMAN PRESCRIPTION DRUG

Previous 1 2 Next

ARMAS PHARMACEUTICALS INC

FDA Labeler Code

Armas Pharmaceuticals, Inc. holds FDA Labeler Code 72485, which can be verified at https://www.fda.gov/industry/structured-product-labeling-resources/ndcnhric-labeler-codes .



ARMAS PHARMACEUTICALS, INC.

Company Information

Name: Armas Pharmaceuticals Inc.

State of Incorporation: New Jersey (NJ Corporate # 450256359)

Ownership: John L. Niemi (66% owner)
303 W. Main St., Ste 200
Freehold, NJ 07728

Joseph A. Niemi (34% owner)
303 W. Main St., Ste 200
Freehold, NJ 07728

Officers:

Joseph A Niemi--President
303 W. Main St., Ste 200
Freehold, NJ 07728
[redacted]

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ARMAS PHARMACEUTICALS INC.
0450256359

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on March 30, 2018.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

ANSHU PATHAK
87 SOUTH SHORE DRIVE
SOUTH AMBOY, NJ 08879

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 19th day of August, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6156311689

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

New Jersey Department of Health
P.O. Box 369, Trenton, New Jersey 08625-0369
Drug and Medical Device Certificate of Registration

Information recorded in the system as of 4/10/2025

Registration Number: 5005503 **Registered as:** Manufacturer and Wholesale

Name: ARMAS PHARMACEUTICALS INC.

DBA:

Address: 303 W MAIN ST, STE 200, FREEHOLD, NJ 07728

Original Issue Date: 09/18/2018 **Expiration Date:** 01/31/2026

Current Issue Date: 01/29/2025

Disciplines: No

THE HARTFORD

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy STE 206
Reno, NV 89521

RIDER

Attached to and forming part of Bond # 13BSBIP5750 ,
on behalf of Armas Pharmaceuticals, Inc.
of 151 Route 33, Suite 203, Manalapan, NJ 07726
in favor of Nevada State Board of Pharmacy
and in the amount of Twenty-Five Thousand ($25,000.00) Dollars.

It is understood and agreed that effective August 18, 2022
The principal's address shall be changed
from 151 Route 33, Suite 203, Manalapan, NJ 07726
to 303 West Main Street, Freehold, NJ 07728

All other conditions and terms re main as originally written.

Signed, Sealed, and Dated September, 9th , 2022

Hartford Fire Insurance Company

By: Phyllis A. Clark

Phyllis Clark , Attorney-in-Fact

The above rider is hereby agreed to and accepted:

By: _____

Form GENCNG (Rev. 0701/22)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 13BSBIP5750

Application/License No. _____

Armas Pharmaceuticals, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 151 Route 33 E, Suite 203, Manalapan, NJ 07726 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Point Drive, 6th Floor, Brea, CA 92821 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 5, 2021 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

13BSBIP5750

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9th day of February, 2021.

APPLICANT/PRINCIPAL

Armas Pharmaceuticals, Inc.

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Richard J. Loschiavo Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-11
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: SCIROCCO GROUP
Agency Code: 13-659335

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast,** a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Phyllis Clark
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 13BSBIP5750
Naming Armas Pharmaceuticals, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Shelby Wiggins

Shelby Wiggins, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 20th day of May, 2021, before me personally came Joelle LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Jessica Ciccone

Jessica Ciccone
My Commission HH 122280
Expires June 20, 2025

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of September 9, 2022.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Armas Pharmaceuticals Inc.

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address): 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Telephone: 732-637-1971 Website: www.armaspharma.com

Licensing Company Email: armas@altalawgroup.com

Section 2: Personal Information

First: Joseph Middle: Last: Niemi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Telephone: [redacted] Email: JoeNiemi@armaspharma.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

n/a

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Kean University		2003-2007	
Address	**City**	**State**	**Zip**
1000 Morris AVE	Union	NJ	07083
Diploma/Degree obtained, if any			
Bachelor of Science, Marketing			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/31/2013-present	[redacted]	Millstone Twp.	NJ	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Armas Pharmacueticals Inc.			04/2019 -present	
Business Address		**City**	**State**	**Zip**
303 W.Main St., Ste 200		Freehold	NJ	07728
Phone	**Title**		**Number of Employed Hours**	
732-637-1971	COO		13,100	
Description of Duties				
Manage operations, including distribution of Armas-label pharmaceutical products.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Joseph A. Niemi, **certify that as the designated representative for**

Armas Pharmaceuticals Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JN I am at least 21 years of age;
3. JN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Joseph A. Niemi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

8-16-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph A. Niemi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/24

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Monmouth

I, Joseph A. Niemi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Joseph A. Niemi

10/15/24

Date

Subscribed and Sworn to before me this 15 day of OCTOBER.

Notary Public Signature

JENIFER ARABIA
Notary Public, State of New Jersey
Comm. # 50197283
My Commission Expires 6/10/2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Armas Pharmaceuticals Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address): 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Telephone: 732-637-1971 Website:

Licensing Company Email: Armas@AltaLawGroup.com

Section 2: Personal Information

First: Joseph Middle: Last: Niemi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Telephone: 732-637-1971 Email: JoeNiemi@armaspharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Kean University		09/2003-05/2007	
Address	**City**	**State**	**Zip**
1000 Morris Ave, Ste 1	Union	NJ	07083
Diploma/Degree obtained, if any			
B.S., Marketing			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/2013 - present	[redacted]	Millstone Twp.	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Armas Pharmaceuticals Inc.	04/2019 - present

Business Address	City	State	Zip
303 W. Main St., Ste 200	Freehold	NJ	07728

Phone	Title
732-637-1971	President

Description of Duties

Oversee all aspects of generic pharmaceutical business

Business Name	From - To (MM/YY – MM/YY)
Somerset Therapeutics LLC	08/2016 - 03/2019

Business Address	City	State	Zip
300 Franklin Square Dr	Somerset	NJ	08873

Phone	Title
	Vice President, Sales

Description of Duties

Responsible for sales to national accounts, oversee national sales team, responsible for product launches

Business Name	From - To (MM/YY – MM/YY)
Wockhart USA	10/2012 - 08/2016

Business Address	City	State	Zip
20 Waterview Blvd #3	Parsippany	NJ	07005

Phone	Title
	National Accounts

Description of Duties

Handled sales to national accounts

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph A. Niemi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/15/24

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Monmouth

I, Joseph A. Niemi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Joseph A. Niemi

10/15/24

Date

Subscribed and Sworn to before me this 15 day of OCTOBER.

Notary Public Signature

JENIFER ARABIA
Notary Public, State of New Jersey
Comm. # 50197283
My Commission Expires 6/10/2027

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/ Wholesaler Information

Name of Pharmacy/ MDEG/ Wholesaler/Dispensing Site: Armas Pharmaceuticals Inc

Pharmacy/ MDEG/ Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Mailing Address (if different from physical address): 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Telephone: 732-637-1971 Website:

Licensing Company Email: Armas@AltaLawGroup.com

Section 2: Personal Information

First: John Middle: Last: Niemi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 303 W. Main St., Ste 200

City: Freehold State: NJ Zip: 07728

Telephone: 732-637-1971 Email: johnniemi@armaspharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY–MM/YY)	
Kean University		09/1975-09/1979	
Address	City	State	Zip
1000 Morris Ave, Ste 1	Union	NJ	07083
Diploma/Degree obtained, if any			
B.S., Biology			

School Name		From - To (MM/YY–MM/YY)	
Bloomfield High School		09/1971 - 05/1975	
Address	City	State	Zip
160 Broad St	Bloomfield	NJ	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY–MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY–MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY–MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY–MM/YY)	Address	City	State	Zip
2018 - present	[redacted]	Cream Ridge	NJ	[redacted]
1994 - 2018	[redacted]	Old Bridge	NJ	[redacted]
From - To (MM/YY–MM/YY)	Address	City	State	Zip
From - To (MM/YY–MM/YY)	Address	City	State	Zip
From - To (MM/YY–MM/YY)	Address	City	State	Zip
From - To (MM/YY–MM/YY)	Address	City	State	Zip
From - To (MM/YY–MM/YY)	Address	City	State	Zip
From - To (MM/YY–MM/YY)	Address	City	State	Zip
From - To (MM/YY–MM/YY)	Address	City	State	Zip
From - To (MM/YY–MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY–MM/YY)	
Armas Pharmaceuticals Inc.			05/2018 - present	
Business Address		**City**	**State**	**Zip**
303 W. Main St., Ste 200		Freehold	NJ	07728
Phone	**Title**			
732-637-1971	Executive Chairman			
Description of Duties				
Shareholder; Chair the Board of Directors				

Business Name			From - To (MM/YY–MM/YY)	
Amneal Pharmaceuticals			11/2012 - 05/2018	
Business Address		**City**	**State**	**Zip**
1 New England Ave		Piscataway	NJ	08854
Phone	**Title**			
	Vice President, Sales			
Description of Duties				
Oversee sales, marketing, commercialization, product launches				

Business Name			From - To (MM/YY–MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY–MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY–MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following where applicable:

Date of Event/ Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/ Agency/ Court		
Reason/ Charge				
Plaintiff/ Defendant/ Claimant/ Respondent			Lawsuit/ Arbitration/ Bankruptcy	
Name of Business/ Industry/ Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John L. Niemi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10-15-24

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Monmouth

I, John L. Niemi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature John L. Niemi

10-15-24

Date

Subscribed and Sworn to before me this 15 day of OCTOBER.

Notary Public Signature

JENIFER ARABIA
Notary Public, State of New Jersey
Comm. # 50197283
My Commission Expires 6/10/2027

(Seal)

ARMAS PHARMACEUTICALS INC.

Employee List

Joseph A. Niemi, President
Jenifer Arabia, Director Sales & Marketing
Scott Koenig, Chief Commerical Officer

4Z

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Cepheid

Physical Address: 44509 Pacific Commons Blvd

City: Fremont State: CA Zip: 94538

Mailing Address (if different from physical address): 904 E Caribbean Dr

City: Sunnyvale State: CA Zip: 94089

Telephone: 408-548-4191 Website: https://www.cepheid.com/en-US.html

Name of Designated Representative (DR): Michael Ornelas

Licensing Company Email: Establishment.Registration@cepheid.c DR Email: mike.ornelas@cepheid.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Military, Specialty Distributors		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Feb 11, 2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed w/i last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CA

Parent Company (if any): Beckman Coulter, Inc

Corporation/Organization Name: Cepheid

Mailing Address: 904 E Caribbean Dr

City: Sunnyvale State: CA Zip: 94089

Telephone: (800) 742-2345 Email: becap.info@beckman.com

Contact Person Name: Kevin O'Reilly

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Cepheid

Facility Name

Scott Campbell

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Feb 10, 2025

Date

Board Use Only	Date Received: 2/24/25	Amount: $1000.00 CC ✓

Description of Operations

Cepheid is a medical device distributor of Class I and Class II medical devices. Cepheid's products are distributed to hospitals for use in laboratories.

FDA FEI Number:
FDA Registration: 3004530258

Distributor Information:
Cepheid
44509 Pacific Commons Blvd, Fremont, CA 94538
Contact: Mike Ornelas, (669) 215-8167

Cepheid has 130 employees working on site during normal business hours.

Cepheid's hours of operation are 12:00 am – 11:59pm Monday through Friday and 6:00am – 6:30pm Saturday and Sunday.

Cepheid's records are stored at their Fremont, CA facility.

Cepheid's facility square footage is 178,910.

FDA

SEARCH

Home Food Drugs Medical Devices Radiation-Emitting Products Vaccines, Blood & Biologics Animal & Veterinary Cosmetics Tobacco Products

Establishment Registration & Device Listing

FDA Home Medical Devices Databases

New Search Back To Search Results

Establishment:
CEPHEID
44509 Pacific Commons Boulevard
Fremont, CA 94538
Registration Number: 3017994049
FEI Number*: 3017994049
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
CEPHEID
904 CARIBBEAN DRIVE
Sunnyvale, CA US 94089
Owner/Operator Number: 9062742

Official Correspondent:
Scott Campbell
904 CARIBBEAN DRIVE
Sunnyvale, CA 94089
Phone: 847-7789812

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 01/06/2025
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products
Advisory Committees
Science & Research
Regulatory Information
Safety
Emergency Preparedness
International Programs
News & Events
Training and Continuing Education
Inspections/Compliance
State & Local Officials
Consumers
Industry
Health Professionals
FDA Archive
Vulnerability Disclosure Policy

U.S. Department of Health & Human Services



Company Information

Company Name: Cepheid
Address: 44509 Pacific Commons Blvd
City, State, Zip: Fremont, CA 94538
Phone: (408) 548-4191
Website: www.radiometer.com
E-mail: Establishment.Registration@cepheid.com

FEIN: 77-0441625
State of Formation: California
Date Incorporated: 03/04/1996
File Number: 1962219

Ownership Information

Cepheid's Parent Company is Beckman Coulter, Inc.

Parent Company Address: 250 South Kraemer Blvd, Brea, CA 92821
Parent Company Phone: (800) 742-2345
Parent Company FEIN: 95-1040600

Officers

Vitor Rocha, President
Business Address: 904 E Caribbean Dr, Sunnyvale, CA 94089
Business Phone: 425-241-7044

Charles Mwangi, SVP and Chief Financial Officer
Business Address: 904 E Caribbean Dr, Sunnyvale, CA 94089
Business Phone: (888) 336-2743

Scott Campbell, SVP Quality, Regulatory, and Clinical Affairs
Business Address: 904 E Caribbean Dr, Sunnyvale, CA 94089
Business Phone: 408-495-7911

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	CEPHEID
Entity No.:	1962219
Registration Date:	03/04/1996
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of August 08, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 236290734

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

The Board is unable to provide legal advice. General information about facility licenses issued by the Board is available on the Board's website at https://www.pharmacy.ca.gov/applicants/apply_facility.shtml as well as the Pharmacy Law Book.
Provided below are the statutes and regulations that most likely pertain to the questions you are asking along with the link to the Pharmacy Law book.

A Wholesaler License is required before any firm or organization may distribute, broker or transact the sale or return of dangerous drugs or dangerous devices in California. Wholesalers sell and distribute dangerous drugs and dangerous devices (also called "legend" items or prescription-required drugs and devices) to other business entities who are authorized by law to purchase the items or to licensed health care providers who are authorized by law to possess the dangerous drugs and dangerous devices. Wholesalers are not authorized to sell or distribute these items directly to patients unless the wholesaler is delivering dialysis drugs and devices to home dialysis patients in case(s) or full shelf package lots (see section 4054 of the California Business & Professions Code).

A Wholesaler License is also required of customs brokers who sell for resale or negotiate for distribution any dangerous drug or device included in section 4022 of the Business and Professions Code. A wholesaler permit is also required for reverse distributors who arrange for the destruction of outdated or damaged dangerous drugs or devices.

Additionally, Per **BPC *4160*** *(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that* ***only*** *distributes dangerous drugs and dangerous devices* ***of its own manufacture*** *is exempt from this section and Section 4161.*

Wholesaler/Nonresident Wholesaler Requirements

- Section 4022 Definition of Dangerous Drugs and Dangerous Devices
- Section 4043 Definition of Wholesaler
- Section 4160 Requirements for a Wholesaler License
- Section 4161 Requirements for a Nonresident Wholesaler License
- Section 4162 Surety Bond Requirements
- Section 4053 Requirements for a Designated Representative License
- Section 4022.5 Designated Representative, Designated Representative-in-Charge
- Section 1780 Minimum Standard for wholesale

All the best,

Wholesaler Processing Desk
California State Board of Pharmacy

ZS, Licensing Analyst
California State Board of Pharmacy
(916) 518-3100| FAX (916) 574-8617 | www.pharmacy.ca.gov
Be Aware and Take Care: Talk to your Pharmacist!

From: Nichole Frame <Nichole.Frame@twolabs.com>
Sent: Thursday, April 17, 2025 5:23 AM
To: Wlsstatus@DCA <Wlsstatus@dca.ca.gov>
Subject: California Resident Medical Device Private Label Distributor Licensure

Mark I. Sedar

From: Nichole Frame <Nichole.Frame@twolabs.com>
Sent: Thursday, April 17, 2025 10:02 AM
To: Pharmacy Licensing
Subject: RE: Nevada Out-of-State Wholesaler Application-Cepheid - Proof of exemption
Attachments: RE: Nevada Out-of-State Wholesaler Application-Cepheid

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Good day,

Please find the below email regarding the attached request for proof of exemption from licensure in California for Cepheid's distribution facility. Cepheid is manufacturing its own products at their Lodi, CA location, which holds the appropriate CA Manufacturing permit required (previously supplied copy of the Lodi, CA license); their products are then distributed from their Fremont, CA location. Since Cepheid is manufacturing its own products, as the owner of those products and both facilities related to the manufacture and distribution of those products, no license is required by CA for the distribution facility in Fremont, CA according to the exemption highlighted in the email communication below. Please let us know if this is satisfactory for proof of exemption for Cepheid.

Respectfully,

Nichole Frame
Senior Licensing Analyst
Commercial-Regulatory
TwoLabs PHARMA SERVICES
6620 Mooney Street Suite 340 | Dublin OH | 43017
mobile 304.270.7571 | **hours** M. – F. 7:30 AM – 4:00 PM
website | email | LinkedIn

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From: Wlsstatus@DCA <Wlsstatus@dca.ca.gov>
Sent: Thursday, April 17, 2025 11:38 AM
To: Nichole Frame <Nichole.Frame@twolabs.com>
Subject: RE: California Resident Medical Device Private Label Distributor Licensure

[External]

Hello,

Good day,

I am reaching out today on behalf of Cepheid, a California-based Private Label Distributor located in Fremont, CA. Cepheid's products, medical devices with no drugs or drug components, are manufactured in Lodi, CA at their second location which currently holds a CA DOH Manufacturer Permit as required. Cepheid's devices are transferred from their Lodi, CA facility to their Fremont, CA facility for warehousing and distribution. No actual manufacture occurs onsite at Cepheid's Fremont, CA location and all products are products owned and labeled by Cepheid. These products are distributed to hospital pharmacies for use in laboratories.

Given this information, can you confirm if a license is required for Cepheid's Fremont, CA location?

Thank you for your time.

Respectfully,

Nichole Frame
Senior Licensing Analyst
Commercial-Regulatory

TwoLabs PHARMA SERVICES

6620 Mooney Street Suite 340 | Dublin OH | 43017
mobile 304.270.7571 | **hours** M. – F. 7:30 AM – 4:00 PM
website | **email** | **LinkedIn**

Please consider the environment before printing this email.

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RESIDENT STATE EXEMPTION

4155. Corporate Form Not Required

Nothing in this article shall be construed as requiring the applicant or holder of a pharmacy permit pursuant to Section 4110 to be a pharmacy corporation.

4156. Unprofessional Conduct by Corporation

A pharmacy corporation shall not do, or fail to do, any act where doing or failing to do the act would constitute unprofessional conduct under any statute or regulation. In the conduct of its practice, a pharmacy corporation shall observe and be bound by the laws and regulations that apply to a person licensed under this chapter.

Article 11. Wholesalers, Third-Party Logistics Providers and Manufacturers

4160. Wholesaler or Third-Party Logistics Provider: License Required

(a) A person shall not act as a wholesaler or third-party logistics provider of any dangerous drug or dangerous device unless he or she has obtained a license from the board.

(b) Upon approval by the board and the payment of the required fee, the board shall issue a license to the applicant.

(c) (1) A separate license shall be required for each place of business owned or operated by a wholesaler or third-party logistics provider. Each place of business may only be issued a single license by the board, except as provided in paragraph (2). Each license shall be renewed annually and shall not be transferable. At all times during which a place of business is open for business, at least one designated representative, in the case of a wholesaler, or designated representative-3PL in the case of a third-party logistics provider, shall be present. A wholesaler that only acts as a reverse distributor may use either a designated representative or a designated representative-reverse distributor to fulfill this requirement.

(2) A wholesaler and a third-party logistics provider under common ownership may be licensed at the same place of business provided that all of the following requirements are satisfied:

(A) The wholesaler and the third-party logistics provider each separately maintain the records required under Section 4081.

(B) Dangerous drugs and dangerous devices owned by the wholesaler are not commingled with the dangerous drugs and dangerous devices handled by the third-party logistics provider.

(C) Any individual acting as a designated representative for the wholesaler is not concurrently acting as a designated representative-3PL on behalf of the third-party logistics provider. Nothing in this subparagraph shall be construed to prohibit an individual from concurrently holding a license to act as a designated representative and to act as a designated representative-3PL.

(D) The wholesaler has its own designated representative-in-charge responsible for the operations of the wholesaler and the third-party logistics provider has its own responsible manager responsible for the operations of the third-party logistics provider. The same individual shall not concurrently serve as the responsible manager and the designated representative-in-charge for a wholesaler and a third-party logistics provider licensed at the same place of business.

(E) The third-party logistics provider does not handle the prescription drugs or prescription devices owned by a prescriber.

(F) The third-party logistics provider is not a reverse third-party logistics provider.

(G) The wholesaler is not acting as a reverse distributor.

(d) Every wholesaler shall be supervised or managed by a designated representative-in-charge. The designated representative-in-charge shall be responsible for the wholesaler's compliance with state and federal laws governing wholesalers. As part of its initial application for a license, and for each renewal, each wholesaler shall, on a form designed by the board, provide identifying information and the California license number for a

designated representative or pharmacist proposed to serve as the designated representative-in-charge. The proposed designated representative-in-charge shall be subject to approval by the board. The board shall not issue or renew a wholesaler license without identification of an approved designated representative-in-charge for the wholesaler. The designated representative-in-charge shall maintain an active license as a designated representative with the board at all times during which he or she is designated as the designated representative-in-charge. A wholesaler that only acts as a reverse distributor may identify and allow a designated representative-reverse distributor to perform in this capacity. That individual shall maintain an active license as a designated representative-reverse distributor.

(e) Each place of business of a third-party logistics provider shall be supervised and managed by a responsible manager. The responsible manager shall be responsible for the compliance of the place of business with state and federal laws governing third-party logistics providers and with the third-party logistics provider's customer specifications, except where the customer's specifications conflict with state or federal laws. As part of its initial application for a license, and for each renewal, each third-party logistics provider shall, on a form designated by the board, provide identifying information and the California license number for a designated representative-3PL proposed to serve as the responsible manager. The proposed responsible manager shall be subject to approval by the board. The board shall not issue or renew a third-party logistics provider license without identification of an approved responsible manager for the third-party logistics provider. The responsible manager shall maintain an active license as a designated representative-3PL with the board at all times during which he or she is designated as the responsible manager.

(f) A wholesaler shall notify the board in writing, on a form designed by the board, within 30 days of the date when a designated representative-in-charge ceases to act as the

designated representative-in-charge, and shall on the same form propose another authorized licensee to take over as the designated representative-in-charge. The proposed replacement designated representative-in-charge shall be subject to approval by the board. If disapproved, the wholesaler shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a designated representative-in-charge is approved by the board.

(g) A third-party logistics provider shall notify the board in writing, on a form designed by the board, within 30 days of the date when a responsible manager ceases to act as the responsible manager, and shall on the same form propose another designated representative-3PL to take over as the responsible manager. The proposed replacement responsible manager shall be subject to approval by the board. If disapproved, the third-party logistics provider shall propose another replacement within 15 days of the date of disapproval, and shall continue to name proposed replacements until a responsible manager is approved by the board.

(h) A drug manufacturer premises licensed by the Food and Drug Administration or licensed pursuant to Section 111615 of the Health and Safety Code that only distributes dangerous drugs and dangerous devices of its own manufacture is exempt from this section and Section 4161.

(i) The board may issue a temporary license, upon conditions and for periods of time as the board determines to be in the public interest. A temporary license fee shall be required in an amount established by the board as specified in subdivision (f) of Section 4400. When needed to protect public safety, a temporary license may be issued for a period not to exceed 180 days, subject to terms and conditions that the board deems necessary. If the board determines that a temporary license was issued by mistake or denies the application for a permanent license, the temporary license shall terminate upon either personal service of the notice of termination upon the licenseholder or service by certified mail, return receipt requested, at the licenseholder's

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 03/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

Holder Identifier :

PRODUCER
Aon Risk Services Central, Inc.
Philadelphia PA Office
100 North 18th Street
16th Floor
Philadelphia PA 19103 USA

CONTACT NAME:
PHONE (A/C, No, Ext): (866) 283-7122 FAX (A/C, No.): (800) 363-0105
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE		NAIC #
INSURER A:	ACE American Insurance Company	22667
INSURER B:	Indemnity Insurance Co of North America	43575
INSURER C:	ACE Fire Underwriters Insurance Co.	20702
INSURER D:		
INSURER E:		
INSURER F:		

INSURED
Cepheid
904 CARIBBEAN DRIVE
SUNNYVALE CA 94089 USA

COVERAGES **CERTIFICATE NUMBER:** 570111262257 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			HDOG47311962	07/01/2024	10/15/2025	EACH OCCURRENCE	$2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$2,000,000
							MED EXP (Any one person)	$10,000
							PERSONAL & ADV INJURY	$2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$5,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$5,000,000
	OTHER							
A	AUTOMOBILE LIABILITY			ISAH10705629	07/01/2024	10/15/2025	COMBINED SINGLE LIMIT (Ea accident)	$5,000,000
	X ANY AUTO						BODILY INJURY (Per person)	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	
	DED RETENTION							
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			WLRC70304454 WC AOS	07/01/2024	07/01/2025	X PER STATUTE OTH-ER	
A	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N	N/A		WLRC70304417 WC(AZ,CA,MA)	07/01/2024	07/01/2025	E.L. EACH ACCIDENT	$2,000,000
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-EA EMPLOYEE	$2,000,000
							E.L. DISEASE-POLICY LIMIT	$2,000,000

Certificate No : 570111262257

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: Location: 44509 Pacific Commons Blvd., Fremont, CA 94538.

CERTIFICATE HOLDER

Cepheid
904 East Caribbean Drive
Sunnyvale CA 94089 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

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AGENCY CUSTOMER ID: 570000096789

LOC #:

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
Aon Risk Services Central, Inc.	Cepheid
POLICY NUMBER: See Certificate Number: 570111262257	
CARRIER: See Certificate Number: 570111262257 / NAIC CODE	EFFECTIVE DATE

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: ACORD 25 **FORM TITLE:** Certificate of Liability Insurance

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER	
INSURER	
INSURER	
INSURER	

ADDITIONAL POLICIES If a policy below does not include limit information, refer to the corresponding policy on the ACORD certificate form for policy limits.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFFECTIVE DATE (MM/DD/YYYY)	POLICY EXPIRATION DATE (MM/DD/YYYY)	LIMITS	
	WORKERS COMPENSATION							
C		N/A		SCFC70304491 WC (WI)	07/01/2024	07/01/2025		

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NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 019093638

Application/License No. _____

CEPHEID, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
44509 Pacific Commons Blvd Fremont, CA 94538, as
Address of Applicant/Principal
PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY, a
Surety Company
corporation organized under the laws of the state of MA
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
175 Berkeley Street Boston, MA 02116 as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on September 20, 2024.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

CALIFORNIA ACKNOWLEDGMENT CIVIL CODE § 1189

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Santa Clara }

On 30 October 2024 before me, Cynthia Ann Scott, Notary Public.
Date *Here Insert Name and Title of the Officer*

personally appeared Ganesh Iyer
Name(s) of Signer(s)

who proved to me on the basis of satisfactory evidence to be the person(s) whose name(s) is/are subscribed to the within instrument and acknowledged to me that he/she/they executed the same in his/her/their authorized capacity(ies), and that by his/her/their signature(s) on the instrument the person(s), or the entity upon behalf of which the person(s) acted, executed the instrument.

CYNTHIA ANN SCOTT
Notary Public - California
Santa Clara County
Commission # 2342172
My Comm. Expires Jan 18, 2025

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature CA Scott
Signature of Notary Public

Place Notary Seal and/or Stamp Above

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada Pharmaceutical Wholesaler Surety Bond

Document Date: 20 September 2024 Number of Pages: 5

Signer(s) Other Than Named Above: Sara Owens

Capacity(ies) Claimed by Signer(s)

Signer's Name: Ganesh Iyer	Signer's Name:
☐ Corporate Officer – Title(s):	☐ Corporate Officer – Title(s):
☐ Partner – ☐ Limited ☐ General	☐ Partner – ☐ Limited ☐ General
☐ Individual ☐ Attorney in Fact	☐ Individual ☐ Attorney in Fact
☐ Trustee ☐ Guardian or Conservator	☐ Trustee ☐ Guardian or Conservator
☒ Other: VP, Strategic Finance	☐ Other:
Signer is Representing: Cepheid	Signer is Representing:

©2019 National Notary Association

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 20th day of September, 2024.

APPLICANT/PRINCIPAL
CEPHEID

COMPANY

Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Sara Owens, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Dana Donahue

Witness Trisha Dorsaneo

Countersigned by:

N/A

Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual SURETY

LIBERTY MUTUAL INSURANCE COMPANY

FINANCIAL STATEMENT – DECEMBER 31, 2023

Assets	
Cash and Bank Deposits	$1,850,245,073.00
*Bonds – U.S Government	$3,859,565,383.00
*Other Bonds	$21,048,805,773.00
*Stocks	$19,937,271,802.00
Real Estate	$122,228,711.00
Agents' Balances or Uncollected Premiums	$8,208,660,427.00
Accrued Interest and Rents	$186,906,667.00
Other Admitted Assets	$15,677,869,683.63
Total Admitted Assets	**$70,891,553,519.63**

Liabilities	
Unearned Premiums	$10,298,963,305.00
Reserve for Claims and Claims Expense	$28,848,537,243.00
Funds Held Under Reinsurance Treaties	$360,714,151.00
Reserve for Dividends to Policyholders	$1,310,198.00
Additional Statutory Reserve	$296,126,000.00
Reserve for Commissions, Taxes and Other Liabilities	$7,622,413,466.63
Total	**$47,428,064,363.63**
Special Surplus Funds	$209,508,757.00
Capital Stock	$10,000,075.00
Paid in Surplus	$13,834,867,488.00
Unassigned Surplus	$9,409,112,836.00
Surplus to Policyholders	$23,463,489,156.00
Total Liabilities and Surplus	**$70,891,553,519.63**

* Bonds are stated at amortized or investment value; Stocks at Association Market Values.
The foregoing financial information is taken from Liberty Mutual Insurance Company's financial statement filed with the Massachusetts Department of Insurance.

I, TIM MIKOLAJEWSKI, Assistant Secretary of Liberty Mutual Insurance Company, do hereby certify that the foregoing is a true, and correct statement of the Assets and Liabilities of said Corporation, as of December 31, 2023, to the best of my knowledge and belief.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation at Seattle, Washington, this 8th day of March, 2024.

LIBERTY MUTUAL INSURANCE COMPANY INCORPORATED 1912 MASSACHUSETTS

Timothy A. Mikolajewski

Timothy A. Mikolajewski, Assistant Secretary

LMS-1262/LMIC

Barbara D. Richardson, Commissioner of Insurance

Non-Resident Producer

Casualty, Property

SARA P OWENS

100 N 18TH ST FL 16
PHILADELPHIA, PA 19103-2707

is authorized to transact business as described above

License No: 3447025 Issue Date: 06-12-2019 Expiration Date: 07-01-2025

Generated by Sircon 269669374

Nevada Division of Insurance THIS IS TO CERTIFY THAT SARA P OWENS 100 N 18TH ST FL 16, PHILADELPHIA, PA 19103-2707 LICENSE NUMBER: 3447025	IS HEREBY AUTHORIZED TO TRANSACT BUSINESS IN ACCORDANCE TO THE LICENSE DESCRIPTION SHOWN BELOW: **Non-Resident Producer** Casualty, Property Issue Date: 06-12-2019 Expiration Date: 07-01-2025 Generated by Sircon 269669374

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Cepheid — MDEG License # (if applicable): _____

Physical Address: 44509 Pacific Commons Blvd

City: Fremont — State: CA — Zip: 94538

Mailing Address (if different from physical address): 904 E Caribbean Dr

City: Sunnyvale — State: CA — Zip: 94089

Telephone: 408-548-4191 — Website: https://www.cepheid.com/en-US.html

Licensing Company Email: Establishment.Registration@cepheid.com

Section 2: Personal Information

First: Michael — Middle: Sheehan — Last: Ornelas

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X

Mailing Address: 44509 Pacific Commons Blvd

City: Fremont — State: CA — Zip: 94538

Telephone: 408-548-4191 — Email: Establishment.Registration@cepheid.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, Berkeley		/ - /	
Address	**City**	**State**	**Zip**
100 Academic Hall # 1234	Berkeley	CA	94720-
Diploma/Degree obtained, if any			
Bachelors of Arts, Microbiology			

School Name		From - To (MM/YY – MM/YY)	
BELLARMINE COLLEGE PREP		09 - 79 / 05 / 8	
Address	**City**	**State**	**Zip**
960 W. HEDDING ST	SAN JOSE	CA	95126
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/03 - present	[redacted]	San Jose	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Cepheid			02/18 - present	
Business Address		**City**	**State**	**Zip**
44509 Pacific Commons Blvd		Fremont	CA	94538
Phone	**Title**		**Number of Employed Hours**	
408-548-4191	Director, Quality		40/week	
Description of Duties				
see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Genomic Health Inc			11/07 - 02/18	
Business Address		**City**	**State**	**Zip**
101 Galveston Drive		Redwood City	CA	94063
Phone	**Title**		**Number of Employed Hours**	
1-866-662-6897	Director Quality Systems and Compliance		40/week	
Description of Duties				
see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/4/25
Date

I, Michael Ornelas, **certify that as the MDEG Administrator for**

Cepheid,

that I (initial that you have read and meet the following requirements):

1. MJO Have a high school diploma or its equivalent;
2. MJO Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MJO Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MJO Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Ornelas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/4/25

Date

Board Use Only	Date Received:

Mike Ornelas

[redacted]

QUALITY SYSTEMS DIRECTOR

Quality System Management • Compliance • Regulatory Agency Management

Accomplished Quality Systems Director with extensive experience in medical device development, manufacture and service. Proven expertise in managing compliance auditing, supplier quality, change control, and regulatory agency management. Consistently successful in both start-up environments and global corporations on a variety of product platforms ranging from home use hand-held devices to capital medical device equipment. Advanced team leadership skills with a history of success in managing global teams and projects to productive outcomes. Outstanding communicator, adept at working with global cross-functional teams.

CORE COMPETENCIES

- ISO and FDA regulations
- Regulatory Agency management
- IVDR, MDR, and CE Mark
- Corrective and Preventive Action
- Global Supplier program management
- Global Change Control management
- Global Audit program management
- Sterile Devices/IVD/Radiation-Emitting Devices

CAREER ACCOMPLISHMENTS

- Established Quality System in start-up environments.
- Successfully achieved CE Mark and TGA approval for Specimen Transportation Kit.
- Established Change Management process with custom raw material suppliers.
- Facilitated the management of several FDA audits resulting in zero (0) observations.
- As Divisional Management Representative, significantly reduced the number of findings identified at Respiratory sites during ISO audits.
- Established Divisional Internal Audit program and re-engineered Supplier Quality program at over 7 Respiratory sites ensuring harmonized internal audit practices and improved supplier management resulting in effective results.
- Provided leadership as Core Team member for the relocation of a Covidien Respiratory Service Facility and Divisional Facility to new locations.
- Experienced in the development, manufacture, and service of a wide range of products including genomic-based diagnostic tests, sterile products, electromechanical products, and radiation emitting products for Home use, Clinician's use, and Institutional use.

PROFESSIONAL EXPERIENCE

CEPHEID – Fremont, CA
44509 Pacific Commons Blvd 1-888-336-2743 2/18 to present

Senior Director Quality Systems

Provides management Global strategic direction and operational coordination of activities to ensure compliance with FDA, ISO, and other applicable global regulatory requirements as well as alignment with company objectives and Quality Standards. Direct Sunnyvale responsibility and Global oversight for Quality System processes including CAPA, Internal Audits, Learning and Development, Document Control, and Product Safety & Environmental Compliance.

Key Achievements:

- Achieved multi-site ISO/MDSAP certification including the certification of new sites.
- Established Global Internal and CAPA program
- Successfully implemented ComplianceWire to automate Quality System training requirements globally.

GENOMIC HEALTH INC. – Redwood City, CA
101 Galveston Drive 1-866-662-6897 11/07 to 2/18

Director Quality Systems and Compliance

Developed organizational capability and provided functional leadership for Quality Assurance and Document Control Departments. Established CAPA program, Supplier Qualification & Monitoring, and Production and Process Controls. Provided leadership in improving the Calibration program, Equipment Validation protocols, and Document Control efficiency.

Key Achievements:

- Established Quality Assurance Department.
- Established QC Acceptance Activities and Manufacturing Production and Process Controls by overseeing the creation of QC Acceptance SOPs and Manufacturing SOPs and Batch Records.
- Improved Supplier relationships by implementing Supplier Scorecards and Awards.
- Successfully achieved CE marking and TGA approval for Specimen Transportation Kit.
- Improved Document Control Department efficiency by implementing DocuSign for electronic approvals.

MEDTRONIC (FORMERLY COVIDIEN) – Pleasanton, CA 10/05-11/07

Divisional Director Quality Systems and Regulatory Compliance

Divisional Director of Quality Systems and Regulatory Compliance for over 11 combined global development, manufacturing and service facilities. Designated as Divisional Management Representative. Provided divisional leadership, guidance, and support on all Quality System activities at all global Respiratory sites. Directed Quality System responsibilities for newly acquired private labeling and distributor relationships.

Key Achievements:

- Core team member to remediate deficiencies previously identified by FDA regulatory action across multiple Respiratory sites. Remediation resulted in zero (0) observations on FDA revisit.

- Coordinated ISO activities for all North American Respiratory sites including financials, audit scheduling, audit hosting, and site relocations.

- Established Divisional Internal Audit program and Pleasanton site Supplier Quality program. Improved Divisional Supplier Quality program by adopting best practices.

- Successfully directed Quality System activities on multiple distributor and private label alliances, including performing due diligence, establishing Quality Agreements, and delineating Quality Activities within Covidien Respiratory Division.

VARIAN MEDICAL SYSTEMS – Palo Alto, CA
3100 Hansen Way 1-650-493-4000 4/00-10/05
Varian Oncology Systems Quality System Manager

Oncology Divisional Manager for over 5 combined global development, manufacturing, distribution, and service facilities. Designated as Deputy Management Representative. Managed internal audit program and Quality System training across Oncology Division. Provided guidance on Quality System regulations including Part 11 for all global Oncology sites.

Key Achievements:

- Successfully re-engineered and continued management of Internal Audit program encompassing 5 sites and 3 auditors resulting in meaningful and effective audit results.

- Coordinated ISO activities for Oncology division across 5 global sites including financial, audit scheduling, and audit hosting.

- Hosted FDA and other 3rd Party audits resulting in successful outcomes.

AVOCET MEDICAL – San Jose, CA 9/97-4/00
Quality Manager

Responsible for all Quality Assurance and Quality Control activities and personnel in a start-up environment.

Key Achievements:

- Established a Quality Assurance and Quality Control department by initially hiring and continuing to manage 12 professional level personnel in performing Quality Assurance/ Quality Control activities.

- Hosted FDA/ISO/CSA audits resulting in successful outcomes.

SMITHKLINE DIAGNOSTICS INC. – Palo Alto, CA 11/96-9/97
Quality Supervisor

Scheduled and coordinated 4 professional level personnel in performing Quality Control activities; including laboratory test and inspections of raw materials, in-process materials, and finished materials.

Key Achievements:

- Participated in the successful transfer of multiple products from design into manufacturing.

- Developed, modified, and validated Quality Control test methods to streamline testing.

- Hosted 3rd part and ISO audits resulting in successful outcomes.

BEHRING DIAGNOSTICS INC. – Cupertino, CA 11/88-11/96
Technical Manufacturing Supervisor

Responsible for managing and providing technical, logistical, and administrative direction to 6 professional level personnel in the manufacture and evaluation of high quality reagent diagnostic assays.

Key Achievements:

- Ensured product valued at $40 to $70 million in revenue was manufactured on time and error free meeting all quality standards.

EDUCATION

Bachelors of Arts, Microbiology • University of California, Berkeley
Certified Quality Auditor (CQA)
Successfully completed written examination for ISO Lead Auditor
Six Sigma Green Belt Certification

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Cepheid

Pharmacy/Wholesaler License # (if applicable)

Physical Address 44509 Pacific Commons Blvd

City Fremont State CA Zip 94538

Mailing Address (if different from physical address) 904 E Caribbean Dr

City Sunnyvale State CA Zip 94089

Telephone 408-548-4191 Website https://www.cepheid.com/en-US.html

Licensing Company Email Establishment.Registration@cepheid.com

Section 2: Personal Information

First Michael Middle Sheehan Last Ornelas

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 44509 Pacific Commons BLVD

City Fremont State CA Zip 94538

Telephone [redacted] Email mike.ornelas@cepheid.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, Berkeley		/ - /	
Address	**City**	**State**	**Zip**
100 Academic Hall # 1234	Berkeley	CA	94720-1234
Diploma/Degree obtained, if any			
Bachelors of Arts, Microbiology			

School Name		From - To (MM/YY – MM/YY)	
BELLARMINE COLLEGE PREP		09 79 - 05 / 83	
Address	**City**	**State**	**Zip**
960 W HEDDING ST	SAN JOSE	CA	95126
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/03 - present	[redacted]	San Jose	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Cepheid			02/18 - present	
Business Address		City	State	Zip
44509 Pacific Commons Blvd		Fremont	CA	94538
Phone	Title		Number of Employed Hours	
408-548-4191	Director, Quality		40/week	
Description of Duties				
see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Genomic Health Inc			11/07 - 02/18	
Business Address		City	State	Zip
101 Galveston Drive		Redwood City	CA	94063
Phone	Title		Number of Employed Hours	
1-866-662-6897	Director Quality Systems and Compliance		40/week	
Description of Duties				
see attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		NA
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/4/25
Date

I, Michael Ornelas, **certify that as the designated representative for**

Cepheid,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MJO I am at least 21 years of age;
3. MJO I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MJO I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MJO I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MJO I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MJO I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael Ornelas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/4/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Ornelas

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 2/4/25

2/10/25

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Michael Ornelas, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 2/4/25

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

See attached California Jurat Certificate

(Seal)

CALIFORNIA JURAT GOVERNMENT CODE § 8202

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California

County of Santa Clara

Subscribed and sworn to (or affirmed) before me on this 10th day of February, 2025, by

Date Month Year

(1) Michael Orrelas

(and (2) _____),

Name(s) of Signer(s)

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

C. A. SCOTT
Notary Public - California
Santa Clara County
Commission # 2507639
My Comm. Expires Jan 18, 2029

Signature C A Scott

Place Notary Seal and/or Stamp Above *Signature of Notary Public*

OPTIONAL

Completing this information can deter alteration of the document or fraudulent reattachment of this form to an unintended document.

Description of Attached Document

Title or Type of Document: Nevada Designated Representative Application

Document Date: 10 February 2025 Number of Pages: 9

Signer(s) Other Than Named Above: NONE

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Cepheid Employee List - Fremont, CA

Associate
Jellydie Finau
Rene Medina Amador
Alvin Queri
Sam Rodriguez
Bhupinder Kaur
Nai Saephanh
Moe Mohammed
Melbin Bautista
Ricardo Gallegos
Rob Haworth
Israel Escobar
Fenton Ly
Ify Igboanugo
Neha Gudi
Phuoc Quach
Brian Jew
Jason Seto
Andrew Ku
Paul Simons
Janssen Capili
Brett Stanger
Andrew Franco
Octavio M Garcia
Joseph Bauer
Vicky Ng
Raja Sadaula
Larry Valenzuela
Vincent Mitchell
James Lizotte
Jesse Guel
Karamjit Dhillon
Rod Castro
Antelmo Morales
Dieu Tran
Brian Hutt
Danny Cruz
Richard Eckerman
Robert Rosales
Gabriel Ruiz
Annalisa Mendoza
Sean Sablan-Truscott
Anthony Monchez
Dindo Quizon
Luis E Rodriguez
Jesse Vargas (On Leave)

Confidential - Company Proprietary

Michael Moreno
Priscilla Martinez
Kent Lino
Jufelan Lantano
Jaime Gomez
John Bautista
Jorge Justo
Brix Cabanag
Rolando Partida
Randy Acosta
Joey Lizotte
Brian Swift (On Leave)
Carlos Vasquez
David Romero
Jeff Freitas
Arnold Esparza
Chaloy Hardwick
Ronald Rodriguez
Juliana Cardenas
Christopher Oceguera
Luis Lopez Gil
Jefferson Lukban
Omar Abenir
Mark Lester Dela Paz
David Barrientes
Harold Hidalgo
Raylon Ferguson
Roberto Moran
Richard Dewar
Henry Perez
Adrian Farfan
Robert Ortiz
Christine Gonzalez
Andy Choy
Ramon Ochoa
Lewis Phanphongsa
Malesa Sookvamdee
Rithy Phann
Vannack Phann
Atumaleti Vaiaoga
Paul Marlangaue
Lawrence Johnson
Favian Arteaga
Ronald Andrino
Arnel Paat
Abelardo Yabut
Tagaloa Vaiaoga

David Uiagalelei
Edras Chavarria
Randy Mendoza
Delane Green
Brittany Hindes
Jasmine Loung
Angel Arreguin
Robert Silva
Alexander Hoang
Laureano Baluyot
Edward Arredondo
Jose Baca Gonzalez
Johnny Truong

4AA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Cresilon, Inc.

Physical Address: 86 34th Street, Suite: D603/D604

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: (347) 435-2226 Website: https://cresilon.com/

Name of Designated Representative (DR): Hassaan Ahmad

Licensing Company Email: hassaan@cresilon.com DR Email: hassaan@cresilon.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10 Feb 2025
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): N/A

Corporation/Organization Name: Cresilon, Inc.

Mailing Address: 86 34th Street, Suite D603/D604

City: Brooklyn State: NY Zip: 11232

Telephone: (347) 435-2226 Email: hassaan@cresilon.com

Contact Person Name: Hassaan Ahmad

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Cresilon, Inc.

Facility Name

Hassaan Ahmad

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10Feb2025

Date

Board Use Only	Date Received: 3/4/25	Amount: $1000 CK 1666095

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
CRESILON INC
86 34th St Ste D603/D604
Brooklyn, NY 11232
Registration Number: 3012888343
FEI Number*: 3012888343
Status: Active
Date Of Registration Status: 2024

Owner/Operator:

Cresilon Inc[6]
86 34th Street Suite D603/D604
Brooklyn, NY US 11232
Owner/Operator Number: 10091402[7]

Official Correspondent:
David Lennarz
Registrar Corp
144 Research Drive
Hampton, VA 23666
Phone: 1-757-2240177

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 10/14/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10091402&OwnerOperatc

Cresilon List of Corporate Officers

Corporate Officers	Title	Business Address	Contact Number
Joe Landolina	CEO & Co-Founder	86 34th Street, D603/D604 Brooklyn, NY 11232	347-269-1430; ext. 101
Isaac Miller	EVP & Co-Founder	86 34th Street, D603/D604 Brooklyn, NY 11232	347-269-1440; ext.102
Hassaan W. Ahmad	Chief Operating Officer	86 34th Street, D603/D604 Brooklyn, NY 11232	347-435-2226; ext.103
Scott Levine	Chief Financial Officer	86 34th Street, D603/D604 Brooklyn, NY 11232	347-618-6110; ext.110

Delaware

The First State

I, CHARUNI P. SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CRESILON, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CRESILON, INC." WAS INCORPORATED ON THE THIRD DAY OF JANUARY, A.D. 2012.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. P. Sanchez

Charuni P. Sanchez, Secretary of State

5090128 8300

SR# 20250381978

Authentication: 202854452

Date: 02-04-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

CRESILON, INC. X

GENERAL INFO | ENFORCEMENT ACTIONS

Type	Manufacturer
Legal Name	CRESILON, INC.
Trade Name	---
Street Address	86 34TH STREET SUITE D603/D604 BROOKLYN NY 11232
Registration No	040521
Date First Registered	January 24, 2024
Registration Begins	January 24, 2024
Registered Through	December 31, 2026
Supervisor	AHMAD HASSAAN
Establishment Status	Active
Successor	NONE

May 5, 2025 01:17 PM (ET)
https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=040521&professionCode=020

CRESILON, INC. X

GENERAL INFO | ENFORCEMENT ACTIONS

Registration No: 040521

No Enforcement Actions Found

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-26

NAME OF SUPERVISOR
HASSAAN AHMAD

THIS IS TO CERTIFY

CRESILON, INC.
86 34TH STREET
SUITE D603/D604
BROOKLYN, NY 11232

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-FOURTH DAY OF JANUARY, 2024.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF DECEMBER, 2026.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
040521

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

76D - Cresilon Ownership - Nevada BOP - Full Stock Ledger

Final Audit Report 2025-02-07

Created:	2025-02-07
By:	Hassaan Ahmad (hassaan@cresilon.com)
Status:	Signed
Transaction ID:	CBJCHBCAABAA85xy_5SlPYOiDQzbKiuzMmy-8XjN0iQt

"76D - Cresilon Ownership - Nevada BOP - Full Stock Ledger" History

Document created by Hassaan Ahmad (hassaan@cresilon.com)
2025-02-07 - 6:23:06 PM GMT

Document emailed to Scott Levine (slevine@cresilon.com) for signature
2025-02-07 - 6:23:12 PM GMT

Document e-signed by Scott Levine (slevine@cresilon.com)
Signature Date: 2025-02-07 - 6:23:56 PM GMT - Time Source: server

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2025-02-07 - 6:23:56 PM GMT

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Cresilon Ownership

For Nevada State Board of Pharmacy

Type	Full Name	Telephone Number	Authorized Agent	% Ownership
Individual	Joe Landolina			11.270%
Legal Entity	Pacific Premier Trust LLC Custodian FBO William Chuang IRA	+1 (303) 658-3228	David Schoening	9.136%
Individual	Thomas Hamilton			5.002%
Individual	Isaac Miller			3.519%
Individual	William Chuang			2.459%
Individual	John Martello			1.584%
Individual	William Murphy			1.329%
Legal Entity	Bespoke Explorer, LP	+1 (215) 206-9507	Docks Sutherland; Samantha Smith	1.255%
Individual	Sean McCance			1.235%
Individual	Cooper Pulliam			1.175%
Individual	*******phere			0.921%
Individual	*******ening			0.749%
Legal Entity	White Rose Nominees Ltd			0.719%
Individual	*******nberg			0.714%
Legal Entity	Bespoke Fund One, LP			0.679%
Individual	*******ender			0.633%
Individual	*******Brand			0.622%
Individual	*******truve			0.561%
Individual	*******Smith			0.524%
Legal Entity	Southern Cross Trust			0.506%
Individual	*******Blatt			0.502%
Legal Entity	Barrett Share Trust			0.497%
Individual	*******t Fox			0.448%
Individual	*******itson			0.440%
Individual	*******ilson			0.425%
Legal Entity	Harnar Living Trust			0.423%
Individual	*******artin			0.423%
Legal Entity	Curtis D Walker Living Trust			0.421%
Legal Entity	Beacon Investments LLC			0.420%
Legal Entity	Stephen A Wilson Revocable Trust			0.405%
Individual	*******urner			0.399%
Individual	*******Tosco			0.392%

Individual	*******R Fry	0.378%
Individual	*******uffer	0.377%
Individual	*******right	0.372%
Individual	*******stman	0.369%
Legal Entity	Velcro LLC	0.369%
Individual	*******fsson	0.352%
Individual	*******Canna	0.349%
Legal Entity	Harriet G August Irrevocable Trust dtd 12/16/2020	0.349%
Legal Entity	Austin Family Securities Ventures LP	0.345%
Individual	*******Hydok	0.345%
Individual	*******Hardt	0.344%
Individual	******* Myer	0.337%
Legal Entity	Gerald A Tomsic 1995 Trust	0.327%
Individual	*******er Jr	0.323%
Individual	*******llwig	0.322%
Individual	*******neret	0.321%
Legal Entity	Huntington Hudson, LLC	0.317%
Individual	*******ofsky	0.308%
Individual	*******Ahmad	0.304%
Individual	******* Rowe	0.304%
Individual	*******ittoe	0.298%
Individual	*******Ahmad	0.296%
Legal Entity	Pleasant Valley Fund, LLC	0.295%
Legal Entity	Alliance Trust Co Cust FBO Brian M Miller Roth IRA	0.295%
Legal Entity	Strata Trust Company Cust FBO Alexander Tosi IRA	0.286%
Individual	*******arter	0.283%
Individual	*******ersen	0.277%
Legal Entity	Redshield Capital LLC	0.277%
Individual	*******llwig	0.276%
Legal Entity	Strata Trust Company Cust FBO Thomas C Rolfstad IRA	0.268%
Individual	*******tcher	0.267%
Individual	*******Sarma	0.259%
Legal Entity	Pauline Shender Legacy Trust U/A 9/1/2020	0.247%
Legal Entity	Peakland Innovation Group	0.246%
Legal Entity	Langeliers Family Trust	0.244%
Individual	*******rrell	0.241%
Individual	******* Tosi	0.239%
Legal Entity	Kingdom Partners LLC	0.233%
Individual	*******mpert	0.231%
Individual	*******Gumas	0.227%
Legal Entity	Strata Trust Company Cust FBO Roger Walt Langeliers IRA 300002265	0.221%

Individual	******* Berg	0.217%
Legal Entity	Sanjay & Jayshree Patel Family Trust	0.215%
Individual	*******ogers	0.214%
Individual	*******r Rea	0.213%
Individual	*******onner	0.213%
Individual	*******Wells	0.213%
Individual	*******Suwyn	0.210%
Individual	*******Tracy	0.208%
Legal Entity	The Childers Living Trust	0.208%
Individual	*******hofer	0.205%
Legal Entity	Currie Family Credit Shelter Trust dtd 06/26/1987	0.202%
Individual	*******kumet	0.202%
Legal Entity	Ardara Capital LP	0.202%
Legal Entity	Strata Trust Company Cust FBO Roger Langeliers Roth IRA	0.202%
Individual	*******nieur	0.194%
Individual	*******na Xu	0.188%
Legal Entity	The Buffington Crace Revocable Living Trust dated March 6, 2020	0.187%
Legal Entity	Ananda Investment Services LLLP	0.185%
Legal Entity	Hippo Investments LLC	0.185%
Individual	*******rugos	0.185%
Individual	*******n Jr.	0.185%
Individual	*******ailey	0.185%
Individual	*******Reddy	0.185%
Legal Entity	The Henry V. and Inell A. Chase Trust	0.185%
Individual	*******ailey	0.185%
Legal Entity	Wamoh LLC	0.180%
Individual	*******nhart	0.180%
Individual	*******ocker	0.176%
Individual	*******orcos	0.172%
Individual	*******owitz	0.171%
Individual	*******Hardt	0.171%
Individual	*******mmata	0.171%
Legal Entity	GHO Commercial	0.169%
Legal Entity	FF Trust	0.166%
Individual	*******pivey	0.166%
Legal Entity	White Rose Nominees Ltd	0.161%
Individual	*******alker	0.160%
Individual	*******auber	0.154%
Individual	*******orozo	0.153%
Individual	*******n May	0.152%
Legal Entity	Strata Trust Company Cust FBO Terry Mitchell IRA	0.152%

Individual	*******minen	0.150%
Legal Entity	Strata Trust Company Cust FBO Michael F Zupan IRA	0.149%
Individual	******* Avon	0.149%
Legal Entity	Jerry B Watkins Declaration of Trust	0.148%
Individual	*******oeder	0.148%
Legal Entity	The Harry T Gordon Revocable Living Trust	0.147%
Legal Entity	Jack Cavin Holland 1979 Trust uad 2/14/1979	0.147%
Individual	*******Bryan	0.143%
Individual	******* Juve	0.143%
Individual	******* Saul	0.142%
Individual	*******ulson	0.141%
Individual	*******eiser	0.141%
Individual	*******Snook	0.141%
Legal Entity	Law Office of Kenneth E. Chyten 401(k) Profit Sharing Plan	0.140%
Legal Entity	Show Black Securities LLC	0.140%
Individual	*******erdak	0.138%
Individual	*******ng Gu	0.138%
Legal Entity	Bahr Family Limited Partnership	0.138%
Individual	*******Ghosh	0.137%
Individual	*******erson	0.135%
Legal Entity	Rajaee Trust dated 4/23/99	0.135%
Legal Entity	Strata Trust Company Cust FBO David S Perry SEP IRA	0.135%
Individual	*******gaker	0.135%
Individual	*******epard	0.131%
Individual	*******owley	0.129%
Individual	*******Cohen	0.128%
Individual	*******oonan	0.127%
Individual	*******evara	0.126%
Individual	*******alwar	0.125%
Legal Entity	Equity Trust Company Cust FBO Leonard Edward Samuels Roth IRA	0.124%
Legal Entity	Ashbaugh Living Trust	0.123%
Individual	*******arito	0.123%
Legal Entity	Newkumet Ltd	0.123%
Legal Entity	Blaine 2000 Revocable Trust	0.121%
Individual	*******stein	0.121%
Individual	******* Jess	0.121%
Legal Entity	MIS Equity Strategies LP	0.120%
Individual	*******nazuk	0.119%
Individual	*******umers	0.118%
Individual	*******Betts	0.118%
Legal Entity	Barron Holdings LLC	0.115%

Legal Entity	Strata Trust Company Cust FBO William Murphy Roth IRA	0.115%
Individual	*******ssman	0.115%
Individual	******* Lane	0.111%
Individual	*******/Wros	0.111%
Individual	******* Shah	0.111%
Individual	*******inson	0.111%
Individual	*******axler	0.110%
Individual	*******Nolan	0.110%
Legal Entity	Chess Family Trust	0.110%
Individual	*******Narra	0.110%
Individual	*******erson	0.109%
Individual	*******Gates	0.109%
Legal Entity	The Clarke-Ignatowicz Family Trust	0.109%
Individual	*******artin	0.108%
Legal Entity	Eldoret LLC	0.108%
Legal Entity	Bhadresh Patel & Priti Patel Inter Vivos Trust	0.108%
Individual	*******Lowry	0.108%
Individual	*******fikwu	0.104%
Legal Entity	Innovating Capital Partners LP	0.103%
Individual	*******chens	0.103%
Individual	*******Trapp	0.102%
Individual	*******leman	0.102%
Legal Entity	Strata Trust Company Cust FBO Nigel Timothy IRA	0.101%
Individual	*******Bruce	0.101%
Individual	*******rmona	0.101%
Individual	*******Mader	0.101%
Legal Entity	JTH III Living Trust dtd 12/18/2018	0.101%
Individual	*******Shell	0.101%
Individual	*******inger	0.101%
Legal Entity	Millennium Trust Company Cust FBO Louis Schaufele IRA xxxxx5610	0.101%
Individual	*******nessy	0.101%
Legal Entity	Strata Trust Company Cust FBO Ann Darda IRA	0.101%
Legal Entity	Strata Trust Company Cust FBO Darin Shelton IRA	0.101%
Individual	*******evens	0.101%
Individual	*******human	0.100%
Individual	*******Mehta	0.100%
Legal Entity	Eileen F Wenschlag Revocable Trust	0.099%
Individual	*******stein	0.098%
Individual	*******nwell	0.098%
Legal Entity	FMC Investments, LLC	0.098%
Individual	*******tners	0.098%

Individual	*******Roney	0.098%
Legal Entity	Philippe Zeltzman EPSP 401k FBO Philippe Zeltzman Roth # 100 121 94 42	0.098%
Legal Entity	Strata Trust Company Cust FBO Samantha Renee Jones IRA	0.098%
Legal Entity	The Dorm Room Fund I, LP	0.098%
Individual	*******Blech	0.098%
Legal Entity	Chitayat Holdings LLC	0.097%
Legal Entity	Kadi Family Trust	0.097%
Individual	*******onnor	0.097%
Individual	******* King	0.097%
Individual	*******mlata	0.097%
Individual	*******rmony	0.096%
Individual	*******Adams	0.096%
Individual	*******Burke	0.096%
Legal Entity	4P's Enterprises, LLC	0.095%
Individual	******* Darr	0.095%
Individual	*******Rabin	0.094%
Individual	*******Snook	0.093%
Individual	*******guyen	0.092%
Legal Entity	Anne-Scott Investments LLC	0.092%
Individual	*******ng Li	0.092%
Individual	*******ilson	0.092%
Individual	*******ewman	0.092%
Individual	*******Haber	0.092%
Legal Entity	IRA Financial Trust Co CFBO Douglas Townsend IRA	0.092%
Individual	*******emert	0.092%
Individual	*******Snook	0.092%
Individual	*******rgene	0.092%
Individual	*******ullin	0.092%
Individual	*******y Jr.	0.092%
Individual	*******rcher	0.092%
Individual	*******ullin	0.092%
Individual	*******erson	0.092%
Individual	******* Wang	0.092%
Individual	*******Zhang	0.092%
Individual	*******nfeld	0.090%
Individual	*******iffer	0.089%
Legal Entity	The Robert L Bahr Revocable Trust 1985	0.088%
Legal Entity	Randall J. Wolfe Revocable Living Trust UAD 10/1/2020	0.087%
Individual	*******nhart	0.086%
Legal Entity	Growing Impact Ventures, LP	0.085%
Legal Entity	Coruscant LLC	0.085%

Individual	*******doble	0.084%
Individual	*******Susie	0.079%
Individual	*******Sista	0.079%
Individual	*******nella	0.079%
Individual	*******gbers	0.079%
Individual	*******ssler	0.076%
Individual	*******ssler	0.076%
Individual	*******hback	0.076%
Individual	*******Arndt	0.076%
Individual	*******ibler	0.076%
Individual	*******hnson	0.076%
Legal Entity	Pacific Premier Trust Cust FBO William Webbe IRA	0.075%
Individual	******* Rood	0.075%
Individual	*******rertz	0.075%
Legal Entity	Nancy L Cowgill Trust	0.075%
Individual	******* Diaz	0.075%
Individual	*******eller	0.075%
Legal Entity	Anthony Nieto 401k Profit Sharing Plan	0.074%
Individual	*******bbott	0.074%
Individual	*******nston	0.072%
Legal Entity	Strata Trust FBO Mark Renelt Trad IRA	0.072%
Legal Entity	KJL Investment Group LLC Self Direted IRA Kirk Leonardelli	0.072%
Individual	*******Keogh	0.072%
Individual	*******owich	0.072%
Legal Entity	Volcanic Gardens Real Estate LLC	0.072%
Individual	*******ibson	0.071%
Individual	*******briel	0.071%
Legal Entity	Ladd Hill Development LLC	0.070%
Individual	*******iller	0.070%
Legal Entity	Jeffrey F Brugos Trust	0.069%
Legal Entity	Patrick Mullin Cust FBO James M Mullin UGMA	0.069%
Individual	*******t III	0.069%
Individual	*******rlson	0.068%
Legal Entity	Black River Energy LLC	0.067%
Individual	*******Kline	0.067%
Individual	*******iffer	0.067%
Individual	*******erten	0.067%
Individual	*******rship	0.067%
Individual	*******e III	0.067%
Individual	*******mothy	0.067%
Individual	*******evitt	0.067%

Legal Entity	Ragan Hexum Properties LLC	0.067%
Legal Entity	Rajaee Family Trust dated 10/10/03	0.067%
Individual	*******Dodge	0.067%
Individual	*******pardi	0.065%
Individual	*******agner	0.065%
Legal Entity	Robert C Lannert Trust dtd 5/1/1998	0.065%
Legal Entity	Jack Cavin Holland 1979 Trust uad 2/14/1979	0.065%
Individual	*******eeler	0.065%
Individual	*******arone	0.064%
Individual	*******Cohen	0.063%
Individual	*******ekken	0.063%
Individual	*******rertz	0.062%
Individual	*******White	0.062%
Legal Entity	Calcott Family Trust	0.062%
Individual	******* Hall	0.062%
Legal Entity	DDG22 LLC	0.062%
Individual	*******rdner	0.062%
Individual	*******itter	0.062%
Individual	*******n Jr.	0.062%
Legal Entity	Kadi Family Trust	0.062%
Legal Entity	Kingdom Partners LLC	0.062%
Individual	*******stein	0.061%
Individual	*******qi Li	0.061%
Individual	*******ivell	0.060%
Legal Entity	Cohen Family Trust	0.059%
Legal Entity	Due Mondi Investments Ltd	0.058%
Individual	*******Thoet	0.058%
Individual	*******erger	0.058%
Individual	*******stein	0.057%
Legal Entity	Anthony & Angela Reed Family Trust	0.056%
Individual	*******rsham	0.056%
Individual	******* Beck	0.056%
Individual	*******Bryan	0.056%
Legal Entity	Strata Trust Company Cust FBO James T Hays III IRA	0.055%
Individual	*******nolds	0.055%
Legal Entity	Xenium Trust U/A dtd 1/1/2012	0.055%
Individual	*******dland	0.055%
Individual	*******shura	0.055%
Individual	*******Patel	0.055%
Individual	*******ilson	0.055%
Legal Entity	Edwin H Richberg, Roth IRA	0.053%

Legal Entity	Tynes Family Trust	0.053%
Individual	*******erson	0.052%
Individual	*******iades	0.052%
Individual	*******iller	0.052%
Individual	*******erman	0.051%
Individual	*******Adams	0.051%
Individual	*******Mayes	0.051%
Individual	*******forth	0.051%
Individual	*******utton	0.051%
Legal Entity	IRAR Trust FBO Bruce Inglis Sep IRA 35-39056	0.051%
Individual	******* Sorg	0.051%
Individual	*******einer	0.051%
Individual	*******aring	0.051%
Individual	*******Zupan	0.051%
Individual	*******itzky	0.051%
Individual	*******Sahai	0.051%
Individual	*******Sahai	0.051%
Individual	*******baker	0.051%
Individual	******* Amin	0.051%
Individual	*******hmann	0.051%
Individual	*******Bader	0.050%
Individual	*******g Kim	0.050%
Individual	*******Brown	0.050%
Individual	*******Rowan	0.050%
Individual	*******ufele	0.049%
Individual	*******ngham	0.049%
Individual	*******nnell	0.049%
Individual	*******anadé	0.049%
Individual	*******laney	0.049%
Individual	*******homas	0.049%
Legal Entity	S Bruce Lansky Revocable Trust	0.049%
Individual	*******llard	0.049%
Individual	*******iller	0.048%
Individual	*******r Das	0.048%
Legal Entity	Continuation Capital Inc. (Paul Winkle)	0.048%
Legal Entity	Strata Trust Company FBO James G Diemert Roth IRA# 2020 48968	0.048%
Individual	*******itter	0.048%
Individual	*******Coyne	0.048%
Individual	*******Felix	0.048%
Individual	*******Louks	0.048%
Legal Entity	Hill Family Trust 06/02/2006	0.048%

Individual	*******obert	0.048%
Individual	*******edron	0.048%
Individual	*******chael	0.048%
Individual	*******ven R	0.048%
Legal Entity	Renouf Family Trust dtd 3/31/1989	0.048%
Individual	*******elzen	0.048%
Individual	*******icone	0.048%
Individual	*******Illya	0.048%
Legal Entity	Strata Trust Company Cust FBO Troy Stevens IRA	0.048%
Legal Entity	Eleven11 Financial LLC (Nicholas Salerno)	0.048%
Individual	*******ifrin	0.047%
Individual	*******tcher	0.047%
Individual	*******adden	0.047%
Legal Entity	Bruce L Levy Revocable Trust dtd 11/28/2012	0.047%
Individual	*******onnor	0.047%
Individual	*******Khara	0.047%
Individual	*******Misch	0.047%
Individual	******* Wahl	0.047%
Legal Entity	A&M Trust	0.046%
Individual	*******telle	0.046%
Individual	*******zieri	0.046%
Legal Entity	Charles & Clare Trick 2020 Trust dtd 08.19.20	0.046%
Individual	*******lecek	0.046%
Individual	*******ngton	0.046%
Legal Entity	Equity Trust Company Cust FBO Gerald Koppes IRA #200226156	0.046%
Individual	*******hmidt	0.046%
Individual	*******rossi	0.046%
Legal Entity	Strata Trust Company Cust FBO James E Butcher IRA	0.046%
Individual	*******rtman	0.046%
Individual	*******otter	0.046%
Individual	*******carlo	0.046%
Legal Entity	Strata Trust Company FBO James G Diemert IRA# 2019 43377	0.045%
Individual	*******ewart	0.044%
Individual	*******orsey	0.043%
Individual	*******oates	0.043%
Individual	*******hieco	0.043%
Individual	******* Sego	0.043%
Legal Entity	Strata Trust Company Cust FBO Charles Eugene Mayes Jr IRA	0.042%
Individual	*******Ahmed	0.042%
Individual	*******Kenna	0.041%
Legal Entity	George H Murphy 1988 Living Trust	0.041%

Legal Entity	Strata Trust Company Cust FBO Eric Schuler IRA	0.041%
Individual	*******Ellis	0.041%
Individual	*******egall	0.039%
Legal Entity	JHK, LP	0.039%
Individual	*******erman	0.039%
Individual	*******chens	0.039%
Individual	*******uming	0.039%
Individual	*******Snook	0.038%
Individual	*******ndpre	0.037%
Individual	*******Baker	0.037%
Individual	*******itore	0.037%
Individual	*******ghton	0.037%
Individual	*******dmire	0.037%
Individual	*******Moken	0.037%
Legal Entity	Strata Trust Company Cust FBO Harry Beller IRA	0.037%
Individual	*******rertz	0.037%
Individual	*******ulkis	0.037%
Individual	*******t III	0.036%
Individual	*******ailin	0.036%
Legal Entity	Pacific Premier Trust Cust FBO Mark J Feldman Roth IRA	0.036%
Legal Entity	Strata Trust Company Cust FBO Mark William Renelt Roth IRA #300005568	0.036%
Individual	*******auhan	0.036%
Individual	*******alwar	0.036%
Individual	*******Seitz	0.036%
Individual	******* Eike	0.035%
Individual	*******tigan	0.035%
Individual	*******y Mai	0.035%
Individual	*******immer	0.035%
Individual	*******a Das	0.035%
Individual	*******iller	0.034%
Individual	*******iller	0.034%
Individual	*******iefer	0.034%
Individual	*******artin	0.034%
Legal Entity	Strata Trust Company FBO Matthew Richter Roth IRA 300003488	0.034%
Individual	*******oshua	0.034%
Individual	*******iam J	0.034%
Individual	*******n III	0.034%
Individual	*******nauer	0.034%
Individual	*******nston	0.034%
Legal Entity	Ladd Hill Development LLC	0.034%
Individual	*******llock	0.034%

Individual	*******nitti	0.034%
Individual	******* Shah	0.034%
Individual	*******odkin	0.034%
Individual	*******hbone	0.034%
Individual	*******iller	0.034%
Legal Entity	Strata Trust Company Cust FBO Verena Fabian IRA #202045346	0.033%
Individual	*******nning	0.033%
Legal Entity	Flying S Ranch Trust	0.033%
Individual	******* Kahn	0.032%
Legal Entity	Strata Trust Company Cust FBO Donald Ray Crowley IRA	0.032%
Individual	*******eloso	0.032%
Individual	*******chael	0.031%
Individual	*******borty	0.031%
Individual	******* Karp	0.031%
Legal Entity	Bradley Resources Co LLC	0.031%
Individual	*******Hanks	0.031%
Legal Entity	Conniff Family Trust	0.031%
Individual	*******Perry	0.031%
Individual	******* Hart	0.031%
Legal Entity	Future LLC - Jack R. Frank II	0.031%
Legal Entity	John M. Wenschlag Rev. Trust	0.031%
Individual	*******akass	0.031%
Legal Entity	NuView IRA Inc FO Bruce Clarke IRA	0.031%
Individual	*******. Mut	0.031%
Legal Entity	Thomas E. Prasil Trust	0.031%
Individual	*******outen	0.031%
Individual	*******Burns	0.031%
Individual	*******itter	0.031%
Individual	*******ghton	0.031%
Individual	******* Imes	0.031%
Individual	*******James	0.031%
Individual	*******iller	0.031%
Legal Entity	Strata Trust Company Cust FBO Anne Gullquist Mullin IRA	0.031%
Individual	*******mmons	0.031%
Individual	*******Azizi	0.031%
Individual	*******ibson	0.031%
Legal Entity	Northlea Partners LLP	0.030%
Individual	*******cheib	0.030%
Individual	*******Smith	0.030%
Individual	*******Weber	0.030%
Individual	*******scher	0.030%

Individual	*******aples	0.028%
Individual	*******Trapp	0.028%
Individual	*******Singh	0.028%
Individual	*******Rodef	0.028%
Individual	*******etson	0.028%
Legal Entity	Strata Trust Company Cust FBO Joseph W Hostetler IRA	0.028%
Legal Entity	Consulting for Strategic Growth 1, Ltd.	0.028%
Legal Entity	GBS Living Trust	0.028%
Individual	*******inder	0.028%
Individual	*******andor	0.027%
Individual	*******liams	0.027%
Individual	*******pland	0.027%
Legal Entity	Strata Trust Company Cust FBO Christine O'Rourke SEP IRA	0.027%
Individual	*******urcio	0.027%
Individual	*******Lucas	0.025%
Legal Entity	Bradley & Lori Abeson Rev Family Trust	0.025%
Individual	*******ndlay	0.025%
Individual	******* Care	0.025%
Legal Entity	Strata Trust Company Cust FBO Christine ORourke	0.025%
Legal Entity	Strata Trust Company Cust FBO Michael Welby IRA	0.025%
Individual	*******rertz	0.025%
Individual	*******olous	0.025%
Individual	*******insky	0.025%
Legal Entity	NuView IRA, Custodian for Stefan F. Nowina-IRA	0.025%
Individual	*******ewski	0.025%
Individual	*******Alati	0.025%
Legal Entity	Parikh Family Trust dtd June 13, 1988	0.025%
Individual	*******bbins	0.025%
Individual	*******chell	0.025%
Legal Entity	Mitchell Family Investments II LLC	0.025%
Individual	******* Tosi	0.025%
Individual	*******arper	0.025%
Individual	*******Brand	0.025%
Legal Entity	Peter B. Rauenbuehler and Mary L. Mines Living Trust	0.025%
Individual	*******Dalal	0.025%
Legal Entity	Mandel Living Trust Sole & Separate Property	0.025%
Individual	*******Gutek	0.025%
Legal Entity	Cuming Family GST Non-Exempt Trust 04/22/11	0.024%
Legal Entity	Strata Trust Company Cust FBO Gerald Hartke IRA #202045776	0.024%
Individual	*******ately	0.024%
Legal Entity	Hamilton Distribution LLC (Garlon Frost)	0.024%

Individual	*******Rojas	0.024%
Individual	*******truve	0.024%
Individual	*******vir M	0.024%
Individual	*******nfrey	0.024%
Individual	*******en II	0.024%
Individual	*******salyn	0.024%
Individual	*******ledge	0.024%
Individual	*******laria	0.024%
Individual	*******delli	0.024%
Individual	*******icone	0.024%
Individual	*******aynor	0.024%
Individual	*******uhaus	0.024%
Individual	*******dison	0.024%
Individual	*******nhart	0.024%
Legal Entity	Strata Trust Company Cust FBO Lori Ann Renelt Roth IRA #300007132	0.024%
Legal Entity	Strata Trust Company Cust FBO Loria Ann Renelt IRA #300006484	0.024%
Legal Entity	Strata Trust Company Cust FBO Mark William Renelt IRA #300006240	0.024%
Legal Entity	The Joseph & Karen Perricone Family Trust	0.024%
Legal Entity	Thomas A Ewig Jr Revocable Living Trust	0.024%
Individual	*******Nunoo	0.024%
Legal Entity	Mandava Kotha Revocable Living Trust	0.024%
Individual	*******phens	0.024%
Individual	*******Rocco	0.024%
Individual	*******o III	0.024%
Legal Entity	Romero Holdings LLC	0.024%
Legal Entity	Don Ross Legacy Trust	0.023%
Individual	*******Mario	0.023%
Legal Entity	A&M Trust	0.023%
Legal Entity	Strata Trust Company Cust FBO Adam Schofield IRA	0.023%
Individual	*******y III	0.023%
Individual	*******nford	0.023%
Individual	*******ocyba	0.023%
Individual	*******oland	0.023%
Legal Entity	EKM Capital LLC	0.023%
Individual	*******nsend	0.023%
Legal Entity	KAM Capital LLC	0.023%
Individual	*******inrin	0.023%
Individual	*******Lewis	0.023%
Individual	*******enger	0.023%
Individual	*******nberg	0.023%
Individual	*******oeder	0.023%

Legal Entity	Strata Trust Company Cust FBO Ryan Merriam Roth IRA	0.023%
Individual	*******Foley	0.023%
Individual	*******Jones	0.023%
Individual	******* Howe	0.022%
Individual	******* Saxe	0.021%
Individual	******* Ades	0.020%
Legal Entity	The Javaherneshan Family Trust	0.020%
Individual	*******iller	0.020%
Legal Entity	EAX Group Ventures, LLC	0.020%
Legal Entity	Equity Trust Company FBO James Robert Marx IRA Account Z126677	0.020%
Individual	*******emesh	0.020%
Legal Entity	Hammerstone Capital 1, LLC	0.020%
Individual	*******llins	0.020%
Individual	*******nahan	0.020%
Individual	*******pgyal	0.020%
Individual	*******imsey	0.020%
Individual	******* Amin	0.019%
Individual	*******ennie	0.019%
Individual	*******hanna	0.019%
Individual	*******Brett	0.019%
Individual	*******latte	0.019%
Legal Entity	Strata Trust Company Cust FOB Thomas J Burke Trad IRA	0.018%
Individual	*******Dubin	0.017%
Individual	******* Hall	0.017%
Individual	*******ownie	0.017%
Individual	*******Patel	0.017%
Individual	*******ustin	0.017%
Individual	*******ownie	0.017%
Legal Entity	The Stephen Cobos and Stephanie Y. Cobos Joint Family Trust	0.017%
Individual	*******lling	0.017%
Individual	*******laski	0.017%
Individual	******* King	0.017%
Individual	*******lling	0.017%
Individual	*******Carey	0.017%
Individual	*******Simon	0.017%
Individual	*******Gupta	0.017%
Individual	*******lliot	0.017%
Individual	*******field	0.017%
Individual	*******llern	0.017%
Individual	*******lumbo	0.017%
Individual	*******oukas	0.017%

Individual	*******lliot	0.017%
Individual	*******wford	0.017%
Legal Entity	Ltd Lezarb	0.017%
Individual	*******holas	0.017%
Individual	*******asteh	0.017%
Individual	*******nnell	0.017%
Legal Entity	Transcendent Development Group Inc	0.017%
Individual	*******Shipp	0.017%
Individual	*******wartz	0.016%
Individual	*******Cobos	0.016%
Individual	*******eyney	0.016%
Individual	*******nfeld	0.016%
Legal Entity	GKG Investments, LLC	0.016%
Individual	*******Weiss	0.016%
Individual	*******ldwin	0.016%
Individual	******* Gray	0.016%
Individual	*******olman	0.016%
Individual	*******churi	0.016%
Individual	*******emann	0.016%
Individual	*******Lynch	0.015%
Individual	*******lippe	0.015%
Individual	*******ryman	0.015%
Individual	*******sford	0.015%
Legal Entity	Equity Trust Company Cust FBO Frederick J Gawronski IRA	0.015%
Individual	*******Smith	0.015%
Individual	*******Zhang	0.015%
Individual	*******rewyn	0.015%
Individual	*******ammed	0.015%
Individual	*******onway	0.015%
Individual	*******lfaro	0.015%
Legal Entity	Law Office of Kenneth E Chyten 401k Profit Sharing Plan	0.015%
Individual	*******Foner	0.015%
Individual	*******thews	0.015%
Individual	*******otter	0.015%
Legal Entity	Millennium Trust Co LLC Cust FBO Janet Schalk IRA-B9852	0.015%
Individual	*******aroon	0.015%
Individual	*******t Day	0.015%
Legal Entity	Strata Trust Company Cust FBO Diana K Berg	0.015%
Individual	*******loots	0.015%
Individual	*******saint	0.015%
Individual	*******lerno	0.015%

Individual	*******doyan	0.015%
Individual	******* Rios	0.015%
Individual	*******ilkes	0.015%
Individual	*******nberg	0.015%
Individual	*******ngash	0.015%
Individual	******* Bovi	0.015%
Legal Entity	Strata Trust Company Cust FBO Susan M Frattasio IRA	0.015%
Individual	*******nbeis	0.015%
Individual	*******liner	0.014%
Legal Entity	Strata Trust Company Cust FBO Michael Zupan Roth IRA	0.014%
Individual	*******w III	0.014%
Individual	*******ganti	0.014%
Individual	*******Swift	0.013%
Individual	*******ustgi	0.013%
Individual	*******White	0.013%
Individual	*******llbee	0.013%
Individual	*******edell	0.012%
Individual	*******e Jr.	0.012%
Individual	*******Tracy	0.012%
Individual	*******Moten	0.012%
Legal Entity	Anthony Nieto 401k Profit Sharing Plan	0.012%
Individual	*******Moura	0.012%
Individual	*******Barak	0.012%
Individual	*******ngela	0.012%
Individual	*******iplin	0.012%
Individual	*******Andra	0.012%
Individual	*******Dowdy	0.012%
Individual	*******ammed	0.012%
Individual	*******tchen	0.012%
Legal Entity	Midland Trust Company Cust FBO Michael Khamis #1734987	0.012%
Individual	*******hmann	0.012%
Individual	*******Brian	0.012%
Individual	*******tthew	0.012%
Individual	*******hnson	0.012%
Legal Entity	Strata Trust Company Cust FBO Jeffrey Weiner Roth IRA	0.012%
Legal Entity	Strata Trust Company Cust FBO Kellie Davis Inh IRA Bene for Jacqueline Paulson	0.012%
Legal Entity	The Joseph M Summers & Pamela J Summers Revocable Living Trust dtd 10/20/23	0.012%
Individual	*******seman	0.012%
Individual	*******rolla	0.012%
Legal Entity	Equity Trust Company Custodian FBO Scott Christopher Patterson, IRA	0.012%
Individual	*******elsen	0.012%

Legal Entity	Robert A. & Marguerite A. Dole Trust 03/10/11	0.011%
Individual	*******oulos	0.011%
Individual	*******Ghosh	0.011%
Individual	*******iskie	0.011%
Individual	*******eaver	0.011%
Individual	*******ttani	0.010%
Individual	******* Tong	0.010%
Individual	*******st AS	0.010%
Individual	*******ittle	0.010%
Individual	*******udson	0.010%
Individual	*******McCoy	0.010%
Individual	******* Pena	0.010%
Individual	*******Duran	0.010%
Individual	*******latte	0.010%
Individual	*******pbell	0.010%
Individual	*******srael	0.010%
Individual	*******ascio	0.010%
Individual	*******hmitt	0.010%
Legal Entity	Judith and Abbie Israel Trust	0.010%
Individual	*******Demps	0.010%
Individual	*******leach	0.010%
Individual	******* Sato	0.010%
Individual	*******Bondi	0.010%
Individual	*******ering	0.010%
Individual	*******araju	0.010%
Individual	*******Costa	0.010%
Individual	*******nchin	0.010%
Individual	*******berte	0.010%
Individual	*******orjee	0.010%
Individual	*******mpson	0.010%
Individual	*******n Lee	0.009%
Individual	*******nkoop	0.009%
Individual	******* Hill	0.009%
Individual	*******iller	0.009%
Legal Entity	Strata Trust Compay Cust FBO Charles Eugene Mayes Jr Roth IRA	0.008%
Individual	*******Cobos	0.008%
Individual	*******Allen	0.008%
Individual	*******rlean	0.008%
Legal Entity	Strata Trust Company Cust FBO Daniel Cheyney Roth IRA	0.007%
Legal Entity	Strata Trust Company Cust FBO Devonia Cheyney Roth IRA	0.007%
Individual	*******shner	0.007%

Individual	*******Irwin	0.007%
Individual	*******Winks	0.007%
Individual	*******llbee	0.007%
Individual	*******08/98	0.007%
Individual	*******ippel	0.006%
Legal Entity	Northlea Partners LLLP	0.006%
Legal Entity	Boston Light Advisors, LLC	0.005%
Individual	******* Razi	0.005%
Individual	*******arnes	0.005%
Individual	*******organ	0.005%
Individual	*******n Chu	0.005%
Individual	*******ndley	0.005%
Individual	*******Hardt	0.005%
Individual	*******Exter	0.005%
Individual	*******s Sr.	0.005%
Individual	*******tista	0.005%
Individual	*******ebaum	0.005%
Individual	*******hayer	0.005%
Individual	*******ubler	0.005%
Individual	*******Osher	0.005%
Individual	*******Lahat	0.005%
Individual	******* Gill	0.005%
Individual	*******Lonni	0.005%
Individual	*******fpour	0.004%
Individual	*******elson	0.004%
Individual	*******TWROS	0.003%
Individual	******* Jeff	0.002%
Legal Entity	John W. Cuming IRA	0.002%
Individual	*******Hegde	0.002%
Individual	*******t Ten	0.002%
Individual	*******Nalle	0.002%
Individual	*******Tracy	0.002%
Individual	*******y Jr.	0.002%
Individual	*******aeger	0.002%
Individual	*******Tracy	0.002%
Individual	*******ymour	0.001%
Individual	******* Nair	0.001%
Legal Entity	Martha S. Roney Trust UAD 02/05/02	0.001%
Individual	*******Neill	0.001%
Individual	*******arter	0.000%
Individual	*******James	0.000%

Individual	*******eorge	0.000%
Individual	*******Borge	0.000%
Individual	*******ndita	0.000%
Legal Entity	Nancy Cowgill Trust	0.000%
	TOTAL	**100.000%**

- END OF STOCK LEDGER -

Reviewed & Approved By:

Signature: Scott Levine

Email: slevine@cresilon.com

Scott Levine
Chief Financial Officer
Cresilon, Inc.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 39BSBJH1469

Application/License No. _____

Cresilon, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
86 34th Street, Suite D603/D604, Brooklyn, NY 11232, as
(Address of Applicant/Principal)
PRINCIPAL, and Hartford Fire Insurance Company, a
(Surety Company)
corporation organized under the laws of the state of Connecticut
(State of Incorporation)
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza, Hartford, CT 06155 - 0001 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 14, 2024.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

39BSBJH1469

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 14th day of November, 2024.

APPLICANT/PRINCIPAL

Cresilon, Inc.

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Abigail Curtiss, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: LOCKTON COMPANIES LLC
Agency Code: 39-427620

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Abigail Curtiss

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 39BSBJH1469
Naming Cresilon, Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of November 14, 2024.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

CERTIFICATE OF LIABILITY INSURANCE

1/1/2026

DATE (MM/DD/YYYY): 1/10/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	Lockton Companies, LLC DBA Lockton Insurance Brokers, LLC in CA CA license #0F15767 1185 Avenue of the Americas, Ste. 2010 New York NY 10036 (646) 572-7300	CONTACT NAME:	
		PHONE (A/C, No, Ext):	FAX (A/C, No):
		E-MAIL ADDRESS:	
		INSURER(S) AFFORDING COVERAGE	NAIC #
		INSURER A : Pacific Indemnity Company	20346
INSURED 1553781	Cresilon, Inc. 86 34th Street, SuiteD603/D604 Brooklyn, NY 11232	INSURER B : Federal Insurance Company	20281
		INSURER C : Chubb Custom Insurance Company	38989
		INSURER D :	
		INSURER E :	
		INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** 21291070 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:	N	N	3598-77-68 WUC	1/1/2025	1/1/2026	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ Excluded
								$
B	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY SCHEDULED AUTOS X HIRED AUTOS ONLY X NON-OWNED AUTOS ONLY	N	N	(25)7358-28-55	1/1/2025	1/1/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
							BODILY INJURY (Per person)	$ XXXXXXX
							BODILY INJURY (Per accident)	$ XXXXXXX
							PROPERTY DAMAGE (Per accident)	$ XXXXXXX
								$ XXXXXXX
B	X UMBRELLA LIAB X OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $	N	N	9364-62-57	1/1/2025	1/1/2026	EACH OCCURRENCE	$ 9,000,000
							AGGREGATE	$ 9,000,000
								$ XXXXXXX
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	(26) 7175-16-61	1/1/2025	1/1/2026	X PER STATUTE OTH-ER	
							E.L. EACH ACCIDENT	$ 1,000,000
							E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
C	Products Liability	N	N	36065770	1/1/2025	1/1/2026	Aggregate: $10,000,000 Occurrence: $10,000,000 Deductible: $10,000	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

21291070
Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Cresilon, Inc. MDEG License # (if applicable): N/A

Physical Address: 86 34th Street, Suite D603/D604

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: (347) 435-2226 Website: https://cresilon.com/

Licensing Company Email: hassaan@cresilon.com

Section 2: Personal Information

First: Hassaan Middle: W Last: Ahmad

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 86 34th Street, Suite D603/D604

City: Brooklyn State: NY Zip: 11232

Telephone: 347 269 1407 Ext: 103 Email: hassaan@cresilon.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
NYU School of Engineering		Sep 2010- May 2014	
Address	**City**	**State**	**Zip**
6 Metrotech Ctr	Brooklyn	NY	11201
Diploma/Degree obtained, if any			
BS- Chemical & Biomolecular Engineering			

School Name		From - To (MM/YY – MM/YY)	
John P Stevens High School		Sep 2006- May 2010	
Address	**City**	**State**	**Zip**
855 Grove Ave	Brooklyn	NY	08820
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
July 1994-Present	[redacted]	Edison	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Cresilon, Inc.			May 2012 to Present
Business Address	**City**	**State**	**Zip**
86 34th Street, Suite D603/D604	Brooklyn	NY	11232
Phone	**Title**		**Number of Employed Hours**
347 269 1407	Chief Operating Officer		24, 960 Hours

Description of Duties

I was responsible for creating, managing and implementing all of Cresilon's Quality and Regulatory Policies and Procedures. I managed the Quality Assurance, Quality Control, Regulatory Affairs and Manufacturing Departments.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, HASSAAN AHMAD, **certify that as the MDEG Administrator for** CRESILON, INC.,

that I (initial that you have read and meet the following requirements):

1. Yes Have a high school diploma or its equivalent;
2. Yes Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. Yes Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. Yes Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hassaan Ahmad
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10Feb2025
Date

Board Use Only	Date Received: 3/4/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Cresilon, Inc.

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 86 34th Street, Suite D603/D604

City Brooklyn State NY Zip 11232

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone (347) 435 2226 Website Cresilon.com

Licensing Company Email hassaan@cresilon.com

Section 2: Personal Information

First Hassaan Middle W Last Ahmad

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 86 34th Street, Suite D603/D604

City Brooklyn State NY Zip 11232

Telephone 347 269 1407 Ext: 103 Email hassaan@cresilon.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
NYU School of Engineering		Sep 2010 - Sep 2014	
Address	**City**	**State**	**Zip**
6 Metrotech Ctr	Brooklyn	NY	11201
Diploma/Degree obtained, if any			
BS- Chemical & Biomolecular Engineering			

School Name		From - To (MM/YY – MM/YY)	
John P Stevens High School		Sep 2006 - Sep 2010	
Address	**City**	**State**	**Zip**
855 Grove Ave	Edison	NJ	08820
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
July 1994- Present	[redacted]	Edison	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Cresilon, Inc.			May 2012 to Present	
Business Address		**City**	**State**	**Zip**
86 34th Street, Suite D603/D604		Brooklyn	NY	11232
Phone	**Title**		**Number of Employed Hours**	
347 269 1407	Chief Operating Officer		24, 960 Hours	
Description of Duties				
I was responsible for creating, managing and implementing all of Cresilon's Quality and Regulatory Policies and Procedures. I managed the Quality Assurance, Quality Control, Regulatory Affairs and Manufacturing Departments.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

10 Feb 2025
Date

I, HASSAAN AHMAD, **certify that as the designated representative for**

Cresilon, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. YES I am at least 21 years of age;
3. YES I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. YES I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. YES I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. YES I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. YES I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Hassaan Ahmad

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10 Feb 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hassaan Ahmad

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10 Feb 2025

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Kings

I, HASSAAN AHMAD, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10 Feb 2025

Date

Subscribed and Sworn to before me this 10 day of Feb 2025

Notary Public Signature

GEDALIA MARYL
Notary Public - State of New York
No. 01MA6226310
Qualified in Kings County
My Commission Expires Aug. 09, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Cresilon, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 86 34th Street, Suite D603/D604

City Brooklyn State NY Zip 11232

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone (347) 435-2226 Website Cresilon.com

Licensing Company Email hassaan@cresilon.com

Section 2: Personal Information

First Joseph (Joe) Middle Alexander Last Landolina

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 86 34th Street, Suite D603/D604

City Brooklyn State NY Zip 11232

Telephone +1 3472691430;ext 101 Email joe@cresilon.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
New York University		Sep 2010- May 2014	
Address	**City**	**State**	**Zip**
6 Metrotech Ctr	Brooklyn	NY	11201
Diploma/Degree obtained, if any			
BS. Chemical & Biomolecular Engineering			

School Name		From - To (MM/YY – MM/YY)	
Pine Bush High School		Sept 2006 - May 2010	
Address	**City**	**State**	**Zip**
118 State Route 302	Pine Bush	NY	12566
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2020-Present	[redacted]	Brooklyn	NY	[redacted]
From - To (MM/YY – MM/YY)		City	State	
2020-2016		Brooklyn	NY	
From - To (MM/YY – MM/YY)		City	State	
2016-2015		Brooklyn	NY	
From - To (MM/YY – MM/YY)		City	State	
2015-2012		Brooklyn	NY	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Cresilon, Inc.			Sep 2010- Present
Business Address	**City**	**State**	**Zip**
86 34th Street	Brooklyn	NY	11232
Phone	**Title**		
(347) 435-2226	CEO & Co-Founder		
Description of Duties			
I oversee the growth of Cresilon. I am responsible for setting the overall direction of the company and navigating market entry in three separate highly-regulated market verticals globally.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Landolina

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted) — Date: 10 Feb 2025

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Kings

I, Joseph Landolina, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature — **Date:** 10 Feb 2025

Subscribed and Sworn to before me this 10Th day of Feb 2025.

Notary Public Signature

GEDALIA MARYL
Notary Public - State of New York
No. 01MA6226310
Qualified in Kings County
My Commission Expires Aug. 09, 2026

(Seal)

Employee_Name
AHMAD, HASSAAN W
AHMAD, OMAR M
ALVES, AGNES
ALY, MERNA
AMBROSE, KEVIN F
AMEZCUA ALVAREZ, JULIAN
BAIOUAK, MAROUANE
BAUMSTEIN, OLIVIA HENIN
BOHAICHUK, OKSANA
BOYSEN, BRITTANY L
BURWELL, MELISSA A
CARRUTH, TYLER
CHERNOUSOV, YEVHEN
CLODFELTER, JOHN
COLETTO, ANTHONY
DODDI, RAMA
DRIS, IRENE
DUFFY, KARINA A
EASTLAND, KENDALL E
FERNANDES, CALINE ELVEERA
FERRARA, JIM
FERREE, SANDRA L
FREASO, ROBERT
FUSHEK, CHRISTIAN
HABASSI, HAMZA
HALL, ZACHARY T
JENKINS-JOHNSTON, NIAA
JONES, JASON
KESSLER, DONNIE
KHALED, YASMINE
KHOURY, NIDAL
KIM, JENNIFER
KURTI, ODETA
LANDOLINA, JOE
LESKODY, BRENNA
LEVINE, SCOTT
LEWIS, MATTHEW E
LUM, CHRISTINA L
LUTTATI, JOHN
MAK, BRADLEY R
MATOS-STUART, MIRELSA
MOORE, CHRISTOPHER
OPFER, SCOT
PANDITA, NAMITA
PARK, STACEY
PRISCO, NILDA

Employee_Name
RAVI, DIPTI
REED, MICHAEL
ROQUE, LESBETH S
ROSADO RODRIGUEZ, REYNALDO R
ROSARIO-MELENDEZ PhD, ROSELIN
RYAN, HALEY E
SCHEPIS, KYLE
SEETHARAMAIAH, CHANDINI
SELIMAJ, ADELA
STEIN, KEVIN M
STRAUSS, SHELBY A
SURVI, RUBY
TARALLO, NICHOLAS ROBERT
TOUATI, AURIA V
URBAN, STEPHANIE
VARGAS, ISMAEL
VAYKOVICH, CIDNEE
VEGA, LEAH
VYAS, LEENA
WENDELL, DARIA
WYLLIE-ASHTON, MELISA
YUAN, AMELIA LINGLI
ZAMBAK, FUNDA

4BB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: FUJIFILM Irvine Scientific, Inc.

Physical Address: 2511 Daimler Street

City: Santa Ana State: CA Zip: 92705

Mailing Address (if different from physical address): 1830 East Warner Avenue

City: Santa Ana State: CA Zip: 92705

Telephone: 949-261-7800 Website: https://www.irvinesci.com/

Name of Designated Representative (DR): Marlin Terbrueggen

Licensing Company Email: fisitmrequest@fujifilm.com DR Email: ashley.m.werner@fujifilm.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
■ Others: Clinics		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

09/10/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): FujiFilm Holdings Americas Corporation

Corporation/Organization Name: FujiFilm Irvine Scientific, Inc.

Mailing Address: 1830 East Warner Avenue

City: Santa Ana State: CA Zip: 92705

Telephone: 949.261.7800 x297 Email: ashley.m.werner@fujifilm.com

Contact Person Name: Ashley Werner

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

FUJIFILM Irvine Scientific, Inc.
Facility Name

Ashley Werner
Print Name of Authorized Person Submitting Application

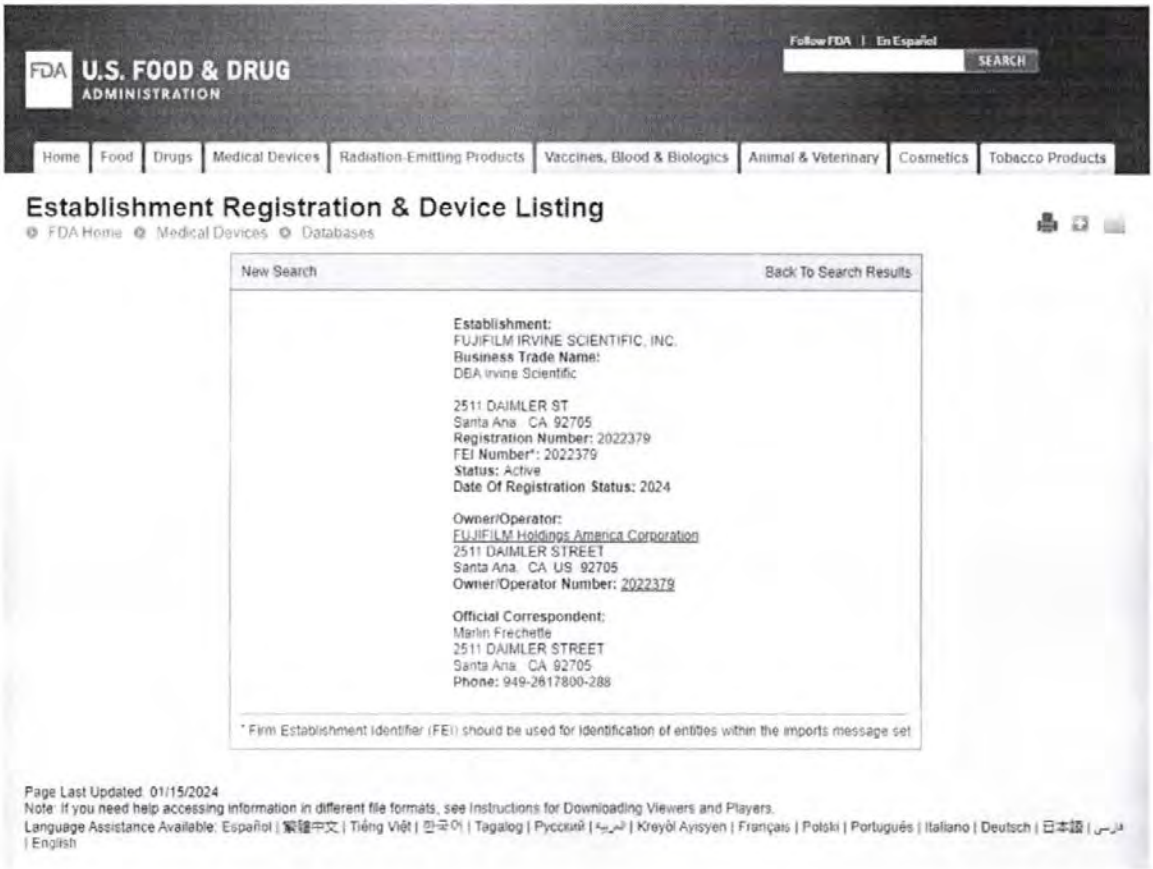
Original signature of Authorized Person (copies or stamps not accepted)

09/10/2024
Date

Board Use Only	Date Received: 9/15/24	Amount: $1000-CK 00000160477

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓



verified
M.H 10/2/24

List of FUJIFILM Irvine Scientific, Inc. Directors and Officers

Directors:

Toshihisa Iida

Jun Higuchi

Tomoyuki Hasegawa

Timothy Mullane

Officers:

Yutaka Yamaguchi, Chairman & Chief Executive Officer, 1830 East Warner Avenue, Santa Ana, CA 92705

Timothy Mullane, President & Chief Operating Officer, 1830 East Warner Avenue, Santa Ana, CA 92705

Kenya Nakashima, Treasurer & Chief Financial Officer, 1830 East Warner Avenue, Santa Ana, CA 92705

Sarah Karlgaard, Secretary, 1830 East Warner Avenue, Santa Ana, CA 92705,

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	FUJIFILM IRVINE SCIENTIFIC, INC.
Entity No.:	0599332
Registration Date:	05/27/1970
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

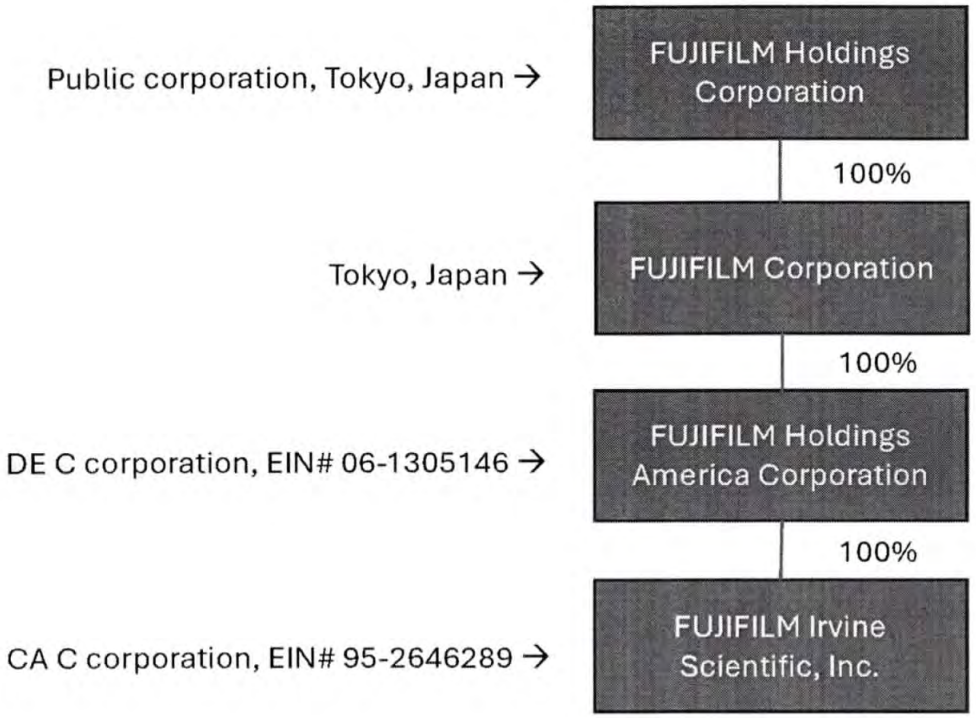
IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of April 03, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 196803736

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

FISI Ownership Chart



STATE OF CALIFORNIA

DEPARTMENT OF PUBLIC HEALTH
FOOD AND DRUG BRANCH

MEDICAL DEVICE MANUFACTURING LICENSE

FUJIFILM Irvine Scientific, Inc.
Irvine Scientific
2511 Daimler St.
Santa Ana, CA 92705

LICENSE NUMBER: 99508
EXPIRATION DATE: 6/8/2025

The person named herein is licensed to manufacture devices through the expiration date of this license. This license is issued in accordance with the California Health and Safety Code and is not transferable to any other person or place. The licensee is required by law to immediately notify the California Department of Public Health of any change in the information reported in the application.

Food and Drug Branch, 1500 Capitol Avenue, MS 7602, PO Box 997435, Sacramento, CA 95899-7435 (916) 650-6500

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY)
08/22/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Willis Towers Watson Northeast, Inc.
c/o 26 Century Blvd
P.O. Box 305191
Nashville, TN 372305191 USA

CONTACT NAME: Willis Towers Watson Certificate Center
PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378
E-MAIL ADDRESS: certificates@willis.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A: Mitsui Sumitomo Insurance Company of Ameri	20362
INSURER B: Federal Insurance Company	20281
INSURER C:	
INSURER D:	
INSURER E:	
INSURER F:	

INSURED
FUJIFILM Irvine Scientific, Inc.
1830 E Warner
Santa Ana, CA 92705

COVERAGES CERTIFICATE NUMBER: W34525884 REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:			GL 2122426	04/01/2024	04/01/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ 1,000,000 $ 1,000,000 $ 10,000 $ 1,000,000 $ 2,000,000 $ Excluded
A	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY			BVR8402901	04/01/2024	04/01/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ 1,000,000 $ $ $
	UMBRELLA LIAB OCCUR EXCESS LIAB CLAIMS-MADE DED RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A					PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $ $
B	Products/Completed Operations			35801933	06/01/2024	06/01/2025	Each Occurrence Aggregate:	$5,000,000 $5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
This Voids and Replaces Previously Issued Certificate Dated 08/22/2024 WITH ID: W34522858.

At the following premises:
- 1830 E. Warner Avenue, Santa Ana, CA
- 2511 Daimler Street, Santa Ana, CA
- 2601 Daimler Street, Santa Ana, CA

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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The ACORD name and logo are registered marks of ACORD

SR ID: 26340469 BATCH: 3592351

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	015226350
For	PHARMACEUTICAL WHOLESALER SURETY BOND
Dated effective	01/22/2025 (MONTH, DAY, YEAR)
Executed by	FUJIFILM Irvine Scientific, Inc., as Principal, (PRINCIPAL)
And by	Liberty Mutual Insurance Company, as Surety, (SURETY)
And in favor of	NEVADA STATE BOARD OF PHARMACY (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Bond Amount	$25,000.00	$100,000.00
Adding Location	N/A	2511 Daimler St. Santa Ana, CA 92705

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **02/25/2025**
(MONTH, DAY, YEAR)

Signed and Sealed **02/26/2025**
(MONTH, DAY, YEAR)

FUJIFILM Irvine Scientific, Inc.
PRINCIPAL

BY _____
TITLE

Liberty Mutual Insurance Company
SURETY

BY _____
Michelle Anne McMahon, ATTORNEY-IN-FACT

POWER OF ATTORNEY

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint Michelle Anne McMahon all of the city of New York, state of NY its true and lawful attorney-in-fact, with full power and authority hereby conferred to sign, execute and acknowledge the following surety bonds, undertakings, recognizances, contracts of indemnity, and all other surety obligations related thereto, the execution of which shall be binding upon the Companies as if it had been duly signed and executed by its own officers:

Principal Name: FUJIFILM Irvine Scientific, Inc.

Obligee Name: NEVADA STATE BOARD OF PHARMACY

Surety Bond Number: 015226350 **Bond Amount:** See Bond Form

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 26th day of February, 2025.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 26th day of February, 2025, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2029
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of February, 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 015226350

Application/License No. _____

FUJIFILM Irvine Scientific, Inc (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1830 East Warner Avenue, Santa Ana, CA 92705 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on January 22, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 22nd day of January, 2025.

APPLICANT/PRINCIPAL

FUJIFILM Irvine Scientific, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness

Witness

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Michelle Anne McMahon, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness **Erika Prodell**

Witness **Glenn Tapawan**

Countersigned by:

Nevada Resident Agent **Jonathan Raymond Gleason**
Non-Resident Agent License Number: **3816389**

Posted February 20, 2020

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8210646 - 985949**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Connor Wolpert, Doritza Mojica, Gentry Stewart, Jennifer Godere, Jonathan Gleason, Joshua Sanford, Kathryn Pryor, Kyle Williams, Michelle Anne McMahon, Nicholas Miller, Richard Hackner, Robyn Salley, Sarah Murtha

all of the city of Hartford state of CT each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 22nd day of August 2023.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 22nd day of August 2023 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 22nd day of January 2025.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: FUJIFILM Irvine Scientific, Inc. MDEG License # (if applicable): ____

Physical Address: 2511 Daimler Street

City: Santa Ana State: CA Zip: 92705

Mailing Address (if different from physical address): 1830 East Warner Avenue

City: Santa Ana State: CA Zip: 92705

Telephone: 949-261-7800 Website: https://www.irvinesci.com/

Licensing Company Email: fisitmrequest@fujifilm.com

Section 2: Personal Information

First: Marlin Middle: Lizbeth Last: Terbrueggen

Alias(es, nicknames, name changes, etc.): Marlin Lizbeth Frechette

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Santa Ana State: CA Zip: [redacted]

Telephone: 949-261-7800 x288 Email: marlin.frechette@fujifilm.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Hope International University		9/2003 - 10/2005	
Address	City	State	Zip
2500 Nutwood Ave	Fullerton	CA	92831
Diploma/Degree obtained, if any			
Bachelor of Science, School of Professional Studies			

School Name		From - To (MM/YY – MM/YY)	
Instituto Union y Esfuerzo		11/86 - 11/89	
Address	City	State	Zip
Barrio Las Flores	Villanueva, Cortes	Honduras	N/A
Diploma/Degree obtained, if any			
High School & Book Keeping			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2015-Present	[redacted]	Seal Beach	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
FUJIFILM Irvine Scientific, Inc.		10/2017 - Present	
Business Address	**City**	**State**	**Zip**
1830 East Warner Avenue	Santa Ana	CA	92705
Phone	**Title**	**Number of Employed Hours**	
949-261-7800 x297	Chief Quality Officer (CQO)	~ 14,560	
Description of Duties			
Quality Control, Quality Assurance, Regulatory Affairs, Product Compliance, Design Control and Risk Management, Validations and Project Management.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ **Provide all the following *where applicable:***

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Marlon Arbuyo — 02/26/2025

Original Signature (electronic, copies or stamps not accepted) Date

I, Marlin Terbrueggen, **certify that as the MDEG Administrator for**

FUJIFILM Irvine Scientific, Inc.,

that I (initial that you have read and meet the following requirements):

1. MT Have a high school diploma or its equivalent;
2. MT Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MT Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MT Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marlin Terbrueggen
Print Name (First, Last)

Marlin Terbrueggen
Original Signature (electronic, copies or stamps not accepted)

02/26/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler FUJIFILM Irvine Scientific, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2511 Daimler Street

City Santa Ana State CA Zip 92705

Mailing Address (if different from physical address) 1830 East Warner Avenue

City Santa Ana State CA Zip 92705

Telephone 949-261-7800 Website https://www.irvinesci.com/

Licensing Company Email fisitmrequest@fujifilm.com

Section 2: Personal Information

First Marlin Middle Lizeth Last Terbrueggen

Alias(es, nicknames, name changes, etc.) Marlin Lizbeth Frechette

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 1830 East Warner Avenue

City Santa Ana State CA Zip 92705

Telephone 949-261-7800 x288 Email marlin.frechette@fujifilm.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY - MM/YY)	
Hope International University		9/2003 - 10/2005	
Address	City	State	Zip
2500 Nutwood Ave	Fullerton	CA	92831
Diploma/Degree obtained, if any			
Bachelor of Science, School of Professional Studies			

School Name		From - To (MM/YY - MM/YY)	
Instituto Union y Esfuerzo		11/86 - 11/89	
Address	City	State	Zip
Barrio Las Flores	Villanueva, Corts	Honduras	N/A
Diploma/Degree obtained, if any			
High School & Book Keeping			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY - MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2015 - Present	[redacted]	Seal Beach	CA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
FUJIFILM Irvine Scientific, Inc.			10/2017- Present	
Business Address		City	State	Zip
1830 East Warner Avenue		Santa Ana	CA	92705
Phone	Title		Number of Employed Hours	
949.261.7800 x288	Chief Compliance & Quality Officer (CQO)		70,720	
Description of Duties				
Quality Control, Quality Assurance, Regulatory Affairs, Product Compliance, Design Control and Risk Management, Validations and Project Management.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic copies or stamps not accepted)

02/20/2025
Date

I, Marlin Terbrueggen, **certify that as the designated representative for**

FUJIFILM Irvine Scientific, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MT I am at least 21 years of age;
3. MT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Marlin Terbrueggen

Print Name (First, Last)

Marlin Terbrueggen

Original Signature (electronic, copies or stamps not accepted)

02/26/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Marlin Terbrueggen

Print Name (First, Last)

Marlin Terbrueggen

Original Signature (electronic, copies or stamps not accepted)

02/26/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Orange County

I, Marlin Lizeth Terbrueggen, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Marlin Terbrueggen

Original Signature

03/04/2025

Date

Subscribed and Sworn to before me this _____ day of _____

Notary Public Signature

PLEASE SEE CA NOTARY ATTACHMENT

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

STATE OF CALIFORNIA
COUNTY OF ORANGE

On the 4th day of March, 2025, before me, Layla Leigh Rodriguez, Notary Public, personally appeared MARLIN LIZETH TERBRUEGGEN, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that she executed the same in her authorized capacity, and that by her signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of California that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

(Seal)

Signature of Notary Public

LAYLA LEIGH RODRIGUEZ
Notary Public - California
Orange County
Commission # 2433482
My Comm. Expires Jan 8, 2027

FUJIFILM Irvine Scientific, Inc. 2511 Daimler St., Santa Ana, CA 92705 Facility employees

Employee Name

Agtarap, Ryan
Aguila, Erick
Aguilar, Jose E
Aguilar, Juan L
Arreola, Anthony
Arzate Gallegos, Efrain
Ayala, Raul
Banila, Darwin C
Barahona, Denia
Basave Vargas, Jose
Beltran, Maribel
Berreto, Wilmer O
Bobadilla, Giovanna
Cabalo, Robert
Castillo Gonzalez, Hugo B
Chavez, Luis
Cruz, Erik Alexis
Dao, Helen
Dean, Jasmine
Estrada, Carla
Felizola, Cristian
Garcellano, Alson
Garcia, Maria I
Guerrero, Alberto
Guerrero, Alberto J
Gutierrez, Alejandro
Guzman, Jesus
Kasbati, Muhammad F
Lonbera, Yesenia
Lopez, Jose L
Macias, Carlos
Manrras, Miguel
Meneses, Olga
Mora, Carlos
Navarette, Martin
Navas Lievano, Noel
Ngo, Lam
Nguyen, Kevin N
Nguyen, Thai T
Olivos, Aaron
Orbegoso, Marilia
Ostorga, Ana
Pelaez, Gerardo
Perez Baltazar, Miguel
Picasso, Bertha S
Ponce, Pamela C

Ramirez de Quintanilla, Gesen
Ramirez, Salvador
Ramos, Candelario
Reyes, Jesus
Romero, Cinthia L
Romero, Estevan O
Ruiz Gutierrez, Mariano
Samson, Michael
Solis Garcia, Gabriel
Sosa, Rocio
Steele, Donovan P
Tosi, Ensenada
Villanueva, Ferdie
Villapania, Alexa
Villegas, Salvador
Vitug, Erickson
Vo, Jimmy T
Wilkinson, Damien
Zambrano, Jorge

4CC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Fusion Orthopedics USA, LLC

Physical Address: 6859 E. Rembrandt Ave, Ste 122

City: Mesa State: AZ Zip: 85212

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 602-757-3360 Website: fusionorthopedics.com

Name of Designated Representative (DR): Nathan Peterson

Licensing Company Email: sam@fusionorthopedics.com DR Email: nathan@fusionorthopedics.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	■ Manufacturer
■ Practitioners	☐ Controlled Substances	■ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medstar Distributors, LLC
Address: 1728 E Lockwood St City: Mesa State: AZ Zip: 85203
Name: DBSurgical, LLC
Address: 8602 S. Glen Forest Ct City: Oak Creek State: WI Zip: 53154
Name: Woodis & Associates, Inc.
Address: 9020 Pleasant Valley Drive City: Kearney State: NE Zip: 68845
Name: W2 Medical, LLC
Address: 8175 Hunters Pl City: Indianapolis State: IN Zip: 46236

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Arizona
Parent Company (if any):
Corporation/Organization Name: Fusion Orthopedics USA, LLC
Mailing Address: 6859 E Rembrandt Ave, Ste 122
City: Mesa State: AZ Zip: 85212
Telephone: 6027573360 Email: sam@fusionorthopedics.com
Contact Person Name: Sam Rocereta

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Fusion Orthopedics USA, LLC

Facility Name

Samuel Rocereta

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/21/25

Date

Board Use Only	Date Received: 3/24/25	Amount: $1000 cc

FDA

FDA Home[1] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
FUSION ORTHOPEDICS USA, LLC
Business Trade Name:
FUSION ORTHOPEDICS, LLC

6859 E Rembrandt Ave
Ste 122
Mesa AZ 85212
Registration Number: 3013365802
FEI Number*: 3013365802
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types
Please Review Listings For Further Information
Date Of Registration Status: 2025

Owner/Operator:
Fusion Orthopedics, LLC.[6]
4135 S Power Rd
Suite 110
Mesa AZ US 85212
Owner/Operator Number: 10053147[7]

Official Correspondent:
Adam Cundiff
4135 S Power Rd
Suite 110
Mesa AZ 85212
Phone: 1-800-4036876

*Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 03/10/2025

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph: 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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- Claudia Swindle – Sales Rep Southern California
- Alex Perns – Sales Rep Chicago
- Joe Long – Senior Product Specialist & Sales Rep Chicago
- Phil Hon – Sales Rep Chicago
- Corby Vowell – IP Litigation Attorney
- Jennifer Brinkerhoff – Patent Agent
- Scott Kamholz – IPR Attorney

Officers and Directors

- Adam Cundiff – Chief Executive Officer
- Nathan Peterson – President
- Daniel Griffin – General Manager
- Krystylle Richarson – Director of Quality
- Eli Jacobson – Director of Engineering and Regulatory Affairs
- Neel Patel – Associate Director of Marketing and IT
- Chris Weaver – Director of Sales – Southeast
- Adlei DaSilva – Director of Sales – Great Lakes
- Steven Perns – National Director of Education and Director of Chicago Sales
- Sergio Urquiza – Director of Sales – North Central
- Erin Nesbit – Director of Sales – South Carolina & Director of Biologics
- Mark Ridgway – Director of Sales – Northeast
- Jon Dobosh – Director of Sales & Trauma Market Development – NE
- Eric Cracraft – Director of Trauma
- Andrew Ruggles – Director of Sales – South Central
- Brett Hartley – National Director of Health Systems
- Janeen Rose – Director of National Accounts - East
- Todd Butterfield – Associate Director of National Accounts
- Boping Shan – Director of Supply Chain
- Sam Rocereta – General Counsel

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

CERTIFICATE OF GOOD STANDING

I, the undersigned Executive Director of the Arizona Corporation Commission, do hereby certify that:

Fusion Orthopedics USA, LLC

ACC file number: 23151266

was incorporated under the laws of the State of Arizona on 11/03/2020, and that, according to the records of the Arizona Corporation Commission, said limited liability company is in good standing in the State of Arizona as of the date this Certificate is issued.

This Certificate relates only to the legal existence of the above named entity as of the date this Certificate is issued, and is not an endorsement, recommendation, or approval of the entity's condition, business activities, affairs, or practices.

IN WITNESS WHEREOF, I have hereunto set my hand, affixed the official seal of the Arizona Corporation Commission, and issued this Certificate on this date: **03/18/2025**

Douglas R. Clark, Executive Director

Employees/Independent Contractors

- Alejandra Pardo – Associate Coordinator
- Samantha Jackson – Event/Travel Coordinator
- Claudia Triana - Custodian
- Catalina Pardo – Quality Engineer
- Edward Chan – Research and Development Engineer
- Niki Baradaran Naghshineh – Mechanical Engineering Associate
- Makaelah Napolitano – Quality Engineering Associate
- Audrey Davis – Quality Engineering Associate
- Austin White – Associate Web Developer
- John Stacy – Motion Graphic Designer
- Zack Klennert – Software Engineer Associate
- Tatiana Melian – Social Media Manager
- Carter Giambri – Data Analyst
- Ying Li – Senior Accountant
- Macy Breeze – Senior Account Specialist
- Brooke Hormann – Account Receivable Specialist
- David Branshaw – Clinical Education Specialist
- Josiah Butterfield – Manager of National Accounts
- Nicole DeMelo Santos – Health Systems Pricing Specialist
- Alison Patton – Supply Chain Manager – Domestic
- Summer Hiser – Data Entry Specialist
- Sophia Melian – Supply Chain Specialist
- Hailey Aguirre – Data Entry Specialist
- Helena Valdez – Supply Chain Associate
- Min Che – Supply Chain Risk Analyst
- Yuki Takei – Supply Chain Associate
- Hugo Gamboa – Fulfillment Specialist
- David Warrick – Inventory Specialist
- Trenton Krumwied – Inventory Control Specialist
- Mustafa Rahee – Data Entry Specialist
- Vanessa Calderon – Sales Rep Arizona
- Dylan Woods – Associate Product Specialist
- Evan Barraza – Strategic Sales Manager – Arizona
- Abby Wasson – Sales Rep PNW
- Emily Willenborg – Sales Rep PNW
- Kevin Maher – Sales Rep PNW
- Logan Hess – Sales Rep PNW
- Patrick Jaco – Sales Rep PNW
- Patrick Carter – Sales Rep NE
- Lilly Olson – Sales Rep Wisconsin
- Dave Parks – Sales Rep Wisconsin

List of Shareholders and their Percentage Ownership

MEMBER NAME	% of Ownership
Fusion QOF, LLC	99.00%
Fusion QOF II, LLC	1.00%

STATE OF ARIZONA

Office of the
CORPORATION COMMISSION

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Douglas R. Clark, Executive Director

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 05/10/2024
Receipt Number: 2024173974
Receipt Amount $: 1000.00

Manufacturer - Manufacturer

PERMIT NO
M002479

EXPIRES
10/31/2026

Issued to : Fusion Orthopedics USA, LLC
Fusion QOF, LLC
6859 E. REMBRANDT AVE, STE 122 MESA, AZ 85212

Fusion Orthopedics USA, LLC
6859 E. REMBRANDT AVE, STE 122
MESA, AZ 85212

Kam Gandhi
EXECUTIVE DIRECTOI

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Fusion Orthopedics USA, LLC
LICENSE NUMBER : M002479
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.

You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law

In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.

Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.

Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 05/10/2024
Receipt
Number: 2024173979
Receipt Amount $: 1000.00

Wholesaler - Full Service

PERMIT NO
W003910

EXPIRES
10/31/2026

Issued to : Fusion Orthopedics USA, LLC
Fusion QOF, LLC
6859 E REMBRANDT AVE STE 122 MESA, AZ 85212

Fusion Orthopedics USA, LLC
6859 E REMBRANDT AVE STE 122
MESA, AZ 85212

Kam Gadda
EXECUTIVE DIRECTOI

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : Fusion Orthopedics USA, LLC
LICENSE NUMBER : W003910
EXPIRES : 10/31/2026

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
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You are required by law to notify the Board of any home address and/or employment change within 10 business days

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Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100269837

Application/License No. _____

Fusion Orthopedics, USA, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 6859 E. Rembrandt Ave, Ste 122, Mesa, AZ 85212 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of Iowa (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 6700 Westown Parkway, West Des Moines, IA 50266 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 1, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of November, 20 23.

APPLICANT/PRINCIPAL

COMPANY

Fusion Orthopedics, USA, LLC

Authorized Representative

SURETY

Merchants Bonding Company (Mutual)

Surety Company's Representative

Gail T Hayes, Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Amy Glanzer

Witness Amy Glanzer

Countersigned by:

Nevada Resident Agent Gail T. Hayes (NR)

LP 2079 NV (5/21)

Posted February 20, 2020

MERCHANTS BONDING COMPANY

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually,

Gail T Hayes

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 2nd day of November , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.

On this 2nd day of November , 2023 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA
Kim Lee
Commission Number 702737
My Commission Expires
April 14, 2024

Kim Lee
Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 2nd day of November , 2023 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
Secretary

POA 0018 (10/22)

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/31/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Breinholt Anderson Insurance Consultants LLC
4140 E. Baseline Road, Suite 201
Mesa AZ 85206

CONTACT NAME: Tiffany Zelinko
PHONE (A/C, No, Ext): 480-935-7000 FAX (A/C, No): 480-935-7009
E-MAIL ADDRESS: certificates@baicins.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : At Bay Specialty Insurance Company	19607
INSURER B : Atlantic Specialty Insurance Company	27154
INSURER C : OBI National Insurance Company	14190
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Fusion Orthopedics USA, LLC
Fusion Orthopedics, LLC
6859 E Rembrandt Ave, Suite 122
Mesa AZ 85212

FUSIORT-01

COVERAGES **CERTIFICATE NUMBER:** 1529353202 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
B	X COMMERCIAL GENERAL LIABILITY	Y	Y	711-01-86-35-0000	1/1/2025	1/1/2026	EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 15,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						PERSONAL & ADV INJURY	$ 1,000,000
	X POLICY PRO-JECT LOC						GENERAL AGGREGATE	$ 2,000,000
	OTHER:						PRODUCTS - COMP/OP AGG	$ Excluded
								$
B	AUTOMOBILE LIABILITY	Y		711-01-86-35-0000	1/1/2025	1/1/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
B	X UMBRELLA LIAB X OCCUR			711-01-86-35-0000	1/1/2025	1/1/2026	EACH OCCURRENCE	$ 9,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$ 9,000,000
	DED X RETENTION $ 10,000							$
C	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY		Y	406-05-00-97-0000	1/1/2025	1/1/2026	X PER STATUTE OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N: N N/A						E.L. EACH ACCIDENT	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000
B	Prod Liab - Claims Made	Y	Y	750-00-05-54-0000	1/1/2025	1/1/2026	Each Occ $10,000,000	Agg $10,000,000
A	Cyber 1st Layer, Claims Made			AB6734800-01	9/23/2024	9/23/2025	Cyber Occ/Agg	$3,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Evidence of Insurance for
Fusion Orthopedics USA, LLC
6859 E Rembrandt Ave, Suite 122
Mesa AZ 85212

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Fusion Orthopedics USA, LLC MDEG License # (if applicable): _____

Physical Address: 6859 E. Rembrandt Ave, Ste 122

City: Mesa State: AZ Zip: 85212

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 6027573360 Website: fusionorthopedics.com

Licensing Company Email: sam@fusionorthopedics.com

Section 2: Personal Information

First: Nathan Middle: _____ Last: Peterson

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 6859 E. Rembrandt Ave, Ste 122

City: Mesa State: AZ Zip: 85212

Telephone: [redacted] Email: nathan@fusionorthopedics.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		08/2003 - 05/2007	
Address	**City**	**State**	**Zip**
525 E. University Dr	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Bachelor's in Science			

School Name		From - To (MM/YY – MM/YY)	
West High School		08/1997 - 06/2001	
Address	**City**	**State**	**Zip**
1200 New Stine Rd	Bakersfield	CA	93309
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2025 - present	[redacted]	Gilbert	AZ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/2020 - 01/2025		Gilbert	AZ	
From - To (MM/YY – MM/YY)		City	State	
08/2011 - 06/2020		Gilbert	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Fusion Orthopedics USA, LLC			11/2020 - present
Business Address	**City**	**State**	**Zip**
6859 E. Rembrandt Ave, Ste 122	Mesa	AZ	85212
Phone	**Title**		**Number of Employed Hours**
480-258-1400	President		6,552

Description of Duties

Securing distribution deals with facilities. Designing and developing innovative products. Developing and executing go-to-market, revenue growth and market penetration strategies. Overall management of the company and employees.

Business Name			From - To (MM/YY – MM/YY)
Fusion Orthopedics, LLC			09/2014 - present
Business Address	**City**	**State**	**Zip**
4135 S. Power Rd, Ste 118	Mesa	AZ	85212
Phone	**Title**		**Number of Employed Hours**
480-258-1400	President		18,720

Description of Duties

Securing distribution deals with facilities. Designing and developing innovative products. Developing and executing go-to-market, revenue growth and market penetration strategies. Overall management of the company and employees.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✓	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/19/2022		NV	Reno	Washoe

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
22-525	Nevada State Board of Pharmacy

Reason/Charge
Unlicensed Activity in Nevada

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

Fusion Orthopedics, LLC received a letter from the State Board of Pharmacy on December 19, 2022 claiming Fusion Orthopedics, LLC had engaged in the business of wholesaling and/or distributing prescription drugs/medical products or devices into the State of Nevada without a license.

Fusion Orthopedics, LLC was unaware of Nevada statutes NRS 639.100, NRS 639.233, NAC 639.593 and NAC 639.6944. Fusion Orthopedics, LLC has since cease material operations and is in the process of winding down, but Fusion Orthopedics USA, LLC has looked into these statutes and is submitting this application to be in compliance with these statutes.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.	✓	

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/22/2025	01/22/2025	AZ	Phoenix	Maricopa
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
24-0617	Arizona Board of Pharmacy			
Reason/Charge				
Unlicensed Activity in Arizona				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Name of Business/Industry/Entity				
Fusion Orthopedics USA, LLC				

Provide explanation below:

Fusion Orthopedics USA, LLC was winding up, and waiting on construction for its office to be finished before it could submit its permit applications to the Arizona State Board of Pharmacy, as finalized building plans and a lease are a requirement for the permits. The permit process from the time the application was submitted, to the time it was processed and permits were issued was nearly a 12 month period, on top of the length of time office construction took. Fusion Orthopedics USA, LLC was cited for selling medical devices during that time frame without the required permit. The proper permits have since been obtained, and now Fusion Orthopedics USA, LLC is submitting this application to be in compliance with Nevada statutes NRS 639.100, NRS 639.233, NAC 639.593 and NAC 639.6944, as the Arizona permits are a prerequisite to obtaining the appropriate Nevada permits.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

I, Nathan Peterson, **certify that as the MDEG Administrator for**

Fusion Orthopedics USA, LLC,

that I (initial that you have read and meet the following requirements):

1. NP Have a high school diploma or its equivalent;
2. NP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. NP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. NP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Peterson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/13/2025
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Fusion Orthopedics USA, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 6859 E. Rembrandt Ave, Ste 122

City: Mesa State: AZ Zip: 85212

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 602-757-3360 Website: fusionorthopedics.com

Licensing Company Email: sam@fusionorthopedics.com

Section 2: Personal Information

First: Nathan Middle: Last: Peterson

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: 6859 E. Rembrandt Ave, Ste 122

City: Mesa State: AZ Zip: 85212

Telephone: [redacted] Email: nathan@fusionorthopedics.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		08/2003 - 05/2007	
Address	**City**	**State**	**Zip**
525 E University Dr	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Bachelor's in Science			

School Name		From - To (MM/YY – MM/YY)	
West High School		08/1997 - 06/2001	
Address	**City**	**State**	**Zip**
1200 New Stine Rd	Bakersfield	CA	93309
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2025 - present	[redacted]	Gilbert	AZ	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/2020 - 01/2025		Gilbert	AZ	
From - To (MM/YY – MM/YY)		City	State	
08/2011 - 06/2020		Gilbert	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Fusion Orthopedics USA, LLC			11/2020 - present	
Business Address		**City**	**State**	**Zip**
6859 E. Rembrandt Ave, Ste 122		Mesa	AZ	85212
Phone	**Title**		**Number of Employed Hours**	
480-258-1400	President		6,552	
Description of Duties				
Securing distribution deals with facilities. Designing and developing innovative products. Developing and executing go-to- market, revenue growth and market penetration strategies. Overall management of the company and employees.				

Business Name			From - To (MM/YY – MM/YY)	
Fusion Orthopedics, LLC			09/2014 - present	
Business Address		**City**	**State**	**Zip**
4135 S. Power Rd, Ste 118		Mesa	AZ	85212
Phone	**Title**		**Number of Employed Hours**	
480-258-1400	President		18,720	
Description of Duties				
Securing distribution deals with facilities. Designing and developing innovative products. Developing and executing go-to-market, revenue growth and market penetration strategies. Overall management of the company and employees.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

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This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
04/28/2022	On Going	AZ	Phoenix	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:2022cv00723	Arizona District Court

Reason/Charge
Patent Infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

The disruptive nature of Fusion's patented IntraLock Fixation System continues to infuriate its competitor Extremity Medical, LLC ("EM"). Fusion Orthopedics, LLC's IntraLock is expertly reviewed, has issued patents from the USPTO, and has a plurality of pending patent applications.

After a cursory review of the lawsuit, it appears EM has undertaken a multi-year campaign to unduly stretch the scope of their patent, which attempts to box out Fusion Orthopedics, LLC's superior IntraLock Fixation System. Fusion Orthopedics, LLC fiercely disputes the baseless singular claim set forth by EM as filed in the U.S. District Court of Arizona. The IntraLock Fixation System does not infringe the claimed EM IO Fix patent.

Fusion Orthopedics, LLC's position is that EM is inequitably attempting to weaponize their patents against companies to gain a market advantage beyond their legal right. This litigation tactic employed by EM is bad for healthcare because it attempts to strangle medical device innovation that may improve patient surgical outcomes and reduce the cost of care.

As a matter of good public policy, Fusion Orthopedics, LLC is deeply committed to combating any such legal tactics by EM and others. It is Fusion's practice to recognize and respect the intellectual property of others. Fusion Orthopedics, LLC is undeterred in their pursuit as an innovator in technology related to foot and ankle orthopedic devices. Fusion Orthopedics, LLC stands by its IntraLock Fixation System, especially when wrongfully accused of patent infringement.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

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Date of Event/Arrest	Disposition Date	State	City	County
03/29/2022	03/16/2023	AZ	Phoenix	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:2022cv00490	Arizona District Court

Reason/Charge
IP infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

Treace Medical filed the lawsuit on March 29, 2022 against Fusion Orthopedics, LLC in the United States District Court for the District of Arizona, Civil Action No. 2:22- cv-00490, alleging patent, trademark, and copyright infringement, as well as various unfair trade practices based on Fusion Orthopedics, LLC's use, sale, and promotion of the Lapilock 4D Advanced Bunion Surgery, including false advertising and unfair competition.

Fusion Orthopedics, LLC subsequently filed counterclaims against Treace Medical, requesting declaratory judgment of non- infringement and invalidity of the patents, declaratory judgment of invalidity of Treace Medical's LAPIPLASTY trademark, as well as various unfair trade practices based on Treace Medical's use, sale, and promotion of the Lapiplasty 3D Bunion Correction, including counterclaims of false descriptions and false advertising.

In March 2023, the parties entered into an agreement to settle this matter. While the terms of the settlement are confidential, Fusion Orthopedics, LLC is pleased with the outcome.

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3-21-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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Date of Event/Arrest	Disposition Date	State	City	County
10/04/2021	On Going	AZ	Mesa	Maricopa
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
CV2021-094708	Maricopa County Superior Court			
Reason/Charge				
Breach of contract.				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Fusion Orthopedics, LLC	Lawsuit			
Name of Business/Industry/Entity				
Fusion Orthopedics, LLC				

Provide explanation below:

This matter revolves around a consulting agreement Fusion Orthopedics, LLC alleges was breached by an independent contractor for failure to provide the services set forth in the agreement, as well as additional clauses of non-competition, non-disclosure. The independent contractor alleges he performed under the consulting agreement.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

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This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/18/2020	03/24/2021	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2020-093744	Maricopa County Superior Court

Reason/Charge
Breach of contract.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

Fusion Orthopedics, LLC filed suit against a facility for breach of contract for failing to pay outstanding invoices on products sold by Fusion Orthopedics, LLC to the facility. Ultimately, the facility filed for bankruptcy.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
07/19/2024	11/12/2024	AZ	Phoenix	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV-24-01773-PHX-DJH	Arizona District Court

Reason/Charge
Tortious Interference

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics USA, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics USA, LLC

Provide explanation below:

Conventus Orthopaedics filed the lawsuit on July 19, 2024 against Fusion Orthopedics USA, LLC and a number of Fusion employees in the United States District Court for the District of Arizona, Civil Action No. 2:24-cv-01773-DJH, alleging breach of contract, misappropriation of trade secrets and tortious interference, as well as sought a TRO. The TRO was denied and Conventus Orthopaedics subsequently voluntarily dismissed the case without prejudice.

Fusion filed a motion for an award of attorneys' fees. In November 2024, the parties entered into an agreement to settle this matter, including the attorneys' fees, and dismissed the case with prejudice. While the terms of the settlement are confidential, Fusion Orthopedics USA, LLC is pleased with the outcome.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

I, Nathan Peterson, **certify that as the designated representative for**

Fusion Orthopedics USA, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. NV I am at least 21 years of age;
3. NV I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. NV I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. NV I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. NV I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. NV I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Nathan Peterson
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Peterson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-21-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Nathan Peterson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-21-2025

Date

Subscribed and Sworn to before me this 21 day of March 2025.

Notary Public Signature

SAMUEL ROCERETA
Notary Public - Arizona
Maricopa County
Commission # 67358
My Comm. Expires Oct 30,

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Fusion Orthopedics USA, LLC

Physical Address 6859 E. Rembrandt Ave. Ste 122

City Mesa State AZ Zip 85212

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 602-757-3360 Website fusionorthopedics.com

Licensing Company Email sam@fusionorthopedics.com

Section 2: Personal Information

First Nathan Middle _____ Last Peterson

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ■ M ☐ F ☐ X

Mailing Address 6859 E. Rembrandt Ave. Ste 122

City Mesa State AZ Zip 85212

Telephone [redacted] Email nathan@fusionorthopedics.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials NP

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		08/2003 - 05/2007	
Address	**City**	**State**	**Zip**
525 E. University Dr	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Bachelor's in Science			

School Name		From - To (MM/YY – MM/YY)	
West High School		08/1997 - 06/2001	
Address	**City**	**State**	**Zip**
1200 New Stine Rd	Bakersfield	CA	93309
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2025 - present	[redacted]	Gilbert	AZ	[redacted]
From - To (MM/YY – MM/YY) 06/2020 - 01/2025		Gilbert	AZ	
From - To (MM/YY – MM/YY) 08/2011 - 06/2020		Gilbert	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials NP

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Fusion Orthopedics USA, LLC			11/2020 - present	
Business Address		**City**	**State**	**Zip**
6859 E. Rembrandt Ave, Ste 122		Mesa	AZ	85212
Phone	**Title**			
480-258-1400	President			
Description of Duties				
Securing distribution deals with facilities. Designing and developing innovative products. Developing and executing go-to-				

Business Name			From - To (MM/YY – MM/YY)	
Fusion Orthopedics, LLC			09/2014 - present	
Business Address		**City**	**State**	**Zip**
4135 S. Power Rd, Ste 118		Mesa	AZ	85212
Phone	**Title**			
480-258-1400	President			
Description of Duties				
Securing distribution deals with facilities. Designing and developing innovative products. Developing and executing go-to- market, revenue growth and market penetration strategies. Overall management of the company and employees.				

Business Name			From - To (MM/YY – MM/YY)	
Advance Medical LLC			06/2007 - 02/2018	
Business Address		**City**	**State**	**Zip**
3129 E Battala Ct		Gilbert	AZ	85297
Phone	**Title**			
480-258-1400	President			
Description of Duties				
Securing sales of orthopedic medical devices and implants for manufacturers and distributors. Building and maintaining strong relationships with customers, including orthopedic surgeons, operating room staff, and procurement professionals.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
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Phone	Title		
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Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

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Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

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2:2022cv00723	Arizona District Court

Reason/Charge
Patent Infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

The disruptive nature of Fusion's patented IntraLock Fixation System continues to infuriate its competitor Extremity Medical, LLC ("EM"). Fusion Orthopedics, LLC's IntraLock is expertly reviewed, has issued patents from the USPTO, and has a plurality of pending patent applications.

After a cursory review of the lawsuit, it appears EM has undertaken a multi-year campaign to unduly stretch the scope of their patent, which attempts to box out Fusion Orthopedics, LLC's superior IntraLock Fixation System. Fusion Orthopedics, LLC fiercely disputes the baseless singular claim set forth by EM as filed in the U.S. District Court of Arizona. The IntraLock Fixation System does not infringe the claimed EM IO Fix patent.

Fusion Orthopedics, LLC's position is that EM is inequitably attempting to weaponize their patents against companies to gain a market advantage beyond their legal right. This litigation tactic employed by EM is bad for healthcare because it attempts to strangle medical device innovation that may improve patient surgical outcomes and reduce the cost of care.

As a matter of good public policy, Fusion Orthopedics, LLC is deeply committed to combating any such legal tactics by EM and others. It is Fusion's practice to recognize and respect the intellectual property of others. Fusion Orthopedics, LLC is undeterred in their pursuit as an innovator in technology related to foot and ankle orthopedic devices. Fusion Orthopedics, LLC stands by its IntraLock Fixation System, especially when wrongfully accused of patent infringement.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

(Applicant's Initials NP) 7 of 9

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Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:2022cv00490	Arizona District Court

Reason/Charge
IP infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

Treace Medical filed the lawsuit on March 29, 2022 against Fusion Orthopedics, LLC in the United States District Court for the District of Arizona, Civil Action No. 2:22- cv-00490, alleging patent, trademark, and copyright infringement, as well as various unfair trade practices based on Fusion Orthopedics, LLC's use, sale, and promotion of the Lapilock 4D Advanced Bunion Surgery, including false advertising and unfair competition.

Fusion Orthopedics, LLC subsequently filed counterclaims against Treace Medical, requesting declaratory judgment of non- infringement and invalidity of the patents, declaratory judgment of invalidity of Treace Medical's LAPIPLASTY trademark, as well as various unfair trade practices based on Treace Medical's use, sale, and promotion of the Lapiplasty 3D Bunion Correction, including counterclaims of false descriptions and false advertising.

In March 2023, the parties entered into an agreement to settle this matter. While the terms of the settlement are confidential, Fusion Orthopedics, LLC is pleased with the outcome.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

(Applicant's Initials NP) 7 of 9

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This is in response to Question # 5 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/04/2021	On Going	AZ	Mesa	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV2021-094708		Maricopa County Superior Court		
Reason/Charge				
Breach of contract.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Fusion Orthopedics, LLC			Lawsuit	
Name of Business/Industry/Entity				
Fusion Orthopedics, LLC				

Provide explanation below:

This matter revolves around a consulting agreement Fusion Orthopedics, LLC alleges was breached by an independent contractor for failure to provide the services set forth in the agreement, as well as additional clauses of non-competition, non-disclosure. The independent contractor alleges he performed under the consulting agreement.

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Date

(Applicant's Initials) 7 of 9

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This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
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Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV2020-093744		Maricopa County Superior Court		
Reason/Charge				
Breach of contract.				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Fusion Orthopedics, LLC			Lawsuit	
Name of Business/Industry/Entity				
Fusion Orthopedics, LLC				

Provide explanation below:

Fusion Orthopedics, LLC filed suit against a facility for breach of contract for failing to pay outstanding invoices on products sold by Fusion Orthopedics, LLC to the facility. Ultimately, the facility filed for bankruptcy.

Original Signature (electronic, copies or stamps not accepted)

3.21.2025
Date

(Applicant's Initials NP) 7 of 9

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
07/19/2024	11/12/2024	AZ	Phoenix	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV-24-01773-PHX-DJH	Arizona District Court

Reason/Charge
Tortious interference

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics USA, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics USA, LLC

Provide explanation below:

Conventus Orthopaedics filed the lawsuit on July 19, 2024 against Fusion Orthopedics USA, LLC and a number of Fusion employees in the United States District Court for the District of Arizona, Civil Action No. 2:24-cv-01773-DJH, alleging breach of contract, misappropriation of trade secrets and tortious interference, as well as sought a TRO. The TRO was denied and Conventus Orthopaedics subsequently voluntarily dismissed the case without prejudice.

Fusion filed a motion for an award of attorneys' fees. In November 2024, the parties entered into an agreement to settle this matter, including the attorneys' fees, and dismissed the case with prejudice. While the terms of the settlement are confidential, Fusion Orthopedics USA, LLC is pleased with the outcome.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

(Applicant's Initials NP) 7 of 9

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Peterson

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3.21.2025

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Nathan Peterson, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3.21.2025

Date

Subscribed and Sworn to before me this 21 day of March 2025

Notary Public Signature

SAMUEL ROCERETA
Notary Public - Arizona
Maricopa County
Commission # 673565
My Comm. Expires Oct 30, 2028

(Seal)

Applicant's initials NP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (04/22/2021)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler: Fusion Orthopedics USA, LLC

Physical Address: 6859 E. Rembrandt Ave. Ste 122

City: Mesa State: AZ Zip: 85212

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 602-757-3360 Website: fusionorthopedics.com

Licensing Company Email: sam@fusionorthopedics.com

Section 2: Personal Information

First: Adam Middle: Last: Cundiff

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 6859 E. Rembrandt Ave. Ste 122

City: Mesa State: AZ Zip: 85212

Telephone: [redacted] Email: adam@fusionorthopedics.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Date of Service: From: _____ to: _____

Military Occupation/Specialty: _____

Branch: ☐ Army/ Reserves ☐ Navy/ Reserves ☐ Airforce/ Reserves ☐ Marine Corps/ Reserves ☐ Coast Guard/ Reserves ☐ National Guard

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Applicant's initials: [signature] 1

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		08/2011 - 12/2014	
Address	**City**	**State**	**Zip**
525 E University Dr	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Bachelor's in Science			

School Name		From - To (MM/YY – MM/YY)	
Life School College Prep		08/2001 - 06/2002	
Address	**City**	**State**	**Zip**
580 E Old Linden Road	Show Low	AZ	85901
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Show Low High School		08/1998 - 06/2001	
Address	**City**	**State**	**Zip**
N. Cougar Ln.	Show Low	AZ	85901
Diploma/Degree obtained, if any			
Transferred to Life School College Prep			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2020 - present	[redacted]	Gilbert	AZ	[redacted]
01/2012 - 04/2020		Gilbert	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Applicant's initials _____

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Fusion Orthopedics USA, LLC				From - To (MM/YY – MM/YY): 11/2020 - present
Business Address: 6859 E. Rembrandt Ave, Ste 122		City: Mesa	State: AZ	Zip: 85212
Phone: 480-760-5087	Title: Chief Executive Officer			
Description of Duties: Chief Executive Officer				

Business Name:				From - To (MM/YY – MM/YY): 09/2014 - present
Business Address: 4135 S. Power Rd, Ste 118		City: Mesa	State: AZ	Zip: 85212
Phone: 480-760-5087	Title: Chief Executive Officer			
Description of Duties: Chief Executive Officer				

Business Name:				From - To (MM/YY – MM/YY): 04/2010 - present
Business Address: 4135 S. Power Rd, Ste 118		City: Mesa	State: AZ	Zip: 85212
Phone: 480-760-5087	Title: Chief Executive Officer			
Description of Duties: Chief Executive Officer				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Applicant's initials _____

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

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This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
04/28/2022	On Going	AZ	Phoenix	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2:2022cv00723		Arizona District Court		
Reason/Charge				
Patent Infringement				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Fusion Orthopedics, LLC			Lawsuit	
Name of Business/Industry/Entity				
Fusion Orthopedics, LLC				

Provide explanation below:

The disruptive nature of Fusion's patented IntraLock Fixation System continues to infuriate its competitor Extremity Medical, LLC ("EM"). Fusion Orthopedics, LLC's IntraLock is expertly reviewed, has issued patents from the USPTO, and has a plurality of pending patent applications.

After a cursory review of the lawsuit, it appears EM has undertaken a multi-year campaign to unduly stretch the scope of their patent, which attempts to box out Fusion Orthopedics, LLC's superior IntraLock Fixation System. Fusion Orthopedics, LLC fiercely disputes the baseless singular claim set forth by EM as filed in the U.S. District Court of Arizona. The IntraLock Fixation System does not infringe the claimed EM IO Fix patent.

Fusion Orthopedics, LLC's position is that EM is inequitably attempting to weaponize their patents against companies to gain a market advantage beyond their legal right. This litigation tactic employed by EM is bad for healthcare because it attempts to strangle medical device innovation that may improve patient surgical outcomes and reduce the cost of care.

As a matter of good public policy, Fusion Orthopedics, LLC is deeply committed to combating any such legal tactics by EM and others. It is Fusion's practice to recognize and respect the intellectual property of others. Fusion Orthopedics, LLC is undeterred in their pursuit as an innovator in technology related to foot and ankle orthopedic devices. Fusion Orthopedics, LLC stands by its IntraLock Fixation System, especially when wrongfully accused of patent infringement.

Original Signature (electronic, copies or stamps not accepted)

3-14-2025
Date

Applicant's initials

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This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/29/2022	03/16/2023	AZ	Phoenix	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:2022cv00490	Arizona District Court

Reason/Charge
IP infringement

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

Treace Medical filed the lawsuit on March 29, 2022 against Fusion Orthopedics, LLC in the United States District Court for the District of Arizona, Civil Action No. 2:22- cv-00490, alleging patent, trademark, and copyright infringement, as well as various unfair trade practices based on Fusion Orthopedics, LLC's use, sale, and promotion of the Lapilock 4D Advanced Bunion Surgery, including false advertising and unfair competition.

Fusion Orthopedics, LLC subsequently filed counterclaims against Treace Medical, requesting declaratory judgment of non- infringement and invalidity of the patents, declaratory judgment of invalidity of Treace Medical's LAPIPLASTY trademark, as well as various unfair trade practices based on Treace Medical's use, sale, and promotion of the Lapiplasty 3D Bunion Correction, including counterclaims of false descriptions and false advertising.

In March 2023, the parties entered into an agreement to settle this matter. While the terms of the settlement are confidential, Fusion Orthopedics, LLC is pleased with the outcome.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
10/04/2021	On Going	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2021-094708	Maricopa County Superior Court

Reason/Charge
Breach of contract.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Fusion Orthopedics, LLC	Lawsuit

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

This matter revolves around a consulting agreement Fusion Orthopedics, LLC alleges was breached by an independent contractor for failure to provide the services set forth in the agreement, as well as additional clauses of non-competition, non-disclosure. The independent contractor alleges he performed under the consulting agreement.

Original Signature (electronic, copies or stamps not accepted)

5-14-25
Date

Applicant's initials

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This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/18/2020	03/24/2021	AZ	Mesa	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV2020-093744		Maricopa County Superior Court		
Reason/Charge				
Breach of contract.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Fusion Orthopedics, LLC		Lawsuit		
Name of Business/Industry/Entity				
Fusion Orthopedics, LLC				

Provide explanation below:

Fusion Orthopedics, LLC filed suit against a facility for breach of contract for failing to pay outstanding invoices on products sold by Fusion Orthopedics, LLC to the facility. Ultimately, the facility filed for bankruptcy.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials

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This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
07/19/2024	11/12/2024	AZ	Phoenix	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV-24-01773-PHX-DJH		Arizona District Court		
Reason/Charge				
Tortious interference				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Fusion Orthopedics USA, LLC			Lawsuit	
Name of Business/Industry/Entity				
Fusion Orthopedics USA, LLC				

Provide explanation below:

Conventus Orthopaedics filed the lawsuit on July 19, 2024 against Fusion Orthopedics USA, LLC and a number of Fusion employees in the United States District Court for the District of Arizona, Civil Action No. 2:24-cv-01773-DJH, alleging breach of contract, misappropriation of trade secrets and tortious interference, as well as sought a TRO. The TRO was denied and Conventus Orthopaedics subsequently voluntarily dismissed the case without prejudice.

Fusion filed a motion for an award of attorneys' fees. In November 2024, the parties entered into an agreement to settle this matter, including the attorneys' fees, and dismissed the case with prejudice. While the terms of the settlement are confidential, Fusion Orthopedics USA, LLC is pleased with the outcome.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

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This is in response to Question # 5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
06/23/2020	10/21/2020	AZ	Mesa	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV2020-093805		Maricopa County Superior Court		
Reason/Charge				
Real Estate Dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
X7 Properties, LLC			Lawsuit	
Name of Business/Industry/Entity				
X7 Properties, LLC				

Provide explanation below:

This matter between X7 Properties, LLC and Emily Martineau revolved around a clouded title to real property.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials AZ

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/09/2020	08/31/2021	AZ	Mesa	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV2020-096540		Maricopa County Superior Court		
Reason/Charge				
Real Estate Dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
X7 Properties, LLC			Lawsuit	
Name of Business/Industry/Entity				
X7 Properties, LLC				

Provide explanation below:

This matter between X7 Properties, LLC and Emily Martineau revolved around a clouded title to real property.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
04/27/2021	10/13/2021	AZ	Mesa	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV2021-092073		Maricopa County Superior Court		
Reason/Charge				
Real Estate Dispute				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
X7 Properties, LLC			Lawsuit	
Name of Business/Industry/Entity				
X7 Properties, LLC				

Provide explanation below:

This matter between Collection Agency Services Revocable Trust, James Cundiff, Teresa Cundiff, X7 Properties, LLC, Rhett Martineau and Emily Martineau revolved around a clouded title to real property.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
12/05/2022	02/16/2023	AZ	Chandler	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CC2022213137		San Tan Justice Court		
Reason/Charge				
Breach of Contract				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Adam Cundiff			Lawsuit	
Name of Business/Industry/Entity				
Adam Cundiff				

Provide explanation below:

This matter revolved around a contract dispute between Ramon Roman and Dario Martinez. I was ultimately dismissed from this case and awarded reasonable attorneys' fees.

Original Signature (electronic, copies or stamps not accepted)

3-17-2025
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
09/29/2016	10/15/2017	AZ	Chandler	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CC2016176259	San Tan Justice Court

Reason/Charge
Breach of Contract

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff

Provide explanation below:

This dispute revolved around a property damage claim.

Original Signature (electronic, copies or stamps not accepted)

3-14-25

Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/06/2009	06/30/2010	AZ	Mesa	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
CV2009-090978		Superior Court Maricopa County		
Reason/Charge				
Breach of Contract and Fraud				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Plaintiffs Adam Cundiff, Transcapital, LLC, Investor Recovery Trust, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC and Liberty Capital Group, LLC			Lawsuit	
Name of Business/Industry/Entity				
Plaintiffs Adam Cundiff, Transcapital, LLC, Investor Recovery Trust, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC and Liberty Capital Group, LLC				

Provide explanation below:

Adam Cundiff, and companies he was affiliated with, were plaintiffs against defendants for breach of contract and common law fraud, and securities fraud. The case has ultimately been consolidated to CV2007-008311.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials _____ 6

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
07/16/2008		AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2008-092140	Superior Court Maricopa County

Reason/Charge
Breach of Contract.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff and Magic Carpet Investment Group, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff and Magic Carpet Investment Group, LLC

Provide explanation below:

This matter revolved around a partnership dispute.



Original Signature (electronic, copies or stamps not accepted)

3-14-2024

Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
04/14/2008	06/14/2010	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2008-008323	Superior Court Maricopa County

Reason/Charge
Breach of Contract and Fraud

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC and Business Growth Advisors, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC and Business Growth Advisors, LLC

Provide explanation below:

Consolidated under CV2007-008311.

Original Signature (electronic, copies or stamps not accepted)

3-14-25

Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/21/2008	03/29/2012	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2008-003972	Superior Court Maricopa County

Reason/Charge
Breach of Contract and Fraud

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC Business Growth Advisors, LLC, Liberty Capital Group, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC Business Growth Advisors, LLC, Liberty Capital Group, LLC

Provide explanation below:

Adam Cundiff was Plaintiff and Counter-defendant in this action for breach of contract and common law fraud.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials 6

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/25/2007	10/12/2007	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2007-009375	Superior Court Maricopa County

Reason/Charge
Breach of Contract and Fraud

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC Business Growth Advisors, LLC, Liberty Capital Group, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC Business Growth Advisors, LLC, Liberty Capital Group, LLC

Provide explanation below:

Consolidated under CV2007-008311.

Original Signature (electronic, copies or stamps not accepted)

3-14-25

Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/23/2007	10/12/2007	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2007-009235	Superior Court Maricopa County

Reason/Charge
Breach of Contract and Fraud

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC, Liberty Capital Group, LLC, Investor Recovery Trust, Freedom Property Holdings, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC, Liberty Capital Group, LLC, Investor Recovery Trust, Freedom Property Holdings, LLC

Provide explanation below:

Consolidated under CV2007-008311.

Original Signature (electronic, copies or stamps not accepted)

3-14-2005
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/10/2007	02/28/2018	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2007-008311	Superior Court Maricopa County

Reason/Charge
Breach of Contract and Fraud

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC, Liberty Capital Group, LLC, Investor Recovery Trust, Freedom Property Holdings, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff, Transcapital, LLC, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC, Liberty Capital Group, LLC, Investor Recovery Trust, Freedom Property Holdings, LLC

Provide explanation below:

Adam Cundiff was Plaintiff and Counter-defendant in this action for breach of contract and common law fraud.

Original Signature (electronic, copies or stamps not accepted)

3-14-25
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
04/24/2007	04/28/2008	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2007-007115	Superior Court Maricopa County

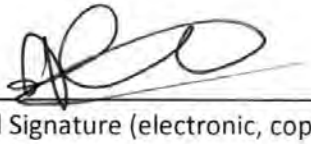
Reason/Charge
Breach of Contract and Fraud

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff, Dezert Heat Worldwide, LLC, Business Growth Advisors, LLC

Provide explanation below:

Consolidated under CV2007-008311.



Original Signature (electronic, copies or stamps not accepted)

3-14-2025

Date

Applicant's initials 

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4 & 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/30/2007	12/05/2008	AZ	Mesa	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
CV2007-005734	Superior Court Maricopa County

Reason/Charge
Breach of Contract and Fraud

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Adam Cundiff, Creekside Capital, LLC, Binkcorp Capital, LLC, Aspen Grove Capital Partners I, LP, Aspen Grove Ventures, LLC, Aspen Grove Capital, LLC, Aspen Grove Capital Group, LLC	Lawsuit

Name of Business/Industry/Entity
Adam Cundiff, Creekside Capital, LLC, Binkcorp Capital, LLC, Aspen Grove Capital Partners I, LP, Aspen Grove Ventures, LLC, Aspen Grove Capital, LLC, Aspen Grove Capital Group, LLC

Provide explanation below:

Adam Cundiff was a defendant and was released from the case pursuant to a motion to dismiss for failure to state a claim.

Original Signature (electronic, copies or stamps not accepted)

3-14-2025
Date

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
08/12/2010	07/23/2012	NM	Albuquerque	Bernalillo

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
D-202-CV-201009625	Albuquerque District Court

Reason/Charge
Breach of Contract

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
SmileLabs, LLC	Lawsuit

Name of Business/Industry/Entity
SmileLabs, LLC

Provide explanation below:

Breach of contract dispute that was ultimately dismissed.

Original Signature (electronic, copies or stamps not accepted)

3-14-2025
Date

Applicant's initials

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Adam Cundiff

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-14-25

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, Adam Cundiff, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-14-25

Date

Subscribed and Sworn to before me this 14th day of 2025.

Notary Public Signature

SAMUEL ROCERETA
Notary Public - Arizona
Maricopa County
Commission # 673585
My Comm. Expires Oct 30, 2028

(Seal)

Applicant's initials

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/19/2022	04/12/2023	NV	Reno	Washoe

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
22-525	Nevada State Board of Pharmacy

Reason/Charge
Unlicensed Activity in Nevada

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Fusion Orthopedics, LLC

Provide explanation below:

Fusion Orthopedics, LLC and its executives, Adam Cundiff and Nathan Peterson, received a letter from the State Board of Pharmacy on December 19, 2022 claiming Fusion Orthopedics, LLC had engaged in the business of wholesaling and/or distributing prescription drugs/medical products or devices into the State of Nevada without a license.

Fusion Orthopedics, LLC was unaware of Nevada statutes NRS 639.100, NRS 639.233, NAC 639.593 and NAC 639.6944. Fusion Orthopedics, LLC has since ceased material operations and is in the process of winding down, but Fusion Orthopedics USA, LLC has looked into these statutes and is submitting this application to be in compliance with these statutes.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
01/22/2025	01/22/2025	AZ	Phoenix	Maricopa

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
24-0617	Arizona State Board of Pharmacy

Reason/Charge
Unlicensed Activity in Arizona

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
Fusion Orthopedics USA, LLC

Provide explanation below:

Fusion Orthopedics USA, LLC was winding up, and waiting on construction for its office to be finished before it could submit its permit applications to the Arizona State Board of Pharmacy, as finalized building plans and a lease are a requirement for the permits. The permit process from the time the application was submitted, to the time it was processed and permits were issued was nearly a 12 month period, on top of the length of time office construction took. Fusion Orthopedics USA, LLC was cited for selling medical devices during that time frame without the required permit. The proper permits have since been obtained, and now Fusion Orthopedics USA, LLC is submitting this application to be in compliance with Nevada statutes NRS 639.100, NRS 639,233, NAC 639.593 and NAC 639.6944, as the Arizona permits are a prerequisite to obtaining the appropriate Nevada permits.

Original Signature (electronic, copies or stamps not accepted)

3-21-2025
Date

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
06/23/2008 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2007-008311
CV 2008-008323

06/20/2008

HONORABLE JOHN A. BUTTRICK

CLERK OF THE COURT
C. Castro
Deputy

MAURICE TANNER, et al.

RICHARD L COBB

v.

TRANSCAPITAL L L C, et al.

LEAH K MAHAFFY

JOSHUA R FOREST
ANDREW S FRIEDMAN
NANCY R GILES
HUBERT E KELLY
KEVIN KOELBEL
STEVEN C MAHAFFY
JOSHUA BLAKE MAYES
DOCKET-CIVIL-CCC
FILE ROOM-CSC
JUDGE GAINES

CASE CONSOLIDATION

Pursuant to a Stipulated Joint Motion to Consolidate filed June 17, 2008.

IT IS ORDERED consolidating cause numbers CV2007-008311 and CV2008-008323 under cause number **CV2007-008311** for all further proceedings.

Office Distribution

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

FILED
5/26/2010
Clerk of the Court

5/22/2010

COURT ADMINISTRATION

Ct. Admin
Deputy

Case Number: CV2008-092140

Magic Carpet Investment Group L L C

V.

Paul Montano

The Judge assigned to this action is the Honorable Karen Ann Potts

JUDGMENT OF DISMISSAL

Court records reflect this case was previously place or extended on the Inactive Calendar for dismissal per Rule 38.1 (d), Arizona Rule of Civil Procedure, unless specified action was taken before a certain date. The date has passed, and the specified action has not been taken. IT IS THEREFORE ORDERED dismissing all unadjudicated claims of this case without prejudice for lack of prosecution.

SPECIAL COMMISSIONER

Superior Court of Maricopa County - integrated Court Information System

Endorsee Party Listing

Case Number: CV2008-092140

Party Name	Attorney Name	
Magic Carpet Investment Group L L C	Steven C Mahaffy	Bar ID: 022934

Office Distribution

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

**FILED*
9/2/2009
Clerk of the Court

8/29/2009

COURT ADMINISTRATION

Ct. Admin
Deputy

Case Number: CV2009-090978

Transcapital L L C

V.

Henry & Horne L L P

The Judge assigned to this action is the Honorable Karen Ann Potts

JUDGMENT OF DISMISSAL

The time for serving the summons and complaint as required by Rule 4 (I), Arizona Rules of Civil Procedure, and any extensions which may have been granted, has expired, and no defendants have been served.

IT IS ORDERED dismissing the above entitled action without prejudice.

SPECIAL COMMISSIONER

Superior Court of Maricopa County - integrated Court Information System

Endorsee Party Listing

Case Number: CV2009-090978

Party Name	Attorney Name	
Adam Cundiff	Steven C Mahaffy	Bar ID: 022934
Business Growth Advisors L L C	Steven C Mahaffy	Bar ID: 022934
Dezert Heat Worldwide L L C	Steven C Mahaffy	Bar ID: 022934
Investor Recovery Trust, The	Steven C Mahaffy	Bar ID: 022934
James Cundiff	Steven C Mahaffy	Bar ID: 022934
Jeremiah Cundiff	Steven C Mahaffy	Bar ID: 022934
Liberty Capital Group L L C	Steven C Mahaffy	Bar ID: 022934
Transcapital L L C	Steven C Mahaffy	Bar ID: 022934

Michael K. Jeanes, Clerk of Court
*** Filed ***
JUN 30 2010 8:00AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2009-090978

06/29/2010

HONORABLE KAREN POTTS

CLERK OF THE COURT
T. Haaser
Deputy

TRANSCAPITAL L L C, et al.

STEVEN C MAHAFFY

v.

HENRY & HORNE L L P, et al.

JOSEPH E ANTHONY II

C T CORP SYSTEM
NO ADDRESS ON RECORD

MINUTE ENTRY

The Court has considered Defendant Henry & Horne's and Flemings' Motion to Dismiss Complaint, Plaintiffs' Response, Defendants' Reply, and the oral argument of counsel. Defendants argue: (1) this Court's should not have granted Ariz.R.Civ.P. 60(c) relief and reinstated this action on December 8, 2009, thereby rendering Plaintiffs' negligence claims time barred as a matter of law, and (2) Plaintiffs' fraud claim fails to comply with Rule 9(b). Rule 60(c) provides that the court may relieve a party from a final order on the grounds of mistake, inadvertence, surprise, or excusable neglect. Both parties have set forth detailed facts regarding the interplay between this matter and another matter pending in Superior Court[1] (the "Tanner Matter") to support their respective arguments as to whether Plaintiffs' actions do or do not constitute excusable neglect.

By way of procedural background, the Court issued a Minute Entry in this matter on June 6, 2009, warning Plaintiffs that the matter would be dismissed on July 6, 2009 if service was not timely accomplished as required by Rule 4(i) or an order granting an extension of time to serve was not obtained. This matter was dismissed by Minute Entry Order dated August 29, 2009,

[1] CV2007-008311

more than a month and a half after the service deadline, for failure to serve the Complaint within 120 days of its filing. On December 8, 2009, this Court granted Plaintiffs' Motion seeking relief under Rule 60(c) and reinstating this action. At the time this Motion was granted, Defendants had not been served.

The Court now has before it detailed facts regarding the circumstances underlying Plaintiffs' claim of excusable neglect. The Court agrees with Defendants that the dismissal of this action was not due to excusable neglect, but rather to Plaintiffs' failure to ensure that its' claims were preserved in this action while it participated in a negotiated settlement in the Tanner Matter. These facts are analogous to *Maher v. Urman, 211 Ariz. 543, 124 P.3d 770 (App. 2005)*, and the cases cited therein. The circumstances here do not constitute excusable neglect. In essence, Plaintiffs were relying upon a promise to file new claims, under an amended complaint, as a term of an unsigned settlement agreement in another case (the Tanner Matter) in order to perpetuate the claims being made in this case. Certainly the only way to preserve the claims pending in this case was to serve the Complaint to ensure the claims were not lost while settlement negotiations and the execution of the settlement continued. This is especially true since this action was filed just within the statute of limitations, making Plaintiffs long aware that a dismissal of this action would render the matter time barred. For these reasons, this matter should not have been reinstated and Plaintiffs' negligence claims are time barred as a matter of law pursuant to A.R.S. §12-542. The remainder of Defendants arguments are thus moot.

For the foregoing reasons,

IT IS ORDERED granting Defendant Henry & Horne's and Flemings' Motion to Dismiss Complaint, vacating this Court's December 8, 2009 Order (filed on December 9, 2009), and affirming the Judgment of Dismissal dated August 29, 2009 (filed September 2, 2009).

IT IS FURTHER ORDERED signing this minute entry as a formal order of this Court.

Honorable Karen A. Potts
Judicial Officer of Superior Court

[1] CV2007-008311

Clerk of the Superior Court
*** Electronically Filed ***
03/24/2021 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2020-093744

03/23/2021

HONORABLE JANICE CRAWFORD

CLERK OF THE COURT
V. Felix
Deputy

FUSION ORTHOPEDICS L L C

SAMUEL ROCERETA

v.

TRUSTED CARE EAST VALLEY A Z, L L C, et al.

BRIAN A CABIANCA

JENNIFER JOAN AXEL
JUDGE CRAWFORD

MINUTE ENTRY

The Court has received notification that a petition under the Bankruptcy Code has been filed by **Trusted Care East Valley AZ, LLC and Trusted Care North Valley AZ, LLC** in case nos. 21-01878 and 21-01880. .

IT IS ORDERED this case shall remain on the Dismissal Calendar until **September 13, 2021** as to **Trusted Care East Valley AZ, LLC and Trusted Care North Valley AZ, LLC.**

This case/claim(s) will be dismissed on **September 13, 2021** unless prior to the scheduled dismissal date Plaintiff demonstrates it has moved to lift the stay but the request has not been ruled upon or has been denied; it has sought to reduce the claim(s) against the debtor to judgment in the Bankruptcy Court in an adversary proceeding and the adversary proceeding has not yet been resolved despite diligence in seeking such a resolution; it has obtained severance of the claim(s) against the debtor from the claim(s) against the other parties to the action, if any; or it has demonstrated a reasonable basis for continuance of the case on the Dismissal Calendar.

Any party may ask the Court to schedule an informal status conference before the dismissal date to inform the Court what action, if any, is undertaken in the Bankruptcy Court that would permit this case to proceed.

X7 Properties, LLC
4135 S. Power Rd, Suite #110,
Mesa, AZ 85212
Email: sam@x7properties.com
Phone: 480-336-2558 ext. 2558

Samuel Rocereta, Esq.
Bar No. 035983
In-House Counsel for Plaintiff

THE SUPERIOR COURT OF MARICOPA COUNTY IN THE STATE OF ARIZONA
222 E. Javelina Avenue, Mesa, AZ 85210, (602)-506-3204

X7 PROPERTIES, LLC Plaintiff, v. Emily Martineau Defendant,	Case No. CV2020-093805 Order to Dismiss Without Prejudice

This matter having come before the Court upon Motion to Dismiss Without Prejudice, the Court having considered same and good cause shown,

IT IS HEREBY ORDERED that said Motion be granted this matter is dismissed without prejudice as of this 20 day of Oct, 2020

JUDGE/COMMISSIONER OF THE SUPERIOR COURT

HONORABLE DAVID J. PALMER
MARICOPA COUNTY SUPERIOR COURT

Granted as Submitted
See eSignature page

Clerk of the Superior Court
*** Electronically Filed ***
K. Tiero, Deputy
8/31/2021 8:00:00 AM
Filing ID 13303873

Rocereta Law Group, PLLC
4135 S. Power Rd, Ste 118,
Mesa, AZ 85212
T: (602) 388-1629
E-mail: *sam@x7properties.com*
Attorneys for Plaintiffs
By: Samuel Rocereta, Esq.
Bar No. 035983

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

X7 PROPERTIES, LLC, Plaintiff vs. EMILY MARTINEAU and RHETT MARTINEAU, wife and husband, Defendants	Case No.: CV2020-096540 **ORDER OF DISMISSAL WITH PREJUDICE** (Assigned to the Honorable Rodrick Coffey)

This matter having come on before this Court, the Court having read the Motion and Stipulation to Dismiss Complaint Against Emily Martineau and Rhett Martineau with Prejudice and good cause appearing therefore,

IT IS HEREBY ORDERED dismissing the Complaint against Defendants Emily Martineau and Rhett Martineau, with prejudice, each party to bear his, her or its own attorneys' fees and court costs.

DATED ____ day of _____, 2021.

_____
Honorable Rodrick Coffey
Judge of the Superior Court

eSignature Page 1 of 1

Filing ID: 13303873 Case Number: CV2020-096540
Original Filing ID: 13276487

Granted as Submitted

/S/ Rodrick Coffey Date: 8/27/2021
Judicial Officer of Superior Court

ENDORSEMENT PAGE

CASE NUMBER: CV2020-096540

SIGNATURE DATE: 8/27/2021

E-FILING ID #: 13303873

FILED DATE: 8/31/2021 8:00:00 AM

SAMUEL ROCERETA

EMILY MARTINEAU
[redacted]

RHETT MARTINEAU
[redacted]

CLERK OF THE SUPERIOR COURT
FILED
10-13-2021 9:45a.m.
S. Dickinson, Deputy

ARIZONA PROPERTY LAW
AN ARIZONA LIMITED LIABILITY COMPANY
1525 South Higley Road, Suite 104
Gilbert, Arizona 85296
T: 480.939.4884
E-mail: *docket@arizonapropertylaw.com*
Attorneys for Plaintiffs
By: Scott L. Potter, Bar No. 025157

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

COLLECTION AGENCY SERVICES REVOCABLE TRUST,

Plaintiff

vs.

JAMES CUNDIFF and TERESA CUNDIFF, husband and wife, EMILY MARTINEAU and RHETT MARTINEAU, wife and husband, X7 PROPERTIES, LLC, an Arizona limited liability company, JOHN DOES I-V; JANE DOES I-V; BLACK CORPORATIONS I-V and WHITE PARTNERSHIPS I-V,

Defendants

Case No.: CV2021-092073

ORDER OF DISMISSAL WITH PREJUDICE

(Assigned to the Commissioner Brian Kaiser)

This matter having come on before this Court, the Court having read the Motion and Stipulation to Dismiss Complaint Against Emily Martineau and Rhett Martineau and to Dismiss Counterclaim Against Collection Agency Services Revocable Trust with Prejudice and good cause appearing therefore,

//

//

IT IS HEREBY ORDERED dismissing the Complaint against Defendants/Counterclaimants Emily Martineau and Rhett Martineau, with prejudice, each party to bear his, her or its own attorneys' fees and court costs.

IT IS FURTHER ORDERED dismissing the Counterclaim against Plaintiff/Counterdefendant Collection Agency Services Revocable Trust, with prejudice, each party to bear his, her or its own attorneys' fees and court costs.

DATED 5 day of Oct, 2021.

Commissioner Brian Kaiser
Judge of the Superior Court

Clerk of the Superior Court
*** Electronically Filed ***
S. Allen, Deputy
10/4/2021 2:55:34 PM
Filing ID 13452471

In the Superior Court of the State of Arizona
In and For the County of Maricopa

Plaintiff's Attorney:

Samuel Rocereta
Bar Number: 035983, issuing State: AZ
Law Firm: Rocereta Law Group, PLLC
4135 S. Power Rd, Suite 118
Mesa, AZ 85212
Telephone Number: (602)388-1629
Email address: sam@fusionorthopedics.com

CV2021-094708

Plaintiff:

Fusion Orthopedics, LLC
4135 S. Power Rd, Suite 118
Mesa, AZ 85212

Defendant:

Craig Schelling
[redacted]
Fortine, MT [redacted]

Discovery Tier t3

Case Category: Contracts
Case Subcategory: Other Contract (Breach of Contract)

AZturboCourt.gov Form Set #6131403

FILED
Mar. 19, 09 2:20 PM
MICHAEL K. JEANES, Clerk
By T. Tankersley, Deputy

Ed Hendricks, Sr., State Bar No. 002359
Ed Hendricks, Jr., State Bar No. 016539
Pamela B. Petersen, Of Counsel, State Bar. No. 011512
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2398 East Camelback Road
Phoenix, Arizona 85016
(602) 508-9010
Paulconant@thomsonconant.com

Attorneys for Plaintiff-Trustee James C. Sell

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

JAMES C. SELL, Trustee,

Plaintiff,

v.

RUSSELL L. SEWELL et. al,

Defendants.

NO. CV2007-005734

PROPOSED ORDER OF DISMISSAL OF SPECIFIED PARTIES FROM THIRD AMENDED COMPLAINT

(Assigned to Hon. Douglas L. Rayes)

Pursuant to the agreement of James C. Sell and Thomas and Debra Fairbanks, and good cause appearing therefor,

IT IS HEREBY ORDERED dismissing the following parties, **without prejudice,** from the Third Amended Complaint, each party to bear its own attorneys' fees and costs:

1. THOMAS FAIRBANKS AND DEBRA FAIRBANKS, husband and wife; and
2. TRIPLE V INVESTMENTS, LLC, a foreign limited liability company.

ORDER OF DISMISSAL OF SPECIFIED PARTIES
FROM THIRD AMENDED COMPLAINT

SIGNED IN OPEN COURT this 15 day of January, 2009.

Hon. Douglas L. Rayes
Superior Court Judge

489462

Michael K. Jeanes, Clerk of Court
*** Electronically Filed ***
12/10/2008 8:00 AM

SUPERIOR COURT OF ARIZONA
MARICOPA COUNTY

CV 2007-005734

12/05/2008

JUDGE DOUGLAS L. RAYES

CLERK OF THE COURT
T. Tankersley
Deputy

JAMES C SELL

ED HENDRICKS SR.

v.

RUSSELL L SEWELL, et al.

RICHARD G HIMELRICK

HAL MICHAEL CLYDE
MERWIN D GRANT
ERIC M JACKSON
KEITH M KNOWLTON
STEVEN C MAHAFFY
WILLIAM J MALEDON
PAUL J MCGOLDRICK
BRIAN J SCHULMAN
ROBERT A SHULL
NANCY K SWIFT
DAXTON R WATSON

RULING MINUTE ENTRY

Defendants Adam Cundiff and Jane Doe Cundiff, Creekside Capital, LLC, and Binkcorp Capital, LLC (collectively "Adam Cundiff Defendants") have filed a Motion to Dismiss for failure to state a claim upon which relief can be granted. This motion was taken under advisement after the oral argument of November 24, 2008. For the reasons set forth below, the Motion to Dismiss is granted.

The Adam Cundiff Defendants allege that the Third Amended Complaint ("Complaint") fails to make any specific allegations against Adam and Jane Doe Cundiff, Creekside Capital, and Binkcorp Capital, and ask this Court to dismiss the Complaint with prejudice as to those Defendants. Plaintiff agrees that it has not alleged that the Adam Cundiff Defendants made affirmative misrepresentations to investors or were otherwise actively involved in the sale of Mathon securities. However, Plaintiff asserts that the Adam Cundiff Defendants are the ultimate owners of CTAC Group LLC from which they knowingly received illegal proceeds and are therefore liable under A.R.S. § 44-1991(A)(1) and (3).

After reviewing the Complaint, the Court agrees that it does not contains specific factual assertions against the Adam Cundiff Defendants to support Plaintiff's theory of liability against them. While there are many specific allegations against James Cundiff and CTAC, the Complaint does not specify the role the Adam Cundiff Defendants played in the alleged fraudulent scheme. Although Plaintiff's Response contains such allegations, reiterated by Plaintiff at oral argument, these allegations are not contained in the Complaint. However, the Court is mindful that it should be liberal in allowing amendments to a complaint when Rule 9(b) and/or A.R.S. § 44-2082(A) are violated. See Spudnuts, Inc. v. Lane, 131 Ariz. 424, 426, 641 P.2d 912, 914 (App. 1982).

IT IS ORDERED granting the Adam Cundiff Defendant's Motion to Dismiss.

IT IS FURTHER ORDERED granting Plaintiff's Motion for Leave to Amend Third Amended Complaint by no later than January 10, 2009.

FILED
JUL 21 2009 2:50 PM
MICHAEL K. JEANES, Clerk
By S. Castro
Deputy

Martin R. Galbut (#002943)
Olivier A. Beabeau (#020986)
Keith R. Galbut (#022869)
GALBUT & GALBUT, P.C.
2425 East Camelback Road, Suite 1020
Phoenix, Arizona 85016
Phone: 602.955.1455
Fax: 602.955.1585
Attorneys for Thornton Plaintiffs

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

MAURICE TANNER, et al.

Plaintiffs,

vs.

TRANSCAPITAL, LLC, et al.

Defendants.

Case No. CV2007-008311

NON-DISCHARGEABLE JUDGMENT

Consolidated with cases:

CV2007-007115
CV2007-009235
CV2007-009375

Based upon a Stipulation of the Parties, and for good cause appearing,

IT IS HEREBY ORDERED, ADJUDGED AND DECREED:

1. Defendant Adam Cundiff has breached her payment obligations to Plaintiffs James and Ruth Thorntons as required by private settlement agreement.

2. Defendant Adam Cundiff shall pay Plaintiffs James and Ruth Thornton the principal sum of ~~_____ and 00/100 Dollars~~ ($ 11,047.01).

3. Defendant Adam Cundiff shall pay Plaintiffs James and Ruth Thornton their reasonable attorneys' fees and costs in an amount to be determined upon the submission of a properly supported application.

4. Interest shall accrue, and shall be paid on the unpaid principal balance at the rate of twelve percent (12%) per annum, compounded, until the principal balance is paid in full to Plaintiffs James and Ruth Thornton.

5. This judgment is non-dischargeable in bankruptcy.

6. That pursuant to Ariz. Rev. Stat. § 33-421, this judgment may be recorded against and act as a lien upon real property.

7. That there is no just reason for delay in entry of this judgment and the Clerk is directed to enter said judgment forthwith.

DONE IN OPEN COURT this 17th day of July, 2009.

Maricopa County Superior Court Judge

John A. Buttrick

Michael K Jeanes, Clerk of Court
*** Electronically Filed ***
S. Bagnall, Deputy
7/17/2014 12:21:00 PM
Filing ID 5993372

Olivier A. Beabeau (#020986)
Keith R. Galbut (#022869)
Charles J. Morrow (#026322)
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Phoenix, Arizona 85016
Phone: 602.955.1455
Fax: 602.955.1585
docket@galbutlaw.com
Attorneys for Plaintiff

IN THE SUPERIOR COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

MAURICE TANNER, et al., Plaintiffs, vs. TRANSCAPITAL LLC, et al.; Defendants.	Case No. CV2007-008311 **AFFIDAVIT FOR RENEWAL OF NON-DISCHARGEABLE JUDGMENT AGAINST ADAM CUNDIFF**

STATE OF ARIZONA)
) ss:
County of Maricopa)

Charles J. Morrow, being first duly sworn, upon oath, deposes and states as follows:

1. I am an attorney with the law firm of Galbut & Galbut, P.C. ("Counsel"), which represents Plaintiffs James and Ruth Thornton ("Plaintiffs") in this action, and I am admitted to the practice of law in the State of Arizona.

2. I am an attorney of record in this action for Plaintiffs.

3. I have personal knowledge of the matters set forth herein and have been in the private practice of law in the field of commercial litigation since 2008.

4. On July 17, 2009, judgment was entered in Plaintiff's favor against Defendant Adam Cundiff in the total principal amount of $11,047.01 (the "Judgment").

5. The Judgment provides for Plaintiff to be paid post-judgment interest in the amount of 12%, compounded, from July 17, 2009 until paid.

6. The Judgment was recorded with the Maricopa County Recorder's Office on August 12, 2009 at record number 2009-0749313. A true and correct copy of the recorded Judgment is attached hereto as Exhibit "1."

7. No execution is anywhere outstanding or unreturned upon the Judgment.

8. A payment in the amount of $5,000.00 has been made in satisfaction of the Judgment.

9. There are no set-offs or counterclaims in favor of Defendant.

10. The amount of post-judgment interest due on the Judgment for the period July 17, 2009 – July 17, 2010 is $1,325.64 ($11,047.01*.12).

11. The amount of post-judgment interest due on the Judgment for the period July 17, 2010 – July 17, 2011 is $1,484.72 ($12,372.65*.12).

12. The amount of post-judgment interest due on the Judgment for the period July 17, 2011 – July 17, 2012 is $1,662.88 ($13,857.37*.12).

13. The amount of post-judgment interest due on the Judgment for the period July 17, 2012 – December 3, 2012 is $709.25 ($15,520.25*.12/365*139). The principal balance as of December 3, 2012 was $11,229.51 ($16,229.50 - $5,000.00).

14. The amount of post-judgment interest due on the Judgment for the period December 3, 2012 – December 3, 2013 is $1,347.54 ($11,229.51*.12).

15. 226 days have passed between December 3, 2013 and July 17, 2014.

16. The amount of post-judgment interest due on the Judgment for the period December 3, 2013 – July 17, 2014 is $934.49 ($12,577.05*.12/365*226).

17. The total amount due on the Judgment as of July 17, 2014 is $13,511.54 ($12,577.05 + $934.49).

18. This affidavit is made for the purpose of renewing the Judgment pursuant to A.R.S. § 12-1612.

Under penalty of perjury I declare that the foregoing is true and correct.

DATED this 17th day of July, 2014.

Charles J. Morrow

SUBSCRIBED AND SWORN to before me this 17th day of July, 2014.

SUNSHINE NYE
Notary Public - State of Arizona
MARICOPA COUNTY
My Commission Expires
July 9, 2016

Notary Public

CERTIFIED COPY

FILED
4-09-08 2:20pm
MICHAEL K. JEANES, Clerk
By L. L. Nixon
L. Nixon, Deputy

IN THE SUPERIOR COURT FOR THE STATE OF ARIZONA
IN AND FOR THE COUNTY OF MARICOPA

JOSEPH SUSCO and NICOLE SUSCO, husband and wife, MICHAEL MCALLISTER and MICHELLE MCALLISTER, husband and wife Plaintiffs, vs. TRANSCAPITAL, LLC, an Arizona limited liability company; BUSINESS GROWTH ADVISORS, LLC, an Arizona limited liability company; LIBERTY CAPITAL GROUP an Arizona limited liability company; JEREMIAH CUNDIFF and KRISTI CUNDIFF, husband and wife; JAMES S. CUNDIFF and TERESA CUNDIFF, husband and wife; ADAM J. CUNDIFF and JANE DOE CUNDIFF, husband and wife; DEZERT HEAT WORLDWIDE, LLC, an Arizona limited liability company; DEZERT HEAT HOLDING COMPANY LLC, an Arizona limited liability company; DEZERT HEAT ENTERTAINMENT, INC., an Arizona Corporation; MIKO WADY and JANE DOE WADY; husband and wife; DOES 1-10; ABC LLC's I-X; ABC CORPORATIONS I-X. Defendants.	NO: CV 2008-003972 **ORDER DISMISSING CASE** (Honorable Edward O. Burke)

Pursuant to the Stipulation between Plaintiff and TransCapital, LLC, Business Growth Advisors, LLC, Liberty Capital Group, LLC, Jeremiah Cundiff and Kristi Cundiff, husband and wife, James S. Cundiff and Teresa Cundiff, husband and wife, Adam J. Cundiff and Andrea Cundiff, husband and wife and Dezert Heat Worldwide, LLC, TransCapital/Cundiff-related

Does, TransCapital/Cundiff-related ABC LLC's, and TransCapital/Cundiff-related ABC Corporations ("TransCapital Parties Pursuant to the Susco and McCallister Law Suit CV 2008-003972") and TransCapital, LLC, Jeremiah Cundiff, personally, Kristi Cundiff, personally, James S. Cundiff, personally, Teresa Cundiff, personally and Adam Cundiff, personally ("TransCapital Parties Pursuant to the Settlement Agreement and Release of October 2007") (both TransCapital groups collectively referred to as the "TransCapital Parties"), and for good cause shown,

IT IS ORDERED:

1. Plaintiffs' claims and any claims or counterclaims that could have been brought under this cause of action by Plaintiff against TransCapital Parties or by TransCapital Parties against Plaintiffs, whether brought or not, are hereby dismissed with prejudice; and
2. The claims asserted by Plaintiff against non-TransCapital Parties are dismissed without prejudice; and
3. Each party shall pay their own attorney's fees and costs.

RESPECTFULLY SUBMITTED this 7 day of ~~March~~ April, 2008.

Edward O. Burke

Edward O. Burke
Judge of the Superior Court

The foregoing instrument is a full, true and correct copy of the original on file in this office.

Attest MAY 8 2023 20

JEFF FINE, Clerk of the Superior Court of the State of Arizona, in and for the County of Maricopa.

By _____, Deputy Clerk

Maricopa County Justice Courts, Arizona

San Tan Justice Court 201 East Chicago Street Ste 102, Chandler AZ 85225 602-372-3400

CASE NUMBER: CC2016176259 SC

ADAM CUNDIFF
[redacted]
GILBERT, AZ [redacted]

Plaintiff(s) Name/Address/Phone

BAJA READY MIX LLC
7431 W TURNEY AVE
PHOENIX, AZ 85033

Defendant(s) Name/Address/Phone

Attorney for Plaintiff (s) Name/Address/Phone

Attorney for Defendant(s) Name/Address/Phone

NOTICE OF PENDING DISMISSAL OF LAWSUIT

A final judgment (including a Judgment of Dismissal) has not been entered within ten (10) months from the date of this lawsuit being filed. Neither party has filed a written Motion to extend the time for an Entry of Judgment to a particular date.

Unless this requirement is met within two (2) months from the date of this notice, the Court will dismiss the lawsuit for failure to have a Judgment timely entered.

The lawsuit will be dismissed on or after this date: 10/07/2017

I CERTIFY that I delivered / mailed a copy of this document to:

☒ Plaintiff at the above address ☐ Plaintiff's attorney ☐ Defendant at the above Address ☐ Defendant's attorney

Date: 8/7/2017 By DH
Clerk

JCRCP Rule 144e: If a final judgment has not been entered within ten (10) months from the date a lawsuit is filed, or if a party has not filed a written motion to extend the time for entry of judgment to a particular date, the court will mail a notice to the plaintiff and to any defendant who has appeared in the lawsuit informing them that unless this requirement is met wihin two (2) months from the date of mailing, the court will dimsiss the lawsuit for failure to have judgment timely entered. If the requirement not been met within two (2) months from the mailing of the court's notice, the court may dismiss the lawsuit without further notice to the parties. [ARCP 38.1(d), 41(b)]

ORDER OF DISMISSAL

IT IS ORDERED dismissing this case without prejudice and without further notice

Date: _____ /s/ Sam Goodman 10/15/17

Justice of the Peace

Order of Dismissal will not be sent but remains in the Court's file.

CV 8150-122 R: 12/21/15

Certificate of Mailing
Maricopa County Justice Courts

Case Number: CC2016176259 SC

I CERTIFY that I mailed/delivered a copy to:

☐ Plaintiff at the above address

☒ Plaintiff's Attorney

☐ Garnishee

☐ Defendant at the above address

☐ Defendant's Attorney

☐ Other

Date: 10/17/2017

Clerk: LH

ROCERETA LAW GROUP, PLLC
4135 S. Power Rd., Ste. 118
Mesa, AZ 85212
Tel.: 602-388-1629
Email: sam@fusionorthopedics.com
By: Samuel Rocereta, Esq., Bar No. 035983

Attorneys for Defendant Adam Cundiff

IN THE SAN TAN JUSTICE COURT OF THE STATE OF ARIZONA

IN AND FOR THE COUNTY OF MARICOPA

RAMON ROMAN, Plaintiff, vs. DARIO MARTINEZ, and ADAM CUNDIFF Defendant(s).	Case No.: **CC2022213137** **PROPOSED ORDER DISMISSING PLAINTIFF'S COMPLAINT AGAINST DEFENDANT ADAM CUNDIFF** (Assigned to Hon. Goodman)

This matter having come before the Court upon the Motion to Dismiss, the Court having considered same and good cause shown.

IT IS HEREBY ORDERED Plaintiff Ramon Roman's Complaint against Defendant Adam Cundiff is hereby dismissed with prejudice.

IT IS FURTHER ORDERED that Defendant Adam Cundiff is hereby granted an award of reasonable attorney fees in moving to dismiss this Complaint.

IT IS FURTHER ORDERED that counsel for Defendant Adam Cundiff shall submit a China Doll Affidavit in support of attorneys' fees within 10 days of this Order.

DATED _____ day of _____, 20___.

s/ Sherwood Johnston, III, 2/16/2023

JUDGE OF THE JUSTICE COURT

JUSTICE OF THE PEACE SAN TAN JUSTICE COURT MARICOPA COUNTY ARIZONA

Certificate of Mailing
Maricopa County Justice Courts

Case Number: CC2022213137 RC

I CERTIFY that I mailed/delivered a copy to:

- ☐ Plaintiff at the above address
- ☒ Plaintiff's Attorney
- ☐ Garnishee
- ☒ Defendant at the above address
- ☐ Defendant's Attorney
- ☐ Other

Date: 2/23/2023

Clerk: JN

UNITED STATES DISTRICT COURT

DISTRICT OF ARIZONA

Treace Medical Concepts, Inc., Plaintiff, vs. Fusion Orthopedics, LLC, Defendant.	No. No. 2:22-cv-00490-SRB **ORDER**
Fusion Orthopedics, LLC, Counter-Claimant, vs. Treace Medical Concepts, Inc. Counter-Defendant	

Upon review of the parties' Stipulation for Voluntary Dismissal, and good cause appearing,

IT IS HEREBY ORDERED approving the parties' Stipulation for Voluntary Dismissal.

IT IS FURTHER ORDERED that the Joint Stipulation and Order lodged under seal at Dkt. 160 is hereby **ENTERED**.

. . .

. . .

IT IS FURTHER ORDERED dismissing the above-captioned action with prejudice, with each party to bear its own attorneys' fees and costs. This Court retains jurisdiction to enforce the Joint Stipulation and Order.

Dated this 15th day of March, 2023.

Susan R. Bolton
United States District Judge

UNITED STATES DISTRICT COURT
DISTRICT OF ARIZONA

Civil Cover Sheet

This automated JS-44 conforms generally to the manual JS-44 approved by the Judicial Conference of the United States in September 1974. The data is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. The information contained herein neither replaces nor supplements the filing and service of pleadings or other papers as required by law. This form is authorized for use only in the District of Arizona.

The completed cover sheet must be printed directly to PDF and filed as an attachment to the Complaint or Notice of Removal.

Plaintiff(s): **Extremity Medical, LLC**

County of Residence: Outside the State of Arizona

County Where Claim For Relief Arose: Maricopa

Defendant(s): **Fusion Orthopedics, LLC**

County of Residence: Maricopa

Plaintiff's Atty(s):

William Klain
Lang & Klain, P.C.
6730 N. Scottsdale Rd., Suite 101
Scottsdale, Arizona 85253
4805344873

Defendant's Atty(s):

II. Basis of Jurisdiction: **3. Federal Question (U.S. not a party)**

III. Citizenship of Principal Parties **(Diversity Cases Only)**

Plaintiff:- **N/A**
Defendant:- **N/A**

IV. Origin : **1. Original Proceeding**

V. Nature of Suit: **830 Patent**

VI.Cause of Action: **35 U.S.C. Sect. 100, et seq., Patent Infringement**

VII. Requested in Complaint

Class Action: **No**
Dollar Demand:
Jury Demand: **Yes**

VIII. This case **is not related** to another case.

Signature: William G. Klain

Date: 4/28/22

If any of this information is incorrect, please go back to the Civil Cover Sheet Input form using the *Back* button in your browser and change it. Once correct, save this form as a PDF and include it as an attachment to your case opening documents.

Revised: 01/2014

FILED
SECOND JUDICIAL DISTRICT
2012 JUL 23 AM 11:20

IN THE COURT OF APPEALS OF THE STATE OF NEW MEXICO

LISETTE NEGRON and DAVID NEGRON,

Plaintiffs-Appellants,

vs.

No. 30,949
Bernalillo County
CV-2010-9625

SMILELABS, LLC., an Arizona Limited Liability Company,

Defendant-Appellee.

COURT OF APPEALS OF NEW MEXICO
FILED
JUN 04 2012

ORDER

This Court has considered Appellee SmileLabs, LLC's motion to dismiss and Appellants, Lisette and David Negron's response.

THE COURT ORDERS that the motion to dismiss the appeal is granted.

THE COURT FURTHER ORDERS that Appellee's request for attorney's fees is hereby denied.

MICHAEL D. BUSTAMANTE, Judge

CYNTHIA A. FRY, Judge

COPY TO: Judge, Mallott
DATE: 7/23/12

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF ARIZONA

Conventus Orthopaedics Incorporated,

Plaintiff,

v.

Fusion Orthopedics USA LLC, et al.,

Defendants.

No. CV-24-01773-PHX-DJH

ORDER

This matter is before the Court on the parties' Joint Stipulation of Dismissal with Prejudice (Doc. 54), filed on November 11, 2024. Accordingly,

IT IS ORDERED the Joint Stipulation of Dismissal (Doc. 54) is GRANTED and that this action is DISMISSED with prejudice, each party to bear their own costs and fees.

IT IS FURTHER ORDERED that the Motion for Award of Attorneys' Fees (Doc. 40) shall be TERMINATED.

IT IS FURTHER ORDERED directing the Clerk of Court to terminate this action in its entirety.

Dated this 12th day of November, 2024.

Honorable Diane J. Humetewa
United States District Judge

4DD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Getinge Group Logistics Americas, LLC

Physical Address: 160 Princeton-Hightstown Road

City: East Windsor State: NJ Zip: 08520

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.getinge.com

Name of Designated Representative (DR): Robert S Prezant

Licensing Company Email: GGL@SLSNY.com DR Email: robert.prezant@getinge.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: Devices (Rx), Devices (Containing a Drug), Devices (Rx Convenience Kit, Containing a Drug Component)	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Distribution sites within organization, US Government		☒ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Maquet Cardiopulmonary GmbH
Address: Kehler Str. 31 City: Rastatt State: Germany Zip: 76437
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

N/A **Section 4: Publicly Traded Corporation**

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): Datascope Corp.
Corporation/Organization Name: Getinge Group Logistics Americas, LLC
Mailing Address: c/o State License Servicing 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: GGL@SLSNY.com
Contact Person Name: Christine Cannon

N/A **Section 6: Partnership**

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A **Section 7: Sole Owner**

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 3025504317	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Getinge Group Logistics Americas, LLC

Facility Name

Francis A Kozar

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

March 4, 2025

Date

Board Use Only	Date Received: 3/17/25	Amount: check $1000 1967

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
Getinge Group Logistics America, LLC
160 Princeton Highstown Road
E Windsor, NJ 08520
Registration Number: 3012092534
FEI Number*: 3025504317
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Getinge
45 Barbour Pond Dr
Wayne, NJ US 07470
Owner/Operator Number: 10055718

Official Correspondent:
Robert Prezant
GGLA
160 Princeton Highstown Road
E Windsor, NJ 08520
Phone: 862-2900407

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 01/13/2025
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

Getinge Group Logistics Americas, LLC

Corporate Address: 45 Barbour Pond Drive , Suite 229, Wayne, NJ 07470 USA
FEIN: 61-1802977
www.getinge.com

Drug Labeler Code: N/A
Incorporation State: DE
Incorporation Date: 09/08/2016

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
EWN	160 Princeton-Hightstown Road East Windsor, NJ 08520 County: Mercer	3025504317	N/A - No CS	064306381	No	(609) 422-9547	(862) 290-0407

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Robert S Prezant	[redacted]	Designated Representative		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Datascope Corp.	1300 MacArthur Blvd. Mahwah, NJ 07430	N/A	100	N/A	13-2529596	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Francis A Kozar	[redacted]	V.P. Logistics Americas & President		[redacted]		
Alistair David Ryan		CFO & Secretary				
Peter Antonio Diaz		Director Operations & Treasurer				
Erica Maya Gallagher		Assistant Secretary				

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
InCorp Services, Inc.			

Company Particulars

GETINGE

Getinge Group Logistics Americas, LLC
List of Officers

Alistair David Ryan - CFO & Secretary

Erica Maya Gallagher - Assistant Secretary

Francis A Kozar - V.P. Logistics Americas & President

Peter Antonio Diaz - Director Operations & Treasurer

Frank Kozar

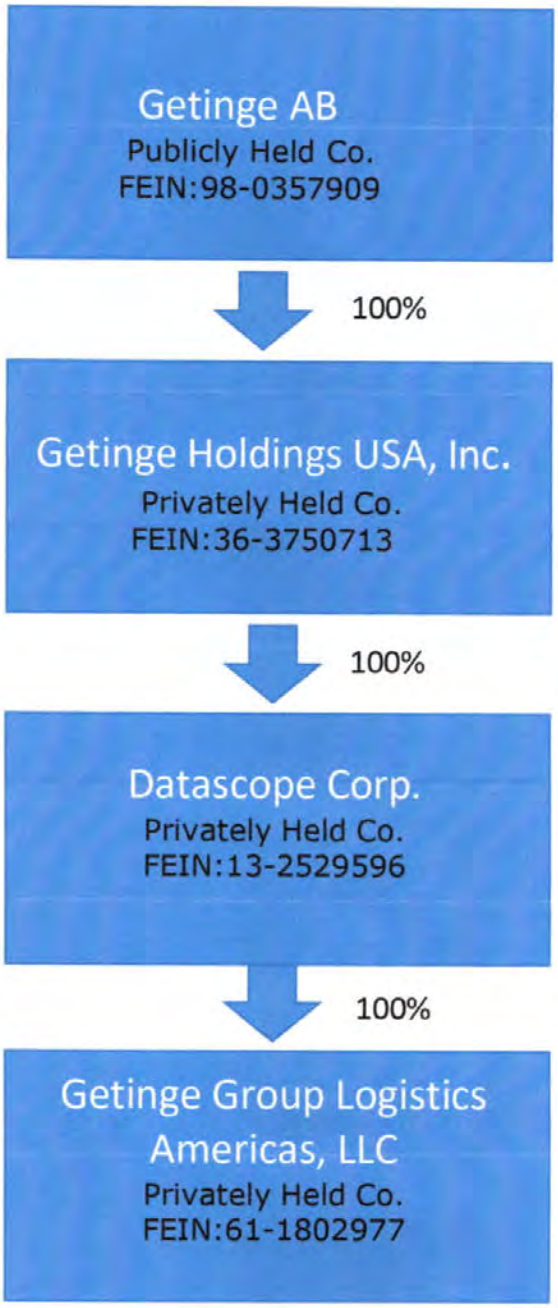
Getinge Group Logistics Americas LLC Phone: + 973-709-7899

45 Barbour Pond Drive

Wayne, NJ USA

Org Chart

Getinge Group Logistics Americas, LLC
Ownership Chart



Good Standing

Delaware

The First State

I, KRISTOPHER E. KNIGHT, ACTING SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GETINGE GROUP LOGISTICS AMERICAS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-THIRD DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "GETINGE GROUP LOGISTICS AMERICAS, LLC" WAS FORMED ON THE EIGHTH DAY OF SEPTEMBER, A.D. 2016.

Kristopher E. Knight, Acting Secretary of State

6145301 8300

SR# 20250229422

Authentication: 202766262

Date: 01-23-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Home State (NJ) Exempt

RELATED REGISTRATIONS AND INQUIRIES

- **Controlled Dangerous Substance Registration:** Manufacturers and wholesalers must register with the **New Jersey Drug Control Unit** if they will handle controlled dangerous substances. The State of New Jersey has established a Drug Control Unit within **the Department of Law and Public Safety**, for the purpose of assisting in the enforcement of those provisions of the New Jersey Controlled Dangerous Substances (CDS) Act which relate to persons who, or firms that, manufacture, prescribe, distribute, dispense or conduct research or analysis utilizing controlled substances. To register to handle CDS, please contact the New Jersey Drug Control Unit.

- **Logistics Provider** means an entity that receives drugs from the original manufacturer and delivers them at the direction of that manufacturer, and does not purchase, sell, trade, or take title to the drugs. Logistics Providers are not wholesale distributors and may not register. Logistics Providers that are located in New Jersey and are engaged in the storage or packing of food, vitamin supplements, or cosmetics must register as a wholesale food-cosmetic establishment.

- **Durable Medical Equipment Provider** means an entity that delivers durable medical equipment directly to the consumer or patient. Durable Medical Equipment Providers which do not conduct wholesale distribution business may not register. Licensure for Durable Medical Equipment Providers is not available through this office. Consult your local Medicare/Medicaid office for further guidance.

- **Vitamin Supplement or Cosmetic Manufacturers or Distributors** which operate a facility in New Jersey that stores or manufactures vitamin supplements or cosmetics must register as a wholesale food-cosmetic establishment.

CERTIFICATE OF LIABILITY INSURANCE

DATE(MM/DD/YYYY): 04/15/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME:	
Aon Risk Services Central, Inc. Philadelphia PA Office 100 North 18th Street 16th Floor Philadelphia PA 19103 USA	PHONE (A/C, No, Ext): (866) 283-7122	FAX (A/C, No.): (800) 363-0105
	E-MAIL ADDRESS:	

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Getinge Group Logistics Americas LLC 160 Princeton Hightstown Road East Windsor NJ 08520 USA	INSURER A: Zurich American Ins Co	16535
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 570112109661 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

Limits shown are as requested

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			GLC007999909	07/01/2024	07/01/2025	EACH OCCURRENCE	$5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$300,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$5,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$10,000,000
	OTHER							
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	
	☐ ANY AUTO						BODILY INJURY (Per person)	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	
	☐ DED ☐ RETENTION							
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N						☐ PER STATUTE ☐ OTH-ER	
	ANY PROPRIETOR / PARTNER / EXECUTIVE OFFICER/MEMBER EXCLUDED? ☐ N/A						E.L. EACH ACCIDENT	
	(Mandatory in NH)						E.L. DISEASE-EA EMPLOYEE	
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE-POLICY LIMIT	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Evidence of Coverage.

CERTIFICATE HOLDER

Getinge Group Logistics Americas, LLC
160 Princeton Hightstown Road
East Windsor NJ 08520 USA

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Aon Risk Services Central, Inc.

Holder Identifier :

Certificate No : 570112109661

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The ACORD name and logo are registered marks of ACORD

Bond
w/ Continuance

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. K41736768

Application/License No. _____

Getinge Group Logistics Americas, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 160 Princeton Hightstown Rd. East Windsor, NJ 08520 (Address of Applicant/Principal), as PRINCIPAL, and Federal Insurance Company (Surety Company), a corporation organized under the laws of the state of Indiana (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 202B Halls Mill Road, Whitehouse Station, NJ 08889 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 10th, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 10th day of November, 2023.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Kelly M. Shea, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

HOLLY A. BOSLAND
NOTARY PUBLIC OF NEW JERSEY
Commission No. 2227110
Commission Expires July 1, 2024

Posted February 20, 2020

CHUBB

Power of Attorney

Federal Insurance Company | Vigilant Insurance Company | Pacific Indemnity Company
Westchester Fire Insurance Company | ACE American Insurance Company

Know All by These Presents, that **FEDERAL INSURANCE COMPANY**, an Indiana corporation, **VIGILANT INSURANCE COMPANY**, a New York corporation, **PACIFIC INDEMNITY COMPANY**, a Wisconsin corporation, **WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** corporations of the Commonwealth of Pennsylvania, do each hereby constitute and appoint Jessica M Greene, Christopher K. Shea and Kelly M. Shea of Rochester, New York -------

each as their true and lawful Attorney-in-Fact to execute under such designation in their names and to affix their corporate seals to and deliver for and on their behalf as surety thereon or otherwise, bonds and undertakings and other writings obligatory in the nature thereof (other than bail bonds) given or executed in the course of business, and any instruments amending or altering the same, and consents to the modification or alteration of any instrument referred to in said bonds or obligations.

In Witness Whereof, said **FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY** and **ACE AMERICAN INSURANCE COMPANY** have each executed and attested these presents and affixed their corporate seals on this **2nd** day of **March, 2020.**

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

Steven M Haney

Stephen M. Haney, Vice President

STATE OF NEW JERSEY
County of Hunterdon ss

On this **2nd** day of **March, 2020** before me, a Notary Public of New Jersey, personally came Dawn M. Chloros and Stephen M. Haney, to me known to be Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY, the companies which executed the foregoing Power of Attorney, and the said Dawn M. Chloros and Stephen M. Haney, being by me duly sworn, severally and each for herself and himself did depose and say that they are Assistant Secretary and Vice President, respectively, of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY and know the corporate seals thereof, that the seals affixed to the foregoing Power of Attorney are such corporate seals and were thereto affixed by authority of said Companies; and that their signatures as such officers were duly affixed and subscribed by like authority.

Notarial Seal

KATHERINE J. ADELAAR
NOTARY PUBLIC OF NEW JERSEY
No. 2316685
Commission Expires July 16, 2024

Notary Public

CERTIFICATION

Resolutions adopted by the Boards of Directors of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, and PACIFIC INDEMNITY COMPANY on August 30, 2016; WESTCHESTER FIRE INSURANCE COMPANY on December 11, 2006; and ACE AMERICAN INSURANCE COMPANY on March 20, 2009:

"RESOLVED, that the following authorizations relate to the execution, for and on behalf of the Company, of bonds, undertakings, recognizances, contracts and other written commitments of the Company entered into in the ordinary course of business (each a "Written Commitment"):

(1) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise.

(2) Each duly appointed attorney-in-fact of the Company is hereby authorized to execute any Written Commitment for and on behalf of the Company, under the seal of the Company or otherwise, to the extent that such action is authorized by the grant of powers provided for in such person's written appointment as such attorney-in-fact.

(3) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to appoint in writing any person the attorney-in-fact of the Company with full power and authority to execute, for and on behalf of the Company, under the seal of the Company or otherwise, such Written Commitments of the Company as may be specified in such written appointment, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(4) Each of the Chairman, the President and the Vice Presidents of the Company is hereby authorized, for and on behalf of the Company, to delegate in writing to any other officer of the Company the authority to execute, for and on behalf of the Company, under the Company's seal or otherwise, such Written Commitments of the Company as are specified in such written delegation, which specification may be by general type or class of Written Commitments or by specification of one or more particular Written Commitments.

(5) The signature of any officer or other person executing any Written Commitment or appointment or delegation pursuant to this Resolution, and the seal of the Company, may be affixed by facsimile on such Written Commitment or written appointment or delegation.

FURTHER RESOLVED, that the foregoing Resolution shall not be deemed to be an exclusive statement of the powers and authority of officers, employees and other persons to act for and on behalf of the Company, and such Resolution shall not limit or otherwise affect the exercise of any such power or authority otherwise validly granted or vested."

I, Dawn M. Chloros, Assistant Secretary of FEDERAL INSURANCE COMPANY, VIGILANT INSURANCE COMPANY, PACIFIC INDEMNITY COMPANY, WESTCHESTER FIRE INSURANCE COMPANY and ACE AMERICAN INSURANCE COMPANY (the "Companies") do hereby certify that

(i) the foregoing Resolutions adopted by the Board of Directors of the Companies are true, correct and in full force and effect.
(ii) the foregoing Power of Attorney is true, correct and in full force and effect.

Given under my hand and seals of said Companies at Whitehouse Station, NJ, this 10th day of November 2023

Dawn M. Chloros

Dawn M. Chloros, Assistant Secretary

IN THE EVENT YOU WISH TO VERIFY THE AUTHENTICITY OF THIS BOND OR NOTIFY US OF ANY OTHER MATTER, PLEASE CONTACT US AT:
Telephone (908) 903-3493 Fax (908) 903-3656 e-mail: surety@chubb.com

CORPORATION ACKNOWLEDGMENT

STATE OF New Jersey
COUNTY OF Passaic

On this 15th day of November in the year 2023, before me personally came Francis A. Kozar to me known, who, being by me duly sworn, did depose and say he resides in Wayne: that he is the President of Getinge Group Logistics Americas, LLC the limited liability company described in and which executed the foregoing instrument; that the seal affixed to the said instrument is such corporate seal; and that it was so affixed by order of the Board of Directors of the said corporation, and that he signed his name thereto by like order.

Notary Public

SURETY ACKNOWLEDGMENT

STATE OF NEW YORK
COUNTY OF MONROE

On this 10th day of November in the year 2023, before me personally came Kelly M. Shea to me known, who, being by me duly sworn, did depose and say that he resides in Rochester, New York : that he is the Attorney-In-Fact of Federal Insurance Company the corporation described in and which executed the foregoing instrument; that the seal affixed to the said instrument is such corporate seal; and that it was so affixed by order of the Board of Directors of the said corporation, and that he signed his name thereto by like order.

Jessica M. Greene
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01GR6412198
Qualified in Monroe County
Commission Expires December 21, 2024

Notary Public

FEDERAL INSURANCE COMPANY

STATEMENT OF ASSETS, LIABILITIES AND SURPLUS TO POLICYHOLDERS

Statutory Basis

December 31, 2021

(in thousands)

ASSETS		*LIABILITIES AND SURPLUS TO POLICYHOLDERS*	
Cash and Short Term Investments	$ (567,306)	Outstanding Losses and Loss Expenses	$ 8,701,383
United States Government, State and Municipal Bonds	4,271,534	Reinsurance Payable on Losses and Expenses	1,484,196
Other Bonds	5,994,673	Unearned Premiums	2,400,711
Stocks	675,588	Ceded Reinsurance Premiums Payable	366,332
Other Invested Assets	1,647,712	Other Liabilities	498,472
TOTAL INVESTMENTS	12,022,201	TOTAL LIABILITIES	13,451,094
Investments in Affiliates:		Capital Stock	20,980
Great Northern Ins. Co.	414,638	Paid-In Surplus	2,711,474
Vigilant Ins. Co.	354,696	Unassigned Funds	1,903,522
Chubb Indemnity Ins. Co.	183,242		
Chubb National Ins. Co.	190,801	SURPLUS TO POLICYHOLDERS	4,635,976
Other Affiliates	116,373		
Premiums Receivable	1,726,653		
Other Assets	3,078,466		
TOTAL ADMITTED ASSETS	$ 18,087,070	TOTAL LIABILITIES AND SURPLUS	$ 18,087,070

Investments are valued in accordance with requirements of the National Association of Insurance Commissioners. At December 31, 2021 investments with a carrying value of $509,085,162 were deposited with government authorities as required by law

STATE OF PENNSYLVANIA

COUNTY OF PHILADELPHIA

John Taylor, being duly sworn, says that he is Senior Vice President of Federal Insurance Company and that to the best of his knowledge and belief the foregoing is a true and correct statement of the said Company's financial condition as of the 31 st day of December, 2021

Sworn before me this March 16, 2022

Senior Vice President

Jaime L Yates
Notary Public

September 19, 2023
My commission expires

Commonwealth of Pennsylvania - Notary Seal
Jaime L. Yates, Notary Public
Philadelphia County
My commission expires September 19, 2023
Commission number 1357070
Member, Pennsylvania Association of Notaries

Bond Continuance

Received By: Jessica Greene
NFP Property & Casualty Services Inc
6215 Sheridan Drive
Amherst, NY 14221

Received From: Getinge USA Sales, LLC
45 Barbour Pond Drive
Wayne, NJ 07470

Receipt For Payment # 77

Account Number	Date
GETIUSA-01	1/31/2025

Bonds

Policy Number
K41736768

Effective Date	Expiration Date
11/10/2024	11/10/2025

Company
Chubb Group of Insurance Companies

Amount Received: $313.00

This is to certify that we received payment from the above listed insured in the amount of $313.00

This is to certify that Getinge Group Logistics Americas' $25,000 Nevada Board of Pharmacy Bond has been paid in full and is in full force for the 11/10/24-11/10/25 term

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Getinge Group Logistics Americas, LLC — MDEG License # (if applicable): N/A
Physical Address: 160 Princeton-Hightstown Road
City: East Windsor — State: NJ — Zip: 08520
Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3
City: Florida — State: NY — Zip: 10921
Telephone: (845) 544-2482 — Website: www.getinge.com
Licensing Company Email: GGL@SLSNY.com

Section 2: Personal Information

First: Robert — Middle: S — Last: Prezant
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X
Mailing Address: [redacted]
City: Bridgewater — State: NJ — Zip: [redacted]
Telephone: [redacted] — Email: robert.prezant@getinge.com
Are you a citizen of the United States? × Yes | No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northern Arizona University		08/76 - 12/79	
Address	**City**	**State**	**Zip**
1900 S Knoles Dr.	Flagstaff	AZ	86011
Diploma/Degree obtained, if any			
Bachelor's of Science Degree in Engineering			

School Name		From - To (MM/YY – MM/YY)	
Pennco Tech		06/82 - 09/83	
Address	**City**	**State**	**Zip**
3815 Otter St	Bristol	PA	19007
Diploma/Degree obtained, if any			
Associates Degree in Electronic Engineering Technology			

School Name		From - To (MM/YY – MM/YY)	
Peddie School		09/72 - 06/75	
Address	**City**	**State**	**Zip**
677 South Main Street	Hightstown	N.J.	08520
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2002 - Present	[redacted]	Bridgewater	NJ	[redacted]
08/1990 - 05/2002		Roswell	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Getinge Group Logistics Americas, LLC		04/2023 - Present	
Business Address	**City**	**State**	**Zip**
160 Princeton-Heightstown Rd	East Windsor	NJ	08520
Phone	**Title**	**Number of Employed Hours**	
(862) 290-0407	Designated Representative	~ 3,720 hours	
Description of Duties			
Manages the Quality Management System for the Getinge Logistics facility. Trains and mentors employees for GMP and GDP compliance. Creates KPIs and month quality report for upper managerment.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	X	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
05/29/1977	01/12/1978	NJ	Seaside Heighs	Ocean

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
1977 C-298	Seaside Heights Municipal Court

Reason/Charge
Possession of marijuana

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Robert S Prezant	

Name of Business/Industry/Entity

Provide explanation below:

Arrested on 05/29/1977 for possession of marijuana. After investigation was found not guilty and acquitted on 1/12/1978. Please see attached.

Original Signature (electronic copies or stamps not accepted) Date

02/26/2025

Robert S. Prezant

I, Robert S Prezant, **certify that as the MDEG Administrator for**

Getinge Group Logistics Americas, LLC,

that I (initial that you have read and meet the following requirements):

1. RP Have a high school diploma or its equivalent;
2. RP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert S Prezant
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/26/2015
Date

Board Use Only	Date Received:

Discipline 1/12/78
Case No: 1977 C-298
Robert Prezant

7/25/2024

Robert Prezant
[redacted]

To Whom it may concern,

I hope this letter finds you well. I am writing to inform you about the 1977 resolution of a legal matter in which I was involved.

On 5/29/1977, I was unlawfully charged with possession of marijuana. After a thorough investigation and legal proceeding, I am pleased to inform you that I have been acquitted of all charges related to this incident. The acquittal was finalized on 01/12/1978 by Seaside Heights Boro Municipal Court, and the court's decision unequivocally clears me of any wrongdoing.

The case against me was based on possession of Marijuana. However, the court found that there was insufficient evidence to support the charges of possession on my person, leading to my full acquittal. This outcome reinforces my commitment to lawful conduct and my respect for the legal system.

I am providing this information to ensure complete transparency and to clarify any misunderstandings that may have arisen due to the charges. If you require any additional information or documentation regarding the case and its resolution, please do not hesitate to contact me.

Thank you for your understanding and consideration.

Sincerely,

Robert Prezant

New Jersey Courts

Independence • Integrity
Fairness • Quality Service

New Jersey Judiciary
Records Request Form

Request Date	Preferred Delivery
07/25/2024	☐ Pick Up ☐ US Mail ☐ On Site Inspection ☐ Fax ■ Email
Request Needed By	
07/26/2024	

Part A: Requestor Identification

Last Name	First Name	Middle Initial
Prezant	Robert	S

Address	Daytime Telephone (Include area code)
[redacted]	[redacted] ext.

City	State	Zip Code	Fax/Email (optional)
Bridgewater	NJ	08807	[redacted]

Part B: Records Request Processing Location

Please select one of the locations below to process your records request.

County Ocean

Division Department of Correcti

☐ Superior Court Clerk's Office

☐ Appellate Division Clerk's Office

☐ Supreme Court Clerk's Office

☐ Tax Court Clerk's Office

☐ Office of the Administrative Director

■ Municipal Court Seaside Heights Boro

☐ Other _____

Part C: Case Identification

Case Name	Docket/Complaint/Ticket Number*
77-284	

*In Criminal and Municipal Cases, if you do not know the docket number, please provide Defendant's information:

Defendant Name and alias(es), if any	Defendant Birth Date	Last 4 digits of Defendant's Social Security Number
Robert Prezant	[redacted]	[redacted]

Indictment/Arrest Date	Indictment/Accusation/ Complaint/Municipal Number	Appeal Number	Sentencing Date	Name of Sentencing Judge
05/29/1977	001 CNT NJ2421-20A4			

Part D: Records Requested by Division

Please describe records requested as completely as possible. Include any case numbers, dates and names of individuals involved. Attach additional pages if necessary.

Need report for Dispostion Date: 01/12/1978 No: WC77413
Agency: NJ2421-20A4
Dispostion: NOT GUILTY/Acquitted
Boro Mun Ct, Seaqside Heights
001 CNT:NJ2421-20A4
Agency case 77-284
Agency: NJ0152600

Part E: Copy Fees

Copy Fees:	Special Copy Requests - **Additional fees will be charged**		Are you a named party or attorney in this case?
5¢ per page letter size 7¢ per page legal size	☐ Seal only ☐ Certified with Seal	☐ Certified without Seal ☐ Exemplified (includes Seal)	■ Yes ☐ No

For Judiciary Use Only

Disposition	Disposition Date
X Delivered ☐ Denied ☐ Unavailable	1/12/1978

If request is denied or records are unavailable, explain here. Attach additional pages if necessary.

For Tax Court Records return this form to: txctrecords.mailbox@njcourts.gov

For all other requests register and submit this form to: Judiciary Electronic Documents Submission system (JEDS)

For questions please email: SCCO.Mailbox@njcourts.gov

Municipal Court
Borough of Seaside Heights
116 Sherman Avenue
Seaside Heights, New Jersey 08751

Daniel Sahin
Judge

Telephone:
732-830-2202

Fax Number:
732-830-6458

CERTIFIED DISPOSITION

STATE OF NEW JERSEY
v.

Robert S. Prezant

CRIMINAL (X) TRAFFIC ( )
BOROUGH ORDINANCE ( )

DOCKET NUMBER	1977 C-298
SUMMONS NUMBER	
CDR NUMBER	
OFFENSE	24:21-20(A)(4) – Repealed: related to prohibition of and penalties for possession, use, or being under influence of controlled dangerous substance
AMENDED OFFENSE	N/A
ARREST/OFFENSE DATE	05/29/1977
COURT DATE	01/12/1978
HEARD BY	N/A

DISPOSITION

GUILTY:	NOT GUILTY: X	DISMISSED:	OTHER:

FINES:	COURT COSTS:
VCCB:	SNF:
DWI FUND:	UNSAFE DRIVING FUND:
CONDITIONAL DISCHARGE:	DEDR:
DARE:	LAB:
OTHER:	OTHER:

DL SUSPENSION:	CONDITIONAL DISCHARGE:
IDRC:	PROBATION:
COMMUNITY SERVICE:	COUNTY JAIL:
OTHER:	OTHER:

REMARKS:

DATED: 07/25/2024

Lea Kirchgessner

SEASIDE HEIGHTS MUNICIPAL COURT
LEA KIRCHGESSNER
DEPUTY COURT ADMINISTRATOR

I certify this court record is a true copy of the original record on file with this court.
Lea Kirchgessner

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Getinge Group Logistics Americas, LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 160 Princeton-Hightstown Road

City: East Windsor State: NJ Zip: 08520

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.getinge.com

Licensing Company Email: GGL@SLSNY.com

Section 2: Personal Information

First: Robert Middle: S Last: Prezant

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Bridgewater State: NJ Zip: [redacted]

Telephone: [redacted] Email: robert.prezant@getinge.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Northern Arizona University		08/96 - 12/99	
Address	**City**	**State**	**Zip**
1900 S Knoles Dr.	Flagstaff	AZ	86011
Diploma/Degree obtained, if any			
Bachelor's of Science Degree in Engineering			

School Name		From - To (MM/YY – MM/YY)	
Pennco Tech		06/82 - 09/83	
Address	**City**	**State**	**Zip**
3815 Otter St	Bristol	PA	19007
Diploma/Degree obtained, if any			
Associates Degree in Electronic Engineering Technology			

School Name		From - To (MM/YY – MM/YY)	
Peddie School		09/72 - 06/75	
Address	**City**	**State**	**Zip**
677 South Main Street	Hightstown	N.J.	08520
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2002 - Present	[redacted]	Bridgewater	NJ	[redacted]
08/1990 - 05/2002		Roswell	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Getinge Group Logistics Americas, LLC				From - To (MM/YY – MM/YY): 04/2023 - Present
Business Address: 160 Princeton-Hightstown Road		City: East Windsor	State: NJ	Zip: 08520
Phone: (609) 422-9547	Title: Designated Representative			Number of Employed Hours: ~ 3,720 hours
Description of Duties: Manages the Quality Management System for the Getinge Logistics facility. Trains and mentors employees for GMP and GDP compliance. Creates KPIs and month quality report for upper managerment.				
Business Name: Mirion Technologies				From - To (MM/YY – MM/YY): 10/2021 - 04/2023
Business Address: 7 Vreeland Rd		City: Florham Park	State: NJ	Zip: 07932
Phone: (201) 825-9500	Title: Quality / Regulatory Manager			Number of Employed Hours: ~ 3,120 hours
Description of Duties: Manages quality control, quality assurance and regulatory activities at the site. This includes incoming and in-process inspection, sampling, vendor and final testing and inspection of finished products, repairs, service as well as adherence to established quality standards and specifications for Nuclear Medial Devices. Responsible for identifying and recommending continuous quality control improvements. Must maintain GMP compliance in accordance with the company's Standard Operating Procedures.				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				
Business Name				From - To (MM/YY – MM/YY)
Business Address		City	State	Zip
Phone	Title			Number of Employed Hours
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Robert S Prezant, **certify that as the designated representative for**

Getinge Group Logistics Americas, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert S Prezant

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/16/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert S Prezant

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/26/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Mercer

I, Robert S Prezant, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature Robert S Prezant

02/26/2025

Date

Subscribed and Sworn to before me this 26 day of FEBRUARY 2025

Stephanie A Zeltzer

Notary Public Signature

(Seal)

STEPHANIE A ZELTZER
Notary Public, State of New Jersey
Comm. # 50228830
My Commission Expires 1/06/2030

Employee List

Sulerki Jiminian
GIOVANNY MELENDEZ
BERNARDO ESPINOSA HERNANDEZ
SANDRA ZAMORA
CLAUDE FOUSHEE
SILENNI ALTAGRACIA MARTINEZ
NANCY JOSEFINA VILCHEZ
ROSA MARINA FIGUEROA
FELICITAS ELIZABETH SILVA
JOCELYN LUCRECIO
TERESA ALBERTO DE PALACIOS
ANGELA STEFANIA HERNANDEZ
Dennis Thomas
Deybi Jaques
Mayra Santiago
Genesis Cruz
Mohamed Turay
Yadira Figueroa Calix
Benjamin Martinez David
Gladys Posada
Reynaldo Larios Bobadilla
Danarauris Scarlet Baez De Los Santos
Tha Khuon
Yusef Henry
Mayra Arias Romero
Rosalia Cabrera Rodriguez
Martha Velez
Kamleshgir Goswami
Narendrakumar Patel
Sandra Santos Zuniga
Michael Adolphe
Neha Patel
Yessenia A. Aracely
Tomas Matos
Gilberto Antonio Nunez Lithgow
Donnie Mallory
Francis Balinski
Kelvin Dilone
Walter Gomez
Pedro Dejesus
Mayri Ruiz
Ricardo Silva
Dulce Maria Flores Martinez
Angel Espada
Justin Westmoreland
Alvaro Rivers

Ravana El
Jose Camacho
Chris Olsen
Rafael Brito
Claire Lang
George Skeens
Pete Diaz
Frank Kozar
Steve Aselta
Myron Barnes
Karen Bartz
Marcus Batiste
Kathy Boyd
Jazmen Fields
Matt Kendrick
Mike Kotsch
Sue Nashburn
Shevon Pottinger
Robert Prezant
Dial Adams
Michael Burns
Stephanie Seltzer
Stephen Dudek
Michael Kane
Paola Gomez

4EE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Glenmark Pharmaceuticals Inc., USA

Physical Address: 749 South PA Route 100 Suite A

City: Allentown State: PA Zip: 18106

Mailing Address (if different from physical address): 750 Corporate Drive

City: Mahwah State: NJ Zip: 07430

Telephone: (551) 262-9770 Website: https://www.glenmarktherapeutics.com/

Name of Designated Representative (DR): Jesse Haring

Licensing Company Email: NewLicensing@glenmarkpharma.com DR Email: jesse.haring@glenmarkgharma.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☒ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☒ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Rajen Sharma.

Original Signature (electronic, copies or stamps not accepted)

12/19/2024

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Please see attached for Top 4 Wholesalers.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Glenmark Holding SA

Corporation/Organization Name: Glenmark Pharmaceuticals Inc., USA

Mailing Address: 750 Corporate Drive

City: Mahwah State: NJ Zip: 07430

Telephone: +41325449450 Email: licensing@glenmarkpharma.com

Contact Person Name: Marc Kikuchi

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	x	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Glenmark Pharmaceuticals Inc., USA
Facility Name

Rajeev Sharma
Print Name of Authorized Person Submitting Application

Rajeev Sharma.
Original signature of Authorized Person (copies or stamps not accepted)

12/19/2024
Date

Board Use Only	Date Received: 12/26/25	Amount: $1000 ck 3907

Top 4 Customer By Volume – January 2025	Address
AmerisourceBergen	8 EASTAGATE AVENUE Little Island CK T45NF24
Mckesson Corporation	6555 State Highway 161 Irivne, TX 75039
CVS	PO BOX 3120 Woonsocket, RI 2895
Cardinal Health	5995 Commerce Center Drive, Groveport, OH 43125

An official website of the United States government Here's how you know

FDA

Home ▶ Drug Databases ▶ NDC ▶ Search Result

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Current through February 10, 2025

You have searched Finished drug products

Search Results: *'glenmark'*

Back to Search Page

Showing 1 to 250 of 323 entries (filtered from 341 total entries) Show entries

Proprietary Name	ANDA Package Code	Strength	Dosage Form	Route	Application Number / Monograph Id	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date
Fluconazole	68462-101-10	50mg/1	TABLET	ORAL	ANDA077253	Glenmark Pharmaceuticals Inc., USA	68462-101	Fluconazole	FLUCONAZOLE	HUMAN PRESCRIPTION DRUG	01/25/2006	N/A
Fluconazole	68462-101-30	50mg/1	TABLET	ORAL	ANDA077253	Glenmark Pharmaceuticals Inc., USA	68462-101	Fluconazole	FLUCONAZOLE	HUMAN PRESCRIPTION DRUG	01/25/2006	N/A
Fluconazole	68462-102-10	100mg/1	TABLET	ORAL	ANDA077253	Glenmark Pharmaceuticals Inc., USA	68462-102	Fluconazole	FLUCONAZOLE	HUMAN PRESCRIPTION DRUG	01/25/2006	N/A
Fluconazole	68462-102-30	100mg/1	TABLET	ORAL	ANDA077253	Glenmark Pharmaceuticals Inc., USA	68462-102	Fluconazole	FLUCONAZOLE	HUMAN PRESCRIPTION DRUG	01/25/2006	N/A
Fluconazole	68462-104-10	200mg/1	TABLET	ORAL	ANDA077253	Glenmark Pharmaceuticals Inc., USA	68462-104	Fluconazole	FLUCONAZOLE	HUMAN PRESCRIPTION DRUG	01/25/2006	N/A
Fluconazole	68462-104-30	200mg/1	TABLET	ORAL	ANDA077253	Glenmark Pharmaceuticals Inc., USA	68462-104	Fluconazole	FLUCONAZOLE	HUMAN PRESCRIPTION DRUG	01/25/2006	N/A
Ondansetron	68462-105-30	4mg/1	TABLET, FILM COATED	ORAL	ANDA077535	Glenmark Pharmaceuticals Inc., USA	68462-105	Ondansetron	ONDANSETRON HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/25/2007	N/A
Ondansetron	68462-105-33	4mg/1	TABLET, FILM COATED	ORAL	ANDA077535	Glenmark Pharmaceuticals Inc., USA	68462-105	Ondansetron	ONDANSETRON HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/25/2007	N/A
Ondansetron	68462-106-30	8mg/1	TABLET, FILM COATED	ORAL	ANDA077535	Glenmark Pharmaceuticals Inc., USA	68462-106	Ondansetron	ONDANSETRON HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/25/2007	N/A
Ondansetron	68462-106-33	8mg/1	TABLET, FILM COATED	ORAL	ANDA077535	Glenmark Pharmaceuticals Inc., USA	68462-106	Ondansetron	ONDANSETRON HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	06/25/2007	N/A
Topiramate	68462-108-05	25mg/1	TABLET, FILM COATED	ORAL	ANDA077827	Glenmark Pharmaceuticals Inc., USA	68462-108	Topiramate	TOPIRAMATE	HUMAN PRESCRIPTION DRUG	07/30/2020	N/A
Topiramate	68462-108-10	25mg/1	TABLET, FILM COATED	ORAL	ANDA077827	Glenmark Pharmaceuticals Inc., USA	68462-108	Topiramate	TOPIRAMATE	HUMAN PRESCRIPTION DRUG	03/27/2009	N/A

Glenmark
A new way for a new world

Description of Operations

Glenmark Pharmaceuticals Inc, USA is a Self-Distributor of Prescription Drugs and Controlled Substance products. Glenmark Pharmaceuticals Inc, USA's distributes its own-labeled products (Labeler Code 68462) to Wholesalers, Retail Pharmacies, and Specialty Pharmacies throughout the United States.

Distribution:

Glenmark Pharmaceuticals Inc, USA
749 South PA Route 100 Suite A, Allentown, PA 18106.

Hours of operation are 5:30 am – 6:30pm Monday through Friday.
This location has 45 employees working full time during normal operational hours.
Facility Square Footage is 160,000 sq. ft.

Glenmark Pharmaceuticals Inc, USA's *does not manufacture its own products*.

Manufacturers

Glenmark uses the following manufacturers to produce and package finished drug product:

CMO Name: Douglas Manufacturing Limited
Address: Corner Central Park Drive and Te Pai Place, Lincoln, Auckland, New Zealand 0610
FEIN: 3005641565

CMO Name: Glenmark Pharmaceuticals Limited
Address: Plot No. S-7, Colvale-Bardez Industrial Estate, Colvale, Goa, India 403513
FEIN: 3004672766

CMO Name: Glenmark Pharmaceuticals Limited
Address: Village Kishanpura, Baddi Nalagarh Road, Solan, Baddi, Himachal Pradesh, India 173205
FEIN: 3005757050

CMO Name: Glenmark Pharmaceuticals Limited
Address: Plot No. 2, Phase-2, Pharma Zone SEZ Pithampur, Dhar, Madhya Pradesh, India, 454755
FEIN: 3008565058

CMO Name: Glenmark Pharmaceuticals Limited
Address: Plot No. B-25, MIDC, Shendra, Aurangabad, Maharashtra, India 431154
FEIN: 3009915929



Company Information

Glenmark Pharmaceuticals Inc., USA
749 South PA Route 100 Suite A
Allentown, PA 18106
Phone: (551) 262-9770
Website: https://www.glenmarktherapeutics.com/
E-mail: NewLicensing@glenmarkpharma.com

FEIN: 75-3102019
State of Formation: DE
Date Incorporated: 12/11/2002
File Number: 3600881

Ownership Information

Glenmark Pharmaceuticals Inc., USA is 100% owned by Glenmark Holding SA

Parent: Glenmark Holding SA
Parent Company Address: Chemin de la Combeta 5, La Chaux-de-Fonds Switzerland CH-2300
Parent Company Phone: +41325449450
Parent Company FEIN: N/A Foreign

Officers

Marc Kikuchi, CEO, President & Business Head North America
Business Address: 750 Corporate Drive, Mahwah, NJ 07430
Business Phone: (201) 684-8000

Rajeev Sharma, Senior Vice President, Treasurer and Chief Financial Officer
Business Address: 750 Corporate Drive, Mahwah, NJ 07430
Business Phone: (201) 684-8000

Laura Lester, SVP & General Counsel
Business Address: 750 Corporate Drive, Mahwah, NJ 07430
Business Phone: (201) 684-8000

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "GLENMARK PHARMACEUTICALS INC., USA" IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE ELEVENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "GLENMARK PHARMACEUTICALS INC., USA" WAS INCORPORATED ON THE ELEVENTH DAY OF DECEMBER, A.D. 2002.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

3600881 8300

SR# 20243652882

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204360974

Date: 09-11-24

Pennsylvania
Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

Glenmark Pharmaceuticals Inc., USA 749 South PA Route 100, Suite A; Allentown, PA 18106
Certificate(s): **3000010702** issued: 12/09/2024 expires: 12/31/2025; **8000003209** issued: 12/09/2024 expires: 12/31/2025

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version

Database Version

Certificate of Licensure

Certificate No. 8000003209
(A certificate starting with a number 4, 5 or 6 does not permit the possession or sale of controlled substances or prescription drugs.)

Category:

Wholesaler/Distributor

Drug & Device Registration
2525 N. 7th ST.
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

GLENMARK PHARMACEUTICALS INC., USA
749 SOUTH PA
ROUTE 100, SUITE A
ALLENTOWN, PA 18106

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: December 09, 2024
Expiration Date: The Last Day of December, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Certificate of Registration

Certificate No. 3000010702
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Distributor (Prescription)

Drug & Device Registration
2525 N. 7th ST.
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

GLENMARK PHARMACEUTICALS INC., USA
749 SOUTH PA
ROUTE 100, SUITE A
ALLENTOWN, PA 18106

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: December 09, 2024
Expiration Date: The Last Day of December, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

Pennsylvania
Department of Health

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RG0696128	09-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-25-2025

GLENMARK PHARMACEUTICALS INC., USA
749 S ROUTE 100
ALLENTOWN, PA 18106

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RG0696128	09-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-25-2025

GLENMARK PHARMACEUTICALS INC., USA
749 S ROUTE 100
ALLENTOWN, PA 18106

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RG0696128	09-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	03-25-2025

GLENMARK PHARMACEUTICALS INC., USA
749 S ROUTE 100
ALLENTOWN, PA 18106

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

GENERAL SURETY RIDER

To be attached and form a part of

Bond No. **US00141843SU24A**

For NV 25k Pharmaceutical Wholesaler

Dated effective 08/27/2024 (MONTH, DAY, YEAR)

Executed by Glenmark Pharmaceuticals Inc., USA, as Principal, (PRINCIPAL)

And by XL Specialty Insurance Company, as Surety, (SURETY)

And in favor of Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Add Location	301 Island Road, Mahwah, NJ 07430	301 Island Road, Mahwah, NJ 07430 - 749 South PA Route 100 Suite A, Allentown, PA 18106

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **01/27/2025**

(MONTH, DAY, YEAR)

Signed and Sealed **01/27/2025**

(MONTH, DAY, YEAR)

Glenmark Pharmaceuticals Inc., USA
PRINCIPAL

XL SPECIALTY INSURANCE COMPANY CORPORATE SEAL DELAWARE

BY _____

TITLE

XL Specialty Insurance Company
SURETY

BY _____

Doritza Mojica, ATTORNEY-IN-FACT

Power of Attorney
XL Specialty Insurance Company
XL Reinsurance America Inc.

BOND NUMBER US00139384SU24A
LIMITED POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That XL Specialty Insurance Company, a Delaware insurance companies with offices located at 505 Eagleview Blvd., Exton, PA 19341, and XL Reinsurance America Inc., a New York insurance company with offices located at 70 Seaview Avenue, Stamford, CT 06902, , do hereby nominate, constitute, and appoint:

Doritza Mojica

each its true and lawful Attorney(s)-in-fact to make, execute, attest, seal and deliver for and on its behalf, as surety, and as its act and deed, where required, any and all bonds and undertakings in the nature thereof, , for the penal sum of no one of which is in any event to exceed $100,000,000.00.

Such bonds and undertakings, when duly executed by the aforesaid Attorney (s) - in - Fact shall be binding upon each said Company as fully and to the same extent as if such bonds and undertakings were signed by the President and Secretary of the Company and sealed with its corporate seal.

The Power of Attorney is granted and is signed by facsimile under and by the authority of the following Resolutions adopted by the Board of Directors of each of the Companies on the 26th day of July 2017.

RESOLVED, that Gary Kaplan, Daniel Riordan, Maria Duhart, Gregory Boal and Kevin Mirsch are hereby appointed by the Board as authorized to make, execute, seal and deliver for and on behalf of the Company, any and all bonds, undertakings, contracts or obligations in surety or co-surety with others and that the Secretary or any Assistant Secretary of the Company be and that each of them hereby is authorized to attest the execution of any such bonds, undertakings, contracts or obligations in surety or co-surety and attach thereto the corporate seal of the Company.

RESOLVED, FURTHER, that Gary Kaplan, Daniel Riordan, Maria Duhart, Gregory Boal and Kevin Mirsch each is hereby authorized to execute powers of attorney qualifying the attorney named in the given power of attorney to execute, on behalf of the Company, bonds and undertakings in surety or co-surety with others, and that the Secretary or any Assistant Secretary of the Company be, and that each of them is hereby authorized to attest the execution of any such power of attorney, and to attach thereto the corporate seal of the Company.

RESOLVED, FURTHER, that the signature of such officers named in the preceding resolutions and the corporate seal of the Company may be affixed to such powers of attorney or to any certificate relating thereto by facsimile, and any such power of attorney or certificate bearing such facsimile signatures or facsimile seal shall be thereafter valid and binding upon the Company with respect to any bond, undertaking, contract or obligation in surety or co-surety with others to which it is attached.

IN WITNESS WHEREOF, the XL SPECIALTY INSURANCE COMPANY has caused its corporate seal to be hereunto affixed, and these presents to be signed by its duly authorized officers this April 13th, 2018.

XL SPECIALTY INSURANCE COMPANY

XL SPECIALTY INSURANCE COMPANY CORPORATE SEAL DELAWARE

by: Gregory Boal, VICE PRESIDENT

STATE OF PENNSYLVANIA
COUNTY OF CHESTER

Attest: Kevin M. Mirsch, ASSISTANT SECRETARY

On this 13th day of April, 2018, before me personally came Gregory Boal to me known, who, being duly sworn, did depose and say: that he is Vice President of XL SPECIALTY INSURANCE COMPANY, described in and which executed the above instrument; that he knows the seals of said Companies; that the seals affixed to the aforesaid instrument is such corporate seals and were affixed thereto by order and authority of the Boards of Directors of said Companies; and that he executed the said instrument by like order.

REBECCA C. SHALHOUB COMMONWEALTH OF PENNSYLVANIA NOTARY PUBLIC

Commonwealth of Pennsylvania - Notary Seal
Rebecca C. Shalhoub, Notary Public
Northampton County
My commission expires April 28, 2028
Commission number 1268765
Member, Pennsylvania Association of Notaries

Rebecca C. Shalhoub, NOTARY PUBLIC

SB0042

STATE OF PENNSYLVANIA
COUNTY OF CHESTER

I, Kevin M. Mirsch, Assistant Secretary of XL SPECIALTY INSURANCE COMPANY, a corporation of the State of Delaware, do hereby certify that the above and forgoing is a full, true and correct copy of a Power of Attorney issued by said Companies, and that I have compared same with the original and that it is a correct transcript therefrom and of the whole of the original and that the said Power of Attorney is still in full force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation, at the City of Exton, this 27th day of January, 2025

XL SPECIALTY INSURANCE COMPANY CORPORATE SEAL DELAWARE

Kevin M. Mirsch, ASSISTANT SECRETARY

IN WITNESS WHEREOF, XL REINSURANCE AMERICA INC. has caused its corporate seal to be hereunto affixed, and these presents to be signed by its duly authorized officers this 13th day of April, 2018.

XL REINSURANCE AMERICA INC. CORPORATE SEAL NEW YORK

XL REINSURANCE AMERICA INC.

by: Gregory C Boal

Gregory Boal, VICE PRESIDENT

Attest: Kevin M. Mirsch

Kevin M. Mirsch, ASSISTANT SECRETARY

STATE OF PENNSYLVANIA
COUNTY OF CHESTER

On this 13th day of April, 2018, before me personally came Gregory Boal to me known, who, being duly sworn, did depose and say: that he is Vice President of XL REINSURANCE AMERICA INC., described in and which executed the above instrument; that he knows the seal of said Corporation; that the seal affixed to the aforesaid instrument is such corporate seal and was affixed thereto by order and authority of the Board of Directors of

REBECCA C. SHALHOUB COMMONWEALTH OF PENNSYLVANIA NOTARY PUBLIC

Commonwealth of Pennsylvania - Notary Seal
Rebecca C. Shalhoub, Notary Public
Northampton County
My commission expires April 28, 2028
Commission number 1268765
Member, Pennsylvania Association of Notaries

Rebecca C. Shalhoub, NOTARY PUBLIC

STATE OF PENNSYLVANIA
COUNTY OF CHESTER

I, Kevin M. Mirsch, Assistant Secretary of XL REINSURANCE AMERICA INC. a corporation of the State of New York, do hereby certify that the person who executed this Power of Attorney, with the rights, respectively of XL REINSURANCE AMERICA INC., do hereby certify that the above and forgoing is a full, true and correct copy of a Power of Attorney issued by said Corporation, and that I have compared same with the original and that it is a correct transcript therefrom and of the whole original and that the said Power of Attorney is still in full force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seal of said Corporation, at the City of Exton, this 27th day of January, 2025

XL REINSURANCE AMERICA INC. CORPORATE SEAL NEW YORK

Kevin M. Mirsch, ASSISTANT SECRETARY

This Power of Attorney may not be used to execute any bond with an inception date 4/28/2028 12:00:00AM

SB0042

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 107308002

Application/License No. WH02353

Glenmark Pharmaceuticals Inc., USA (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 301 Island Road, Mahwah, NJ 07430 (Address of Applicant/Principal), as PRINCIPAL, and Travelers Casualty and Surety Company of America (Surety Company), a corporation organized under the laws of the state of CT (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Tower Square , Hartford, CT 06183 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ~~ONE HUNDRED THOUSAND~~ Twenty* DOLLARS ($~~100,000.00~~), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on August 27, 2020 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $~~100,000.00~~** payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

* Five Thousand and 00/100 Dollars ($25,000.00)

**$25,000.00

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 27th day of August, 2020.

APPLICANT/PRINCIPAL
Glenmark Pharmaceuticals Inc., USA

By: _____
Authorized Representative

SURETY COMPANY
Travelers Casualty and Surety Company of America

By: _____
Surety Company's Representative

Tanya Nguyen, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Hany Rizkalla

Witness Thomas Callaghan

SIGNED and SEALED in the presence of:

Witness Cassandra Baez

Witness Ian Williams

Countersigned by:

Nevada Resident Agent N/A

DONNA-MARIE WALTERS
NOTARY PUBLIC OF NEW JERSEY
Commission # 50133156
My Commission Expires 7/30/2025

Sworn to and subscribed before me this 10 day of SEPT, 20 20

TRAVELERS

Travelers Casualty and Surety Company of America
Travelers Casualty and Surety Company
St. Paul Fire and Marine Insurance Company
Farmington Casualty Company

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That Travelers Casualty and Surety Company of America, Travelers Casualty and Surety Company, St. Paul Fire and Marine Insurance Company, and Farmington Casualty Company are corporations duly organized under the laws of the State of Connecticut (herein collectively called the "Companies"), and that the Companies do hereby make, constitute and appoint Tanya Nguyen of **Southfield, MI** , their true and lawful Attorney-in-Fact to sign, execute, seal and acknowledge any and all bonds, recognizances, conditional undertakings and other writings obligatory in the nature thereof on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law, including the following bond:

Surety Bond No.: 107308002
OR
Project Description: Pharmaceutical Wholesaler Surety Bond

Principal: Glenmark Pharmaceuticals Inc., USA
Obligee: Nevada State Board of Pharmacy

IN WITNESS WHEREOF, the Companies have caused this instrument to be signed, and their corporate seals to be hereto affixed, this **6th** day of **May, 2019.**

State of Connecticut

By: _____
Robert L. Raney, Senior Vice President

City of Hartford ss.

On this the **6th** day of **May, 2019,** before me personally appeared **Robert L. Raney,** who acknowledged himself to be the Senior Vice President of each of the Companies, and that he, as such, being authorized so to do, executed the foregoing instrument for the purposes therein contained by signing on behalf of said Companies by himself as a duly authorized officer.

IN WITNESS WHEREOF, I hereunto set my hand and official seal.

My Commission expires the **30th** day of **June, 2021**

_____
Anna P. Nowik, Notary Public

This Power of Attorney is granted under and by the authority of the following resolutions adopted by the Boards of Directors of each of the Companies, which resolutions are now in full force and effect, reading as follows:

RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President, any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary may appoint Attorneys-in-Fact and Agents to act for and on behalf of the Company and may give such appointee such authority as his or her certificate of authority may prescribe to sign with the Company's name and seal with the Company's seal bonds, recognizances, contracts of indemnity, and other writings obligatory in the nature of a bond, recognizance, or conditional undertaking, and any of said officers or the Board of Directors at any time may remove any such appointee and revoke the power given him or her; and it is

FURTHER RESOLVED, that the Chairman, the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President may delegate all or any part of the foregoing authority to one or more officers or employees of this Company, provided that each such delegation is in writing and a copy thereof is filed in the office of the Secretary; and it is

FURTHER RESOLVED, that any bond, recognizance, contract of indemnity, or writing obligatory in the nature of a bond, recognizance, or conditional undertaking shall be valid and binding upon the Company when (a) signed by the President, any Vice Chairman, any Executive Vice President, any Senior Vice President or any Vice President, any Second Vice President, the Treasurer, any Assistant Treasurer, the Corporate Secretary or any Assistant Secretary and duly attested and sealed with the Company's seal by a Secretary or Assistant Secretary; or (b) duly executed (under seal, if required) by one or more Attorneys-in-Fact and Agents pursuant to the power prescribed in his or her certificate or their certificates of authority or by one or more Company officers pursuant to a written delegation of authority; and it is

FURTHER RESOLVED, that the signature of each of the following officers: President, any Executive Vice President, any Senior Vice President, any Vice President, any Assistant Vice President, any Secretary, any Assistant Secretary, and the seal of the Company may be affixed by facsimile to any Power of Attorney or to any certificate relating thereto appointing Resident Vice Presidents, Resident Assistant Secretaries or Attorneys-in-Fact for purposes only of executing and attesting bonds and undertakings and other writings obligatory in the nature thereof, and any such Power of Attorney or certificate bearing such facsimile signature or facsimile seal shall be valid and binding upon the Company and any such power so executed and certified by such facsimile signature and facsimile seal shall be valid and binding on the Company in the future with respect to any bond or understanding to which it is attached.

I, **Kevin E. Hughes**, the undersigned, Assistant Secretary of each of the Companies, do hereby certify that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which remains in full force and effect.

Dated this 27th day of August, 2020.

_____
Kevin E. Hughes, Assistant Secretary

To verify the authenticity of this Power of Attorney, please call us at 1-800-421-3880.
Please refer to the above-named Attorney-in-Fact and the details of the bond to which this Power of Attorney is attached.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Glenmark Pharmaceuticals Inc., USA

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 749 South PA Route 100 Suite A

City Allentown State PA Zip 18106

Mailing Address (if different from physical address) 750 Corporate Drive

City Mahwah State NJ Zip 07430

Telephone (551) 262-9770 Website https://www.glenmarktherapeutics.com/

Licensing Company Email NewLicensing@glenmarkpharma.com

Section 2: Personal Information

First Jesse Middle David Last Haring

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 749 S Rte 100

City Allentown State PA Zip 18106

Telephone [redacted] Email jesse.haring@glenmarkgharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Gwynedd-Mercy College, School of Business		01/09 - 01/2012	
Address	City	State	Zip
1325 Sumneytown Pike	Gwynedd Valley	PA	19437
Diploma/Degree obtained, if any			
Bachelor of Business Administration and Organizational Management			

School Name		From - To (MM/YY – MM/YY)	
Quakertown Community High School		09/1999 - 06/2002	
Address	City	State	Zip
600 Park Ave	Quakertown	PA	18951
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/23 - Present	[redacted]	Green lane	PA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04/20 - 11/05		Quakertown	PA	
From - To (MM/YY – MM/YY)		City	State	
10/13 - 04/20		Warminster,	PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Jesse D. Haring

[redacted]

EXPERIENCE:

Glenmark Pharmaceuticals

Manager Transportation and Analytics September 2024 – Present

- Planning and optimizing shipping modes and lanes.
- Managing outbound distribution staff to ensure compliance.
- Collaborating with existing and onboarding new contract carriers.
- Manage shipment track and trace to ensure end to end supply chain visibility.

TEVA PHARMACEUTICALS, North Wales, PA

Supply Chain Analyst I, II, and III April 2017 – September 2024

- Develop a domestic logistics control tower to support and oversee distribution center operations.
- Analyze transportation data to identify cost savings opportunities and reduction in carrier lead time.
- Collaborate with the distribution operational excellence team to create a continuous improvement (CI) strategy.
- Identify delays, adjust schedules, and expedite shipments based upon identified business needs and carrier performance metrics.
- Coordinate functions with other departments, to include Supply Chain Operations, Customer Service, Purchasing Department, and Production Planning.
- Investigate lost and damaged federally regulated controlled drugs to ensure supply chain integrity.

Logistics Coordinator December 2012 – April 2017

- Recognized most cost efficient carriers and coordinate transit of pharmaceuticals to wholesale suppliers.
- Developed, monitored and reported on carrier performance metrics. Continuously sought opportunities for cost savings and service improvements.
- Managed inbound ocean, air, and ground shipments from manufacturing facilities, both domestic and abroad.
- Aided procurement in shipping pharmaceutical packaging equipment in a cost efficient manner without sacrificing service level.

Receiving Group Lead January 2009 – December 2012

- Provided import and export documentation to the receiving team for inventory entry into the Warehouse Management System (WMS).
- Monitored shipping transfers flowing from satellite distribution centers to the main distribution center to confirm adequate carrier performance.
- Delegated work assignments to five Material Handlers in order to maximize organizational efficiency.
- Counseled Material Handlers on arising issues related to daily operation activities.

Shipping Group Lead October 2006 – January 2009

- Supervised 20 Material Handlers to ensure individual performance and group efficiency.
- Coordinated with freight carriers to acquire freight pickups in a timely manner.
- Promoted to Group Lead position, with leadership responsibilities, due to a demonstrated diligent work ethic and growing knowledge of the Warehouse Management System (WMS).

EDUCATION:

Gwynedd-Mercy College, School of Business, Gwynedd Valley, PA

Bachelor of Business Administration and Organizational Management

Graduation, January 2012

GPA: 3.86

SKILLS:

- Microsoft Office Suite
- Manhattan Associates Warehouse Management System (WMS)
- Freight bill pay resolution
- TL spot bidding via TMS (Constellation)
- TMS Optimization
- Freight bidding (TL and LTL)
- Hazmat certified, DOT and IATA
- FedEx Ship Manager
- TranzAct Technologies logistics support software
- SAP ERP software
- Oracle ERP software

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Glenmark Pharmaceuticals, Inc.			09/2024 - Present	
Business Address		**City**	**State**	**Zip**
749 South PA Route 100 Suite A		Allentown	PA	18106
Phone	**Title**		**Number of Employed Hours**	
5512629770	Manager Transportation and Analytics		40/week	
Description of Duties				
Please see attached Resume.				

Business Name			From - To (MM/YY – MM/YY)	
Teva Pharmaceuticals, Inc.			04/17 - 09/24	
Business Address		**City**	**State**	**Zip**
1090 Horsham Rd		North Wales	PA	19454
Phone	**Title**		**Number of Employed Hours**	
	Supply Chain Analyst I, II, and III		40/week	
Description of Duties				
Please see attached Resume.				

Business Name			From - To (MM/YY – MM/YY)	
Teva Pharmaceuticals, Inc.			12/12 - 04/17	
Business Address		**City**	**State**	**Zip**
1090 Horsham Rd		North Wales	PA	19454
Phone	**Title**		**Number of Employed Hours**	
	Logistics Coordinator		40/week	
Description of Duties				
Please see attached Resume.				

Business Name			From - To (MM/YY – MM/YY)	
Teva Pharmaceuticals, Inc.			01/09 - 12/12	
Business Address		**City**	**State**	**Zip**
1090 Horsham Rd		North Wales	PA	19454
Phone	**Title**		**Number of Employed Hours**	
	Receiving Group Lead		40/week	
Description of Duties				
Please see attached Resume.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		x
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

12/19/24
Date

I, Jesse Haring, **certify that as the designated representative for**

Glenmark Pharmaceuticals Inc., USA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JDH I am at least 21 years of age;
3. JDH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JDH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JDH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JDH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JDH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jesse Haring

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/19/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jesse Haring

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Bergen

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/29/25

Date

Subscribed and Sworn to before me this 29th day of January

Lisa D. Pingue

Notary Public Signature

LISA D. PINGUE
NOTARY PUBLIC OF NEW JERSEY
Commission # 50139259
My Commission Expires 10/2/2025

(Seal)

Glenmark Pharmaceuticals Inc., USA
749 South PA Route 100 Suite A
Allentown, PA 18106

Employee List – 2/12/2025

Ravishankar Kannan
Jesse Haring
Piotr Pregner

4FF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Harrow Eye, LLC

Physical Address: 1A Burton Hills Blvd., Ste. 200

City: Nashville State: TN Zip: 37215

Mailing Address (if different from physical address): 1A Burton Hills Blvd., Ste. 200

City: Nashville State: TN Zip: 37215

Telephone: (615) 733-4730 Website: www.harrow.com

Name of Designated Representative (DR): Andrew Boll

Licensing Company Email: compliance.harroweye@pharma.solutions DR Email: Aboll@harrowinc.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: OTC Drugs	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Harrow, Inc.

Corporation/Organization Name: Harrow Eye, LLC

Mailing Address: 1A Burton Hills Blvd., Ste. 200

City: Nashville State: TN Zip: 37215

Telephone: (615) 733-4730 Email: Aboll@harrowinc.com

Contact Person Name: Brett Burrell

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Harrow Eye, LLC

Facility Name

Andrew Boll

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/25/2024

Date

Board Use Only	Date Received: 12/17/24	Amount: $1000 ck 1079

HARROW

Your patients. Our purpose.

Harrow Eye, LLC's List of Officers

Mark Baum, Chief Executive Officer

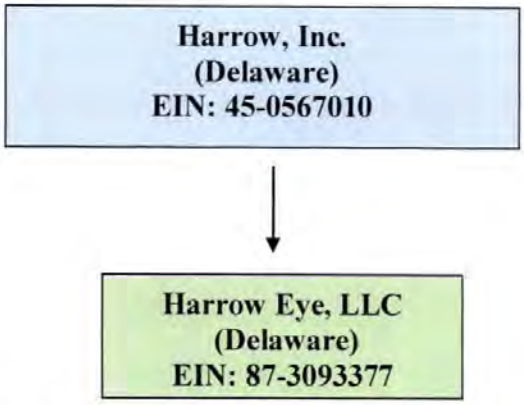
[redacted]

Andrew Boll, Chief Financial Officer, and Secretary

[redacted]

HARROW
Your patients. Our purpose.

CORPORATE STRUCTURE/OWNERSHIP



- Harrow Eye, LLC is a Delaware limited liability company.
- Harrow, Inc. is a Delaware public corporation which owns 100% of the ownership interest in Harrow Eye, LLC.

HARROW EYE, LLC OFFICERS

Name	Position	Requested Information
Mark Baum	CEO	1A Burton Hills Blvd, STE 200 Nashville, TN 37215 (615) 733-4730
Andrew Boll	CFO and Secretary	1A Burton Hills Blvd, STE 200 Nashville, TN 37215 (615) 733-4730

HARROW

Your patients. Our purpose.

Harrow Eye, LLC Top 4 Suppliers	
Supplier	**Corporate Address**
Cardinal	7000 Cardinal Place Dublin, OH 43017
McKesson	6555 State Hwy 161 Irving, TX 75039
AmerisourceBergen	1 West First Avenue Conshohocken, PA 19428
Western Wellness	1555 Doolittle Dr. STE 170 San Leandro, CA 94577-2239

Labeler - Harrow Eye, LLC (118526951) **NDC Labeler Code:** 82667

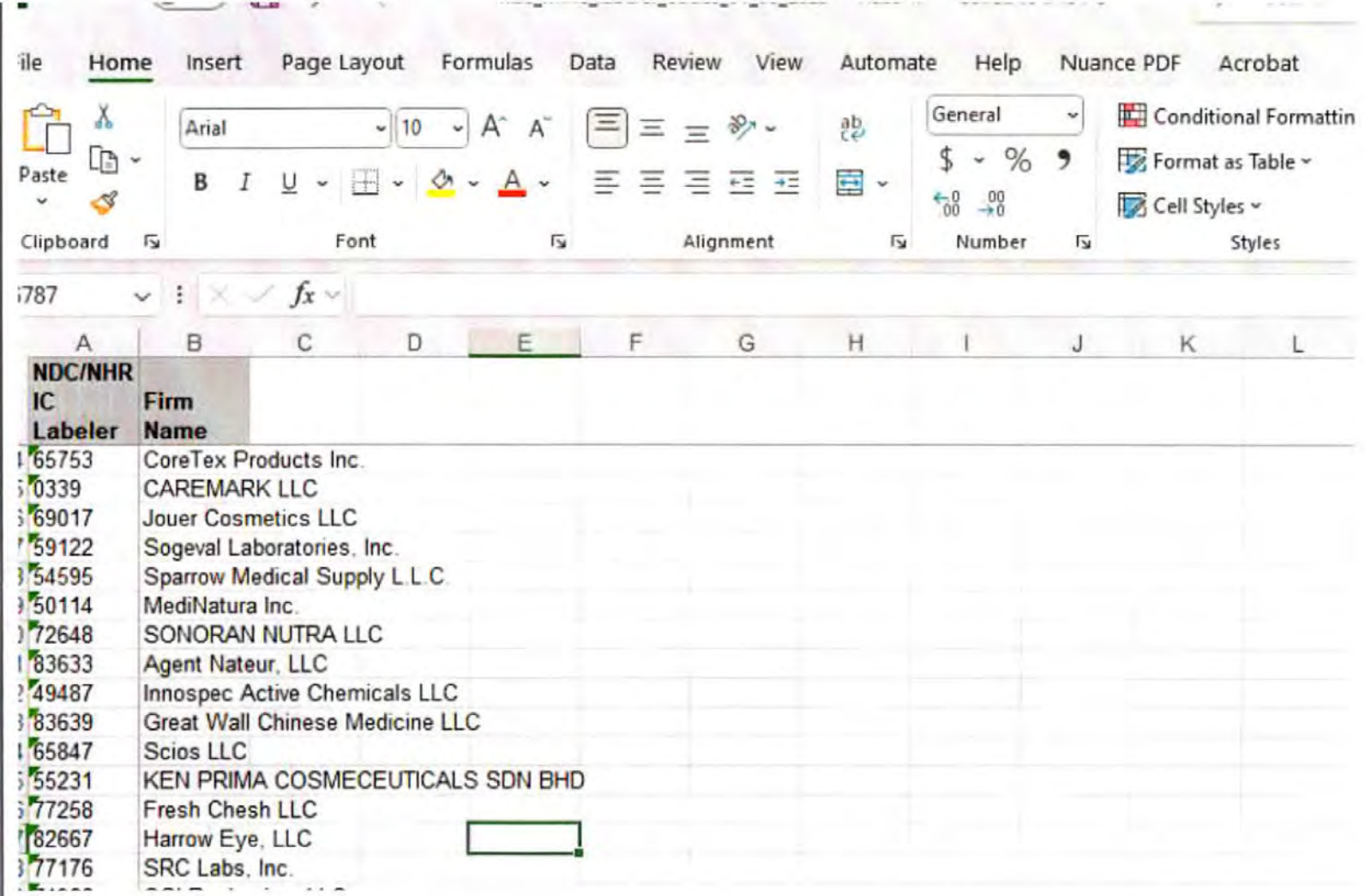
Contact	Address	Telephone Number	Email Address
Nimpa Patel	Address: 1A Burton Hills Blvd Ste 200 City, State, Zip: Nashville, TN, 37215 Country: USA	1-833-208-4271	be-compliance@harrowinc.com

Labeler Detail

Name	Address	ID/FEI	Business Operations
Harrow Eye, LLC	Address: 1A Burton Hills Blvd Ste 200 City, State, Zip: Nashville, TN, 37215 Country: USA	118526951	distributes drug products under own private label(Distributes human prescription drug products), (Distributes human over the counter drug products)

Revised: 3/2025

Harrow



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NDC/NHRIC Labeler	Firm Name
65753	CoreTex Products Inc.
0339	CAREMARK LLC
69017	Jouer Cosmetics LLC
59122	Sogeval Laboratories, Inc.
54595	Sparrow Medical Supply L.L.C.
50114	MediNatura Inc.
72648	SONORAN NUTRA LLC
83633	Agent Nateur, LLC
49487	Innospec Active Chemicals LLC
83639	Great Wall Chinese Medicine LLC
65847	Scios LLC
55231	KEN PRIMA COSMECEUTICALS SDN BHD
77258	Fresh Chesh LLC
82667	Harrow Eye, LLC
77176	SRC Labs, Inc.

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "HARROW EYE, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTY-FIRST DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "HARROW EYE, LLC" WAS FORMED ON THE FOURTH DAY OF OCTOBER, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

6281110 8300

SR# 20251319874

Authentication: 203316003

Date: 03-31-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

TENNESSEE DEPARTMENT OF HEALTH
HARROW EYE LLC
ID NUMBER: 7861
EXPIRATION DATE 06 30 2026
THIS IS TO CERTIFY THAT ALL REQUIREMENTS OF THE STATE OF TENNESSEE
HAVE BEEN MET
BOARD OF PHARMACY
MANUFACTURER
ALL APPLICABLE QUALIFICATIONS AND OR SPECIALTIES PRINTED ON BACK

COMMISSIONER OF HEALTH

HARROW HEALTH INC
1A BURTON HILLS BLVD
SUITE 200
NASHVILLE, TN 37215

State of Tennessee
Department of Health

14082634

Renewal No. 35530

Board of Pharmacy
Manufacturer

HARROW EYE LLC
1A BURTON HILLS BLVD, SUITE 200,
NASHVILLE, TN 37215

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 7861

EXPIRATION DATE: June 30, 2026

Commissioner, Dept. of Health

Jennifer L. Putnam, Esq
Assistant Commissioner, Health Licensure & Regulation

Harrow Eye, LLC License List					
State	License	Number	Status	Issue Date	Expiration
AK	Manufacturer	231422	Active	12/2/2024	6/30/2026
AR	Manufacturer	WD06056	Active	10/11/2024	12/31/2026
CT	Manufacturer	CSM.0002861-OOS	Active	10/8/2024	NA
LA	Drug or Device Distributor	11374	Active	10/18/2024	12/31/2025
MN	Manufacturer	462508	Active	6/9/2022	5/31/2025
MS	Virtual Manufacturer	18975	Active	11/6/2024	12/31/2025
MT	Wholesale Drug Distributor	PHA-WDD-LIC-111133	Active	11/7/2024	11/30/2025
NC	Manufacturer	1913	Active	10/28/2024	12/31/2025
ND	Wholesaler	WHOL3286	Active	10/31/2024	6/30/2025
NH	Manufacturer	08161	Active	10/11/2024	10/11/2026
NJ	Wholesale	5006292	Active	4/5/2023	1/31/2026
NM	Virtual Manufacturer	WD20220276	Active	11/5/2024	1/30/2025
OK	Manufacturer	88-M-8821	Active	11/22/2024	11/30/2025
OR	Manufacturer	M-0003735	Active	7/13/2022	9/30/2025
SD	Wholesaler	600-3703	Active	10/30/2024	12/31/2025
TN	Manufacturer	7861	Active	4/11/2022	6/30/2026
UT	Pharmacy - Class C	14192944-1710	Active	11/19/2024	9/30/2027
VT	Non-Resident Manufacturer	163.0000963	Active	11/21/2024	7/31/2025
WV	Manufacturer	MR0552351	Active	5/6/2022	6/30/2026

BOND RIDER

To be attached to and form part of a Pharmaceutical Wholesaler Bond

Bond No. 0810653, dated 5/5/2022

issued to Imprimis Pharmaceuticals USA, LLC,

as Principal, and Harco National Insurance Company,

as Surety, in favor of State of Nevada and the Nevada State Board of Pharmacy

, as Obligee.

It is understood and agreed that the Bond is changed or revised in the particulars as checked below:

(X) Name of Principal changed to: Harrow Eye, LLC

( ) Amount of bond changed from:

($) DOLLARS,

to:

($) DOLLARS.

(X) Other: Address Change

From: 102 Woodmount Blvd., Suite 610, Nashville, TN 37205

To: 1A Burton Hills Blvd., Suite 200, Nashville, TN 37215

Said Bond shall be subject to all its terms, conditions and limitations, except as herein expressly modified. This Bond Rider shall become effective as of 9/12/2024.

Signed, sealed and dated 9/12/2024

Harco National Insurance Company

By:

Patricia White, Attorney-in-Fact

XDP

POWER OF ATTORNEY

Bond # 0810653

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

PATRICIA WHITE, MARTA COLLETT, DANIELLE ENRIQUEZ, SANDRA CORONA, SHANNON ALVAREZ, KATHLEEN VANDERSLICE, TIMOTHY MCCLELLAN

San Diego, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2023

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2023 , before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC MY COMMISSION EXPIRES 4-16-2024 STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2024

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, **September 12, 2024**

A00874

Irene Martins, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0810653

Application/License No. _____

Imprimis Pharmaceuticals USA, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 102 Woodmount Blvd, STE 610, Nashville, TN 37205 (Address of Applicant/Principal), as PRINCIPAL, and Harco National Insurance Company (Surety Company), a corporation organized under the laws of the state of Illinois (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 9171 Towne Centre Drive, Suite 100, San Diego, CA 92122 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 5/5/2022 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 9th day of May, 2022.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Patricia White, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

Bond # 0810653

HARCO NATIONAL INSURANCE COMPANY
INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

PAUL JEFFREY HERING, PATRICIA WHITE, MARTA COLLETT, DANIELLE ENRIQUEZ, SANDRA CORONA, SHANNON ALVAREZ, KATHLEEN VANDERSLICE, TIMOTHY MCCLELLAN

San Diego, CA

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2021

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Kenneth Chapman
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2021 , before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

SHIRELLE A. OUTLEY NOTARY PUBLIC NEW JERSEY My Comm. Exp. 04-04-2023 No. 50079919

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written

Shirelle A. Outley a Notary Public of New Jersey
My Commission Expires April 4, 2023

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, May 09, 2022

A00874

Irene Martins, Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Harrow Eye, LLC

Pharmacy/Wholesaler License # (if applicable): New Applicant

Physical Address: 1A Burton Hills Blvd., Ste. 200

City: Nashville State: TN Zip: 37215

Mailing Address (if different from physical address): 1A Burton Hills Blvd., Ste. 200

City: Nashville State: TN Zip: 37215

Telephone: (615) 733-4730 Website: www.harrow.com

Licensing Company Email: compliance.harroweye@pharma.solutions

Section 2: Personal Information

First: Andrew Middle: Richard Last: Boll

Alias(es, nicknames, name changes, etc.): NA

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 1A Burton Hills Blvd., Ste. 200

City: Nashville State: TN Zip: 37215

Telephone: (615) 733-4730 Email: Aboll@harrowinc.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)
Huron University			09/2001-12/2004
Address	**City**	**State**	**Zip**
333 9th St. SW	Huron	SD	37350
Diploma/Degree obtained, if any			
B.S. Corporate and Public Finance			

School Name			From - To (MM/YY – MM/YY)
Forest Lake Senior High School			09/1998-06/2001
Address	**City**	**State**	**Zip**
6101 Scandia Trail N	Forest Lake	MN	55025
Diploma/Degree obtained, if any			
High School Diploma			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY)
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name			From - To (MM/YY – MM/YY
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/19-current	[redacted]	Nashville	TN	[redacted]
03/16-06/19		Carlsbad	CA	
02/14-03/16		Carlsbad	CA	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Harrow Eye, LLC			12/11-present	
Business Address		**City**	**State**	**Zip**
1A Burton Hills Blvd Ste 200		Nashville	TN	37215
Phone	**Title**		**Number of Employed Hours**	
(615) 733-4730	CFO/Secretary		33,800	
Description of Duties				
Financial management, oversight, of the market access operations (including drug distribution operations, related polies and procedures, and related record keeping requirements, SEC reporting requirements, mergers and acquisition matters				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Andrew Boll, **certify that as the designated representative for**

Harrow Eye, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AB I am at least 21 years of age;
3. AB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Andrew Boll

Print Name (First, Last)

Andrew Boll

Original Signature (electronic, copies or stamps not accepted)

11/26/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Boll

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/26/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Davidson

I, Andrew Boll, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/26/2024

Date

Subscribed and Sworn to before me this 26 day of November.

Notary Public Signature



Employee Legal Name	Department	Job
Boll, Andrew	GA: Administration	EA-CFO - Chief Financial Officer
Baum, Mark	GA: Administration	EA-CEO - Chief Executive Officer
DiPasquale, Gregory	GA: Administration	SA-SVPHC - Senior Vice President, Head of Commercial
Starkey, Elizabeth	GA: Administration	EA-EXA - Executive Assistant
Sherry, Laura	GA: Accounting	FI-OPSDR - Director, Financial Operations
Sandoval Casco, Jose	GA: Accounting	FI-STACC - Staff Accountant
Cannon, Kayla	GA: Accounting	FI-PA - Payroll Administrator
Balmaceda, Brandon	GA: Accounting	FI-ACC - Accountant
Fuller, Regina	GA: Accounting	APSPEC - AP Specialist
Velazquez, Paulina	GA: Accounting	FI-ACMGR - Accounting Manager
Hooper, Brandon Tyler	GA: Accounting	FI-SEACC - Senior Accountant
Torrez, Amanda	GA: Accounts Receivable	AR-ARSUP - AR Supervisor
Webb, Jamie	GA: Investor Relations	IR-DIRIR - Director of Communications & IR
Guanche, Andrew	GA: Human Resources	HR-STAS - Sr. Talent Acquisition Specialist
Langdon, Kailey	GA: Human Resources	HR-ID - Instructional Designer
Barratt, Kimberly	GA: Human Resources	HR-COSHT - Chief of Staff & Head of Talent
DiMuro, Anne	GA: Human Resources	HR-TM - Talent Manager
Solter, John Eric	GA: Human Resources	HR-OODM - Organizational Operations Development Manager
Scarborough, Garrett	GA: Information Technology	IT-DIR - Director, Information Technology
Walton, Marc	GA: Information Technology	IT-SAT - Systems Analyst II
Sanchez, Brandon	GA: Information Technology	IT-SA - Systems Analyst
Vanatta, Geran	GA: Information Technology	IT-JSD - Jr. Software Developer
Fuhrman, Matthew	GA: Information Technology	IT-ASM - IT Application & Support Manager
Siroya, Ankita	GA: Information Technology	IT-SEM - Software Engineering Manager
Whitney, Michael	GA: Information Technology	IT-SAT - Systems Analyst II
Burrell, Brett	GA: Legal	LG-VPLC - VP Of Legal and Compliance
Chacko, George	GA: Legal	LC - QA Licensing Specialist
Sibucao Potts, Glenda	GA: Regulatory & Compliance	RC-RAM - Regulatory Affairs Manager
Sisodia, Samrat	GA: Regulatory & Compliance	RC-VPRAQ - VP of Regulatory Affairs & Quality
Underhill Bennett, Carrie	GA: Regulatory & Compliance	RC-DRA - Director of Regulatory Affairs
Parker, Shannon	GA: Market Access	MA-FRMIL - Field Reimbursement Manager
Greenwald, Brent	GA: Market Access	MA-RAM - Regional Access Manager
Mathews, Reid	GA: Market Access	MA-SRMGR - Sr. Manager Market Access & Trade
Annavajhala, Prashanth	GA: Market Access	MK-SABM - Sr. Access Brand Manager
Hirschkorn, Keri Lynn	GA: Market Access	MA-DPAS - Director- Payer Access Support
Philo, Robert	GA: Market Access	MA-VPMA - Vice President of Market Access
Vo, My	GA: Market Access	MA-ADPNA- Associate Director Payer National Accounts
Eland-Ellis, Sydney	Pharm Ops: Admin	OP-SSCA - Senior Supply Chain Analyst
Samudre, Sanjay	Pharm Ops: Admin	OP-EMSCT - VP- Ext Manufacturing/Supply Chain & Tech Ops
Saadeh, Dennis Elias	Pharm Ops: R&D	OP-CSO - Chief Scientific Officer
Gedeon, Christina	Pharm Ops: R&D	RD-SPE - Sr. Process Engineer
Nagarkar, Rigved Kishor	Pharm Ops: R&D	RD-SDMST - Sr. Director of MS & T
Nguyen, Nathalie	Medical/Clinical Affairs	MA-FMD- Field Medical Director
Serikbaeva, Anara	Medical/Clinical Affairs	MA-AMMA- Associate Manager, Medical Affairs
Costine, Richard	Medical/Clinical Affairs	CA-SDMCA - Senior Director, Head of Medical and Clinical
Nwosu, Amadi	Pharm Ops: Quality	QA-QAMC - QA Manager-CMO
Patel, Neepa	Pharm Ops: Quality	QA-ADQC- Associate Director of Quality & Compliance
Torres, Solenni	Pharm Ops: Quality	QA-QACMO - Quality Assurance Specialist, CMO
Patel, Vidhi	Pharm Ops: Quality	QA-QACMO - Quality Assurance Specialist, CMO
Jimeson, Jessica	Marketing: Admin	MK-SBMGR - Sr. Brand Manager
Javier, Ilio	Marketing: Admin	IT-DES - Designer
Hamaoui, Bert	Marketing: Admin	MK-SDMM - Sr. Digital Marketing Manager
Ashmore, Chrystal	Marketing:Medicare D	MK-SBMGR - Sr. Brand Manager
Doman, Kimberly	Marketing:Medicare D	MK-SBMGR - Sr. Brand Manager

Munding, Ryan Michael	Marketing: Admin	DM-SGD - Sr. Graphic Designer
Spurrier, Kati	Marketing: Medicare B	MK-SBMGR - Sr. Brand Manager
Ballard, Janna	Sales: Admin/Analytics	SA-SOM - Sales Operations Manager
Curtis, Scott	Sales: Admin/Analytics	SA-CSEM - CRM and Sales Enablement Manager
Ong, Nhi A	Sales: Admin/Analytics	SA-HCO - Head of Commercial Operation
Matthews, Staci	Sales: Sales Training	SA-RTM - Regional Training Manager
Carder, Timothy Robert	Sales: Sales Training	SA-NDT - National Director of Training
Colvin, Jennifer	Sales: Sales Training	SA-RTM - Regional Training Manager
Quintero, Loreli	Sales: Sales Training	SA-RTM - Regional Training Manager
Kepchar, Bridget	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Saharek, Trent Daniel	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Lockrem, Sean	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Mandelberg, Michael	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Payne, Brian	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Whitehead, Mike	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Whittington, Amanda	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Brooks, Autumn	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Mueller, Gregory	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Wilde, Joel	Sales: Medicare B	SA-CASD - Central Area Sales Director
Kang, Melissa	Sales: Medicare B	SA-ASD - Area Sales Director
DiBlasi, Christian	Sales: Medicare B	SA-ASD - Area Sales Director
Palmisano, Lauren	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Diliberto, David	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Wymard, Kristin	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Amberson, Brett	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Herd, Stephen	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Graham, Lauren	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Camacho, Jonathan	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Campbell, Donald	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Dubrow, Victor	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Hill, David Brian	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Hopkins, Elizabeth	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Lucania, Nicholas John	Sales: Medicare B	MA-RAM - Regional Access Manager
Lyon, Michael	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Peebles, Thomas Christopher	Sales: Medicare B	SA-SRDSA - Senior Director of Strategic Accounts
Robinson, Joseph	Sales: Medicare B	SA-VPSI - Vice President of Sales- IHEEZO
Rogers, Cheryl	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Simmons, Edward	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
West, Jacob W	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Fernandez, Cecilia	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Cummings, Cristina	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Sluder, Barbara	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Mullaney, Lisa	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Truong, Tracy	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Fox, Julia	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Renz, Bridget	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Hardy, Sean	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Giunceo, Gina	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Stephens, Alison Kimberly	Sales: Medicare D	SA-ASM- Area Sales Manager
Niemann, John	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Bryant Jr., Dwight	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Daily, Colleen	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Fox, Adam	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Ball, Blakely	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Karoutsos, Anna	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology

Yuh, Ian	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Voorhees, Jessica	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Mashal, Danielle	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Cox, Mindy	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Thompson, Toby	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Randall, Lynn	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Searle, Marie	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Daywood, Lizette	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Stahl, Ricky	Sales: Medicare D	SA-SASM - Senior Area Sales Manager
Shuffler, Amy	Sales: Medicare D	SA-SASM - Senior Area Sales Manager
Balius, Marsha	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Bennett, Madeline	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Burkhardt, Robert	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Atlee, Betsy	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Jeffress, Jerry Mack	Sales: Medicare D	SA-ASD - Area Sales Director
Knight, Charniece	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Lloyd, Maria Zanardo	Sales: Medicare D	SA-VPDYP- Vice President of Dry Eye Portfolio
Martin, Robert	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Martinez, Eduardo	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Moloney, Robert	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Moriarty, Richard James	Sales: Medicare D	SA- ASM - Area Sales Manager
O'Keefe, Daniel Ty	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Aguero- Vasconcelos, Gigi	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Kent, Bruce	Sales: Inside Sales	SA-NDST - National Director of Sales-Triesence
Brown, Michael	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Hunter, Melanie	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Cochrane, Connor	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Rogers, Jaxen	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Sartin, Haley	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Davis-Allen, Jordan	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Genkin, Veronica	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Ballek, Frank	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Dada, Omar Nazheef	Sales: Inside Sales	SA-ISM- Inside Sales Manager
Shaw, Trey	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Dellinger, Parker	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Ramsey, Kaylee	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Comperry, Amanda	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Link, Ryan	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Kutsch, Morgan	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Dillard, Bridgit	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Von Mann, Ryan	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Rynd, Olivia	Sales: Inside Sales	SA-ISM- Inside Sales Manager
Kearney, Tracy	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Crawford, Brooke	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Davis, Jonathan	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Donovan, Rachel	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Cloud, Morgan	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Cohol, Brianna	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Crafton, Sarah	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Danyo, Hayden	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Eaves, Samuel	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Flatt, Peyton	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Foster, Ronta	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Hutton, Samantha	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Jeffries, Jacob	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative

Johantges III, Carl Joseph	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Legg, Kathryn	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Minter, Sidney	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Muldoon, Katherine	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Schreiber, John	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Smith, Madalyn	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Woodham, Kenneth	Sales: Inside Sales	SA-TSR - Therapeutic Sales Representative
Bellamay, Brislan	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Kinlaw, Vivian	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Anthony, Keisha	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Benton, Mariana	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Spinelli, William	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Kassan, Diana	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Pasqua, Keith	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Fusco, Danielle	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Hedrick, Curtis	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Pottkotter, Carl	GA: Information Technology	IT-VPT- Vice President of Technology
Crimmins, Michael	GA: Information Technology	IT-BIA- Business Intelligence Architect
Armstrong, Cole	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Brown, Ricky	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Malysza, Tim	Sales: Medicare B	SA-KAM - Key Account Manager - Ophthalmology
Wells, Angela	GA: Market Access	MA-FRMIL - Field Reimbursement Manager
Deselle, Sandy	Medical/Clinical Affairs	MA-NDFMA- National Director, Field Medical Affairs
Tsao, Anna	Medical/Clinical Affairs	MA-MADMA- Associate Director, Medical Affairs
Scisciani, Dave	Sales: Strategic Accounts	SA-VPSA- Vice President of Strategic Accounts
Galvez, Dawn	Sales Admin/Analytics	SA-VPCO- Vice President of Commercial Operations
Staack, Ashley	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Tassa, Debbie	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Reeder, Shay	GA: Market Access	MA-FRMIL - Field Reimbursement Manager
Furlong, Tami	Sales: Medicare B	SA-SKAM- Sr. Key Accont Manager
Harrison, Aly	Sales: Medicare B	SA-VPPP- Vice President, Posterior Portfolio
Bueti, Nicola	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Cooley, Brett	Sales: Strategic Accounts	SA-SRDSA - Senior Director of Strategic Accounts
Sanders, Beth	Sales: Strategic Accounts	SA-SRDSA - Senior Director of Strategic Accounts
Greenwald, Sherry	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Snyder, Kelsey	Sales: Medicare D	SA-KAM - Key Account Manager - Ophthalmology
Kondari, Sweta	Pharm Ops: Quality	QA-SRPS- Sr. Pharmacovigilance Specialist

4GG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: HTL-Strefa, Inc.

Physical Address: 113 Towne Lake Pkwy

City: Woodstock State: GA Zip: 30188

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 770-528-0410 Website: www.mtdglobal.com

Name of Designated Representative (DR): Erica K. Coleman

Licensing Company Email: quality@htl-strefa.com DR Email: erica.coleman@htl-strefa.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: HTL-Strefa, S.A.
Address: ADAMOWEK 7 City: OZORKOW, LODZKIE State: PL Zip: 95-035

Name: Pikdare, S.p.A.
Address: Via Saldarini Catelli 10 City: Casnate State: Italy Zip: 22070

Name: SOL-MILLENNIUM EUROPE SP.
Address: Z O.O. ul. Twarda 1 City: Warszawa State: PL Zip: 18 00-105

Name: Yangzhou Medline Industries (China)
Address: No.1, Huafa Road, Economic Develop City: Yangzhou, Jiangsu State: China Zip: 225000

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Georgia State Incorporation since 2007
Parent Company (if any): MTD Group
Corporation/Organization Name: HTL-Strefa, Inc.
Mailing Address: 113 Towne Lake Pkwy, Suite 120
City: Woodstock State: GA Zip: 30188
Telephone: 770-528-0410 Email: Erica.Coleman@HTL-Strefa, Inc.
Contact Person Name: Erica Coleman

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

HTL-Strefa, Inc.

Facility Name

Sylvie Verdon

Print Name of Authorized Person Submitting Application

Sylvie L. Verdon

Original signature of Authorized Person (copies or stamps not accepted)

10/04/2024

Date

Board Use Only	Date Received: 10/7/24	Amount: $1000-cc

Nevada Supporting Information/Documentation

Copy of FDA registration

Verified 10/11/24

Establishment:
HTL-STREFA, INC.
113 Towne Lake Pkwy Ste 120
Woodstock, GA 30188
Registration Number: 3006142663
FEI Number*: 3006142663
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
HTL-STREFA S.A.
ADAMOWEK 7
OZORKOW, PL 95-035
Owner/Operator Number: 9028458

Official Correspondent:
Sylvie L Verdon
HTL-Strefa Inc.
113 Towne Lake Pkwy Ste 120
Woodstock, GA 30188
Phone: 1-770-5280410

Establishment:
HTL-STREFA S.A.
ADAMOWEK 7
OZORKOW Lodzkie, PL 95-035
Registration Number: 9613304
FEI Number*: 3004034544
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
HTL-STREFA S.A.
ADAMOWEK 7
OZORKOW, PL 95-035
Owner/Operator Number: 9028458

Official Correspondent:
Justyna Zemigala
ADAMOWEK 7
OZORKOW, PL 95-035
Phone: 48-42-2700006

US Agent:
Sylvie Verdon
HTL-Strefa, Inc.
113 Towne Lake Pkwy
Woodstock, GA US 30188
Phone: 770 5280410 Ext
Fax: 770 5280411
Email: Sylvie.Verdon@Htl-Strefa.Com

Establishment:
PIKDARE S.P.A.
Business Trade Name:
PIKDARE S.R.L.

Via Saldarini Catelli 10
Casnate Con Bernate Como, IT 22070
Registration Number: 3014165712
FEI Number*: 3014165712
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
PIKDARE S.P.A.
Via Saldarini Catelli 10
Casnate Con Bernate, Como IT 22070
Owner/Operator Number: 10056385

Official Correspondent:
Roberta Zanoni
Via Saldarini Catelli 10
Casnate Con Bernate, Como IT 22070
Phone: 39-031-7297757

US Agent:
Sylvie Verdon
HTL-Strefa, Inc.
113 Towne Lake Pkwy
Woodstock, GA US 30188
Phone: 770 5280410 Ext
Fax: 770 5280411
Email: Sylvie.Verdon@Htl-Strefa.Com

List of All HTL-Strefa, Inc. Officers and Directors

- Carl Ward, CEO/General Manager, 113 Towne Lake Pkwy, Ste 120, Woodstock, GA, 30188
- Armando Amselem, CFO, 113 Towne Lake Pkwy, Ste 120, Woodstock, GA, 30188
- Charles Bouaziz, MTD Group CEO, 113 Towne Lake Parkway, Suite 120, Woodstock, GA, 30188
- Brad Adams, V,P. of Finance, 113 Towne Lake Pkwy, Ste 120, Woodstock, GA, 30188
- Christopher Woeste, V.P. Sales, 113 Towne Lake Pkwy, Ste 120, Woodstock, GA, 30188
- Erica Coleman, Director Operations & IT, 113 Towne Lake Pkwy, Ste 120, Woodstock, GA, 30188
- Sylvie Verdon, Director of Regulatory Affairs North America, 113 Towne Lake Pkwy, Ste 120, Woodstock, GA, 30188
- Patricia Gaillard, Director of Marketing,

List of all HTL-Strefa, Inc. corporation shareholders and their percent ownership

The authorized capital stock of the Corporation shall consist of 2,000 shares of voting common stock.

- **State of Georgia evidence document is ATTACHED.**

Control Number : 07007164

STATE OF GEORGIA

Secretary of State

Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFICATE OF EXISTENCE

I, **Brad Raffensperger**, the Secretary of State of the State of Georgia, do hereby certify under the seal of my office that

HTL-STREFA, INC.
a **Domestic Profit Corporation**

was formed in the jurisdiction stated below or was authorized to transact business in Georgia on the below date. Said entity is in compliance with the applicable filing and annual registration provisions of Title 14 of the Official Code of Georgia Annotated and has not filed articles of dissolution, certificate of cancellation or any other similar document with the office of the Secretary of State.

This certificate relates only to the legal existence of the above-named entity as of the date issued. It does not certify whether or not a notice of intent to dissolve, an application for withdrawal, a statement of commencement of winding up or any other similar document has been filed or is pending with the Secretary of State.

This certificate is issued pursuant to Title 14 of the Official Code of Georgia Annotated and is prima-facie evidence that said entity is in existence or is authorized to transact business in this state.

Docket Number	: 28125310
Date Inc/Auth/Filed	: 01/24/2007
Jurisdiction	: Georgia
Print Date	: 09/18/2024
Form Number	: 211

Brad Raffensperger

Brad Raffensperger
Secretary of State

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH005652 Status: Active

HTL-Strefa Inc
113 Towne Lake Pkwy Ste 120
Woodstock GA 30188

Expires: 06/30/2025
Issued: 07/27/2023

Real-time license verification is available at gadch.mylicense.com/verification

Above is your wall certificate license to practice as a **Wholesaler Pharmacy** in the State of Georgia. A pocket-sized license card is below.

Please make note of the expiration date on your license. It is your responsibility to renew your license before it expires.
Please notify the Board if you have a change of address.

STATE OF GEORGIA
Georgia Board of Pharmacy
Wholesaler Pharmacy
LICENSE NO. PHWH005652 Status: Active
HTL-Strefa Inc
113 Towne Lake Pkwy Ste 120
Woodstock GA 30188

Expires: 06/30/2025
Issued: 07/27/2023
Real-time license verification is available at gadch.mylicense.com/verification

Control Number : 07007164

STATE OF GEORGIA

Secretary of State

Corporations Division
313 West Tower
2 Martin Luther King, Jr. Dr.
Atlanta, Georgia 30334-1530

CERTIFICATE OF AMENDMENT

I, **Brad Raffensperger**, the Secretary of State and the Corporation Commissioner of the State of Georgia, hereby certify under the seal of my office that

HTL-STREFA, INC.

a Domestic Profit Corporation

has filed articles/certificate of amendment in the Office of the Secretary of State on 12/21/2023 and has paid the required fees as provided by Title 14 of the Official Code of Georgia Annotated. Attached hereto is a true and correct copy of said articles/certificate of amendment.

WITNESS my hand and official seal in the City of Atlanta and the State of Georgia on **01/04/2024**.

Brad Raffensperger

Brad Raffensperger
Secretary of State

SECRETARY OF STATE
CORPORATIONS DIVISION
12/28/2023 10:30 AM

ARTICLES OF AMENDMENT
TO THE
ARTICLES OF INCORPORATION
OF
HTL-STREFA, INC.

Pursuant to Section 14-2-1003 of the Georgia Business Corporation Code, the Articles of Incorporation of HTL-STREFA, Inc., a Georgia corporation (the "Corporation") are hereby amended according to these Articles of Amendment:

I.

The name of the corporation is HTL-STREFA, Inc.

II.

The Articles of Incorporation of the Corporation are hereby amended by deleting Article II thereof in its entirety and substituting in lieu of said Article II the following:

"II.

The authorized capital stock of the Corporation shall consist of 2,000 shares of voting common stock at $ 14,549.47 par value."

III.

The foregoing amendment was duly adopted and approved by the Board of Directors and the shareholders of the Corporation on October 31, 2023, in accordance with Section 14-2-1003 of the Georgia Business Corporation Code, as amended.

IN WITNESS WHEREOF, the Corporation has caused these Articles of Amendment to be executed by a duly authorized officer of the Corporation on the 31st day of October, 2023.

By: Carl J Ward
Name: Carl Ward
T: Chief Executive Officer

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 04/14/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Insurance Services West, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	**CONTACT NAME:** WTW Certificate Center **PHONE (A/C, No, Ext):** 1-877-945-7378 **FAX (A/C, No):** 1-888-467-2378 **E-MAIL ADDRESS:** certificates@wtwco.com
INSURED HTL-Strefa, Inc 113 Towne Lake Pkwy Ste 120 Woodstock, GA 30188	**INSURER(S) AFFORDING COVERAGE** — **NAIC #** INSURER A : HDI Global Insurance Company — 41343 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** W38654583 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			GLD5934802	01/01/2025	01/01/2026	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 100,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ 2,000,000
								$
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N/A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Nevada Pharmacy Board

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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BANK OF AMERICA

BANK OF AMERICA - CONFIDENTIAL PAGE: 1
DATE: FEBRUARY 19, 2025
IRREVOCABLE STANDBY LETTER OF CREDIT NUMBER: 68202340

APPLICANT
HTL-STREFA INC.
113 TOWNE LAKE PKWY STE. 120
WOODSTOCK, GA 30188
SCRANTON PA

BENEFICIARY
NEVADA STATE BOARD OF PHARMACY
985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

ISSUING BANK
BANK OF AMERICA, N.A.
ONE FLEET WAY
PA6-580-02-30
SCRANTON, PA 18507-1999

AMOUNT
NOT EXCEEDING USD 100,000.00
NOT EXCEEDING ONE HUNDRED THOUSAND AND 00/100'S US DOLLARS

EXPIRATION
NOVEMBER 29, 2025 AT OUR COUNTERS

1. AT THE REQUEST AND ON THE INSTRUCTIONS OF HTL-STREFA INC., WE BANK OF AMERICA N.A. HEREBY ESTABLISH IN FAVOR OF THE BENEFICIARY, THE NEVADA STATE BOARD OF PHARMACY (BOARD), THIS IRREVOCABLE STANDBY LETTER OF CREDIT (CREDIT) IN THE PRINCIPAL SUM OF $100,000.00.

2. THIS CREDIT IS AND HAS BEEN ESTABLISHED FOR THE SOLE BENEFIT OF THE BOARD PURSUANT TO THE TERMS OF NRS 639.515 PERTAINING TO THE INITIAL OR RENEWAL APPLICATION FILED BY THE APPLICANT/LICENSEE.

3. THIS CREDIT IS INTENDED BY THE PARTIES TO SERVE AS A SECURITY DEVICE FOR THE PERFORMANCE BY APPLICANT/LICENSEE OF ITS OBLIGATIONS UNDER APPLICABLE NEVADA LAW REGARDING APPLICANT/LICENSEE'S OPERATION AS A PHARMACEUTICAL WHOLESALER.

4. PURSUANT TO NRS 639.515(4), UPON THE IMPOSITION OF ANY FINES OR COSTS BY THE BOARD AGAINST THE APPLICANT/LICENSEE, THE BOARD SHALL BE ENTITLED TO DRAW UPON THIS CREDIT BY PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING IN THE SAME FORM AS ATTACHMENT A, ATTACHED HERETO, AT OUR OFFICE LOCATED AT THE ADDRESS ABOVE.

5. THE CERTIFICATE OF DRAWING SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY FOR THE BOARD. PRESENTATION BY THE BOARD OF A COMPLETED CERTIFICATE OF DRAWING MAY BE MADE IN PERSON OR BY REGISTERED MAIL, RETURN RECEIPT REQUESTED.

6. UPON PRESENTATION OF A DULY EXECUTED CERTIFICATE OF DRAWING AS ABOVE PROVIDED, PAYMENT SHALL BE MADE TO THE BOARD, TO AN ACCOUNT DESIGNATED BY THE BOARD, IN IMMEDIATELY AVAILABLE FUNDS, AT SUCH TIME

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68202340

AND PLACE AS THE BOARD SHALL SPECIFY.

7. FUNDS MAY BE DRAWN IN ONE OR MORE DRAWINGS NOT TO EXCEED THE PRINCIPAL SUM.

8. IF DEMAND FOR PAYMENT DOES NOT CONFORM TO THE TERMS OF THE CREDIT, WE SHALL GIVE THE BOARD PROMPT NOTICE THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN ACCORDANCE WITH THE TERMS OF THIS CREDIT, STATE THE REASONS THEREFORE, AND AWAIT FURTHER INSTRUCTIONS.

9. UPON BEING NOTIFIED THAT THE DEMAND FOR PAYMENT WAS NOT EFFECTED IN CONFORMITY WITH THE CREDIT, THE BOARD MAY CORRECT ANY SUCH NON-CONFORMING DEMAND FOR PAYMENT.

10. ALL DRAWINGS UNDER THIS CREDIT SHALL BE PAID WITH OUR FUNDS. EACH DRAWING HONORED BY US HEREUNDER SHALL REDUCE, PRO TANTO, THE PRINCIPAL SUM. BY PAYING TO THE BOARD AN AMOUNT DEMANDED IN ACCORDANCE HEREWITH, WE MAKE NO REPRESENTATIONS AS TO THE CORRECTNESS OF THE AMOUNT DEMANDED.

11. THIS CREDIT WILL BE CANCELLED ONLY UPON RECEIPT BY USE OF A CERTIFICATE OF CANCELLATION WHICH SHALL BE IN THE FORM OF ATTACHMENT B, ATTACHED HERETO AND SHALL BE COMPLETED AND SIGNED BY THE EXECUTIVE SECRETARY OF THE BOARD AND THE ORIGINAL LETTER OF CREDIT AND ANY AMENDMENT(S) IF ANY.

12. COMMUNICATIONS WITH RESPECT TO THIS CREDIT SHALL BE IN WRITING AND ADDRESSED TO US AT THE ADDRESS ABOVE AND SHALL SPECIFICALLY REFER TO THIS CREDIT BY THE NUMBER ABOVE.

13. THIS CREDIT MAY NOT BE TRANSFERRED OR ASSIGNED, EITHER IN WHOLE OR IN PART.

14. THIS LETTER OF CREDIT IS SUBJECT TO THE INTERNATIONAL STANDBY PRACTICES (ISP98), INTERNATIONAL CHAMBER OF COMMERCE PUBLICATION NO. 590. THIS CREDIT SHALL BE DEEMED A CONTRACT MADE UNDER THE LAWS OF STATE OF NEVADA, AND ANY ACTION RELATED TO THIS CREDIT SHALL BE FILED IN THE STATE OF NEVADA AND SHALL BE SUBJECT TO THE LAWS OF THE OF THE STATE OF NEVADA. IN THE EVENT OF ANY CONFLICT, THE LAWS OF THE STATE OF NEVADA WILL CONTROL.

15. THIS CREDIT SHALL BE PERPETUAL UNTIL IT IS CANCELLED AS PROVIDED HEREIN.

THEREFORE, BANK OF AMERICA N.A. HAS EXECUTED AND DELIVERED THIS IRREVOCABLE STANDBY LETTER OF CREDIT TO THE BOARD AS OF THE 19 DAY OF FEBRUARY, 2025.

FINANCIAL INSTITUTION

BY:

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68202340

NAME: Timothy J. Rogers

TITLE: A.V.P

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68202340

ATTACHMENT A

NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521 (775) 850-1440 - (775) 850-1444 - FAX
PHARMACY@PHARMACY.NV,GOV

NAME OF FINANCIAL INSTITUTION(ISSUER): BANK OF AMERICA N.A.

ADDRESS:ONE FLEET WAY

CITY: SCRANTON STATE: PA ZIP:18507-1999

NAME OF APPLICANT/LICENSEE:HTL-STREFA INC.

ADDRESS: 113 TOWNE LAKE PKWY STE. 120

CITY: WOODSTOCK STATE: GA ZIP: 30188

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 68202340

TO BENEFICIARY:

NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521 ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. A LAWFUL ORDER IMPOSING FINES AND/OR COSTS AGAINST THE APPLICANT/LICENSEE HAS BEEN ENTERED THAT ENTITLES THE BOARD TO DRAW AGAINST IRREVOCABLE STANDBY LETTER OF CREDIT NO. 68202340 (CREDIT).

2. THE UNDERSIGNED IS AUTHORIZED UNDER THE TERMS OF THE CREDIT TO PRESENT THIS CERTIFICATE OF DRAWING AS THE SOLE MEANS FOR DEMANDING PAYMENT ON THE CREDIT.

3. THE BOARD IS THEREFORE MAKING A DRAWING UNDER THE CREDIT IN THE AMOUNT OF $_____.

4. THE AMOUNT DEMANDED DOES NOT EXCEED THE PRINCIPAL SUM.

5. SUMS RECEIVED SHALL BE USED BY THE BOARD IN ACCORDANCE WITH THE TERMS OF THE CREDIT.

6. THE AMOUNT OF DRAWING REQUESTED SHALL BE PAYABLE TO THE BOARD IN LAWFUL, IMMEDIATELY AVAILABLE FUNDS TO BE RECEIVED BY THE BOARD AT THE ABOVE ADDRESS NO LATER THAT 3:00 PM EASTERN TIME ON THE_____DAY OF_____20__.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF DRAWING ON THIS_____DAY

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68202340

OF_____,20__

NEVADA STATE BOARD OF PHARMACY

BY:_____
LARRY PINSON, PHARM.D. EXECUTIVE SECRETARY

THIS IS AN INTEGRAL PART OF LETTER OF CREDIT NUMBER: 68202340

ATTACHMENT B

NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH PKWY, SUITE 206
RENO, NV 89521 (775) 850-1440 - (775) 850-1444 - FAX
PHARMACY@PHARMACY.NV,GOV

CERTIFICATE FOR CANCELLATION

NAME OF FINANCIAL INSTITUTION (ISSUER):BANK OF AMERICA N.A.

ADDRESS: ONE FLEET WAY

CITY: SCRANTON STATE: PA ZIP:18507-1999

NAME OF APPLICANT/LICENSEE:_____

ADDRESS:_____

CITY:_____STATE:_____ZIP:_____

IRREVOCABLE STANDBY LETTER OF CREDIT NO.: 68202340

TO BENEFICIARY: NEVADA STATE BOARD OF PHARMACY 985 DAMONTE RANCH
PKWY, SUITE 206 RENO, NV 89521
ATTN: EXECUTIVE SECRETARY

THE UNDERSIGNED, THE EXECUTIVE SECRETARY FOR THE NEVADA STATE BOARD OF PHARMACY (BOARD) HEREBY CERTIFIES TO THE ISSUER THAT:

1. THE LICENSE FOR WHICH THE CREDIT WAS ISSUED HAS EXPIRED, BEEN REVOKED, BEEN CANCELLED, OR OTHERWISE IS NO LONGER IN EFFECT, THEREBY MAKING THE CANCELLATION OF THE CREDIT APPROPRIATE.

2. THE BOARD THEREFORE REQUESTS THE CANCELLATION OF THE ABOVE-REFERENCED CREDIT.

THEREFORE, THE UNDERSIGNED HAS EXECUTED AND DELIVERED THIS CERTIFICATE OF CANCELLATION ON THIS_____DAY OF _____,20__

NEVADA STATE BOARD OF PHARMACY

BY:_____
LARRY L. PINSON, PHARM.D. EXECUTIVE SECRETARY

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG HTL-Strefa, Inc. MDEG License # (if applicable) _____

Physical Address 113 Towne Lake Pkwy, Suite 120

City Woodstock State GA Zip 30188

Mailing Address (if different from physical address) _____

City Same State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Sylvie Middle L Last Verdon

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Alpharetta State GA Zip [redacted]

Telephone [redacted] Email sylvie.verdon@htl-strefa.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of New Hampshire		09/1982 - 12/1989	
Address	**City**	**State**	**Zip**
105 Main Street	Durham	NH	03824
Diploma/Degree obtained, if any			
M.S.			

School Name		From - To (MM/YY – MM/YY)	
University of New Hampshire		09/1978 - 06/1982	
Address	**City**	**State**	**Zip**
105 Main Street	Durham	NH	03824
Diploma/Degree obtained, if any			
B.S.			

School Name		From - To (MM/YY – MM/YY)	
Lin-Wood High School		09/1974 - 06/1978	
Address	**City**	**State**	**Zip**
72 Linwood Drive	Lincoln	N.H.	03251
Diploma/Degree obtained, if any			
H.S.			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/1996 - Today	[redacted]	Alpharetta	GA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
HTL-Strefa, Inc.			01/2021 - Today
Business Address	**City**	**State**	**Zip**
113 Towne Lake Pkwy	Woodstock	GA	30188
Phone	**Title**	**Number of Employed Hours**	
770-528-0410	Director Regulatory Affairs, N.A.	~7360	

Description of Duties

Regulatory/Quality compliance oversight for product distribution, quality control, complaint handling, FDA/Health Canada establishment registrations/listings, State licensing/certifications, employee training, plus other duties as assigned.

Business Name			From - To (MM/YY – MM/YY)
Verdon Solutions, LLC			01/2018 - 12/2020
Business Address	**City**	**State**	**Zip**
635 Glenrose Trail	Alpharetta	GA	30005
Phone	**Title**	**Number of Employed Hours**	
678-234-1801	Owner/Principal Consultant	~1920	

Description of Duties

Regulatory Affairs consultant for medical device, tissue, and IVD companies. Also provided regulatory training for companies on FDA, Health Canada and European Union regulations.

Business Name			From - To (MM/YY – MM/YY)
Artivion (formerly known as CryoLife)			03/1998 - 01/2018
Business Address	**City**	**State**	**Zip**
1655 Roberts Blvd.	Kennesaw	GA	30144
Phone	**Title**	**Number of Employed Hours**	
770-419-3355	Global Regulatory Affairs Director/Project Management	~38,000	

Description of Duties

Duties included preclinical/clinical research, global regulatory affairs including establishment registrations and product licensing (510k, PMAs, MDLs, CE marking, etc.) for global distribution efforts. Project Management for Product Dev.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted) Date

I, Sylvie L. Verdon, **certify that as the MDEG Administrator for**

HTL-Strefa, Inc.,

that I (initial that you have read and meet the following requirements):

1. SLV Have a high school diploma or its equivalent;
2. SLV Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SLV Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SLV Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sylvie L. Verdon
Print Name (First, Last)

Sylvie L Verdon
Original Signature (electronic, copies or stamps not accepted)

11/05/2024
Date

Board Use Only	Date Received:

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HTL-Strefa, Inc.

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 113 Towne Lake Pkwy Suite 120

City Woodstock State GA Zip 30188

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 770-528-0410 Website _____

Licensing Company Email quality@htl-strefa.com

Section 2: Personal Information

First Erica Middle Karen Last Coleman

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Woodstock State GA Zip [redacted]

Telephone [redacted] Email erica.coleman@htl-strefa.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
South University		06/10 - 12/11	
Address	**City**	**State**	**Zip**
709 Mall Boulevard	Savannah	GA	31406
Diploma/Degree obtained, if any			
n/a			

School Name		From - To (MM/YY – MM/YY)	
Williamsport Area High School		09/86 - 06/90	
Address	**City**	**State**	**Zip**
2990 West Fourth Street	Williamsport	PA	17701
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/19 - current	[redacted]	Woodstock	GA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
09/10 - 10/19		Woodstock	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
HTL-Strefa, Inc			07/23 - current	
Business Address		**City**	**State**	**Zip**
113 Towne Lake Pkwy Suite 120		Woodstock	GA	30188
Phone	**Title**		**Number of Employed Hours**	
770-528-0410	Director of Operations and IT		total 20,800	
Description of Duties				
Maintain and progress relationship with HTL 3PL warehouses and internal Operations / Accounting Team. Continue to provide security for IT operations within facility and assist with quality as needed.				

Business Name			From - To (MM/YY – MM/YY)	
HTL-Strefa, Inc.			11/22 - 07/23	
Business Address		**City**	**State**	**Zip**
113 Towne Lake Pkwy Suite 120		Woodstock	GA	30188
Phone	**Title**		**Number of Employed Hours**	
770-528-0410	Associate Director of Operations and IT		40 + hours per week	
Description of Duties				
Provide leadership and control of distribution logistics, including product traceability. Maintain and keep HTL areas secure and backed up. Assist as needed with Quality and auditing.				

Business Name			From - To (MM/YY – MM/YY)	
HTL-Strefa, Inc.			09/16 - 11/22	
Business Address		**City**	**State**	**Zip**
113 Towne Lake Pkwy Suite 120		Woodstock	GA	30188
Phone	**Title**		**Number of Employed Hours**	
770-528-0410	Quality Manager		40 + hours per week	
Description of Duties				
Maintain Quality Management System and it relates to product integrity, document and record control accuracy. Lead auditor and assist with operations as needed.				

Business Name			From - To (MM/YY – MM/YY)	
HTL-Strefa, Inc			03/15 - 09/16	
Business Address		**City**	**State**	**Zip**
3005 Chastain Meadows Pkwy		Marietta	GA	30066
Phone	**Title**		**Number of Employed Hours**	
770-528-0410	Assistant Operations Manager		40 + hours per week	
Description of Duties				
Buyer/planner for company's needs as it relates to inventory/inventory control and production. Administrator or of Inventory Management System. Assist Operations Manager as needed.				

Business Name			From - To (MM/YY – MM/YY)	
HTL-Strefa, Inc			09/14 - 03/15	
Business Address		**City**	**State**	**Zip**
3005 Chastain Meadows Pkwy.		Marietta	GA	30066
Phone	**Title**		**Number of Employed Hours**	
770-528-0410	National Account Specialst		40 + hours per week	
Description of Duties				
Assist in planning/implementing sales, marketing and product development programs targeted towards existing and new customers.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Eric R Coleman
Original Signature (electronic, copies or stamps not accepted)

09/23/2024
Date

I, Erica Karen Coleman, **certify that as the designated representative for**

HTL-Strefa, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. EKC I am at least 21 years of age;
3. EKC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. EKC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. EKC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. EKC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. EKC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Erica Coleman
Print Name (First, Last)

Erica Coleman
Original Signature (electronic, copies or stamps not accepted)

09/23/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Erica Coleman

Print Name (First, Last)

Erica L Coleman

Original Signature (electronic, copies or stamps not accepted)

09/23/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Georgia, ss. County of Cobb

I, Debora McClung, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Debora McClung

Original Signature

9/23/2024

Date

Subscribed and Sworn to before me this 23 day of Sept.

Debora McClung

Notary Public Signature



(Seal)

List of HTL-Strefa, Inc. Employees

1. Andrea Iuja, Junior Accountant
2. Ashley Ferguson, Director of Retail Sales
3. Aurora Brown, Customer Service Representative
4. Brad Adams, VP of Finance
5. Brian Crowell, Sales Director, GPO and Acute Care
6. Carl Ward, General Manager
7. Christopher Ferrandino, Sales Analyst
8. Christopher Woeste, VP Sales
9. Debora McClung, Manager of Accounting, North America
10. Emily Pupa, Associate Director, Marketing
11. Erica Coleman, Director of Operations and IT
12. Erick Holm, Director of Retail Sales
13. Janine Flannery, Trade Marketing Coordinator
14. Jeffrey Brooks, Director of Retail Sales
15. Kenneth Reinhard, Healthcare Sales Representative – SE
16. Kevin Verbrugge, Strategic Account Manager, LTC
17. Michelle Whitford, Customer Service Manager
18. Patricia Gaillard, Director of Marketing, Diabetes Care
19. Sylvie Verdon, Director of Regulatory Affairs, North America
20. Terry Seals, Quality Manager
21. Timperonce Porter, Customer Service Rep I
22. William Wright III, Hospital Account Executive
23. Yi Zhang, Senior Operations Manager

4HH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: LXO US, Inc.

Physical Address: 1690 Sumneytown Pike, Suite 250

City: Lansdale State: PA Zip: 19446

Mailing Address (if different from physical address): Same

City: _____ State: _____ Zip: _____

Telephone: 888-788-4984 Website: https://lxogroup.com

Name of Designated Representative (DR): Jason Jones

Licensing Company Email: customerservice@nodenpharma.com DR Email: jjones@lxous.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☑ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☑ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Eversana Life Sciences Services, LLC
Address: 4580 S Mendenhall Rd City: Memphis State: TN Zip: 38141
Name: RxCrossroads 3PL LLC
Address: 170 Clermont Road, Ste B City: Shepherdsville State: KY Zip: 40165
Name: Delpharm Milano SRL
Address: Via Salvatore Carnevale, 1, City: 2004 Segrate MI, Italy State: Zip:
Name: Genus Lifesciences Inc.
Address: 514 North 12th Street, City: Allentown State: PA Zip: 18102

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): LXO France
Corporation/Organization Name: LXO US, Inc.
Mailing Address: 1690 Sumneytown Pike, Suite 250
City: Lansdale State: PA Zip: 19446
Telephone: 888-788-4984 Email: customerservice@nodenpharma.com
Contact Person Name: Jason Jones

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7_1_2019_Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

LXO US, Inc.

Facility Name

Jason Jones

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

27 February 2025

Date

Board Use Only	Date Received: 3/4/25	Amount: $1000.00

An official website of the United States government Here's how you know

FDA

Search FDA.gov

Current through March 11, 2025

You have searched Finished drug products

Search Results: *'70839'*

Back to Search Page

Showing 1 to 4 of 4 entries Show 50 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description	Pharm Class	DEA
COCAINE HYDROCHLORIDE	70839-362-04	40mg/mL	SOLUTION	NASAL	NDA209963	LXO US INC.	70839-362	COCAINE HYDROCHLORIDE	COCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	01/29/2024	N/A	NDA AUTHORIZED GENERIC	1 BOTTLE, GLASS in 1 CARTON (70839-362-04) / 4 mL in 1 BOTTLE, GLASS	N/A	CII
Goprelto	70839-359-04	40mg/mL	SOLUTION	NASAL	NDA209963	LXO US Inc.	70839-359	cocaine hydrochloride	COCAINE HYDROCHLORIDE	HUMAN PRESCRIPTION DRUG	02/09/2024	N/A	NDA	1 BOTTLE, GLASS in 1 CARTON (70839-359-04) / 4 mL in 1 BOTTLE, GLASS	N/A	CII
Tekturna	70839-150-30	150mg/1	TABLET, FILM COATED	ORAL	NDA021985	LXO US Inc.	70839-150	aliskiren hemifumarate	ALISKIREN HEMIFUMARATE	HUMAN PRESCRIPTION DRUG	01/01/2017	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE (70839-150-30)	Renin Inhibitor [EPC], Renin Inhibitors [MoA]	N/A
Tekturna	70839-300-30	300mg/1	TABLET, FILM COATED	ORAL	NDA021985	LXO US Inc.	70839-300	aliskiren hemifumarate	ALISKIREN HEMIFUMARATE	HUMAN PRESCRIPTION DRUG	01/01/2017	N/A	NDA	30 TABLET, FILM COATED in 1 BOTTLE (70839-300-30)	Renin Inhibitor [EPC], Renin Inhibitors [MoA]	N/A

Previous 1 Next

Attachment to LXO US, Inc. Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Description of Operations:
LXO US Inc. ("LXO") is a virtual manufacturer selling prescription drugs and controlled substances to wholesalers. As a virtual manufacturer, LXO US Inc. does not manufacture, maintain or warehouse any non-controlled or controlled substances at its facility. As a result, LXO US Inc. does not have a DEA registration. The Landsdale facility is LXO US Inc.'s corporate headquarters.

LXO US Inc.'s hours of operations are Monday through Friday from 9:00 a.m. to 3:00 p.m. ET.

3PL:
Eversana Life Sciences Services, LLC
4580 S Mendenhall Rd,
Memphis, TN 38141
DEA: RD0205333

RxCrossroads 3PL LLC
170 Clermont Road, Ste B
Shepherdsville, KY 40165
DEA: RR0669400

LXO US, Inc. employee

Name	Title	Residence Address	Ownership %
Jason Jones	Head of US	[redacted]	0%

Designated Rep:
Jason Jones, Head of US
[redacted]

Parent Company:
LXO France (100%)
170 Bureaux de la Colline,
92213 Saint-Cloud Cedex, France

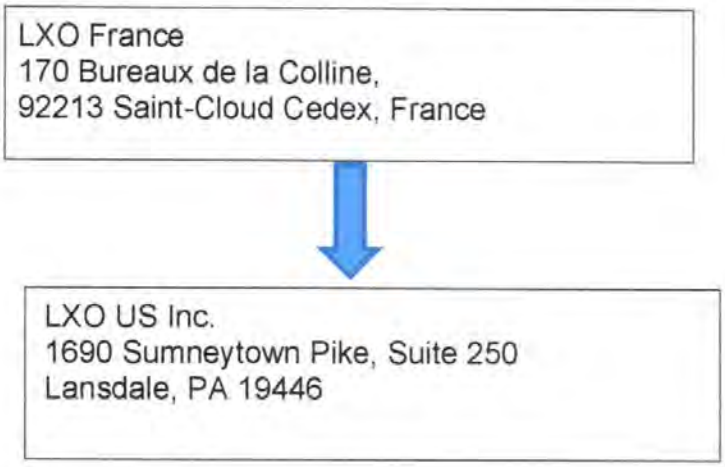
Attachment to LXO US, Inc. Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

Corporate Officer

Name	Title	Residence Address
Jason Jones	Head of US	[redacted]

Attachment to LXO US, Inc. Out-of-State Wholesaler Application (Nevada Board of Pharmacy)

LXO US Inc.'s Ownership (Parent 100%)
LXO US Inc. is a wholly owned subsidiary of LXO US Inc.



LXO US., INC (13534024)

Request Certificate

Initial Filing Date	07/29/2023
Status	Active
Formed In	DELAWARE
Foreign Name	LXO US., INC
Filing Type	Foreign Business Corporation
Principal Address	1690 SUMNYTOWN PIKE SUITE 250 LANSDALE, PA 19446
Mailing Address	1690 SUMNYTOWN PIKE SUITE 250 LANSDALE, PA 19446
Registered Office	Cogency Global Inc. County: DAUPHIN

View History

Request Access

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "LXO US., INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF SEPTEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "LXO US., INC." WAS INCORPORATED ON THE NINETEENTH DAY OF MAY, A.D. 2016.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

6046673 8300

SR# 20243639597

Authentication: 204348720

Date: 09-10-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Certificate of Record

Certificate No. 9500000257

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:
Office/Corporate Location
No product onsite

LXO US., INC.
1690 SUMNEYTOWN PIKE
SUITE 250
LANSDALE, PA 19446

The above business is recognized by the Department of Health as an entity that is doing business in the Commonwealth of Pennsylvania related to pharmaceuticals, medical devices, or cosmetics for which said entity **does not** physically handle, possess, transfer, manufacture, distribute, or retail pharmaceuticals, medical devices or cosmetics at the location on the certificate of record.

Issuance Date: September 08, 2023
Expiration Date: The Last Day of September, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Pennsylvania Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

LXO US., Inc. 1690 Sumneytown Pike Suite 250; Lansdale, PA 19446
Certificate(s): **9500000257** issued: 09/08/2023 expires: 9/30/2025

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version 4.0.0.0

Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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WASHINGTON D.C. 20537

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Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RR0669400	04-30-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	02-02-2024

RXCROSSROADS 3PL LLC
170 CLERMONT RD STE A
SHEPHERDSVILLE, KY 401658826

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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SHEPHERDSVILLE, KY 401658826

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DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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Form DEA-223/511 (9/2016)

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   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
2012

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 1114215

Application/License No. _____

LXO US, INC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1690 Sumneytown Pike, Suite 250 Lansdale, PA 19446 (Address of Applicant/Principal), as PRINCIPAL, and THE HANOVER INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of NH (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 440 Lincoln Street Worcester, MA 01653 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 5, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of February, 2025.

APPLICANT/PRINCIPAL
LXO US, INC

COMPANY

Authorized Representative

SURETY
THE HANOVER INSURANCE COMPANY

Surety Company's Representative

Richard Casas, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

COMMONWEALTH OF PENNSYLVANIA - NOTARY SEAL
Jeanette I Braun Notary Public
Montgomery County
My Commission Expires 7/21/2027
Commission #1263800

SIGNED and SEALED in the presence of:

Witness Ann Formhals

Witness Bartlomiej Siepierski

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

POWER OF ATTORNEY

THIS Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

KNOW ALL PERSONS BY THESE PRESENTS:

That THE HANOVER INSURANCE COMPANY and MASSACHUSETTS BAY INSURANCE COMPANY, both being corporations organized and existing under the laws of the State of New Hampshire, and CITIZENS INSURANCE COMPANY OF AMERICA, a corporation organized and existing under the laws of the State of Michigan, (hereinafter individually and collectively the "Company") does hereby constitute and appoint,

Susan A. Welsh, Christopher P. Troha, Sandra M. Winsted, Salena Wood, Christina L. Sandoval, Derek J. Elston, Judith A. Lucky-Eftimov, Aerie Walton, Bartlomiej Siepierski, Barbara Pannier, Rachel Fore, Kristin L. Hannigan, Jennifer Williams, Nicholas Kertesz, Corinne Chapman, Jean Torres, Roger Paraison, Samantha Chierici, Tara A. Reimer, Dartonya Wright and/or Stephanie Miller

Of **AON Risk Services of Chicago, IL** each individually, if there be more than one named, as its true and lawful attorney(s)-in-fact to sign, execute, seal, acknowledge and deliver for, and on its behalf, and as its act and deed any place within the United States, any and all surety bonds, recognizances, undertakings, or other surety obligations. The execution of such surety bonds, recognizances, undertakings or surety obligations, in pursuance of these presents, shall be as binding upon the Company as if they had been duly signed by the president and attested by the secretary of the Company, in their own proper persons. Provided however, that this power of attorney limits the acts of those named herein; and they have no authority to bind the Company except in the manner stated and to the extent of any limitation stated below:

Any such obligations in the United States, not to exceed Fifty Million and No/100 ($50,000,000) in any single instance

That this power is made and executed pursuant to the authority of the following Resolutions passed by the Board of Directors of said Company, and said Resolutions remain in full force and effect:

RESOLVED: That the President or any Vice President, in conjunction with any Vice President, be and they hereby are authorized and empowered to appoint Attorneys-in-fact of the Company, in its name and as it acts, to execute and acknowledge for and on its behalf as surety, any and all bonds, recognizances, contracts of indemnity, waivers of citation and all other writings obligatory in the nature thereof, with power to attach thereto the seal of the Company. Any such writings so executed by such Attorneys-in-fact shall be binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company in their own proper persons.

RESOLVED: That any and all Powers of Attorney and Certified Copies of such Powers of Attorney and certification in respect thereto, granted and executed by the President or Vice President in conjunction with any Vice President of the Company, shall be binding on the Company to the same extent as if all signatures therein were manually affixed, even though one or more of any such signatures thereon may be facsimile. (Adopted October 7, 1981 – The Hanover Insurance Company; Adopted April 14, 1982 – Massachusetts Bay Insurance Company; Adopted September 7, 2001 – Citizens Insurance Company of America and affirmed by each Company on March 24, 2014)

IN WITNESS WHEREOF, THE HANOVER INSURANCE COMPANY, MASSACHUSETTS BAY INSURANCE COMPANY and CITIZENS INSURANCE COMPANY OF AMERICA have caused these presents to be sealed with their respective corporate seals, duly attested by two Vice Presidents, this **17th** day of November, **2022**.

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

Bryan J. Salvatore, Executive Vice President

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

James H. Kawiecki, Vice President

THE COMMONWEALTH OF MASSACHUSETTS)
COUNTY OF WORCESTER) ss.

On this **17th** day of November, **2022** before me came the above named Executive Vice President and Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, to me personally known to be the individuals and officers described herein, and acknowledged that the seals affixed to the preceding instrument are the corporate seals of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, respectively, and that the said corporate seals and their signatures as officers were duly affixed and subscribed to said instrument by the authority and direction of said Corporations.

ARLEEN V. SIMONS
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
June 15, 2023

Areen V. Simons, Notary Public
My Commission Expires June 15, 2023

I, the undersigned Vice President of The Hanover Insurance Company, Massachusetts Bay Insurance Company and Citizens Insurance Company of America, hereby certify that the above and foregoing is a full, true and correct copy of the Original Power of Attorney issued by said Companies, and do hereby further certify that the said Powers of Attorney are still in force and effect.

GIVEN under my hand and the seals of said Companies, at Worcester, Massachusetts, this _5th__ day of _February_____ 2025_____.

THE HANOVER INSURANCE COMPANY
MASSACHUSETTS BAY INSURANCE COMPANY
CITIZENS INSURANCE COMPANY OF AMERICA

John A. Rowedder, Vice President

CERTIFIED COPY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler LXO US, Inc.

Pharmacy/Wholesaler License # (if applicable) Applying

Physical Address 1690 Sumneytown Pike, Suite 250

City Lansdale State PA Zip 19446

Mailing Address (if different from physical address) SAME

City _____ State _____ Zip _____

Telephone 888-788-4984 Website https://lxogroup.com

Licensing Company Email customerservice@nodenpharma.com

Section 2: Personal Information

First Jason Middle Kennedy Last Jones

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 1690 Sumneytown Pike, Suite 250

City Lansdale State PA Zip 19446

Telephone 888-788-4984 Email customerservice@nodenpharma.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of South Florida			8/1993 - 6/1996	
Address		**City**	**State**	**Zip**
4202 E Fowler Ave		Tampa	FL	33620
Diploma/Degree obtained, if any				
Mass Communications - B.A.				
School Name			**From - To (MM/YY – MM/YY)**	
Hillsborough Community Clg			8/1991 - 8/1993	
Address		**City**	**State**	**Zip**
4001 Tampa Bay Blvd		Tampa	FL	33619
Diploma/Degree obtained, if any				
Associates				
School Name			**From - To (MM/YY – MM/YY)**	
Chamberlain High School			8/1988 - 6/1991	
Address		**City**	**State**	**Zip**
9401 N Blvd		Tampa	FL	33612
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				
School Name			**From - To (MM/YY – MM/YY)**	
Address		**City**	**State**	**Zip**
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/2010 - present	[redacted]	Lansdale	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
LXO US, Inc.			06/23 - Present
Business Address	**City**	**State**	**Zip**
1690 Sumneytown Pike, Suite 250	Lansdale	PA	19446
Phone	**Title**	**Number of Employed Hours**	
888-788-4984	Head of US	3040	

Description of Duties

Head US Pharmaceutical Operations. Responsible for all commercial and operational activities including policies and procedures, storage, distribution, sales, and marketing.

Business Name			From - To (MM/YY – MM/YY)
Emergent BioSolutions (Acquired Adapt Pharma)			10/18 - 01/23
Business Address	**City**	**State**	**Zip**
401 Plymouth Road, Suite 400	Plymouth Meeting	PA	19462
Phone	**Title**	**Number of Employed Hours**	
	General Manager & Global Vice President, Commercial	8000	

Description of Duties

Developed new business strategy to redefine NARCAN business and significantly exceeded 2022 budget.Reshaped commercial strategy and organization to take NARCAN over the counter, first OTC rescue medication, and first Rx to OTC switch granted priority review by FDA. Led all sales, marketing, corporate accounts, trade, access, and operations efforts.

Business Name			From - To (MM/YY – MM/YY)
Adapt Pharma			05/15 - 10/18
Business Address	**City**	**State**	**Zip**
100 Matsonford Rd #201	Radnor	PA	19087
Phone	**Title**	**Number of Employed Hours**	
	Vice President Market Access, Trade, Pricing, Contracting | Executive Director | Director	6400	

Description of Duties

Served as key member of small management team to build NARCAN Nasal Spray brand and organization that was ultimately sold in 2018. Led commercial operations including commercialization strategy, market access, customer service, trade and distribution, commercial analytics, customer operations, sales operations, pricing, contracting and access agreements. Managed unique access needs including full line wholesale, specialty distribution, retail pharmacy, and government entities.

Business Name			From - To (MM/YY – MM/YY)
Teva Pharmaceuticals			06/14 - 05/15
Business Address	**City**	**State**	**Zip**
41 Moores Rd	Malvern	PA	19355
Phone	**Title**	**Number of Employed Hours**	
	Head of Trade Strategy (Branded)	1920	

Description of Duties

Developed and implemented unique and brand specific Trade and Channel strategies. Led commercial collaboration to understand brand/commercial needs to contribute to commercial success through optimal parent and provider access.

Business Name			From - To (MM/YY – MM/YY)
PBM Pharmaceuticals, Remote			08/13 - 06/14
Business Address	**City**	**State**	**Zip**
200 Garrett St STE O	Charlottesville	VA	22902
Phone	**Title**	**Number of Employed Hours**	
	Director of Trade and Distribution	1601	

Description of Duties

Functioned as key member of management to operationalize business sold to Concordia in 2014. Managed trade, distribution, and market access for small pharmaceutical company in a dynamic, start-up environment. Established trade and market access position to maximize revenue for portfolio.

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Endo Pharmaceuticals		06/11 - 03/13	
Business Address	**City**	**State**	**Zip**
1400 Atwater Dr	Malvern	PA	19355
Phone	**Title**	**Number of Employed Hours**	
	Director of Trade	3200	

Description of Duties

Drove Trade Strategy, Operations, and Channel Segment Marketing efforts for organization. Ensured parents had access to products while meeting strategic and financial goals. Developed meaningful analysis to drive decision-making across key corporate functions (forecasting, manufacturing, sales, marketing, corporate/brand finance). Served as organizational subject matter expert (SME) for Retail, Wholesale, Specialty Pharmacy, and Specialty Distribution. Managed operational budget investment of over $100MM. Provided dotted-line leadership to three trade account directors.

Business Name		From - To (MM/YY – MM/YY)	
GlaxoSmithKline Pharmaceuticals		08/00 - 06/11	
Business Address	**City**	**State**	**Zip**
2929 Walnut St	Philadelphia	PA	19104
Phone	**Title**	**Number of Employed Hours**	
	Senior Manager, Vaccines Channel Strategy and Operations	19,000	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

27 February 2025
Date

I, Jason Jones, **certify that as the designated representative for**

LXO US, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ___ I am at least 21 years of age;
3. ___ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ___ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ___ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ___ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ___ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jason Jones
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

27 February 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jason Jones

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

27 February 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Jason Jones, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

27 February 2025

Date

Subscribed and Sworn to before me this 27th day of February 2025

Notary Public Signature

COMMONWEALTH OF PENNSYLVANIA - NOTARY SEAL
Jeanette I Braun Notary Public
Montgomery County
My Commission Expires 7/21/2027
Commission #1263800

(Seal)

Jason Jones

[redacted]

BIOPHARMA COMMERCIAL OPERATIONS EXECUITIVE

Patient Access | Gross-to-net Strategy | Product Commercialization |
Channel Strategy | Sales and Marketing | Pricing and Contracting

Innovative commercial leader with extensive experience across the biopharmaceuticals sector, spanning Market Access, Trade, Marketing, and Sales. Skilled in driving large, mid, and start-up organizations to consistently exceed operational and financial targets. Adept at leveraging a diverse background with an acuity for tactical communication, engaging internal and external stakeholders across functions and hierarchies to facilitate success.

HIGHLIGHTS

- Held full P&L responsibility for $400MM NARCAN business, exceeding revenue and expense expectations.
- Developed and implemented unique channel strategy for NARCAN enabling direct sales to government entities resulting in 100% customer retention and preserved G2N.
- Achieved 99% of lives covered with 90% preferred for NARCAN.
- Negotiated multi-year NARCAN State contracts securing long-term stable revenue.
- Identified need to create unique GPI/GCN for reformulated product that prevented auto substitution at pharmacy, resulting annual sales in excess on $200MM.
- Built, launched, and managed vaccine eCommerce platform gskvaccinesdirect.com resulting in increased customer satisfaction and retention.

EXPERIENCE

LXO US Inc **6/2023- Present**
1690 Sumneytown Pike, Suite 250
Lansdale, PA 19446
Head of US
Head US Pharmaceutical Operations. Responsible for all commercial and operational activities including policies and procedures, storage, distribution, sales, and marketing.

Emergent BioSolutions (Acquired Adapt Pharma), Plymouth Meeting, PA
401 Plymouth Road, Suite 400. Plymouth Meeting, PA 19462 **10/2018 – 1/2023**
General Manager and Global Vice President, Commercial
Headed Emergent NARCAN Commercial Business Unit and all aspects of in-line and pipeline business including full P&L.

- Developed new business strategy to redefine NARCAN business and significantly exceeded 2022 budget.
- Reshaped commercial strategy and organization to take NARCAN over the counter, first OTC rescue medication, and first Rx to OTC switch granted priority review by FDA.
- Led all sales, marketing, corporate accounts, trade, access, and operations efforts.

Vice President, Enterprise Commercial Operations
Appointed to newly created role to identify capability gaps and build infrastructure across broader organization, consisting of four distinct business units. Key to EBSI five-year strategic plan to achieve commercial growth to $2B+.

- **Commercial Insights**: Innovated demand analytics, forecasting, sales operations, and market research resulting in better decision making.
- **Global Pricing and Contracting:** Drove gross to net discipline and compliance through pricing strategy, ROI, government calculations and reporting, contract operations, compliance, and sales order process.

- **Marketing Operations:** Developed and implemented enterprise-wide promotional review process, conference management, materials management, and KOL management.
- **Training and Development:** Coordinated sales training, sales meeting and POA design and execution, advanced learning creation and facilitation, and training analytics to drive consistency, leverage expertise, and rigor across the organization.

Vice President, Customer Operations and Access, NARCAN Business
Retained by Emergent BioSolutions to lead commercial operations and build out NARCAN operational capabilities to support revenue attainment.

Adapt Pharma, Radnor, PA
100 Matsonford Rd #201, Radnor, PA 19087 **5/2015 – 10/2018**

Vice President Market Access, Trade, Pricing, Contracting | Executive Director | Director
Served as key member of small management team to build NARCAN Nasal Spray brand and organization that was ultimately sold in 2018. Led commercial operations including commercialization strategy, market access, customer service, trade and distribution, commercial analytics, customer operations, sales operations, pricing, contracting and access agreements. Managed unique access needs including full line wholesale, specialty distribution, retail pharmacy, and government entities.

- Built commercial infrastructure and launched NARCAN into a disparate, complex market.
- Led market access efforts to secure >97% insured patient access.
- Negotiated and implemented wholesale, specialty, retail, and 3PL agreements ultimately realizing >$5MM in savings.
- Defined and managed government pricing and contract management processes, ensuring compliance and sound contracting and pricing decisions.
- Designed, negotiated, and implemented direct customer contracts securing durable customer relationships and revenue.
- Developed and implemented innovative retail strategies to ensure unprecedented access and pharmacist engagement.
- Implemented national retail programs to educate and inform pharmacists and patients on ability to take home naloxone.
- Aligned with strategic specialty partners to extend sales and marketing reach.
- Established customer operations function to meet unique market needs and grow direct customers.
- Managed gross-to-net models and decisions to maximize organizational profitability.

Teva Pharmaceuticals, Frazer PA **6/2014 – 5/2015**
41 Moores Rd, Malvern, PA 19355

Head of Trade Strategy (Branded)
Developed and implemented unique and brand specific Trade and Channel strategies. Led commercial collaboration to understand brand/commercial needs to contribute to commercial success through optimal patient and provider access.

PBM Pharmaceuticals, Remote **8/2013 – 6/2014**
200 Garrett St STE O, Charlottesville, VA 22902

Director of Trade and Distribution
Functioned as key member of management to operationalize business sold to Concordia in 2014. Managed trade, distribution, and market access for small pharmaceutical company in a dynamic, start-up environment. Established trade and market access position to maximize revenue for portfolio.

Endo Pharmaceuticals, Malvern, PA **6/2011 – 3/2013**
1400 Atwater Dr, Malvern, PA 19355

Director of Trade

Drove Trade Strategy, Operations, and Channel Segment Marketing efforts for organization. Ensured patients had access to products while meeting strategic and financial goals. Developed meaningful analysis to drive decision-making across key corporate functions (forecasting, manufacturing, sales, marketing, corporate / brand finance). Served as organizational subject matter expert (SME) for Retail, Wholesale, Specialty Pharmacy, and Specialty Distribution. Managed operational budget investment of over $100MM. Provided dotted-line leadership to three trade account directors.

ADDITIONAL RELEVANT EXPERIENCE

GlaxoSmithKline Pharmaceuticals, Philadelphia, PA **8/2000-6/2011**
2929 Walnut St, Philadelphia, PA 19104

Senior Manager, Vaccines Channel Strategy and Operations
Product Manager, gskvaccinesdirect.com
Associate Product Manager, VPH Franchise
Sales and Sales Leadership- Multiple award winner

EDUCATION

Bachelor of Arts (BA), Public Relations | Journalism
University of South Florida School of Mass Communications, Tampa, FL

411

Y

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Medisca Inc

Physical Address: 626 Tom Miller Rd.

City: Plattsburgh State: NY Zip: 12901

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 1-800-932-1039 Website: www.medisca.com

Name of Designated Representative (DR): Benjamin Arts

Licensing Company Email: regaffairs@medisca.com DR Email: barts@medisca.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	■ Controlled Substances	■ Repacker
■ Hospitals	■ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Please refer to attached Disciplicary Action statement

MM

Original Signature (electronic, copies or stamps not accepted)

05/17/2024

Date

Disciplinary Actions and Corrective Actions Taken

Please note that the below disciplinary actions have been previously reported to the board.

1. State of Florida, Department of Health – March 26, 2008

MEDISCA sold/and or transferred a legend drug (coal tar) to a person that was not authorized to purchase.

A fine of $250.00 was paid by MEDISCA to settle the matter.

Corrective Action

MEDISCA now only ships to clients that are specifically authorized by MEDISCA in advance to purchase MEDISCA's products. A valid license is a requirement for purchase of the products.

2a. State of Florida, Department of Health – October 22, 2008

As a result of personnel changeover of its Certified Designated Representative, MEDISCA's Out-of-State Prescription Drug Wholesaler Permit was inoperative during the time gap in the personnel changeover. During this gap, MEDISCA shipped a prescription drug to a client in Florida. MEDISCA also inadvertently did not provide pedigree papers to the client.

The Certified Designated Representative was replaced, and the permit was renewed on March 26, 2008. A fine of $1,500.00 was paid by MEDISCA to settle the matter.

2b. New York State Education Department – October 22, 2011

In response to the disciplinary action taken by the Florida Department of Health on October 22, 2008, the New York State Education Department took disciplinary action against MEDISCA on October 22, 2011.

A fine of $1,000.00 was paid by MEDISCA to settle this matter.

Corrective Actions

MEDISCA now has backup licensed Designated Representatives at its Plattsburgh, NY and Las Vegas, NV facilities to ensure that a replacement Designated Representative is available should the current Designated Representative suddenly leave employment, or otherwise ever need to be replaced. This should eliminate the possibility of a time gap resulting from the sudden departure of a Designated Representative.

In addition, a Pedigree Procedure (QC-221) was created to ensure that pedigree papers are provided to every client in Florida.

3. US Department of Justice, Drug Enforcement Administration – December 30, 2010

An inspection conducted by the DEA at MEDISCA's Plattsburgh, NY facility in March 2007 resulted in the following observations:

1- MEDISCA failed to report the distribution of encapsulating machines to the DEA
2- MEDISCA failed to report certain instances of suspicious order activity to the DEA
3- MEDISCA failed to include controlled substance samples, controlled substance waste materials and anabolic steroid substance raw materials in its initial controlled substance inventory
4- MEDISCA's manufacturing records failed to set forth actual controlled substance repackaging yields

MEDISCA asserted defenses to the observations. After negotiations with the Agency, a fine of $350,000.00 was agreed-upon by the parties and paid by MEDISCA to settle the matter. All of MEDISCA's DEA Controlled Substance registrations remain active.

Corrective Actions

Following the DEA's inspection, MEDISCA developed a program to monitor suspicious orders which applies a sliding scale of criteria to spot and report suspicious orders, and also to closely monitor any other activity which indicates a heightened scrutiny. Under this program, MEDISCA makes reports of any unusual activity to the DEA which it regards as suspicious. In addition, MEDISCA has voluntarily established a "Do Not Ship" list, comprised of 41 pharmacies with which MEDISCA no longer conducts business. A "Watch List" has also been voluntarily created where all controlled substance orders from pharmacies on this list are reviewed and approved by management prior to being shipped.

In order to fully know our customers and determine if they are at risk for diversion, on-site audits are also performed on behalf of MEDISCA by a 3rd party expert auditing company. The 3rd party is comprised of ex-DEA agents who are experts in targeting diversion. Self-audits are also performed on a regular basis at MEDISCA's facilities by outside consultants to ensure compliance with DEA regulations.

In addition, the following policies and procedures were implemented to meet the DEA's requirements:

1- Failure to report distribution of encapsulating machines:
Implementation of Policy *"CS-022 Reporting the Purchase of Encapsulating Machines to the DEA"*

2- Failure to report suspicious order activity:
Implementation of Policy *"CS-003 Investigation of Controlled Substance Orders / Suspicious Order Monitoring (SOM)"*

3- Failure to include in its initial controlled substance inventory controlled substance samples, controlled substance waste material, and anabolic steroid substance raw materials:

Medisca®

Implementation of Procedure *"CS-005 Monthly / Biennial Controlled Substances Inventory and Daily Cycle Count Procedure"*

4- Failure of its manufacturing records to set forth actual controlled substance repackaging yields: Implementation of Procedure *"PROD-001 General Production Procedures"*

4. Colorado State Board of Pharmacy – September 16th, 2011

The alleged violation was that MEDISCA failed to submit a Change of Designated Representative application within the 14 allotted days, as per Colorado's Regulation 15.01.14 when the Designated Representative at MEDISCA's Texas facility was suddenly terminated from employment.

It should be noted that MEDISCA's Texas facility did not conduct any business in Colorado until July 2011, once the Colorado Board confirmed that the license was in good standing.

MEDISCA Inc. agreed to pay a fine of $5,500.00 to the Colorado State Board of Pharmacy to settle the matter. The license in question remains Active.

Corrective Action

MEDISCA has tightened its procedures to ensure that should a change of Designated Representative occur at any of MEDISCA's facilities, the states will be notified in a timely fashion and the necessary forms and fees will be submitted in a timely manner.

5a. Food and Drug Administration – March 14th, 2012

Between July 2004 and February 2007, MEDISCA distributed a prescription drug product, Somatropin, to licensed pharmacies. During this time period, a few items (less than five letters) of promotional literature erroneously stating that the product was "FDA approved" or from an "FDA approved facility" were sent to certain clients. The terminology in the letters was incorrect; the documents should have stated that the product was "FDA registered" or from an "FDA registered facility".

This error had been caught and corrected during the company's own internal review process, and the product itself discontinued from sale. However, during an inspection of a pharmacy by the FDA some years later, the erroneous correspondence was found, and was construed by the FDA as a violation of the FDCA's Title 21 U.S.C §§ 331(a), 352(a), 333(a)(l) (Misbranding Drugs). To settle the matter, Mr. Antonio Dos Santos and MEDISCA Inc. pleaded guilty to a misdemeanor charge on October 14, 2011. The result was a $10,000 fine for MEDISCA and a $5,000 fine for Antonio Dos Santos. In addition, the company forfeited its profits from sales of the product. There was no probation or other disciplinary action imposed by the FDA.

5b. Colorado State Board of Pharmacy – March 27th, 2012

In response to the plea agreements with the FDA, the Colorado Board of Pharmacy imposed probation for a period of three years and MEDISCA agreed not to distribute Somatropin into the state of Colorado for the duration of the period of probation.

As noted, MEDISCA unilaterally discontinued all shipments of Somatropin in 2007.

MEDISCA was discharged from probation in June 2015.

5c. Kansas State Board of Pharmacy – June 29th, 2012

In response to the probation imposed by the Colorado Board of Pharmacy in March 2012, the Kansas State Board of Pharmacy also placed MEDISCA on probation and MEDISCA agreed not to distribute Somatropin into the state of Kansas for the duration of the probation period. This probation ran concurrently with the Order of the Colorado Board.

As noted, MEDISCA discontinued all shipments of Somatropin in 2007.

MEDISCA was discharged from probation in August 2015.

5d. Rhode Island Board of Pharmacy – October 18, 2012

In response to the actions taken by the Food and Drug Administration, the Rhode Island Board of Pharmacy placed MEDISCA on probation for a period of 6 months.

MEDISCA was discharged from probation in May 2013.

5e. Illinois Department of Financial and Professional Regulation – November 26, 2012

In response to the actions of the FDA, the Colorado Board of Pharmacy and Kansas Board of Pharmacy, the Illinois Department of Financial and Professional Regulation placed MEDISCA's Nevada and New York facilities on probation indefinitely. MEDISCA agreed not to distribute Somatropin into the state of Illinois for the duration of the probation period.

As noted, MEDISCA discontinued all shipments of Somatropin in 2007.

MEDISCA's Texas facility was placed on indefinite probation on October 23, 2015.

MEDISCA's New York and Nevada facilities were discharged from probation in December 2015 and the Texas facility was discharged in May 2016.

5f. South Carolina Board of Pharmacy – January 10, 2013

In response to the actions of the FDA and other Boards of Pharmacy, the South Carolina Board of Pharmacy placed MEDISCA on probation for a duration of 3 years.

MEDISCA was discharged from probation in March 2016.

5g. Iowa Board of Pharmacy – January 16, 2013

In response to the actions of the FDA and the Colorado Board of Pharmacy in March 2012, the Iowa Board of Pharmacy placed MEDISCA on probation for a period of 3 years. MEDISCA agreed not to distribute Somatropin into the state of Iowa for the duration of the probation period.

As noted, MEDISCA discontinued all shipments of Somatropin in 2007.

MEDISCA was discharged from probation in January 2016.

5h. Tennessee Board of Pharmacy – May 15, 2013

In response to the actions of the other Boards of Pharmacy, the Tennessee Board of Pharmacy placed MEDISCA on indefinite probation. MEDISCA agreed not to distribute Somatropin into the state of Tennessee for the duration of the probation period.

As noted, MEDISCA discontinued all shipments of Somatropin in 2007.

MEDISCA was discharged from probation in March 2017.

5i. Louisiana Board of Pharmacy – May 29, 2013

In response to the actions taken by the South Carolina Board of Pharmacy, the Louisiana Board of Pharmacy placed MEDISCA on probation for a period of 3 years.

MEDISCA was discharged from probation in January 2016.

5j. Michigan Board of Pharmacy – July 12, 2013

In response to the actions of the FDA, the Michigan Board of Pharmacy placed MEDISCA on probation for a duration of 1 year and imposed a $2000 fine. MEDISCA agreed not to distribute Somatropin into the state of Michigan for the duration of the probation period.

As noted, MEDISCA discontinued all shipments of Somatropin in 2007.

MEDISCA was discharged from probation in July 2014.

5k. Oregon Board of Pharmacy – August 30, 2013

In response to the actions taken by the FDA and other Boards of Pharmacy, the Oregon Board of Pharmacy placed MEDISCA on probation for a period of 3 years.

MEDISCA was discharged from probation in August 2016.

5l. Maryland Board of Pharmacy – September 13, 2013

In response to the actions taken by the FDA and other Boards of Pharmacy, the Maryland Board of Pharmacy placed MEDISCA on probation for a duration of 3 years.

MEDISCA was discharged from probation in December 2015.

5m. Indiana Board of Pharmacy – January 16, 2014

In response to the actions taken by the FDA and other Boards of Pharmacy, the Indiana Board of Pharmacy placed MEDISCA on indefinite probation with the ability to petition after three years to have it removed.

MEDISCA was discharged from probation in September 2017.

5n. New Hampshire Board of Pharmacy – February 19, 2014

In response to the actions taken by the FDA and other Boards of Pharmacy, the New Hampshire Board of Pharmacy disciplined MEDISCA.

A fine of $2,000.00 was paid by MEDISCA to settle this matter.

5o. Georgia Board of Pharmacy – March 19, 2014

In response to the actions taken by the FDA and other Boards of Pharmacy, the Georgia Board of Pharmacy placed MEDISCA on probation for 2 years. In addition, a fine of $1500.00 and a $500 administrative fee were paid by MEDISCA to settle this matter.

MEDISCA was discharged from probation in March 2016.

5p. California Board of Pharmacy – April 16, 2014

In response to the actions taken by the FDA and other Boards of Pharmacy, the California Board of Pharmacy disciplined MEDISCA.

MEDISCA became subject to a public reproval and paid $2352 to the Board for the cost associated with the investigation and enforcement of the matter.

5q. Missouri Board of Pharmacy – September 10, 2014

In response to the actions taken by the FDA and other Boards of Pharmacy, the Missouri Board of Pharmacy placed MEDISCA on probation for 3 years.

MEDISCA was discharged from probation in September 2017.

5r. New York State Education Department (NYSED) – January 21, 2015

In response to the actions taken by the FDA, the NYSED placed MEDISCA on probation for a period of 2 years during which time its licenses remain valid (revocation thereof was stayed for the probation period). In addition, MEDISCA was assessed a fine of $10,000 for each state registration.

MEDISCA was discharged from probation in January 2017.

5s. Alabama Board of Pharmacy – August 18, 2015

In response to the actions taken by the FDA and the other State Boards of Pharmacy, the Alabama Board of Pharmacy placed MEDISCA on probation for a period of 2 years. In addition, MEDISCA was assessed a fine of $21,000.

MEDISCA was discharged from probation in August 2017.

5t. Florida Department of Business and Professional Regulation – May 19, 2016

In response to the actions taken by the FDA and the other State Boards of Pharmacy, the Florida Department of Business and Professional Regulation took action against MEDISCA's New York facility on May 19, 2016.

A fine of $3000 was paid to settle this matter and it should be noted that the license in question remains active.

5u. Vermont Board of Pharmacy – December 14, 2016

Medisca®

In response to the actions taken by the FDA and the other State Boards of Pharmacy, the Vermont Board of Pharmacy took action against MEDISCA's New York, Nevada and Texas facilities on December 14, 2016.

A fine of $3000 was paid to settle this matter and it should be noted that the licenses in question remain active.

Corrective Actions

A new procedure was implemented for all employees in 2011. MEDISCA employees have since been trained not to respond to inquiries regarding the approval or registration of products prior to speaking with the Regulatory Affairs Department. Furthermore, all marketing materials will have regulatory and legal review prior to distribution.

Employees have also been informed that all documentation regarding the approval or registration of products must be written by the Regulatory Affairs Department, which in turn will be reviewed by counsel.

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Jiangsu Jiaerke Pharmaceuticals Group Corp., Ltd.
Address: No. 302, Huzhuangtou, Sanhuangmiao City: Changzhou State: China Zip: 213111

Name: Hubei Gedian Humanwell Pharmaceutical Co., Ltd
Address: Gedian Economic Development District, City: Hubei State: China Zip: 436070

Name: Zhejiang Xianju Pharmaceutical Co., Ltd.
Address: 15 West Fengxi Road, Modern Industrial City: Zhejiang State: China Zip: 317300

Name: Curia Spain SAU
Address: Lugar Parque Tecnologico De Boecillo City: Boecillo State: Spain Zip: 47151

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York
Parent Company (if any):
Corporation/Organization Name: Medisca Inc.
Mailing Address: 661 Route 3, Unit C
City: Plattsburgh State: NY Zip: 12901
Telephone: 518-563-4636 Email: regaffairs@medisca.com
Contact Person Name: Benjamin Arts

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019_Fingerprints2/Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medisca Inc.

Facility Name

Mitchell Rubin

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

05/17/2024

Date

Board Use Only	Date Received: 5/21/24	Amount: $1000-check 060755

An official website of the United States government Here's how you know

FDA

Share Tweet Linkedin Email Print

Drug Establishments Current Registration Site

New Search

Search Results for *Medisca*

Showing 1 to 1 of 1 entries (filtered from 4 total entries)

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
MEDISCA Inc.	3030582179	119357348	RELABEL; REPACK	626 Tom Miller Rd., Plattsburgh, New York (NY) 12901, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Friday, Apr 11, 2025

New Search

Medisca

Corporate Ownership/ Director Details:

Name:	Antonio Dos Santos
Title:	President/Beneficial Owner
Percent Ownership:	100%
Residence Address:	[redacted]
Business Address:	
Date of Birth:	
Email:	
SS#:	

Corporate Officers Details:

Name:	**Mitchell Rubin**
Title:	CFO/Treasurer
Percent Ownership:	0%
Residence Address:	[redacted]
Business Address:	
Date of Birth:	
Email:	
SS#:	

Name:	**Maria Zaccardo**
Title:	Executive Vice President/ Secretary
Percent Ownership:	0%
Residence Address:	[redacted]
Business Address:	
Date of Birth:	
Email:	
SS#:	

Name:	**Panagiota Danopoulos**
Title:	Sr Vice President, Global Strategy & Innovation
Percent Ownership:	0%
Residence Address:	[redacted]
Business Address:	
Date of Birth:	
Email:	
SS#:	

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	MEDISCA INC.
DOS ID Number:	1646528
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/24/1992
Statement Status:	CURRENT
Statement Due Date:	06/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on March 06, 2025 at 02:25 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100007601774 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-27

NAME OF SUPERVISOR
BENJAMIN A. ARTS

THIS IS TO CERTIFY

MEDISCA INC.
626 TOM MILLER RD
PLATTSBURGH, NY 12901

is duly recorded as a

REGISTERED WHOLESALER-REPACKER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWENTY-FOURTH DAY OF APRIL, 2024.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF MARCH, 2027.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
040219

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0688032	01-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4	MANUFACTURER	11-27-2024

MEDISCA INC
626 TOM MILLER RD
PLATTSBURGH, NY 12901

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0688032	01-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4	MANUFACTURER	11-27-2024

MEDISCA INC
626 TOM MILLER RD
PLATTSBURGH, NY 12901

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RM0688032	01-31-2026	$3699

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4	MANUFACTURER	11-27-2024

MEDISCA INC
626 TOM MILLER RD
PLATTSBURGH, NY 12901

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Drug Codes
4000 1724 7285 9041 9050 9143 9150 9193 9230 9250 9300 9740 9801

NEW YORK STATE DEPARTMENT OF HEALTH
CONTROLLED SUBSTANCE LICENSE

MEDISCA INC
626 TOM MILLER RD
PLATTSBURGH, NY 12901

Class: 010
MANUFACTURER

Licensed Location:
MEDISCA INC
626 TOM MILLER RD
PLATTSBURGH, NY 12901

Schedule:
II III IV V

HAS GIVEN SATISFACTORY EVIDENCE THAT ALL QUALIFICATIONS AS REQUIRED BY ARTICLE 33 OF THE PUBLIC HEALTH LAW AND PART 80 OF THE ADMINISTRATIVE RULES AND REGULATIONS HAVE BEEN MET AND IS HEREBY GRANTED A LICENSE TO ENGAGE IN CONTROLLED SUBSTANCE ACTIVITY IN THE STATE OF NEW YORK IN THE CLASSIFICATION STATED ABOVE.

LICENSE #: 0100239
EFFECTIVE: Oct 10 2024
EXPIRES: Oct 09 2026

JAMES V. McDONALD, M.D., M.P.H.,
COMMISSIONER OF HEALTH

TO BE PERMANENTLY DISPLAYED AT THE LICENSED SITE

Medisca®
PARTNERS IN WELLNESS

04/29/2024

Medisca Inc. - DEA Controlled Substance & List Chemical Registrations

To Whom It May Concern,

Please be advised that the Drug Enforcement Administration (DEA) application process to obtain controlled substances and list chemical registrations have been initiated for Medisca Inc.'s facility located at 626 Tom Miller Rd., Plattsburgh, NY 12901.

Kindly note that, Medisca Inc will begin to conduct controlled substances and list chemical activities at the facility once the applicable license has been issued by the DEA.

Should you require anything further, do not hesitate to contact the Regulatory Affairs Team at regaffairs@medisca.com.

Sincerely,
Medisca Team

Certificate of Insurance

This is to certify to:

TDC NNY Inc.
109 Industrial Boulevard
Plattsburgh, New York 12901

that policies of insurance as herein described have been issued to the Insured named below and are in force at this date.

Name of Insured – **Medisca Inc. & Al.**

Address of Insured – **6090 Henri Bourassa West, St-Laurent, QC H4R 3A6**

Location and Operations to which this Certificate applies – **626 Tom Miller Road, Plattsburgh, New York 12901 (TDC Building Number 25)**
Wholesaler of fine chemicals and pharmaceutical products

Kind of Policy	Insurer and Policy Number	Effective Date			Expiry Date			Limits of Liability	
		YYYY	MM	DD	YYYY	MM	DD		
Commercial General Liability **Public Liability** **-"Per Occurrence Basis"** **Products and/or Completed Operations** **-"Claims Made Basis"** Retroactive Date: Jan 19,1997 Contractual Liability Primary Insurance and ☒ Non-Contributory ☒ Broad Form Vendors ☒	**Certain Lloyd's Underwriters issued through SUM Strategic Underwriting Managers Inc.** **SUM-LS-08135-009**	2024	05	31	2025	05	31	General Aggregate: Public Liability - per Occurrence: Deductible per Occurrence: Products Liability/Completed Operations - per Claim and in the Aggregate: Deductible per Claim: Tenants' Legal Liability - per Occurrence/Aggregate: Deductible per occurrence: Medical Payments - per Occurrence/Aggregate: Deductible per occurrence:	$15,000,000 $15,000,000 $2,500 $15,000,000 $5,000 $5,000,000 $1,000 $50,000 $1,000

Note: The insurance afforded is subject to the terms, conditions and exclusions of the applicable policy. This Certificate is issued as a matter of information only and confers no rights on the holder and imposes no liability on the Insurer. The Insurer will endeavour to mail to the holder of this Certificate 30 days written notice of any material change in or cancellation of these policies, but assumes no responsibility for failure to do so.

ADDITIONAL INSURED (APPLICABLE TO COMMERCIAL GENERAL LIABILITY):
TDC NNY Inc. is added as Additional Insureds but only with respect to their liability arising out of the ownership, maintenance or use of that part of the premises leased to the Named Insured. HOLD HARMLESS INCLUDED in favor of Additional Insured

All above mentioned limits are in USD currency

June 3, 2024
Date

Quentin Kilby
Damage Insurance Broker
Authorized Representative

FORT | Assurances Insurance | Avantages sociaux Group Benefits

4 Carré Westmount Square
Bureau 200
Westmount (Québec)
H3Z 2S6

T 514 481-0481
1877 481-1481
info@fort-groupe.com
www.fort-groupe.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. MMS4260057

Application/License No. _____

Medisca Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 626 Tom Miller Rd., Plattsburgh, NY 12901, USA (Address of Applicant/Principal), as PRINCIPAL, and Trisura Insurance Company (Surety Company), a corporation organized under the laws of the state of Oklahoma (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is Suite 1504, 2 Stamford Plaza, 281 Tresser Blvd, Stamford, CT 06901 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 25th, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29th day of April, 2024.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Sarah Mainella, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

2 Stamford Plaza
Suite 1504, 281 Tresser Boulevard
Stamford, Connecticut 06901
us.surety@trisura.com

POWER OF ATTORNEY

Bond Number: MMS4260057
Bond issuance date: April 29th, 2024

KNOW ALL MEN BY THESE PRESENTS: That **TRISURA INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Oklahoma, authorized to conduct a surety business, and having its principal place of business at 2 Stamford Plaza, Suite 1504, Tresser Boulevard, Stamford, Connecticut 06901, does hereby constitute and appoint:

John Watt, Andrew Neilans, John Thorpe, Sarah Mainella, Frederic Beauregard, Emily Ritchie, Richard A. Grant, Dylan Smith, Megan Greidanus, Charlotte Melendy, Julia Marturano, Susy Alves

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **TRISURA INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **TRISURA INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **TRISURA INSURANCE COMPANY** at a meeting duly held on the **11th** day of **December, 2020.**

"RESOLVED, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **TRISURA INSURANCE COMPANY** have each executed and attested these presents

on this 25th day of February, 2022.

STATE OF Connecticut
County of Fairfield

George Jamos, Chief Underwriting Officer, Surety

Trisura Insurance Company CORPORATE SEAL

On this **25th** day of **February, 2022,** before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **TRISURA INSURANCE COMPANY**; that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at Fairfield, Connecticut the day and year first above written.

SERENA I. SZEKELY
Notary Public, State of Connecticut
My Commission Expires 10/31/2026

Serena I Szekely seal

, a Notary Public of Connecticut

My Commission Expires: **10/31/2026**

CERTIFICATION

I, the undersigned officer of **TRISURA INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand on this day, April 29th, 2024

Richard Grant

Richard Grant, Vice President, U.S. Surety

TO CONFIRM AUTHENTICITY OF THIS BOND OR DOCUMENT EMAIL: us.surety@trisura.com

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medisca Inc MDEG License # (if applicable): _____

Physical Address: 626 Tom Miller Rd.,

City: Plattsburgh State: NY Zip: 12901

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 1-800-932-1039 Website: www.medisca.com

Licensing Company Email: regaffairs@medisca.com

Section 2: Personal Information

First: Benjamin Middle: Andre Last: Arts

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Plattsburgh State: NY Zip: [redacted]

Telephone: [redacted] Email: barts@medisca.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Chenango Valey Jr-Sr High School		1994 - 1998	
Address	**City**	**State**	**Zip**
1160 Chenango Street	Binghamton	NY	13901
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
State University of New York at Plattsburgh		1998 - 2002	
Address	**City**	**State**	**Zip**
101 Broad St	Plattsburgh	NY	12901
Diploma/Degree obtained, if any			
Bachelor of Science in Biology with Minor in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		2011	
Address	**City**	**State**	**Zip**
4035 S Riverpoint Pkwy	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Masters of Management			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 - current	[redacted]	Plattsburgh	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medisca Inc			2017 to Present	
Business Address		**City**	**State**	**Zip**
661 Route 3, Unit C		Plattsburgh	NY	12901
Phone	**Title**		**Number of Employed Hours**	
518-563-4636	Quality Manager		6,00+	
Description of Duties				
See resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		x
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		x

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/23/2024
Date

I, Benjamin Arts, **certify that as the MDEG Administrator for**

Medisca Inc.,

that I (initial that you have read and meet the following requirements):

1. BA Have a high school diploma or its equivalent;
2. BA Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. BA Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. BA Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Arts

Print Name (First, Last)

Benjamin Arts

Original Signature (electronic, copies or stamps not accepted)

5/23/2024

Date

Board Use Only	Date Received:

Benjamin Andre Arts

[redacted]

EDUCATION:

University of Phoenix
Masters of Management — 8/2011

State University of New York at Plattsburgh
Bachelor of Science in Biology with Minor in Chemistry — 5/2002

CERTIFICATIONS/TRAINING:

Laboratory Animal Technologist (*AALAS*)
Good Laboratory Practices (GLP)
ISO9001 and ISO13485 Trained
Good Manufacturing Practices (GMP)

WORK EXPERIENCE:

2/2017 – Present — MEDISCA, Inc. — Plattsburgh, NY
Quality Manager, US

- Oversee Quality groups at US Locations
  - Plattsburgh NY
  - Irving, TX
- Oversee Customer Complaint Investigations
- Oversee Controlled Substance group
- Oversee bulk receipt, testing and release
- Oversee Quality inspections of Production Labs
- Perform Laboratory Production Audits
- Perform Inspection and Release of Finished Goods
- Conduct Out of Specification Investigations
- Conduct Deviation Investigations
- Maintain KPIs
- Maintain compliance to regulatory standards
- Host Customer Audits
- Host Regulatory Agency Audits
- Perform DEA End of Year Inventory Submissions
- Perform inspections of 3rd Party Service Providers
  - Laboratories
  - Subcontractors
  - Manufacturers

11/2015 – 2/2017 — MEDISCA, Inc. — Plattsburgh, NY
Quality Control Manager

- Oversee bulk receipt, testing and release
- Oversee Quality inspections of Production Labs
- Perform Laboratory Production Audits
- Perform Inspection and Release of Finished Goods
- Conduct Out of Specification Investigations
- Conduct Deviation Investigations
- Maintain KPIs
- Maintain compliance to regulatory standards

6/2014 - 11/2015 — MEDISCA, Inc. — Plattsburgh, NY
Quality Control Supervisor

- Oversee bulk receipt, testing and release
- Oversee Quality inspections of Production Labs
- Perform Laboratory Production Audits
- Perform Inspection and Release of Finished Goods
- Conduct Out of Specification Investigations
- Conduct Deviation Investigations
- Maintain KPI
- Maintain compliance to regulatory standards

2/2010 – 5/2/2014 Mountain Valley Integrated Solutions Plattsburgh, NY

Customer Support Manager

- Oversee ~30 customer support agents and 7 supervisory staff members
- Calculate profitability on an individual level and determine areas of improvement to maximize agent profitability
- Maintain schedules based on projected call volume
- Provide daily and weekly reports to clients
- Implement Plan of Actions to meet client expectations
- Adhere to guidelines of service provided by clients
- Provide resolution to clients' needs and concerns
- Monitor call volume and make staffing adjustments as needed
- Train agents on new campaigns, processes and procedures
- Utilize web-based ordering systems
- Use and interpret call reporting systems for clients
- Implementation of Standard Operating Procedures
- Provide feedback to agents and identify coaching opportunities
- Enforce and document established disciplinary polices
- Represent the company at trade shows and conventions
- Foster business relations with current and prospective clients
- Research and process credit card disputes based on client guidelines
- Represent the company for Unemployment Insurance hearings and provide documentation

5/2002 – 2/2010 **Wyeth Research** Chazy, NY

Veterinary Technician V/Quality Control/Sample Coordinator

- Writing medical records under GLP compliance
- Patient Surgical Monitoring
- Inventory control of medical supplies including controlled substances
- Schedule activities and duties for Veterinary Staff
- Maintain schedule of diagnostic health screening
- Venipuncture specialist (all species)
- Maintenance of computer based animal record system
- Perform radiology diagnostics
- Software and Hardware Validation Procedures including Report Generation
    - Web based animal care management system
    - Electrocardiogram Units
    - Computed Tomography System
        - *Neurologica NL3000 CereTom CT System*
- Representative on Wyeth Chazy Safety Committee
    - OSHA VPP Star Certified Site
- Provide medical care to all species
- Aided in inspections by government bodies/accreditation organizations
    - USDA
    - FDA
    - AAALAC
    - Department of Health
- Trained in GLP Standards

- Quality control documentation
- Abide by animal guidelines as established by USDA
- Processing and packaging of biological substances in accordance with proper transportation regulations using certified packaging materials

4/2005 – 4/2007 **Veterinary Medical Assistance Team (VMAT-1)**

VMAT is an emergency response team under FEMA. VMAT's mission is to provide veterinary medical assistance in the event of a disaster or disease outbreak

- Deployed during Hurricane Katrina/Rita

REVIEWS/PUBLICATIONS:

June 2004 *Nonhuman Primate Enrichment Utilizing Cage Tunnels*
AALAS Tribranch Symposium Poster Contest
Philadelphia, PA

May 2005 *Enrichment: Toys Aren't Just For Kids*
AALAS QUAD Symposium Poster Contest
Albany, NY

May 2005 *Nonhuman Primate Enrichment Utilizing Cage Tunnels*
AALAS QUAD Symposium Poster Contest
Albany, NY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Medisca Inc

Pharmacy/Wholesaler License # (if applicable) Initial application

Physical Address 626 Tom Miller Rd.

City Plattsburgh State NY Zip 12901

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email regaffairs@medisca.com

Section 2: Personal Information

First Benjamin Middle Andre Last Arts

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 626 Tom Miller Rd.

City Plattsburgh State NY Zip 12901

Telephone _____ Email barts@medisca.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Chenango Valey Jr-Sr High School		1994 - 1998	
Address	**City**	**State**	**Zip**
1160 Chenango Street	Binghamton	NY	13901
Diploma/Degree obtained, if any			
High School			
School Name		**From - To (MM/YY – MM/YY)**	
State University of New York at Plattsburgh		1998 - 2002	
Address	**City**	**State**	**Zip**
101 Broad St	Plattsburgh	NY	12901
Diploma/Degree obtained, if any			
Bachelor of Science in Biology with Minor in Chemistry			
School Name		**From - To (MM/YY – MM/YY)**	
University of Phoenix		2011	
Address	**City**	**State**	**Zip**
4035 S Riverpoint Pkwy	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Masters of Management			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 - current	[redacted]	Plattsburgh	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Medisca Inc			2017 to Present	
Business Address		**City**	**State**	**Zip**
661 Route 3, Unit C		Plattsburgh	NY	12901
Phone	**Title**		**Number of Employed Hours**	
518-563-4636	Quality Manager			
Description of Duties				
See attached resume				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/17/24
Date

I, Benjamin Arts, **certify that as the designated representative for**

Medisca Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BA I am at least 21 years of age;
3. BA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Benjamin Arts

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/17/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Arts

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

05/17/2024

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Clinton

I, Benjamin Arts, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/17/2024

Date

Subscribed and Sworn to before me this 17th day of May 2024.

Notary Public Signature

LAWRENCE PATRICK HARNEY
NOTARY PUBLIC STATE OF NEW YORK
CLINTON COUNTY
LIC. #01HA6293152
COMM. EXP. November 25, 2025

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Medisca Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 626 Tom Miller Rd.

City: Plattsburgh State: NY Zip: 12901

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 1-800-932-1039 Website: www.medisca.com

Licensing Company Email: regaffairs@medisca.com

Section 2: Personal Information

First: Antonio Middle: Last: Dos Santos

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: N/A – Canadian Citizen Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: St-Laurent State: Quebec Zip: [redacted]

Telephone: [redacted] Email: regaffairs@medisca.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ICN International Office			
Address	**City**	**State**	**Zip**
Geneva, Switzerland			
Diploma/Degree obtained, if any			
Trained in International Sales and Marketing			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2007 - Present	[redacted]	Saint Laurent	Québec	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Medisca Pharmaceutique Inc			1985 - Present
Business Address	**City**	**State**	**Zip**
6090 Blvd. Henri-Bourassa W	St-Laurent	Quebec	H4R 2L8
Phone	**Title**		
Description of Duties			
President/Owner			

Business Name			From - To (MM/YY – MM/YY)
Medisca Inc.			1992-Present
Business Address	**City**	**State**	**Zip**
661 Route 3, Unit C	Plattsburgh	NY	12901
Phone	**Title**		
Description of Duties			
President/Owner			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

1 Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03/17/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Antonio Dos Santos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/17/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Clinton

I, Antonio Dos Santos, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/17/2025

Date

Subscribed and Sworn to before me this 17th day of March 2025

Notary Public Signature

LAWRENCE PATRICK HARNEY
NOTARY PUBLIC STATE OF NEW YORK
CLINTON COUNTY
LIC. # 01HA6293152
COMM. EXP. November 25, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Medisca Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Initial application

Physical Address: 626 Tom Miller Rd.

City: Plattsburgh State: NY Zip: 12901

Mailing Address (if different from physical address): Same as about

City: _____ State: _____ Zip: _____

Telephone: 1-800-932-1039 Website: www.medisca.com

Licensing Company Email: regaffairs@medisca.com

Section 2: Personal Information

First: Benjamin Middle: Andre Last: Arts

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 626 Tom Miller Rd.

City: Plattsburgh State: NY Zip: 12901

Telephone: 1-800-932-1039 Email: barts@medisca.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Chenango Valey Jr-Sr High School		1994 - 1998	
Address	**City**	**State**	**Zip**
1160 Chenango Street	Plattsburgh	NY	13901
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
State University of New York at Plattsburgh			
Address	**City**	**State**	**Zip**
101 Broad St	Plattsburgh	NY	12901
Diploma/Degree obtained, if any			
Bachelor of Science in Biology with Minor in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix			
Address	**City**	**State**	**Zip**
4035 S Riverpoint Pkwy	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Masters of Management			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 - current	[redacted]	Plattsburgh	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Medisca Inc			2017 to Present
Business Address	**City**	**State**	**Zip**
661 Route 3, Unit C	Plattsburgh	NY	12901
Phone	**Title**		
518-563-4636	Quality Manager		
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

5/17/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Arts

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

5/17/24

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Clinton

I, Benjamin Arts, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

5/17/24

Date

Subscribed and Sworn to before me this 17th day of May, 2024

Notary Public Signature

LAWRENCE PATRICK HARNEY
NOTARY PUBLIC STATE OF NEW YORK
CLINTON COUNTY
LIC. # 01HA6293152
COMM. EXP. November 25, 2025

(Seal)

Employee Name (Last Suffix, First MI)	Job
Armstrong, Stacey L.	Packaging Technician
Arts, Benjamin	Quality Manager US
Barber, Robert M.	QC Inspector
Benjamin, Autumn R.	Staging Clerk
Boling, Erika	Quality Supervisor
Bousquet, Joshua A.	QC Inspector
Boyce, Joseph T.	Shipping Clerk
Cech, Steven	QC Inspector
Champagne, Rachel D.	Packaging Technician
Cole, Alex	Shipping Clerk
Daigdigan-Manor, Carren	Packaging Technician
Daniel, Brock J.	Packaging Technician
Dann, Jessalyn B.	QC Inspector
Darrah, Adam	Receiving and Inv Clerk
Davis, Linda L.	Warehouse LH- BL 10
DeCoste, Mark	Packaging Technician
DiFulvio, Deborah L.	Accounts Receivable Sup
Donoghue, Shayne R.	Receiving Clerk
Downs, Lauren G.	QC Inspector
Dragoon, Wyatt J.	Shipping Clerk
Espinal, Jacqueline	Shipping Clerk
Fleming, Jessica R.	Controlled Sub Admin
Folkes-Starke, Clovel	Packaging Technician
Forget, Robin L.	Accounts Receivable Clerk
Fountain, Betty	Packaging Technician
Fountain, Billiejo	Packaging Technician
Fountain, Schuyler G.	Packaging Technician
Frenyea, Kayla A.	Production Supervisor
Garrand, Zhana M.	Inventory Clerk
Garrant, Jennifer	QC Inspector
Garrow, Michelle L.	Packaging Technician
Girard, Tonya M.	Production Team Lead
Golden, Tod	Packaging Technician
Harney, Danielle D.	Controlled Substance LH
Harney, Larry	Operations Manager
Hart, Kierstin	Shipping Clerk
Heywood, Tammy L.	Packaging Technician
Imondi, Ryan	Shipping Clerk
Keable, Zachary J.	Shipping Team Lead
LaFave III, Donald	Category Buyer US
LaFave, Rayna M.	Packaging Technician
Lambert, Matthew H.	Inv and Receiving Sup
Laporte, Jessica	Packaging Technician
Latour, Austin	Packaging Technician
Leclair, Brandy L.	Shipping International TL
Lucas, Kimberly A.	Packaging Technician
Martin, Ariel E.	Production Team Lead
Martin, Cody R.	Maint & Tech Specialist
Martin, Hailey	Shipping Clerk

Martin, Sean	Quality Investigator
Martin, Zachary	Production Clerk
Martinez, Joshua	Shipping Clerk
Martino, Randi L.	Production Team Lead
Mcgarvey, Alisha	Packaging Technician
Mcnamara, Tyler	Packaging Technician
Nagy, Alexandra L.	QC Specialist
Nagy, Michael A.	QS Specialist Invest
Oliver, Kaysie	Packaging Technician
Oliver-Dragoon, Heather	Packaging Technician
O'Neal, Andre'e	Shipping Clerk
Pombrio, Shelby	Packaging Technician
Provost, Susan E.	Receiving Supervisor
Rizzie, Elisa	Production Team Lead
Robinson, Edward	Packaging Technician
Seymour, Kelsey	QC Specialist
Smith, Bettie	Accounts Receivable Clerk
Smith, James W.	Shipping Supervisor
Smith, Treena L.	Receiving Clerk
Stone, Terry	Shipping Team Lead
Terpstra, Amanda	Inventory Team Lead
Worden, Cory	Shipping International TL

4JJ

MN00737

Nevada, Jacksonville, pg 4

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Medtronic USA, Inc. dba Medtronic Logistics LLC

Physical Address: 6743 Southpoint Dr

City: Jacksonville State: FL Zip: 32216

Mailing Address (if different from physical address): Attn: Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: WWW.MEDTRONIC.COM

Name of Designated Representative (DR): Carlos Lamar Corley

Licensing Company Email: kay.knox@cevalogistics.com DR Email: carlos.l.corley@medtronic.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/24/2017	3/20/2018	CO	Parker	Douglas County (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2017-3679		Colorado Board of Pharmacy		
Reason/Charge				
Failure to report change of designated representative within 30 days				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Medtronic Logistics LLC		Fine and surcharge		
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Medtronic Logistics LLC (CO License WHI 6007) was disciplined for failure to timely report a change of Designated Representative within the require 30 day time period.

Terms of discipline: A fine with surcharge $1150. Medtronic Logistics LLC agreed to comply with Colorado regulations related to pharmacy businesses including timely reporting of Designated Representative changes with payment of associated fees going forward.

Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # ___3___ **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/3/2018	1/23/2019	CO	Parker	Douglas County (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
19-L-0013	Alabama State Board of Pharmacy

Reason/Charge
Failure to report Colorado disciplinary actions as required by Alabama regulations/rules

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Consent Order with administrative fine $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Count 1: (Alabama permit #194466)
Medtronic Logistics LLC, was disciplined for receiving Colorado Stipulation and Final Agency Order (2017-3679)

Count 2:
Medtronic Logistics LLC failed to report the Colorado Stipulation and Final Agency Order (2017-3679) on the Alabama 2019-2020 Renewal Application

Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/7/2021	7/12/2021	CO	Parker	Douglass County, (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2021-PHA-17242	Maine Board of Pharmacy

Reason/Charge
Failure to report disciplinary actions in CO and ME in timely manner

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Consent Agreement $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Medtronic Logistics LLC (Maine permit # WH70002083)

Issue 1
Medtronic Logistics LLC failed to report Colorado disciplinary action (2017-3679) to Maine within 10 days and did not reveal the same action at the time of renewal 12/12/2018. The Maine Board was not made aware of this action until 2/3/2020.

Issue 2
Medtronic Logistics LLC failed to report the Alabama disciplinary actions (19-L-0013) filed against the company within 10 days. The Maine Board of pharmacy was not made aware of this action until 7/18/2019.

Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Medtronic

Medtronic Logistics LLC has experienced the below disciplinary actions:

- Case # 2017-3679 (Colorado) CLS Stipulation and fine ($1150) , Medtronic Logistics LLC, Parker CO, Lic # WHI.0006007
  - Failure to report change of designated representative for 13 months when required to do so within 30 days.
- Case # 19-L-0013 (Alabama) Consent Order with administrative fine $2000, Medtronic Logistics LLC, Parker CO, Lic # 194466
  - CO Case # 2017-3679 CLS Stipulation issued
  - Failure to disclose the Colorado case # 2017-3679 when renewing the 2019-2020 application.
- Case # 2021-PHA-17242 (Maine) Consent Agreement with reprimand and civil penalty $2000 issued to Medtronic Logistics LLC, Parker CO, Lic # WH70002083
  - Failure to report the Colorado case # 2017-3679 within 10 days of final disposition.
  - Failure to report the Colorado case # 2017-3679 on the Maine 2019-2020 renewal application
  - Failure to report the Alabama Case # 19-L-0013 to Maine within 10 days as required by 10 MRS 8003-G(2)(C)

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2017-3679

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MEDTRONIC LOGISTICS, LLC, REGISTRATION NO. WHI 6007,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medtronic Logistics, LLC ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-3679, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2017).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 7, 2006, being issued registration number WHI 6007, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 18501 Plaza Dr., Parker, CO 80134.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, thirteen (13) months transpired between May 31, 2016, date the previous designated representative ceased the position, and June 27, 2017, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board;

(k) Has failed to meet generally accepted standards of pharmacy practice.

12-42.5-303. Wholesaler license requirements.

(5) The designated representative of an applicant for a wholesaler license shall:

(i) Update all of the information required in this part 3 whenever changes occur.

Pharmacy Board Rules and Regulations

15.01.11 Minimum required information for registration.

b. Changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall

impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one (1) lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6007) and the case number (2017-3679) on the check.

9. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges.

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. to appeal this Final Agency Order.

Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none

of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Completion of Terms.** Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent Outlet from the Final Agency Order, and Respondent Outlet's registration will be restored to active and unencumbered status.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

18. **Effective Date.** This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Authorized Representative Dated: 3/20/18

License Compliance Analyst
Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 3nd day of April, 2018.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
MEDTRONIC LOGISTICS LLC	)	BOARD OF PHARMACY
Wholesale Distributor Permit No. 194466	)	CASE NO: 19-L-0013

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Medtronic Logistics LLC (hereinafter referred to as "Medtronic") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as Exhibit "A."

Pursuant to Code of Alabama (1975) Section 41-22-12(f), the parties have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Medtronic violated the applicable provisions based upon the conduct set out in each and every Count of the Statement.

2. Medtronic shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and Medtronic shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Medtronic expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12) Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975) § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Medtronic further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Medtronic hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Medtronic agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Medtronic acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Medtronic acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 19th day of June 2019

Medtronic Logistics LLC

By _____
Its _____

DONE this the 19th day of June 2019

ALABAMA STATE BOARD OF PHARMACY

By _____
Kenny Sanders, President

By _____
James S. Williams
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
MEDTRONIC LOGISTICS LLC	)	**BOARD OF PHARMACY**
Wholesale Distributor Permit No. 194466	)	**CASE NO: 19-L-0013**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Medtronic Logistics LLC**
18501 E Plaza Drive
Parker, Colorado 80134

Pursuant to the provisions of Code of Alabama (1975) § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975) § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on [illegible] 2019 at [illegible] a.m. at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Medtronic Logistics LLC (Medtronic) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Medtronic has been guilty of the following, to-wit:

1. Board Rule 680-X-2-.23 is entitled Drug Manufacturers' Wholesale Distributors.

2. Board Rule 680-X-2-.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include

(a) Compliance with licensing requirements under previously granted license, if any

(b) Compliance with the requirements to maintain records required to be maintained

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution

(d) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety

3 Board Rule 680-X-2.23(3)(k)1. provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health

4 Board Rule 680-X-2.23(3)(k)2. provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no/100 Dollars ($1,000) for each violation

5 Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law

6 Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the

public safety or endangers the public health of the citizens of this state based upon the entry of a Stipulation and Final Agency Order by the Colorado State Board fo Pharmacy on April 3, 2018 attached hereto as Exhibit "A" and/or your failure to notify the Colorado Board of a change in your designated representative for thirteen (13) months when required to do so in thirty (30) days.

COUNT TWO

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your failure to disclose when required to do so on your 2019-2020 Renewal Application the Colorado discipline referenced above.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 22nd day of January 2019.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MEDTRONIC LOGISTICS LLC	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17242	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Medtronic Logistics LLC, for the renewal of its pharmaceutical wholesaler license. The parties to this Consent Agreement are: Medtronic Logistics LLC ("Medtronic"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since February 27, 2013, Medtronic has been licensed in Maine as a pharmaceutical wholesaler with a registered location of 18501 Plaza Drive, Parker, Colorado (license number **WH70002083**).

2. On April 3, 2018, the Colorado State Board of Pharmacy imposed discipline against Medtronic's Colorado registration (WHI 6007) pursuant to a Stipulation and Final Agency Order in Case No. 2017-3679.

3. Medtronic failed to report the Colorado discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On December 12, 2018, the Board received Medtronic's renewal application.

5. On that application, Medtronic responded "No" to the following question: "Since your last renewal, has any jurisdiction taken disciplinary action against any professional license you hold (except this license) or have held or denied your application for licensure?"

6. The Board accordingly renewed Medtronic's pharmaceutical wholesaler license.

7. On June 19, 2019, the Alabama State Board of Pharmacy imposed discipline against Medtronic's Alabama permit (194466) pursuant to a Consent Order in Case No.19-L-0013.

8. Medtronic failed to report the Alabama discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

9. On July 18, 2019, Medtronic reported to the Board for the first time that the Alabama State Board of Pharmacy had disciplined its permit.

10. On February 3, 2020, Medtronic reported to the Board for the first time that the Colorado State Board of Pharmacy had disciplined its registration.

11. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

12. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Medtronic's application for renewal of its license to be a pharmaceutical wholesaler. In lieu of the denial, the Board also voted to offer Medtronic this Consent Agreement. Unless Medtronic either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME

04333-0035, by **July 12, 2021,** the preliminary denial of Medtronic's application for licensure as a pharmaceutical wholesaler will become final.

COVENANTS

13. Medtronic admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken; and

b. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its December 12, 2018 application for renewal of licensure.

14. As discipline for the violation admitted to in paragraph 13 above, Medtronic agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of two thousand dollars ($2,000.00), which penalty is comprised of $1,500.00 for misrepresentation on its application and $500.00 for failing to report discipline within 10 days, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

15. Upon receipt of this signed Consent Agreement with the enclosed payment of the civil penalty from Medtronic, the Board will renew Medtronic's license contingent upon it meeting all other eligibility criteria.

16. Violation of any of the terms or conditions of this Consent Agreement by Medtronic shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. The Board and Medtronic agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Medtronic fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Medtronic, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Medtronic. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Medtronic.

18. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

19. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

20. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

21. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

22. Medtronic acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 6/11/21

MEDTRONIC LOGISTICS LLC

By: [signature]

Print Name: Philip J Albert

Title: Vice President

DATED: 7/8/21

[signature]

BRADLEY S. HAMILTON, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 7/9/21

[signature]

JOHN NICHOLS
Assistant Attorney General

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medtronic Puerto Rico Operations (MPRI)
Address: P.O. Box 6001 City: Villalba State: PR Zip: 00766

Name: Medtronic Ireland Manufacturing UC
Address: Parkmore Business Park West City: Galway State: Irelan Zip: IRE

Name: Medtronic Sophons
Address: 5744 Central Abe, Suite 100 City: Boulder State: CO Zip: 80301

Name: Medtronic Puerto Rico Operations CO
Address: Rd 31 KM 24 HM 4 Ceiba N Indus City: Juncos State: PR Zip: 00777

Section 4: Publicly Traded Corporation

State of Incorporation: Not Applicable
Parent Company (if any): Not Applicable
Corporation Name: Not Applicable
Mailing Address: Not Applicable
City: Not Applicable State: Not Applicabl Zip: Not Applicable
Telephone: Not Applicable Email: Not Applicable
Contact Person Name: Not Applicable
Date of SEC Registration: Not Applicable SEC Registration Number: Not Applicable Stock Exchange Symbol: Not Applica

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Medtronic Inc.
Corporation/Organization Name: Medtronic USA, Inc.
Mailing Address: 710 Medtronic Pkwy, LS245
City: Minneapolis State: MN Zip: 55432
Telephone: 508-261-6083 Email: rob.varner@medtronic.com
Contact Person Name: Robert Varner

Section 6: Partnership

Partnership Name: not applicable
Mailing Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable
Contact Person Name: not applicable

Section 7: Sole Owner

Owner's Name: not applicable
Business Name: not applicable
Business Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
✓ • **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
✓ • **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
✓ • **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
✓ • **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
NA • **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
NA • **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
NA • **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
✓ • **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
✓ • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
✓ • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
NA • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
NA • **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medtronic USA, Inc., dba Medtronic Logistics LLC, 1480 Arthur St, Louisville CO 80027
Facility Name

Robert Varner
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-24-24
Date

Board Use Only	Date Received: 10/7/24	Amount: $1000 cc

Nevada, Jacksonville, pg 42

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
MEDTRONIC XOMED, INC.
6743 SOUTHPOINT DR. NORTH
Jacksonville, FL 32216
Registration Number: 1045254
FEI Number*: 1045254
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
Medtronic, Inc.[6]
710 Medtronic Parkway
Minneapolis, MN US 55432
Owner/Operator Number: 2112641[7]

Official Correspondent:
Gabriela Moreira
6743 Southpoint Drive North
Jacksonville, FL 32216
Phone: 904-2797592

Verified MH 10/23/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2112641&OwnerOperator
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2112641&OwnerOperator

Page Last Updated: 09/30/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of Health & Human Services

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2112641&OwnerOperator

Medtronic USA Inc. Officer List

Name	company title	Business Address
Robert Varner	President	[redacted] Memphis TN [redacted]
Dov Shenkman	Vice President	[redacted] Glencoe IL [redacted]
Punit Menon	Vice President	[redacted] Shorewood, WI [redacted]

September 19, 2024

Nevada State Board of Pharmacy

985 Damonte Ranch PKWY, Suite 206
Reno, NV 89521

Medtronic USA, Inc. maintains 100% ownership of Medtronic Logistics LLC:

Organizational Chart



Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Medtronic USA, Inc.
Date Filed:	06/15/1984
File Number:	4R-233
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 12/18/2024

Steve Simon
Secretary of State
State of Minnesota

Medtronic

Memo to File

Author: Kay Knox

Date: May 23, 2024

Subject: Florida state license exemption

To whom it may concern, Florida offers an exemption to medical device manufacturers through Florida 499.015 which states: (8) Notwithstanding any requirements set forth in this part, a manufacturer of medical devices that is registered with the federal Food and Drug Administration is exempt from this section and s. 499.041(6) if:

(a) The manufacturer's medical devices are approved for marketing by, or listed with the federal Food and Drug Administration in accordance with federal law for commercial distribution; .....

The facility located at 6743 SouthPoint Dr. N, Jacksonville FL qualifies for this exception as it holds FDA registration # 1045254.

Please see the attached print of the FDA Establishment Registration and Device Listing website as evidence.

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 **FAX (A/C, No):** 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Indemnity Insurance Company of North America	43575
INSURER C : ACE Fire Underwriters Insurance Company	20702
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Medtronic, Inc. and its subsidiaries
710 Medtronic Parkway
LC310
Minneapolis, MN 55432

COVERAGES **CERTIFICATE NUMBER:** CHI-010895207-01 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			SPL G24561288 008	05/01/2024	05/01/2026	EACH OCCURRENCE	$	5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	15,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	15,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			ISAH10832810	05/01/2024	05/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$	
	☐ DED ☐ RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N	N / A		WLRC57196166 (AOS) (incl Stop Gap EL: MN,ND,OH,WA,WY)	05/01/2024	05/01/2025	X PER STATUTE ☐ OTH-ER		
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N						E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH)			WLRC57196257 (MO,NC,NE,OK)	05/01/2024	05/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
A	If yes, describe under DESCRIPTION OF OPERATIONS below			SCFC57196518 (PA)	05/01/2024	05/01/2025	E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	Workers Compensation continued			SCFC57196439 (WI)	05/01/2024	05/01/2025	Limit:		See Above
A	Excess Workers Compensation			WCUC57196567 (AZ) excess of $1M SIR	05/01/2024	05/01/2025	Limit:		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance.
RE: 4340 Swinnea Rd, Memphis TN 38118; 6743 Southpoint Dr, Jacksonville FL 32216; 1480 Arthur St, Louisville CO 80027; 4620 N Beach St, Ft Worth TX 76137; 18501 E Plaza Dr., Parker CO 80134; 7611 Northland Dr., Brooklyn Park MN 55428 5300 Airways Blvd, Suite 101, Memphis TN 38116; 2235 Route 322, Suite 200, Swedesboro NJ 08085

CERTIFICATE HOLDER
Medtronic Inc
Attn: LS370
710 Medtronic Parkway
Minneapolis, MN 55432

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN103154363
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC	Medtronic, Inc. and its subsidiaries 710 Medtronic Parkway LC310 Minneapolis, MN 55432
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Professional Health Care Liability:
Policy # SPL G24561288 008
05/01/2024 - 05/01/2026
Carrier: ACE American Insurance Company
$2,000,000 Each Claim
$15,000,000 Aggregate

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SURETY RIDER

To be attached to and form a part of

Bond No. 190054165

dated effective October 2, 2023
(MONTH-DAY-YEAR)

executed by Medtronic USA, Inc. , as Principal,
(PRINCIPAL)

and by Liberty Mutual Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

ADDING COVERED LOCATIONS:

4340 Swinnea Rd, Memphis TN 38118
18501 E Plaza Dr., Parker CO 80134
6743 Southpoint Dr, Jacksonville FL 32216
4620 N Beach St,. Ft Worth TX 76137
5300 Airways Blvd, Suite 101, Memphis TN 38116
7611 Northland Dr., Brooklyn Park MN 55428
1480 Arthur St, Louisville CO 80027
2235 Route 322, Swedesboro NJ 08085

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective November 26, 2024
(MONTH-DAY-YEAR)

Signed and Sealed November 26, 2024
(MONTH-DAY-YEAR)

Medtronic USA, Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Liberty Mutual Insurance Company
(SURETY)

By: Cynthia A. Choren
Cynthia A. Choren, Attorney-In-Fact
NV Non-Resident License No. 221080

S-0443/GEEF 10/99

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of November, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 190054165

Application/License No. _____

Medtronic USA Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5300 Airways Blvd., Memphis, TN 38116 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 5, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of October, 2023.

APPLICANT/PRINCIPAL

Medtronic USA Inc

Eric J. Sodeen, I
Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Cynthia L. Choren
Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact
print name
NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

SIGNED and SEALED in the presence of:

Brittany D. Stuckel
Witness Brittany D. Stuckel

Witness

Heidi A. Notheisen
Witness Heidi A. Notheisen

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of October 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medtronic USA, Inc. dba Medtronic Logistics LLC MDEG License # (if applicable): _____
Physical Address: 6743 Southpoint Drive North
City: Jacksonville State: Florida Zip: 32216
Mailing Address (if different from physical address): Attn: Kay Knox, 4097 E Marquette Ave
City: Terre Haute State: IN Zip: 47805
Telephone: 614-489-5164 Website: www.medtronic.com
Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Carlos Middle: Lamar Last: Corley
Alias(es, nicknames, name changes, etc.): _____
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Address: [redacted]
City: Jacksonville State: FL Zip: [redacted]
Telephone: [redacted] Email: carlos.l.corley@medtronic.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Columbia College		05/2008 - 07/2011	
Address	**City**	**State**	**Zip**
1001 Rogers Street	Columbia	MO	65216
Diploma/Degree obtained, if any			
Bachelors Degree			

School Name		From - To (MM/YY – MM/YY)	
Florida Community College of Jacksonville		01/2003 - 03/2007	
Address	**City**	**State**	**Zip**
101 State Street	Jacksonville	FL	32202
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
William M Raines High School			
Address	**City**	**State**	**Zip**
3663 Raines Avenue	Jacksonville	FL	32209
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2009 - Present	[redacted]	Jacksonville	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medtronic USA, Inc			02/1999 - Present	
Business Address		**City**	**State**	**Zip**
6743 Southpoint Drive North		Jacksonville	FL	32216
Phone	**Title**		**Number of Employed Hours**	
904-332-5316	Distribution Manager		44,000	
Description of Duties				
Responsible for shipping, receiving and the storage of medical devices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Carlos Lamar Corley, **certify that as the MDEG Administrator for**

Medtronic USA, Inc,

that I (initial that you have read and meet the following requirements):

1. CLC Have a high school diploma or its equivalent;
2. CLC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CLC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CLC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carlos Corley
Print Name (First, Last)

Carlos Corley
Original Signature (electronic, copies or stamps not accepted)

09/19/2024
Date

Board Use Only	Date Received: 10/21/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medtronic USA, Inc. dba Medtronic Logistics LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 6743 Southpoint Drive North

City: Jacksonville State: Florida Zip: 32216

Mailing Address (if different from physical address): Attn: Kay Knox, 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Carlos Middle: Lamar Last: Corley

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: Jacksonville State: Fl Zip: [redacted]

Telephone: [redacted] Email: carlos.l.corley@medtronic.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Columbia College		05/2008 - 07/2011	
Address	City	State	Zip
1001 Rogers Street	Columbia	MO	65216
Diploma/Degree obtained, if any			
Bachelors Degree			

School Name		From - To (MM/YY – MM/YY)	
Florida Community College of Jaacksonville		01/2003 - 03/2007	
Address	City	State	Zip
101 State Street	Jacksonville	FL	32202
Diploma/Degree obtained, if any			
Associates Degree			

School Name		From - To (MM/YY – MM/YY)	
William M Raines High School		08/1981 - 06/1984	
Address	City	State	Zip
3663 Raines Avenue	Jacksonville	Fl	32209
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2009 - Present	[redacted]	Jacksonville	Fl	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
N/A				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Medtronic USA, Inc			02/1999 - Present	
Business Address		**City**	**State**	**Zip**
6743 Southpoint Drive North		Jacksonville	Fl	32216
Phone	**Title**		**Number of Employed Hours**	
904-332-5316	Distribution Manager		44,000	
Description of Duties				
Responsible for shipping, receiving and the storage of medical devices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Carlos Lamar Corley, **certify that as the designated representative for**

Medtronic USA, Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CLC I am at least 21 years of age;
3. CLC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CLC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CLC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CLC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CLC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Carlos Corley

Print Name (First, Last)

Carlos Corley

Original Signature (electronic, copies or stamps not accepted)

September 19, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Carlos Corley

Print Name (First, Last)

Carlos Corley

Original Signature (electronic, copies or stamps not accepted)

September 30, 2024 SC

~~September 19, 2024~~

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Duval

I, Carlos Corley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Carlos Corley

Original Signature

September 30, 2024

Date

Subscribed and Sworn to before me this 30th day of September

Samantha Cartagena

Notary Public Signature

SAMANTHA MARIE CARTAGE
Notary Public - State of Flor
Commission # HH 57457
My Comm. Expires Jul 23, 2
Bonded through National Notary As

(Seal)

Medtronic Logistics LLC employee list, Jacksonville FL 10/11/24

Carlos Corley

Nick Vasquez

Mohammad Nasir

Phillip Robinson

Yesenia Newbill

Liz Torres

Antonio Blake

Warner Neil

August Banaban

Jacob Scoville

Jeff Miniano

Mark Harrington

Kileigh Banks

4KK

M000658

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Medtronic USA, Inc. dba Medtronic Logistics LLC

Physical Address: 4340 Swinnea Rd

City: Memphis State: TN Zip: 38118

Mailing Address (if different from physical address): Attn: Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: WWW.MEDTRONIC.COM

Name of Designated Representative (DR): Pamela Summons

Licensing Company Email: kay.knox@cevalogistics.com DR Email: Pam.summons@medtronic.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/24/2017	3/20/2018	CO	Parker	Douglas County (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2017-3679	Colorado Board of Pharmacy

Reason/Charge
Failure to report change of designated representative within 30 days

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Fine and surcharge

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Medtronic Logistics LLC (CO License WHI 6007) was disciplined for failure to timely report a change of Designated Representative within the require 30 day time period.

Terms of discipline: A fine with surcharge $1150. Medtronic Logistics LLC agreed to comply with Colorado regulations related to pharmacy businesses including timely reporting of Designated Representative changes with payment of associated fees going forward.

Rob Un

Original Signature (electronic, copies or stamps not accepted)

9-24-24

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # ___3___. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
4/3/2018	1/23/2019	CO	Parker	Douglas County (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
19-L-0013	Alabama State Board of Pharmacy

Reason/Charge
Failure to report Colorado disciplinary actions as required by Alabama regulations/rules

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Consent Order with administrative fine $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Count 1: (Alabama permit #194466)
Medtronic Logistics LLC, was disciplined for receiving Colorado Stipulation and Final Agency Order (2017-3679)

Count 2:
Medtronic Logistics LLC failed to report the Colorado Stipulation and Final Agency Order (2017-3679) on the Alabama 2019-2020 Renewal Application

Rob Ulm
Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
1/7/2021	7/12/2021	CO	Parker	Douglass County, (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2021-PHA-17242		Maine Board of Pharmacy		
Reason/Charge				
Failure to report disciplinary actions in CO and ME in timely manner				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Medtronic Logistics LLC			Consent Agreement $2000	
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Medtronic Logistics LLC (Maine permit # WH70002083)

Issue 1
Medtronic Logistics LLC failed to report Colorado disciplinary action (2017-3679) to Maine within 10 days and did not reveal the same action at the time of renewal 12/12/2018. The Maine Board was not made aware of this action until 2/3/2020.

Issue 2
Medtronic Logistics LLC failed to report the Alabama disciplinary actions (19-L-0013) filed against the company within 10 days. The Maine Board of pharmacy was not made aware of this action until 7/18/2019.

Rob Ulm
Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Medtronic

Medtronic Logistics LLC has experienced the below disciplinary actions:

- Case # 2017-3679 (Colorado) CLS Stipulation and fine ($1150) , Medtronic Logistics LLC, Parker CO, Lic # WHI.0006007
  - Failure to report change of designated representative for 13 months when required to do so within 30 days.
- Case # 19-L-0013 (Alabama) Consent Order with administrative fine $2000, Medtronic Logistics LLC, Parker CO, Lic # 194466
  - CO Case # 2017-3679 CLS Stipulation issued
  - Failure to disclose the Colorado case # 2017-3679 when renewing the 2019-2020 application.
- Case # 2021-PHA-17242 (Maine) Consent Agreement with reprimand and civil penalty $2000 issued to Medtronic Logistics LLC, Parker CO, Lic # WH70002083
  - Failure to report the Colorado case # 2017-3679 within 10 days of final disposition.
  - Failure to report the Colorado case # 2017-3679 on the Maine 2019-2020 renewal application
  - Failure to report the Alabama Case # 19-L-0013 to Maine within 10 days as required by 10 MRS 8003-G(2)(C)

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2017-3679

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MEDTRONIC LOGISTICS, LLC, REGISTRATION NO. WHI 6007,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medtronic Logistics, LLC ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-3679, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2017).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 7, 2006, being issued registration number WHI 6007, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 18501 Plaza Dr., Parker, CO 80134.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, thirteen (13) months transpired between May 31, 2016, date the previous designated representative ceased the position, and June 27, 2017, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board;

(k) Has failed to meet generally accepted standards of pharmacy practice.

12-42.5-303. Wholesaler license requirements.

(5) The designated representative of an applicant for a wholesaler license shall:

(i) Update all of the information required in this part 3 whenever changes occur.

Pharmacy Board Rules and Regulations

15.01.11 Minimum required information for registration.

b. Changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall

impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one (1) lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6007) and the case number (2017-3679) on the check.

9. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges.

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. to appeal this Final Agency Order.

Respondent Outlet freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none

of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Completion of Terms.** Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent Outlet from the Final Agency Order, and Respondent Outlet's registration will be restored to active and unencumbered status.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

18. **Effective Date.** This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

Authorized Representative Dated: 3/20/18

License Compliance Analyst
Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 3nd day of April, 2018.

State Board of Pharmacy

BY: Wendy Anderson
Wendy Anderson
Program Director

IN THE MATTER OF:	BEFORE THE ALABAMA STATE
MEDTRONIC LOGISTICS LLC	BOARD OF PHARMACY
Wholesale Distributor Permit No. 194466	CASE NO: 19-L-0013

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Medtronic Logistics LLC (hereinafter referred to as "Medtronic") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as Exhibit "A."

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties have agreed to informally resolve this matter by the entry of this Consent Order the terms of which are as follows:

1. The Board finds that Medtronic violated the applicable provisions based upon the conduct set out in each and every Count of the Statement.

2. Medtronic shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and Medtronic shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Medtronic expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12) Code of Alabama (1975) §41-22-12 and §40-22-20 and Code of Alabama (1975) § 20-2-50 et seq. and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Medtronic further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975) §41-22-18.

4. By execution of this Consent Order, Medtronic hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Medtronic agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Medtronic acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Medtronic acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 19th day of June 2019

Medtronic Logistics LLC

By Terry Murray
its Assistant Secretary

DONE this the 19th day of June 2019

ALABAMA STATE BOARD OF PHARMACY

By Kenny Sanders
Kenny Sanders, Sr., President

By
James W. Ward, Jr.
Its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
MEDTRONIC LOGISTICS LLC	)	**BOARD OF PHARMACY**
Wholesale Distributor Permit No. 194466	)	**CASE NO: 19-L-0013**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Medtronic Logistics LLC**
18501 E Plaza Drive
Parker, Colorado 80134

Pursuant to the provisions of Code of Alabama (1975) § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975) § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on [illegible] 2019 at [illegible] a.m. at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242 and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Medtronic Logistics LLC (Medtronic) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Medtronic has been guilty of the following, to-wit:

1. Board Rule 680-X-2-.23 is entitled Drug Manufacturers' Wholesale Distributors.

2. Board Rule 680-X-2-.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include

(a) Compliance with licensing requirements under previously granted license, if any

(b) Compliance with the requirements to maintain records required to be maintained

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution

(d) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety

3 Board Rule 680-X-2 23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health

4 Board Rule 680-X-2 23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and or to impose a fine not to exceed the sum of One Thousand and no 100 Dollars ($1,000) for each violation

5 Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law

6 Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit and/or your operation is not consistent with the

public safety or endangers the public health of the citizens of this state based upon the entry of a Stipulation and Final Agency Order by the Colorado State Board fo Pharmacy on April 3, 2018 attached hereto as Exhibit "A" and or your failure to notify the Colorado Board of a change in your designated representative for thirteen (13) months when required to do so in thirty (30) days.

COUNT TWO

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit and or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your failure to disclose when required to do so on your 2019-2020 Renewal Application the Colorado discipline referenced above.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 22nd day of January 2019.

ALABAMA STATE BOARD OF PHARMACY

By Donna C. Yeatman
Executive Secretary

Nevada, Swinnea Rd, pg 33

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MEDTRONIC LOGISTICS LLC	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17242	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Medtronic Logistics LLC, for the renewal of its pharmaceutical wholesaler license. The parties to this Consent Agreement are: Medtronic Logistics LLC ("Medtronic"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since February 27, 2013, Medtronic has been licensed in Maine as a pharmaceutical wholesaler with a registered location of 18501 Plaza Drive, Parker, Colorado (license number **WH70002083).**

2. On April 3, 2018, the Colorado State Board of Pharmacy imposed discipline against Medtronic's Colorado registration (WHI 6007) pursuant to a Stipulation and Final Agency Order in Case No. 2017-3679.

3. Medtronic failed to report the Colorado discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On December 12, 2018, the Board received Medtronic's renewal application.

5. On that application, Medtronic responded "No" to the following question: "Since your last renewal, has any jurisdiction taken disciplinary action against any professional license you hold (except this license) or have held or denied your application for licensure?"

6. The Board accordingly renewed Medtronic's pharmaceutical wholesaler license.

7. On June 19, 2019, the Alabama State Board of Pharmacy imposed discipline against Medtronic's Alabama permit (194466) pursuant to a Consent Order in Case No.19-L-0013.

8. Medtronic failed to report the Alabama discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

9. On July 18, 2019, Medtronic reported to the Board for the first time that the Alabama State Board of Pharmacy had disciplined its permit.

10. On February 3, 2020, Medtronic reported to the Board for the first time that the Colorado State Board of Pharmacy had disciplined its registration.

11. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

12. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Medtronic's application for renewal of its license to be a pharmaceutical wholesaler. In lieu of the denial, the Board also voted to offer Medtronic this Consent Agreement. Unless Medtronic either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME

04333-0035, by **July 12, 2021,** the preliminary denial of Medtronic's application for licensure as a pharmaceutical wholesaler will become final.

COVENANTS

13. Medtronic admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken; and

b. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its December 12, 2018 application for renewal of licensure.

14. As discipline for the violation admitted to in paragraph 13 above, Medtronic agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of two thousand dollars ($2,000.00), which penalty is comprised of $1,500.00 for misrepresentation on its application and $500.00 for failing to report discipline within 10 days, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

15. Upon receipt of this signed Consent Agreement with the enclosed payment of the civil penalty from Medtronic, the Board will renew Medtronic's license contingent upon it meeting all other eligibility criteria.

16. Violation of any of the terms or conditions of this Consent Agreement by Medtronic shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. The Board and Medtronic agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Medtronic fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Medtronic, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Medtronic. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Medtronic.

18. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

19. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

20. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

21. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

22. Medtronic acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 6/11/21

MEDTRONIC LOGISTICS LLC

By: _____

Print Name: Philip J Albert

Title: Vice President

DATED: 7/8/21

_____

BRADLEY S. HAMILTON, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 7/9/21

_____

JOHN NICHOLS
Assistant Attorney General

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medtronic Puerto Rico Operations (MPRI)
Address: P.O. Box 6001 City: Villalba State: PR Zip: 00766

Name: Medtronic Ireleand Manufacturing UC
Address: Parkmore Business Park West City: Galway State: Irelan Zip: IRE

Name: Medtronic Sophons
Address: 5744 Central Abe, Suite 100 City: Boulder State: CO Zip: 80301

Name: Medtronic Puerto Rico Operations CO
Address: Rd 31 KM 24 HM 4 Ceiba N Indus City: Juncos State: PR Zip: 00777

Section 4: Publicly Traded Corporation

State of Incorporation: Not Applicable
Parent Company (if any): Not Applicable
Corporation Name: Not Applicable
Mailing Address: Not Applicable
City: Not Applicable State: Not Applicabl Zip: Not Applicable
Telephone: Not Applicable Email: Not Applicable
Contact Person Name: Not Applicable

Date of SEC Registration: Not Applicable | SEC Registration Number: Not Applicable | Stock Exchange Symbol: Not Applica

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Medtronic Inc.
Corporation/Organization Name: Medtronic USA, Inc.
Mailing Address: 710 Medtronic Pkwy, LS245
City: Minneapolis State: MN Zip: 55432
Telephone: 508-261-6083 Email: rob.varner@medtronic.com
Contact Person Name: Robert Varner

Section 6: Partnership

Partnership Name: not applicable
Mailing Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable
Contact Person Name: not applicable

Section 7: Sole Owner

Owner's Name: not applicable
Business Name: not applicable
Business Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medtronic USA, Inc., dba Medtronic Logistics LLC, 1480 Arthur St, Louisville CO 80027
Facility Name

Robert Varner
Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

9-24-24
Date

Board Use Only	Date Received: 10/14/24	Amount: $1000 CC

Nevada, Swinnea Rd, pg 40

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
Medtronic Inc, -Swinnea
4340 Swinnea Rd MS SS-46
5300 Airway Blvd. Memphis, TN 38116
Memphis, TN 38118
Registration Number: 3009380063
FEI Number*: 3009380063
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Medtronic, Inc.[6]
710 Medtronic Parkway
Minneapolis, MN US 55432
Owner/Operator Number: 2112641[7]

Official Correspondent:
Robert Cassady
Medtronic Operations Distribution Memphis
4340 Swinnea Road
Bldg. B
Memphis, TN 38118
Phone: 901-3992148

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2112641&OwnerOperator
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Page Last Updated: 11/27/2023

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2112641&OwnerOperator

Medtronic USA Inc. Officer List

Name	company title	Business Address
Robert Varner	President	[redacted] Memphis TN [redacted]
Dov Shenkman	Vice President	[redacted] Glencoe IL [redacted]
Punit Menon	Vice President	[redacted] Shorewood, WI [redacted]

September 19, 2024

Nevada State Board of Pharmacy

985 Damonte Ranch PKWY, Suite 206
Reno, NV 89521

Medtronic USA, Inc. maintains 100% ownership of Medtronic Logistics LLC:

Organizational Chart



Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Medtronic USA, Inc.
Date Filed:	06/15/1984
File Number:	4R-233
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 12/18/2024

Steve Simon
Secretary of State
State of Minnesota

Business Record Details »

Minnesota Business Name

Medtronic Logistics LLC

Business Type
Limited Liability Company (Domestic)

File Number
618784400037

Filing Date
9/18/2012

Renewal Due Date
12/31/2025

Registered Agent(s)
Corporation Service Company

MN Statute
322C

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Manager
Greg Smith
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
USA

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	9/18/2012	Original Filing - Limited Liability Company (Domestic) (Business Name: Medtronic Logistics LLC)	
☐	9/16/2016	Registered Office and/or Agent - Limited Liability Company (Domestic)	
	1/1/2018	Conversion to 322C Due to Statute Mandate – Limited Liability Company (Domestic)	
☐	5/15/2018	Registered Office and/or Agent - Limited Liability Company (Domestic)	

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 Nevada, Swinnea Rd, pg 17

Business Record Details »

Minnesota Business Name
Medtronic USA, Inc.

Business Type
Business Corporation (Domestic)

File Number
4R-233

Filing Date
06/15/1984

Renewal Due Date
12/31/2024

Number of Shares
1,000

Chief Executive Officer
Jennifer Kirk
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

MN Statute
302A

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Registered Agent(s)
Corporation Service Company

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	06/15/1984	Original Filing - Business Corporation (Domestic)	
	06/15/1984	Business Corporation (Domestic) Business Name (Business Name: MEDTRONIC MILACA, INC.)	

	Filing Date	Filing	Effective Date
☐	03/14/1989	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	10/06/1995	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	12/11/1997	Business Corporation (Domestic) Business Name (Business Name: Medtronic USA, Inc.)	
	12/11/1997	Business Corporation (Domestic) Restated Articles	
☐	10/29/1998	Merger - Business Corporation (Domestic)	
☐	04/10/2007	Global Registered Office and/or Agent - Business Corporation (Domestic)	
☐	9/16/2016	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	5/17/2018	Registered Office and/or Agent - Business Corporation (Domestic)	

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Last Updated: 4/18/2025

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

Health Care Facilities

Licensed Facilities

Current Listings

Type = Pharmacy-Manufacturer/Wholesaler/Distributor
County = All
Results = 6

Click here to return to the search page

1

MEDTRONIC LOGISTICS LLC
4340 SWINNEA ROAD
Memphis, TN 38118
Attn: PAM SUMMONS
901-344-1358

Rank: Manufacturer

Facility License Number: 00003131
Status: Licensed
Date of Original Licensure: 11/02/2009
Date of Expiration: 04/30/2027
No Disciplinary Actions

2

MEDTRONIC LOGISTICS LLC
4620 NORTH BEACH STREET
Fort Worth, TX 76137
Attn: MARK RAINWATER
763-514-1762

Rank: Manufacturer

Facility License Number: 00003428
Status: Licensed
Date of Original Licensure: 01/27/2011
Date of Expiration: 03/31/2026
No Disciplinary Actions

3

MEDTRONIC LOGISTICS LLC
7611 NORTHLAND DRIVE
Brooklyn Park, MN 55430
Attn: Anthony Pogreba
763-514-1762

Rank: Manufacturer

Facility License Number: 00003616
Status: Licensed
Date of Original Licensure: 10/21/2011
Date of Expiration: 03/31/2026
No Disciplinary Actions

4

MEDTRONIC LOGISTICS LLC
18501 EAST PLAZA DRIVE
Parker, CO 80134
Attn: Staci Tomaszweski
508-261-6083

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 FAX (A/C, No): 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Indemnity Insurance Company of North America	43575
INSURER C : ACE Fire Underwriters Insurance Company	20702
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Medtronic, Inc. and its subsidiaries
710 Medtronic Parkway
LC310
Minneapolis, MN 55432

COVERAGES **CERTIFICATE NUMBER:** CHI-010895207-01 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			SPL G24561288 008	05/01/2024	05/01/2026	EACH OCCURRENCE	$	5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	15,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	15,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			ISAH10832810	05/01/2024	05/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$	
	EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$	
	DED ☐ RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			WLRC57196166 (AOS) (incl Stop Gap EL: MN,ND,OH,WA,WY)	05/01/2024	05/01/2025	X PER STATUTE ☐ OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N / A		WLRC57196257 (MO,NC,NE,OK)	05/01/2024	05/01/2025	E.L. EACH ACCIDENT	$	1,000,000
A	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			SCFC57196518 (PA)	05/01/2024	05/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
							E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	Workers Compensation continued			SCFC57196439 (WI)	05/01/2024	05/01/2025	Limit:		See Above
A	Excess Workers Compensation			WCUC57196567 (AZ) excess of $1M SIR	05/01/2024	05/01/2025	Limit:		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance.
RE: 4340 Swinnea Rd, Memphis TN 38118; 6743 Southpoint Dr, Jacksonville FL 32216; 1480 Arthur St, Louisville CO 80027; 4620 N Beach St, Ft Worth TX 76137; 18501 E Plaza Dr., Parker CO 80134; 7611 Northland Dr., Brooklyn Park MN 55428 5300 Airways Blvd, Suite 101, Memphis TN 38116; 2235 Route 322, Suite 200, Swedesboro NJ 08085

CERTIFICATE HOLDER
Medtronic Inc
Attn: LS370
710 Medtronic Parkway
Minneapolis, MN 55432

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN103154363
LOC #: Minneapolis

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA LLC	Medtronic, Inc. and its subsidiaries 710 Medtronic Parkway LC310 Minneapolis, MN 55432
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Professional Health Care Liability:
Policy # SPL G24561288 008
05/01/2024 - 05/01/2026
Carrier: ACE American Insurance Company
$2,000,000 Each Claim
$15,000,000 Aggregate

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SURETY RIDER

To be attached to and form a part of

Bond No. 190054165

dated effective October 2, 2023
(MONTH-DAY-YEAR)

executed by Medtronic USA, Inc., as Principal,
(PRINCIPAL)

and by Liberty Mutual Insurance Company, as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

ADDING COVERED LOCATIONS:

4340 Swinnea Rd, Memphis TN 38118
18501 E Plaza Dr., Parker CO 80134
6743 Southpoint Dr, Jacksonville FL 32216
4620 N Beach St,. Ft Worth TX 76137
5300 Airways Blvd, Suite 101, Memphis TN 38116
7611 Northland Dr., Brooklyn Park MN 55428
1480 Arthur St, Louisville CO 80027
2235 Route 322, Swedesboro NJ 08085

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective November 26, 2024
(MONTH-DAY-YEAR)

Signed and Sealed November 26, 2024
(MONTH-DAY-YEAR)

Medtronic USA, Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Liberty Mutual Insurance Company
(SURETY)

By: Cynthia L. Choren
Cynthia L. Choren, Attorney-In-Fact
NV Non-Resident License No. 221080

S-0443/GEEF 10/99

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of November, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 190054165

Application/License No. _____

Medtronic USA Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5300 Airways Blvd., Memphis, TN 38116 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 5, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of October, 2023.

APPLICANT/PRINCIPAL

Medtronic USA Inc

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact

print name

NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Brittany D. Stuckel

Witness Heidi A. Notheisen

Countersigned by:

N/A

Nevada Resident Agent

Posted February 20, 2020

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204866

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of October, 2023.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_022021

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medtronic USA, Inc. dba Medtronic Logistics LLC

Pharmacy/Wholesaler License # (if applicable): MP00658

Physical Address: 4340 Swinnea Road

City: Memphis State: Tn Zip: 38118

Mailing Address (if different from physical address): Attn: Kay Knox, 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Pamela Middle: Carlton Last: Summons

Alias(es, nicknames, name changes, etc.): Pam

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Lakeland State: TN Zip: [redacted]

Telephone: [redacted] Email: pam.summons@medtronic.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Memphis		01/79-12/80	
Address	City	State	Zip
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
Bachelor of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Shelby State College		09/76-12/78	
Address	City	State	Zip
737 Union Ave	Memphis	TN	38103
Diploma/Degree obtained, if any			
Associate Degree in Business			

School Name		From - To (MM/YY – MM/YY)	
Frayser Baptist High School		09/73-05/76	
Address	City	State	Zip
Mountain Terrace	Memphis	Tn	38127
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
NA			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/16 - Present	[redacted]	Lakeland	Tn	[redacted]
12/94-03/16		Bartlett	Tn	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
NA				

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Medtronic			06/98 - Present
Business Address	**City**	**State**	**Zip**
4340 Swinnea Road	Memphis	TN	38118
Phone	**Title**	**Number of Employed Hours**	
901-344-1358	Sr Manager Acounting and Inventory Control	54,080	
Description of Duties			
Manage the inventory at all America's facilities			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			
N A			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N A

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

THIS Page Not Applicable

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Pamela C. Summons, **certify that as the designated representative for**

Medtronic USA, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. PS I am at least 21 years of age;
3. PS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. PS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. PS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. PS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. PS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Pamela Summons

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

September 23, 2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PAM SUMMONS

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

9/23/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Shelby

I, PAM SUMMONS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

9/23/2024

Date

Subscribed and Sworn to before me this 23 day of September 2024

Angela M. Strickland

Notary Public Signature

ANGELA M. STRICKLAND
STATE OF TENNESSEE NOTARY PUBLIC
SHELBY COUNTY
MY COMMISSION EXPIRES 1-25-2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medtronic USA, Inc. dba Medtronic Logistics LLC MDEG License # (if applicable): MP 00458

Physical Address: 4340 Swinnea Rd

City: Memphis State: TN Zip: 38118

Mailing Address (if different from physical address): Attn: Kay Knox, 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Pamela Middle: C Last: Summons

Alias(es, nicknames, name changes, etc.): Pam

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Lakeland State: TN Zip: [redacted]

Telephone: [redacted] Email: pam.summons@medtronic.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Memphis		01/79-12/80	
Address	City	State	Zip
3720 Alumni Ave	Memphis	TN	38152
Diploma/Degree obtained, if any			
Bachelor of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Shelby State College		9/76 - 12/78	
Address	City	State	Zip
737 Union Avenue	Memphis	TN	38103
Diploma/Degree obtained, if any			
Associate Degree in Business			

School Name		From - To (MM/YY – MM/YY)	
Frayser Baptist High School		09/73 -05/76	
Address	City	State	Zip
Mountain Terrace	Memphis	TN	38127
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
N A			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/16 - present	[redacted]	Lakeland	TN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
12/94 - 03/16		Bartlett	TN	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N A

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medtronic			06/98 - Present	
Business Address		**City**	**State**	**Zip**
4340 Swinnea Road		Memphis	TN	38118
Phone	**Title**		**Number of Employed Hours**	
901-344-1358	Sr Manager Accounting and Inventory Control		54,080	
Description of Duties				
Manage the inventory at all America's facilities				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

This Page Not Applicable

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

This page Not applicable

Original Signature (electronic, copies or stamps not accepted) Date

I, Pamela Summons, **certify that as the MDEG Administrator for**

Medtronic USA, Inc.,

that I (initial that you have read and meet the following requirements):

1. PS Have a high school diploma or its equivalent;
2. PS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. PS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. PS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pamela Summons
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

September 23, 2024
Date

Board Use Only	Date Received: 10/4/24

Medtronic Employee list, Swinnea Rd, 09 25 24

Legal Name - First Name	Legal Name - Middle Name	Legal Name - Last Name	Job Title
Misael	Josue	Aguilar Pinto	Ship/Rec/Stores Clerk II
Yolanda		Angarita	Ship/Rec/Stores Clerk II
Keosha	Shamere	Barnett	Inspector II
Keionna	C	Bassett	Import/Export Coord III
Wendy	S	Belle	Inspector IV
Kendall		Billingsley	Quality Engineer II
Natasha	N.	Blevins	Inspector III
Bobby	G	Bly	Plant Maintenance Mechanic IV
Darnetha	Mashell	Booker	Inspector II
Joann		Bowen	Inspector IV
Jasmine	C	Boxley	Design Technician I
Carlos		Bradford	Inspector II
Alma		Burford	Inspector II
Kyle	S	Burks	Quality Technician IV
Shukria		Burl	Inspector II
Veronica	N	Carr	Inspector II
Deiona	L	Carroll	Ship/Rec/Stores Clerk II
James	A	Caughlin	Quality Technician III
Lawrence	R	Chamberlin	Quality Technician V
Darryl		Clark	Ship/Rec/Stores Clerk III
Eric	B	Clark	Quality Technician IV
Tamia		Clark	Machinist I
Antonio	D	Coleman	Inspector IV
Alicia	Michelle	Coltharp	Ship/Rec/Stores Clerk II
Jarrett		Copeland	Ship/Rec/Stores Clerk II
Alandrea	Kay	Cox	Quality Engineer II
Courtney		Crawford	Manufacturing Tech I
Antoine	R	Davis	Quality Technician IV
Len	D	Davis	Toolmaker III

Medtronic Employee list, Swinnea Rd, 09 25 24

Legal Name - First Name	Legal Name - Middle Name	Legal Name - Last Name	Job Title
Holly	Nicole	Delph	Inspector III
Joseph	G	DiMotta	Quality Technician III
Jackie		Dockery	Inspector II
Devin	L	Douglas	Ship/Rec/Stores Clerk III
William	G	Dunaway	Sr Manufacturing Supervisor
Bronson	D	Fennell	Sr Inspection Supv
Kameron		Fisher	Assembler I
Robert	A	Fisk	Inspector IV
Carlio	G	Franklin	Manufacturing Tech II
David		Frazier	Distribution Group Lead IV
Stephen	R	Fulton	Manufacturing Director
Shalandus		Garrett	Quality Engineer II
Christopher	Lynn	Gates	Manufacturing Tech I
Shirley	J	Gilkey	Manufacturing Tech I
Trisha	L	Gillespie	Inspector II
Jamal	Ellis	Glass	Inspector II
Forrest	C	Goo	Sr Prin Quality Engineer
Hunter		Gooch	Manufacturing Tech II
Adrianna	M	Gray	Distribution Supervisor
Candise		Greene	Inspector III
Thomas		Greenlee	Supplier Qual Engineer II
Riley		Gutridge	Machinist I
James		Hall	Distribution Group Lead IV
Chassidy		Harris	Inspector II
Job		Harris	Distribution Supervisor
Micah		Harris	Assembler I
Shanetta	L	Hartfield	Inspector III
Eltoressa	Takeia	Hawkins	Inspector II
Rashunda		Hazzle	Assembler III

Medtronic Employee list, Swinnea Rd, 09 25 24

Legal Name - First Name	Legal Name - Middle Name	Legal Name - Last Name	Job Title
Adam		Hill	Manufacturing Tech I
BreAna		Hodges	Ship/Rec/Stores Clerk II
Michael	L	Honey	Machinist III
Reginald	L	Hooks	Sr Distribution Supervisor
Chauncey		Hopkins	Inspector II
Deborah		Humphreys	Inspector II
Catherine	A	Hunsucker	Project Coordinator V
Darrence	Vaughn	Hunter	Design Technician I
Kimberly	Ann	Hurse	Assembler I
Racquel	Toinette	Isom	Inspector II
Alexandria	Michelle	Jackson	Ship/Rec/Stores Clerk II
Brett	A	Jenkins	Machinist I
Latina	M	Johnson	Assembler II
Maurice	D.	Johnson	Assembler I
Vintrell	T	Johnson	Ship/Rec/Stores Clerk II
Craig	A	Kauffman	Prin Manufacturing Engineer
Matthew	S.	Koch	Configuration Control Clerk II
James	E	Kusmierz	Sr Engineering Manager
Joe		Lee	Manufacturing Manager
Joshwa	Cochese	Lightfoot	Assembler IV
Charles	Henry	Love	Distribution Group Lead IV
Chadwick	P	Massey	Manufacturing Tech I
Dinesha		Mathis	Ship/Rec/Stores Clerk II
Robert	E	Mckinnie	Inspector II
Pamela		Milan	Supplier Qual Engineer I
Sharon	Patricia	Miles	Machinist I
Robyn		Miller	Supplier Qual Engineer II
Mohamud		Mohamed	Design Technician I
Willa	Jingwen	Moon	Accounting Director

Medtronic Employee list, Swinnea Rd, 09 25 24

Legal Name - First Name	Legal Name - Middle Name	Legal Name - Last Name	Job Title
Jacob	Tyler	Muse	Machinist I
Ariel		Myers	Ship/Rec/Stores Clerk II
LaQuaysha	X	Newby Cole	Inspector II
Julius	L	Owens	Inspector III
Lourdes		Parra	Ship/Rec/Stores Clerk II
Andrew	R	Parrish	Quality Technician III
Krutal		Patel	Supplier Qual Engineer II
IaEashia	Y	Patterson	Sr Inspection Supv
Jovon	M	Patterson	Prin Quality Systems Spec
Michael	Henry	Payment	Inspector IV
Lourde		Peralta	Ship/Rec/Stores Clerk II
Alison	R	Porter	Inspector IV
Blake	J	Prather	Sr Distribution Supervisor
Bonjourese	L.	Pritchard	Quality Systems Spec
Philip		Purnell	Inspector II
Robert	M	Raley	Plant Maintenance Mechanic III
Shandra		Ransfer	Design Technician I
Benjamin	Robert	Reardon	Engineering Manager
Lenorris		Reed	Quality Technician II
Maida		Reynoso Perez	Ship/Rec/Stores Clerk II
Sherronda	L	Richardson	Distribution Group Lead IV
Jamila		Roberts	Ship/Rec/Stores Clerk II
Mariela		Rodriguez	Engineering Manager
Nekima	Lashell	Royston	Manufacturing Tech I
Shenese		Royston	Inspector II
Thomas	B	Sanders	Mfg Operations QA Director
Adrian	T	Smith	Assembler II
Russell	E	Sorn	Sr Inspection Supv
Paula	J	Spight	Inspector IV

Medtronic Employee list, Swinnea Rd, 09 25 24

Legal Name - First Name	Legal Name - Middle Name	Legal Name - Last Name	Job Title
Matthew		Stevens	Distribution Group Lead IV
Kristen	C	Stewart	Inspection Spec V
Angela	M	Strickland	Project Coordinator IV
Lorraine	M	Suggs	Inspector II
Malika	D.	Sullivan	Inspector II
Devin	Deandre	Tallie	Quality Technician III
Kevin		Tate	Inspector II
Stephen	Kennedy	Tatum	Ship/Rec/Stores Clerk II
Marlenea	M	Taylor	Inspector IV
Sandra	L	Taylor	Assembler III
Marquis	J	Terry	Manufacturing Tech I
Dean		Thai	Ship/Rec/Stores Clerk II
Joseph		Torres	Sr Employee Relations Spec
Sachin Singh		Vijaya Kishore Singh	Sr Supplier Qual Engineer
Eric	K	Walters	Quality Systems Manager
Jason	Adrian	Washington	Inspector II
Douglas	A	Watkins	Plant Maintenance Mechanic II
Lloyd		White	Distribution Group Lead IV
Teresa	F	White	Buyer/Planner
Ruben	L	Williams	Inspector III
Lashandra	A	Williamson	Project Coordinator IV
Kenneth	Ben	Winterstein	Prin Quality Engineer
Zachary		Wood	Lean Sigma Program Manager
Terrell		Woods	Machinist III
Brennan		Wright	Ship/Rec/Stores Clerk II

4LL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☒ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Medtronic USA, Inc. dba Medtronic Logistics LLC

Physical Address: 18501 E Plaza Dr

City: Parker State: CO Zip: 80134

Mailing Address (if different from physical address): Attn: Kay Knox 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: WWW.MEDTRONIC.COM

Name of Designated Representative (DR): Staci Tomaszewski

Licensing Company Email: kay.knox@cevalogistics.com DR Email: Staci.tomaszweski@medtronic.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☒ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☒ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
6/24/2017	3/20/2018	CO	Parker	Douglas County (Colorado)
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2017-3679		Colorado Board of Pharmacy		
Reason/Charge				
Failure to report change of designated representative within 30 days				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Medtronic Logistics LLC		Fine and surcharge		
Name of Business/Industry/Entity				
Medtronic Logistics LLC				

Provide explanation below:

Medtronic Logistics LLC (CO License WHI 6007) was disciplined for failure to timely report a change of Designated Representative within the require 30 day time period.

Terms of discipline: A fine with surcharge $1150. Medtronic Logistics LLC agreed to comply with Colorado regulations related to pharmacy businesses including timely reporting of Designated Representative changes with payment of associated fees going forward.

Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # ___3___. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	**State**	**City**	**County**
4/3/2018	1/23/2019	CO	Parker	Douglas County (Colorado)

Case #	**Governing**, licensing, **Arresting Presiding Body/Agency/Court**
19-L-0013	Alabama State Board of Pharmacy

Reason/Charge
Failure to report Colorado disciplinary actions as required by Alabama regulations/rules

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/**Bankruptcy**
Medtronic Logistics LLC	Consent Order with administrative fine $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Count 1: (Alabama permit #194466)
Medtronic Logistics LLC, was disciplined for receiving Colorado Stipulation and Final Agency Order (2017-3679)

Count 2:
Medtronic Logistics LLC failed to report the Colorado Stipulation and Final Agency Order (2017-3679) on the Alabama 2019-2020 Renewal Application

Rob Ulm
Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____ **Provide all the following *where applicable:***

Date of Event/Arrest	Disposition Date	State	City	County
1/7/2021	7/12/2021	CO	Parker	Douglass County, (Colorado)

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2021-PHA-17242	Maine Board of Pharmacy

Reason/Charge
Failure to report disciplinary actions in CO and ME in timely manner

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Medtronic Logistics LLC	Consent Agreement $2000

Name of Business/Industry/Entity
Medtronic Logistics LLC

Provide explanation below:

Medtronic Logistics LLC (Maine permit # WH70002083)

Issue 1
Medtronic Logistics LLC failed to report Colorado disciplinary action (2017-3679) to Maine within 10 days and did not reveal the same action at the time of renewal 12/12/2018. The Maine Board was not made aware of this action until 2/3/2020.

Issue 2
Medtronic Logistics LLC failed to report the Alabama disciplinary actions (19-L-0013) filed against the company within 10 days. The Maine Board of pharmacy was not made aware of this action until 7/18/2019.

Original Signature (electronic, copies or stamps not accepted)

9-24-24
Date

Medtronic

Medtronic Logistics LLC has experienced the below disciplinary actions:

- Case # 2017-3679 (Colorado) CLS Stipulation and fine ($1150) , Medtronic Logistics LLC, Parker CO, Lic # WHI.0006007
  - Failure to report change of designated representative for 13 months when required to do so within 30 days.
- Case # 19-L-0013 (Alabama) Consent Order with administrative fine $2000, Medtronic Logistics LLC, Parker CO, Lic # 194466
  - CO Case # 2017-3679 CLS Stipulation issued
  - Failure to disclose the Colorado case # 2017-3679 when renewing the 2019-2020 application.
- Case # 2021-PHA-17242 (Maine) Consent Agreement with reprimand and civil penalty $2000 issued to Medtronic Logistics LLC, Parker CO, Lic # WH70002083
  - Failure to report the Colorado case # 2017-3679 within 10 days of final disposition.
  - Failure to report the Colorado case # 2017-3679 on the Maine 2019-2020 renewal application
  - Failure to report the Alabama Case # 19-L-0013 to Maine within 10 days as required by 10 MRS 8003-G(2)(C)

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2017-3679

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE IN-STATE WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF MEDTRONIC LOGISTICS, LLC, REGISTRATION NO. WHI 6007,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Medtronic Logistics, LLC ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2017-3679, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as an in-state wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2017).

2. Respondent Outlet was originally registered in the State of Colorado on or about December 7, 2006, being issued registration number WHI 6007, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 18501 Plaza Dr., Parker, CO 80134.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, thirteen (13) months transpired between May 31, 2016, date the previous designated representative ceased the position, and June 27, 2017, the date the application and fee were received.

6. Respondent Outlet was required to report a change of designated representative to the Board within thirty (30) days of such change.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board;

(k) Has failed to meet generally accepted standards of pharmacy practice.

12-42.5-303. Wholesaler license requirements.

(5) The designated representative of an applicant for a wholesaler license shall:

(i) Update all of the information required in this part 3 whenever changes occur.

Pharmacy Board Rules and Regulations

15.01.11 Minimum required information for registration.

b. Changes in any information in section 15.01.11 shall be submitted to the Board within thirty calendar days thereof.

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the Board on a form supplied by the Board within thirty calendar days of such change. The incoming designated representative must undergo the required background check.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall

impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one (1) lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board. Respondent Outlet shall write its registration number (WHI 6007) and the case number (2017-3679) on the check.

9. **Compliance.** Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

10. **Other Requirements.** Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges.

c. to have a formal disciplinary hearing pursuant to §§12-42.5-123 and 12-42.5-124, C.R.S.; and

d. to appeal this Final Agency Order.

Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

12. **Acknowledgments.** The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none

of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

14. **Completion of Terms.** Upon satisfactory completion of all terms and conditions set forth in this Final Agency Order, the Board shall release Respondent Outlet from the Final Agency Order, and Respondent Outlet's registration will be restored to active and unencumbered status.

15. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. **Public Record**. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. **Board Order.** This Final Agency Order shall become an order of the Board when it is accepted and signed by the Program Director or authorized Board representative

18. **Effective Date**. This Final Agency Order shall become effective upon (a) mailing by first-class mail to Respondent Outlet at Respondent Outlet's address of record with the Board, or (b) service by electronic means on Respondent Outlet at Respondent Outlet's electronic address of record with the Board. Respondent Outlet hereby consents to service by electronic means if Respondent Outlet has an electronic address on file with the Board.

ACCEPTED AND AGREED BY

Respondent Outlet

[signature] Dated: 3/20/18
Authorized Representative

License Compliance Analyst
Name / Title

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 3nd day of April, 2018.

State Board of Pharmacy

BY: [signature]
Wendy Anderson
Program Director

IN THE MATTER OF:	BEFORE THE ALABAMA STATE
MEDTRONIC LOGISTICS LLC	BOARD OF PHARMACY
Wholesale Distributor Permit No. 194466	CASE NO: 19-L-0013

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Medtronic Logistics LLC (hereinafter referred to as "Medtronic") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement which is attached hereto as **Exhibit "A."**

Pursuant to Code of Alabama (1975) Section 41-22-12(f) the parties have agreed to informally resolve this matter by the entry of this Consent Order, the terms of which are as follows:

1. The Board finds that Medtronic violated the applicable provisions based upon the conduct set out in each and every Count of the Statement.

2. Medtronic shall pay to the Board an administrative fine in the amount of Two Thousand dollars ($2,000.00) within thirty (30) days of the effective date of this Order which is the date it is executed on behalf of the Board. This obligation of payment to the Board shall not be dischargeable in bankruptcy and Medtronic shall not attempt to discharge the same in any bankruptcy proceeding.

3. That Medtronic expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama

(1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Medtronic further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Medtronic hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. That Medtronic agrees that any further violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

6. That Medtronic acknowledges, stipulates and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Medtronic acknowledges, stipulates and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is executing this Consent Order freely and voluntarily without coercion, duress, or threats or pursuant to any promises and had the right to seek advice of counsel before executing this Consent Order.

DONE this the 18th day of June 2019.

Medtronic Logistics LLC

By [illegible]
its [illegible]

DONE this the 19th day of June 2019.

ALABAMA STATE BOARD OF PHARMACY

By Kenny Sanders
Kenny Sanders as its President

By [illegible]
James S[illegible]
its Attorney

WARD & COOPER, LLC
2100 Southbridge Parkway
Suite 645
Birmingham, Alabama 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
MEDTRONIC LOGISTICS LLC	)	**BOARD OF PHARMACY**
Wholesale Distributor Permit No. 194466	)	**CASE NO: 19-L-0013**

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: **Medtronic Logistics LLC**
18501 E Plaza Drive
Parker, Colorado 80134

Pursuant to the provisions of Code of Alabama (1975) § 34-23-32, § 34-23-32.1, § 34-23-34, § 34-23-92(11) and (12) and Code of Alabama (1975) § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on [illegible] 2019 at [illegible] a.m. at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242 and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Medtronic Logistics LLC (Medtronic) as a Wholesale Distributor should not be revoked, suspended or placed on probation or a monetary penalty imposed and/or a renewal of the same should be granted in that it is alleged that Medtronic has been guilty of the following, to-wit:

1. Board Rule 680-X-2-.23 is entitled Drug Manufacturers' Wholesale Distributors.

2. Board Rule 680-X-2-.23(3) provides that the Board of Pharmacy shall consider, at a minimum, certain factors in reviewing the qualifications of those who engage in the wholesale distribution of drugs within Alabama. Those minimum factors

include

(a) Compliance with licensing requirements under previously granted license, if any

(b) Compliance with the requirements to maintain records required to be maintained

(c) The furnishing by the applicant of false or fraudulent material in any application made in connection with drug manufacturing or distribution

(d) Any other factors or qualifications the Board of Pharmacy considers relevant to and consistent with public health and safety

3 Board Rule 680-X-2 23(3)(k)(1) provides that it shall be a violation of this Rule to operate in such a manner as to endanger public health

4 Board Rule 680-X-2 23(3)(k)(2) provides any violation of this Rule may be grounds for the revocation, suspension, probation or refusal to issue the permit and/or to impose a fine not to exceed the sum of One Thousand and no 100 Dollars ($1,000) for each violation

5 Board Rule 680-X-2.23(3)(k)(3) provides that must operate in compliance with applicable Federal and State law

6 Code of Alabama (1975), § 34-23-32 requires a current and valid permit in order to engage in the activities set out therein

COUNT ONE

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit, and/or your operation is not consistent with the

public safety or endangers the public health of the citizens of this state based upon the entry of a Stipulation and Final Agency Order by the Colorado State Board fo Pharmacy on April 3, 2018 attached hereto as Exhibit "A" and/or your failure to notify the Colorado Board of a change in your designated representative for thirteen (13) months when required to do so in thirty (30) days.

COUNT TWO

The Board alleges you have violated the above referenced provisions and you are not qualified to possess the permit and/or your operation is not consistent with the public safety or endangers the public health of the citizens of this state based upon your failure to disclose when required to do so on your 2019-2020 Renewal Application the Colorado discipline referenced above.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 23rd day of January 2019.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

Nevada Parker CO pg2 1

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
MEDTRONIC LOGISTICS LLC	)	CONSENT AGREEMENT
	)	
Case No. 2021-PHA-17242	)	

PARTIES

This document is a Consent Agreement regarding the pending application of Medtronic Logistics LLC. for the renewal of its pharmaceutical wholesaler license. The parties to this Consent Agreement are: Medtronic Logistics LLC ("Medtronic"), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since February 27, 2013, Medtronic has been licensed in Maine as a pharmaceutical wholesaler with a registered location of 18501 Plaza Drive, Parker, Colorado (license number **WH70002083).**

2. On April 3, 2018, the Colorado State Board of Pharmacy imposed discipline against Medtronic's Colorado registration (WHI 6007) pursuant to a Stipulation and Final Agency Order in Case No. 2017-3679.

3. Medtronic failed to report the Colorado discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On December 12, 2018, the Board received Medtronic's renewal application.

Nevada Parker DD pg 32

5. On that application, Medtronic responded "No" to the following question: "Since your last renewal, has any jurisdiction taken disciplinary action against any professional license you hold (except this license) or have held or denied your application for licensure?"

6. The Board accordingly renewed Medtronic's pharmaceutical wholesaler license.

7. On June 19, 2019, the Alabama State Board of Pharmacy imposed discipline against Medtronic's Alabama permit (194466) pursuant to a Consent Order in Case No.19-I.-0013.

8. Medtronic failed to report the Alabama discipline to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

9. On July 18, 2019, Medtronic reported to the Board for the first time that the Alabama State Board of Pharmacy had disciplined its permit.

10. On February 3, 2020, Medtronic reported to the Board for the first time that the Colorado State Board of Pharmacy had disciplined its registration.

11. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

12. At its meeting on January 7, 2021, the Board reviewed the above information and voted to preliminarily deny Medtronic's application for renewal of its license to be a pharmaceutical wholesaler. In lieu of the denial, the Board also voted to offer Medtronic this Consent Agreement. Unless Medtronic either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, ME

04333-0035, by **July 12, 2021,** the preliminary denial of Medtronic's application for licensure as a pharmaceutical wholesaler will become final.

COVENANTS

13. Medtronic admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline as follows:

a. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken; and

b. Pursuant to 10 M.R.S. § 8003(5-A)(A)(1), for making a misrepresentation to the Board on its December 12, 2018 application for renewal of licensure.

14. As discipline for the violation admitted to in paragraph 13 above, Medtronic agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of two thousand dollars ($2,000.00), which penalty is comprised of $1,500.00 for misrepresentation on its application and $500.00 for failing to report discipline within 10 days, payment of which shall be made payable to the "Treasurer, State of Maine" and delivered to Maine Board of Pharmacy, Compliance Division, Office of Professional and Occupational Regulation, 35 State House Station, Augusta, Maine 04333-0035, and must be submitted with the signed Consent Agreement.

15. Upon receipt of this signed Consent Agreement with the enclosed payment of the civil penalty from Medtronic, the Board will renew Medtronic's license contingent upon it meeting all other eligibility criteria.

16. Violation of any of the terms or conditions of this Consent Agreement by Medtronic shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

17. The Board and Medtronic agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Medtronic fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Medtronic, and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Medtronic. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Medtronic.

18. This Consent Agreement is not appealable and is effective until modified or terminated by the parties hereto.

19. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

20. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

21. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

22. Medtronic acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 6/11/21 MEDTRONIC LOGISTICS LLC

By: [signature]

Print Name: Philip J Albert

Title: Vice President

DATED: 7/8/21

[signature]

BRADLEY S. HAMILTON, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 7/9/21

[signature]

JOHN NICHOLS
Assistant Attorney General

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Medtronic Puerto Rico Operations (MPRI)
Address: P.O. Box 6001 City: Villalba State: PR Zip: 00766

Name: Medtronic Ireleand Manufacturing UC
Address: Parkmore Business Park West City: Galway State: Irelan Zip: IRE

Name: Medtronic Sophons
Address: 5744 Central Abe, Suite 100 City: Boulder State: CO Zip: 80301

Name: Medtronic Puerto Rico Operations CO
Address: Rd 31 KM 24 HM 4 Ceiba N Indus City: Juncos State: PR Zip: 00777

Section 4: Publicly Traded Corporation

State of Incorporation: Not Applicable
Parent Company (if any): Not Applicable
Corporation Name: Not Applicable
Mailing Address: Not Applicable
City: Not Applicable State: Not Applicabl Zip: Not Applicable
Telephone: Not Applicable Email: Not Applicable
Contact Person Name: Not Applicable

Date of SEC Registration: Not Applicable | SEC Registration Number: Not Applicable | Stock Exchange Symbol: Not Applica

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Minnesota
Parent Company (if any): Medtronic Inc.
Corporation/Organization Name: Medtronic USA, Inc.
Mailing Address: 710 Medtronic Pkwy, LS245
City: Minneapolis State: MN Zip: 55432
Telephone: 508-261-6083 Email: rob.varner@medtronic.com
Contact Person Name: Robert Varner

Section 6: Partnership

Partnership Name: not applicable
Mailing Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable
Contact Person Name: not applicable

Section 7: Sole Owner

Owner's Name: not applicable
Business Name: not applicable
Business Address: not applicable
City: not applicable State: not applicab Zip: not applicable
Telephone: not applicable Email: not applicable

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Medtronic USA, Inc., dba Medtronic Logistics LLC, 1480 Arthur St, Louisville CO 80027
Facility Name

Robert Varner
Print Name of Authorized Person Submitting Application

Rob Varner
Original signature of Authorized Person (copies or stamps not accepted)

9-24-24
Date

Board Use Only	Date Received: 10/21/24	Amount: $1000-CE

FDA U.S. FOOD & DRUG ADMINISTRATION

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
MEDTRONIC PERFUSION SYSTEMS
18501 E Plaza Dr
PARKER, CO 80134
Registration Number: 1718389
FEI Number*: 1718389
Status: Active
Date Of Registration Status: 2024

Owner/Operator:
Medtronic, Inc.[6]
710 Medtronic Parkway
Minneapolis, MN US 55432
Owner/Operator Number: 2112641[7]

Official Correspondent:
Ryan Calabrese
8200 Coral Sea Street NE
Moundsview, MN 55112
Phone: 763-5263515

Initial M.H 10/23/24

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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Medtronic USA Inc. Officer List

Name	company title	Business Address
Robert Varner	President	[redacted] Memphis TN [redacted]
Dov Shenkman	Vice President	[redacted] Glencoe IL [redacted]
Punit Menon	Vice President	[redacted] Shorewood, WI [redacted]

September 19, 2024

Nevada State Board of Pharmacy

985 Damonte Ranch PKWY, Suite 206
Reno, NV 89521

Medtronic USA, Inc. maintains 100% ownership of Medtronic Logistics LLC:

Organizational Chart



Office of the Minnesota Secretary of State
Certificate of Good Standing

I, Steve Simon, Secretary of State of Minnesota, do certify that: The business entity listed below was filed pursuant to the Minnesota Chapter listed below with the Office of the Secretary of State on the date listed below and that this business entity is registered to do business and is in good standing at the time this certificate is issued.

Name:	Medtronic USA, Inc.
Date Filed:	06/15/1984
File Number:	4R-233
Minnesota Statutes, Chapter:	302A
Home Jurisdiction:	Minnesota

This certificate has been issued on: 12/18/2024

Steve Simon
Secretary of State
State of Minnesota



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FAQs, Glossary and Information

Summary

Details			
Name	MEDTRONIC USA, INC.		
Status	Good Standing	**Formation date**	12/23/1997
ID number	19971207212	**Form**	Foreign Corporation
Periodic report month	December	**Jurisdiction**	Minnesota
Principal office street address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		
Principal office mailing address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		

Registered Agent	
Name	Corporation Service Company
Street address	1900 W Littleton Blvd, Littleton, CO 80120, US
Mailing address	1900 W Littleton Blvd, Littleton, CO 80120, US

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FAQs, Glossary and Information

Summary

Details			
Name	Medtronic Logistics LLC		
Status	Good Standing	**Formation date**	12/16/2012
ID number	20121689956	**Form**	Foreign Limited Liability Company
Periodic report month	September	**Jurisdiction**	Minnesota
Principal office street address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		
Principal office mailing address	710 Medtronic Pkwy, Minneapolis, MN 55432, US		

Registered Agent	
Name	Corporation Service Company
Street address	1900 W Littleton Blvd, Littleton, CO 80120, US
Mailing address	1900 W Littleton Blvd, Littleton, CO 80120, US

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Business Record Details »

Minnesota Business Name
Medtronic USA, Inc.

Business Type
Business Corporation (Domestic)

File Number
4R-233

Filing Date
06/15/1984

Renewal Due Date
12/31/2024

Number of Shares
1,000

Chief Executive Officer
Jennifer Kirk
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

MN Statute
302A

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Registered Agent(s)
Corporation Service Company

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	06/15/1984	Original Filing - Business Corporation (Domestic)	
☐	06/15/1984	Business Corporation (Domestic) Business Name (Business Name: MEDTRONIC MILACA, INC.)	

	Filing Date	Filing	Effective Date
☐	03/14/1989	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	10/06/1995	Registered Office and/or Agent - Business Corporation (Domestic)	
☐	12/11/1997	Business Corporation (Domestic) Business Name (Business Name: Medtronic USA, Inc.)	
	12/11/1997	Business Corporation (Domestic) Restated Articles	
☐	10/29/1998	Merger - Business Corporation (Domestic)	
☐	04/10/2007	Global Registered Office and/or Agent - Business Corporation (Domestic)	
☐	9/16/2016	Registered Office and/or Agent - Business Corporation (Domestic)	
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Business Record Details »

Minnesota Business Name

Medtronic Logistics LLC

Business Type
Limited Liability Company (Domestic)

File Number
618784400037

Filing Date
9/18/2012

Renewal Due Date
12/31/2025

Registered Agent(s)
Corporation Service Company

MN Statute
322C

Home Jurisdiction
Minnesota

Status
Active / In Good Standing

Registered Office Address
2345 Rice Street
Suite 230
Roseville, MN 55113-5603
USA

Manager
Greg Smith
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
USA

Principal Executive Office Address
710 MEDTRONIC PKWY
MINNEAPOLIS, MN 55432-5603
United States

Filing History

Filing History

Select the item(s) you would like to order: Order Selected Copies

	Filing Date	Filing	Effective Date
☐	9/18/2012	Original Filing - Limited Liability Company (Domestic) (Business Name: Medtronic Logistics LLC)	
☐	9/16/2016	Registered Office and/or Agent - Limited Liability Company (Domestic)	
	1/1/2018	Conversion to 322C Due to Statute Mandate – Limited Liability Company (Domestic)	
☐	5/15/2018	Registered Office and/or Agent - Limited Liability Company (Domestic)	

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Department of
Regulatory Agencies
Division of Professions and Occupations

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If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy

Medtronic Logistics, LLC

Medtronic Logistics, LLC

Manufacturer

MFR.0001027	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy

Medtronic Logistics, LLC

Medtronic Logistics, LLC

Manufacturer

MFR.0001027	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	Public Address
Medtronic Logistics, LLC	18501 Plaza Dr Parker, CO 80134-9061

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
MFR.0001027	Original	Manufacturer	Active	09/30/2011	11/01/2024	10/31/2026

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

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CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 02/26/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA LLC
333 South 7th Street, Suite 1400
Minneapolis, MN 55402-2400

CONTACT NAME: Marsh | U.S. Operations & Technology
PHONE (A/C, No, Ext): 866-966-4664 FAX (A/C, No): 212-948-5382
E-MAIL ADDRESS: Minneapolis.CertRequest@marsh.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : ACE American Insurance Company	22667
INSURER B : Indemnity Insurance Company of North America	43575
INSURER C : ACE Fire Underwriters Insurance Company	20702
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Medtronic, Inc. and its subsidiaries
710 Medtronic Parkway
LC310
Minneapolis, MN 55432

COVERAGES **CERTIFICATE NUMBER:** CHI-010895207-01 **REVISION NUMBER:** 2

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			SPL G24561288 008	05/01/2024	05/01/2026	EACH OCCURRENCE	$	5,000,000
	X CLAIMS-MADE ☐ OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	1,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	15,000,000
	X POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$	15,000,000
	OTHER:							$	
A	AUTOMOBILE LIABILITY			ISAH10832810	05/01/2024	05/01/2025	COMBINED SINGLE LIMIT (Ea accident)	$	1,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$	
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$	
	☐ DED ☐ RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			WLRC57196166 (AOS) (incl Stop Gap EL: MN,ND,OH,WA,WY)	05/01/2024	05/01/2025	X PER STATUTE ☐ OTH-ER		
	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N / A					E.L. EACH ACCIDENT	$	1,000,000
B	(Mandatory in NH)			WLRC57196257 (MO,NC,NE,OK)	05/01/2024	05/01/2025	E.L. DISEASE - EA EMPLOYEE	$	1,000,000
A	If yes, describe under DESCRIPTION OF OPERATIONS below			SCFC57196518 (PA)	05/01/2024	05/01/2025	E.L. DISEASE - POLICY LIMIT	$	1,000,000
C	Workers Compensation continued			SCFC57196439 (WI)	05/01/2024	05/01/2025	Limit:		See Above
A	Excess Workers Compensation			WCUC57196567 (AZ) excess of $1M SIR	05/01/2024	05/01/2025	Limit:		1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of Insurance.
RE: 4340 Swinnea Rd, Memphis TN 38118; 6743 Southpoint Dr, Jacksonville FL 32216; 1480 Arthur St, Louisville CO 80027; 4620 N Beach St,. Ft Worth TX 76137; 18501 E Plaza Dr., Parker CO 80134; 7611 Northland Dr., Brooklyn Park MN 55428 5300 Airways Blvd, Suite 101, Memphis TN 38116; 2235 Route 322, Suite 200, Swedesboro NJ 08085

CERTIFICATE HOLDER
Medtronic Inc
Attn: LS370
710 Medtronic Parkway
Minneapolis, MN 55432

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN103154363
LOC #: Minneapolis

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY		NAMED INSURED
MARSH USA LLC		Medtronic, Inc. and its subsidiaries 710 Medtronic Parkway LC310 Minneapolis, MN 55432
POLICY NUMBER		
CARRIER	NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Professional Health Care Liability
Policy # SPL G24561288 008
05/01/2024 - 05/01/2026
Carrier: ACE American Insurance Company
$2,000,000 Each Claim
$15,000,000 Aggregate

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SURETY RIDER

To be attached to and form a part of

Bond No. 190054165

dated effective October 2, 2023
(MONTH-DAY-YEAR)

executed by Medtronic USA, Inc. , as Principal,
(PRINCIPAL)

and by Liberty Mutual Insurance Company , as Surety,

in favor of Nevada State Board of Pharmacy
(OBLIGEE)

in consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

ADDING COVERED LOCATIONS:

4340 Swinnea Rd, Memphis TN 38118
18501 E Plaza Dr., Parker CO 80134
6743 Southpoint Dr, Jacksonville FL 32216
4620 N Beach St,. Ft Worth TX 76137
5300 Airways Blvd, Suite 101, Memphis TN 38116
7611 Northland Dr., Brooklyn Park MN 55428
1480 Arthur St, Louisville CO 80027
2235 Route 322, Swedesboro NJ 08085

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective November 26, 2024
(MONTH-DAY-YEAR)

Signed and Sealed November 26, 2024
(MONTH-DAY-YEAR)

Medtronic USA, Inc.
(PRINCIPAL)

By: _____
(PRINCIPAL)

Liberty Mutual Insurance Company
(SURETY)

By: Cynthia J. Choren
Cynthia J. Choren, Attorney-In-Fact
NV Non-Resident License No. 221080

S-0443/GEEF 10/99

Liberty Mutual. SURETY

POWER OF ATTORNEY

Certificate No: 8204866

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 1st day of July, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
Nathan J. Zangerle, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 1st day of July, 2024, before me personally appeared Nathan J. Zangerle, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes Nathan J. Zangerle, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 26th day of November 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 190054165

Application/License No. _____

Medtronic USA Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 5300 Airways Blvd., Memphis, TN 38116 (Address of Applicant/Principal), as PRINCIPAL, and Liberty Mutual Insurance Company (Surety Company), a corporation organized under the laws of the state of Massachusetts (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street, Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 5, 2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of October, 2023.

APPLICANT/PRINCIPAL

Medtronic USA Inc

Authorized Representative

SURETY COMPANY

Liberty Mutual Insurance Company

Surety Company's Representative

Cynthia L. Choren, Attorney-in-fact

print name

NV Non-Resident License No. 221080

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Brittany D. Stuckel

Witness Heidi A. Notheisen

Countersigned by:

N/A

Nevada Resident Agent

Liberty Mutual. SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: 8204856

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Cynthia L. Choren

all of the city of St. Louis, state of Missouri each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 15th day of February, 2021.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

STATE OF PENNSYLVANIA ss
COUNTY OF MONTGOMERY

On this 15th day of February, 2021, before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at King of Prussia, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII - Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-infact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, of Liberty Mutual Insurance Company, The Ohio Casualty Insurance Company, and West American Insurance Company do hereby certify that this power of attorney executed by said Companies is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 5th day of October 2023

By: _____
Renee C. Llewellyn, Assistant Secretary

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

Marsh MSurety POA LMIC OCIC WAIC Multi Co_022021

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Medtronic USA, Inc. dba Medtronic Logistics LLC — MDEG License # (if applicable): MP01109

Physical Address: 18501 E Plaza

City: Parker — State: CO — Zip: 80134

Mailing Address (if different from physical address): Attn: Kay Knox, 4097 E Marquette Ave

City: Terre Haute — State: IN — Zip: 47805

Telephone: 614-489-5164 — Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Staci — Middle: Lynn — Last: Tomaszewski

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Denver — State: CO — Zip: [redacted]

Telephone: [redacted] — Email: staci.tomaszewski@medtronic.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		08/08-05/10	
Address	City	State	Zip
1151 S. Forest Ave	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Masters Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Purdue University		08/99-05/04	
Address	City	State	Zip
610 Purdue Mall	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
Bachelors of Science Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Lake Central High School		08/95-05/99	
Address	City	State	Zip
8400 Wicker Ave	St. John	IN	46373
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

N A

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/22-09/24	[redacted]	Denver	CO	[redacted]
06/21-04/22		Denver	CO	
07/17-06/21		Phoenix	AZ	
09/07-07/17		Scottsdale	AZ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

NA

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Medtronic USA, Inc.			03/24-~~09/24~~ Current	
Business Address		**City**	**State**	**Zip**
18501 East Plaza Drive		Parker	CO	80134
Phone	**Title**		**Number of Employed Hours**	
303-530-6270	Senior Manager Manufacturing		1,500	
Description of Duties				
Operations Manager for Plant				

Business Name			From - To (MM/YY – MM/YY)	
Medtronic USA, Inc.			09/21-03/24	
Business Address		**City**	**State**	**Zip**
5920 Longbow Drive		Boulder	CO	80301
Phone	**Title**		**Number of Employed Hours**	
303-530-6270	Senior Manager Operational Excellence		7,200	
Description of Duties				
Lean Six Sigma for Manufacturing Site				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
	N/A			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N A

Original Signature (electronic, copies or stamps not accepted)

09/19/24
Date

I, Staci Tomaszewski, **certify that as the MDEG Administrator for**

Medtronic USA,

that I (initial that you have read and meet the following requirements):

1. ST Have a high school diploma or its equivalent;
2. ST Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ST Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ST Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Staci Tomaszewski
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/19/24
Date

Board Use Only	Date Received: 10/21/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Medtronic USA, Inc. dba Medtronic Logistics LLC

Pharmacy/Wholesaler License # (if applicable): Not applicable

Physical Address: 18501 E Plaza Dr,

City: Parker State: CO Zip: 80134

Mailing Address (if different from physical address): Attn Kay Knox, 4097 E Marquette Ave

City: Terre Haute State: IN Zip: 47805

Telephone: 614-489-5164 Website: www.medtronic.com

Licensing Company Email: kay.knox@cevalogistics.com

Section 2: Personal Information

First: Staci Middle: Lynn Last: Tomaszewski

Alias(es, nicknames, name changes, etc.): not applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Denver State: CO Zip: [redacted]

Telephone: [redacted] Email: staci.tomaszewski@medtronic.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Arizona State University		08/08 to 05/10	
Address	City	State	Zip
1151 S Forest Abe	Tempe	AZ	85281
Diploma/Degree obtained, if any			
Masters Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Purdue University		08/99 to 05/04	
Address	City	State	Zip
610 Purdue Mall	West Lafayette	IN	47907
Diploma/Degree obtained, if any			
Bachelors of Science Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Lake Central High School		08/95 to 05/99	
Address	City	State	Zip
8400 Wicker Ave	St. John	IN	46373
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Not applicable		Not applicable	
Address	City	State	Zip
Not applicable	Not applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			

School Name		From - To (MM/YY – MM/YY	
Not applicable		Not applicable	
Address	City	State	Zip
Not applicable	Not applicable	NA	NA
Diploma/Degree obtained, if any			
Not applicable			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
5/22 - present	[redacted]	Denver	CO	[redacted]
06/21 - 04/22		Denver	CO	
07/17 - 06/21		Phoenix	AZ	
09/07 - 07/17		Scottsdale	AZ	
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA
From - To (MM/YY – MM/YY)	Address	City	State	Zip
Not applicable	Not applicable	Not applicable	NA	NA

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Medtronic USA, Inc. dba Medtronic Logistics LLC			03/24~~09/24~~ current
Business Address	**City**	**State**	**Zip**
18501 E Plaza Dr	Parker	CO	80134
Phone	**Title**		**Number of Employed Hours**
303-530-6270	Senior Manager Manufacturing		1500
Description of Duties			
Operations Manager for the Plant			

Business Name			From - To (MM/YY – MM/YY)
Medtronic USA			09/21 - 03/24
Business Address	**City**	**State**	**Zip**
592 Longbow Dr	Boulder	CO	80301
Phone	**Title**		**Number of Employed Hours**
303-530-6270	Senior Manager Operational Excellence		7200
Description of Duties			
Lean Six Sigma for Manufacturing Site			

Business Name			From - To (MM/YY – MM/YY)
not applicable			not applicable
Business Address	**City**	**State**	**Zip**
not applicable	not applicable	NA	NA
Phone	**Title**		**Number of Employed Hours**
not applicable	not applicable		not applicable
Description of Duties			
not applicable			

Business Name			From - To (MM/YY – MM/YY)
not applicable			not applicable
Business Address	**City**	**State**	**Zip**
not applicable	not applicable	NA	NA
Phone	**Title**		**Number of Employed Hours**
not applicable	not applicable		not applicable
Description of Duties			
not applicable			

Business Name			From - To (MM/YY – MM/YY)
not applicable			not applicable
Business Address	**City**	**State**	**Zip**
not applicable	not applicable	NA	NA
Phone	**Title**		**Number of Employed Hours**
not applicable	not applicable		not applicable
Description of Duties			
not applicable			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
Not Applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		V	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Business Name			From - To (MM/YY – MM/YY)	
not applicable			not applicable	
Business Address		City	State	Zip
not applicable		not applicable	NA	NA
Phone	Title		Number of Employed Hours	
not applicable	not applicable		not applicable	
Description of Duties				
not applicable				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N A

Original Signature (electronic, copies or stamps not accepted)

09/19/24
Date

I, Staci Tomaszewski, **certify that as the designated representative for**

Medtronic USA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ST I am at least 21 years of age;
3. ST I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ST I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ST I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ST I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ST I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Staci Tomaszewski
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/19/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Staci Tomaszewski

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

09/19/24

Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Douglas

I, Staci Tomaszewski, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

09/19/24

Date

Subscribed and Sworn to before me this 19th day of September 2024

Notary Public Signature

GRADY M. LONG
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20224031356
MY COMMISSION EXPIRES 08/11/2026

(Seal)

Parker Employee List:

1. Staci Tomaszewski
2. Carlos Marquez
3. Jennifer Yang
4. William Zillmann
5. Greg Salcines
6. Garrett Butler
7. Kim Weickum
8. Meghan Arora
9. Christy Payne
10. Binod Shilpakar
11. Turner Beeck
12. Patrick May
13. Nga Nguyen
14. Cassie (Catherine) Tilton
15. Sam Yang
16. Tabitha Zillmann
17. Zoya Minosyan
18. Xinh Van
19. Sydney Arguto
20. Danielle Wurnitsch
21. Claudia Garcia Cortez (contractor)
22. Quinn Cruz (contract ending 9/27/24)
23. Irina Lobyan
24. Dao Phan
25. Hung Nguyen
26. Debbie Taylor
27. Ha Tran
28. Khanh Truong
29. Khoa Huynh
30. Leidy Cuervo
31. Linna Lien
32. Maria Rodriguez Velazquez
33. Patricia Montano
34. Siswo Prasetio
35. Van Huynh
36. Yen Le

37. Mai Talache
38. Fong Yang
39. Hung Luong
40. Kevin Ly
41. Leng Yang
42. Lien Luong
43. Lieu Davison
44. Ngoc Tang
45. Randy Tran
46. Rhonda King
47. Sivong Yang
48. Tu An Khun
49. Vilayphone Phannaraj
50. Xuan Nguyen
51. Oscar Antano (contractor)
52. Elizabeth Hunt (contractor)
53. Hy Tang Chau (on FMLA)

4MM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Otter Pharmaceuticals, LLC

Physical Address: 100 South Saunders Road, Suite 300, RM 05

City: Lake Forest State: IL Zip: 60045

Mailing Address (if different from physical address): 100 South Saunders Road, Suite 300, RM 05

City: Lake Forest State: IL Zip: 60045

Telephone: (224) 419-7106 Website: www.assertiotx.com

Name of Designated Representative (DR): Sotheara Ith

Licensing Company Email: otterlicensing@assertiotx.com DR Email: sith@assertiotx.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☒ Dangerous Drugs	☐ Manufacturer
☒ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: Specialty Pharmacies		☒ Others: Virtual Manufacturer

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: No Suppliers sold, dispensed or distributed within last year

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Assertio Holdings Inc

Corporation/Organization Name: Otter Pharmaceuticals, LLC

Mailing Address: 100 South Saunders Road, Suite 300, RM 05

City: Lake Forest State: IL Zip: 60045

Telephone: 2244166291 Email: SSchlessinger@assertiotx.com

Contact Person Name: Paul Schwichtenberg

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		x
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		x
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Otter Pharmaceuticals, LLC
Facility Name

Ajay Patel
Print Name of Authorized Person Submitting Application

Ajay Patel
Original signature of Authorized Person (copies or stamps not accepted)

8/21/24
Date

Board Use Only	Date Received: 2/26/25	Amount: $1000 ch 2364

Otter Pharmaceuticals

Description of Operations

Otter Pharmaceuticals, LLC is a Virtual Manufacturer. Otter Pharmaceuticals, LLC is 100% owned by Assertio Holdings who is a Publicly Traded company on the NASDAQ stock exchange under the symbol ASRT and is located in Lake Forest, Illinois. Otter Pharmaceuticals, LLC's product is manufactured by Contract Manufacturers and will be distributed to Wholesalers, Specialty Pharmacies, and Physicians by their Third-Party Logistics Provider, Cardinal SPS , who is licensed to ship pharmaceutical products into your state.

Labeler Code- 82497 ✓ verified 3/4/25

Otter Pharmaceuticals, LLC's hours of operation are 8:30 am – 5:00pm Monday through Friday.

Contract Manufacturers Information:
We are using the following contract manufacturers to produce our product:

Sharp Packaging
7451 Keebler Way
Allentown, PA 18106
FEI# 3004161147

Pharmascience, Inc.
100 de L'Industrie Blvd.
Candiac (Quebec) J5R 1J1
FEI # 3002806578

The above listed CMO's manufacture Otter Pharmaceuticals, LLC's products and packages finished product. At no time do any of the CMO's own the product, contract with Otter Pharmaceuticals, LLC's customers, invoice, nor sell an Otter Pharmaceuticals, LLC product. Otter Pharmaceuticals, LLC's products are not Controlled Substances.

Third Party Logistic information:
For distribution into the commercial supply channels, Cardinal SPS acts as Otter Pharmaceuticals, LLC's Third Party Logistics (3PL) provider to manage the storage and distribution of Otter Pharmaceuticals, LLC's product to Wholesalers, Specialty Pharmacies, and Physicians throughout the United States. Cardinal SPS's address is:

Cardinal SPS
501 Mason Rd. Suite 200
LaVergne, TN 37086
Ashley Warner- 980-296-9016

Cardinal SPS
15 Ingram Blvd
LaVergne, TN 37086
Ashley Warner- 980-296-9016

Otter Pharmaceuticals

Product List

Products	NDC
4 Count Carton - 10mg/0.4mL	**82497-010-04**
Device Label - 10mg/0.4mL	82497-010-02
4 Count Carton - 12.5mg/0.4mL	**82497-012-04**
Device Label - 12.5mg/0.4mL	82497-012-02
4 Count Carton - 15mg/0.4mL	**82497-015-04**
Device Label - 15mg/0.4mL	82497-015-02
4 Count Carton - 17mg/0.4mL	**82497-017-04**
Device Label - 17mg/0.4mL	82497-017-02
4 Count Carton - 20mg/0.4mL	**82497-020-04**
Device Label - 20mg/0.4mL	82497-020-02
4 Count Carton - 22.5mg/0.4mL	**82497-022-04**
Device Label - 22.5mg/0.4mL	82497-022-02
4 Count Carton - 25mg/0.4mL	**82497-025-04**
Device Label - 25mg/0.4mL	82497-025-02

Otter Pharmaceuticals

Ownership Information

Otter Pharmaceuticals, LLC is 100% owned by Assertio Holdings, Inc. which is publicly traded on the NASDAQ (ASRT).

Otter Pharmaceuticals, LLC:
100 South Saunders Road, Suite 300, RM 05, Lake Forest, IL 60045
(224) 419-7106
Tax ID: 87-2523519
Delaware Corporation # 6183315, 08/21/2021

Officers

Ajay Patel, Chief Financial Officer
Business Address: 100 South Saunders Road, Suite 300, Lake Forest, IL 60045
Business Phone: (224) 441-6631
Email: apatel@assertiotx.com
Ownership: 0%

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "OTTER PHARMACEUTICALS, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FIRST DAY OF NOVEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "OTTER PHARMACEUTICALS, LLC" WAS FORMED ON THE TWENTIETH DAY OF AUGUST, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.





6183315 8300

SR# 20244282452

You may verify this certificate online at corp.delaware.gov/authver.shtml

Authentication: 204937775

Date: 11-21-24

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005240

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

LICENSED WHOLESALE DRUG DISTRIBUTOR

BROKER

OTTER PHARMACEUTICALS LLC
100 SAUNDERS RD STE 300
RM 05
LAKE FOREST, IL 60045-2508

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

19839360

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4562441

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
OTTER PHARMACEUTICALS LLC	Lake Forest, IL 60045	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004005240	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	10/04/2023	10/10/2024	12/31/2026	N

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 101406796

Application/License No. _____

Otter Pharmaceuticals, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 100 S. Saunders Rd., Lake Forest, IL 60045 (Address of Applicant/Principal), as PRINCIPAL, and Merchants Bonding Company (Mutual) (Surety Company), a corporation organized under the laws of the state of IA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is P.O. Box 14498 , Des Moines, IA 50306-3498 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 18, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 18th day of February, 2025.

APPLICANT/PRINCIPAL

Otter Pharmaceuticals, LLC
COMPANY

By: _____
Authorized Representative

SURETY

Merchants Bonding Company (Mutual)

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

By: Melissa Heffernan
Surety Company's Representative

Melissa Heffernan, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

Josefina Rojo
Witness Josefina Rojo

_____
Witness

Countersigned by:

n/a
Nevada Resident Agent

Posted February 20, 2020

MERCHANTS
BONDING COMPANY™

POWER OF ATTORNEY

Know All Persons By These Presents, that MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., both being corporations of the State of Iowa, d/b/a Merchants National Indemnity Company (in California only) (herein collectively called the "Companies") do hereby make, constitute and appoint, individually, **Melissa Heffernan**

Surety Bond #: 101406796
Principal: Otter Pharmaceuticals, LLC
Obligee: Nevada State Board of Pharmacy

their true and lawful Attorney(s)-in-Fact, to sign its name as surety(ies) and to execute, seal and acknowledge any and all bonds, undertakings, contracts and other written instruments in the nature thereof, on behalf of the Companies in their business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

This Power-of-Attorney is granted and is signed and sealed by facsimile under and by authority of the following By-Laws adopted by the Board of Directors of Merchants Bonding Company (Mutual) on April 23, 2011 and amended August 14, 2015 and adopted by the Board of Directors of Merchants National Bonding, Inc., on October 16, 2015.

"The President, Secretary, Treasurer, or any Assistant Treasurer or any Assistant Secretary or any Vice President shall have power and authority to appoint Attorneys-in-Fact, and to authorize them to execute on behalf of the Company, and attach the seal of the Company thereto, bonds and undertakings, recognizances, contracts of indemnity and other writings obligatory in the nature thereof."

"The signature of any authorized officer and the seal of the Company may be affixed by facsimile or electronic transmission to any Power of Attorney or Certification thereof authorizing the execution and delivery of any bond, undertaking, recognizance, or other suretyship obligations of the Company, and such signature and seal when so used shall have the same force and effect as though manually fixed."

In connection with obligations in favor of the Florida Department of Transportation only, it is agreed that the power and aut hority hereby given to the Attorney-in-Fact includes any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts required by the State of Florida Department of Transportation. It is fully understood that consenting to the State of Florida Department of Transportation making payment of the final estimate to the Contractor and/or its assignee, shall not relieve this surety company of any of its obligations under its bond.

In connection with obligations in favor of the Kentucky Department of Highways only, it is agreed that the power and authority hereby given to the Attorney-in-Fact cannot be modified or revoked unless prior written personal notice of such intent has been given to the Commissioner-Department of Highways of the Commonwealth of Kentucky at least thirty (30) days prior to the modification or revocation.

In Witness Whereof, the Companies have caused this instrument to be signed and sealed this 18th day of February , 2025 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

MERCHANTS BONDING COMPANY (MUTUAL)
MERCHANTS NATIONAL BONDING, INC.
d/b/a MERCHANTS NATIONAL INDEMNITY COMPANY

By Larry Taylor
President

STATE OF IOWA
COUNTY OF DALLAS ss.
On this 18th day of February, 2025 , before me appeared Larry Taylor, to me personally known, who being by me duly sworn did say that he is President of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC.; and that the seals affixed to the foregoing instrument are the Corporate Seals of the Companies; and that the said instrument was signed and sealed in behalf of the Companies by authority of their respective Boards of Directors.

NOTARIAL SEAL IOWA

PENNI MILLER
Commission Number 787952
My Commission Expires
January 20, 2027

Notary Public

(Expiration of notary's commission does not invalidate this instrument)

I, William Warner, Jr., Secretary of MERCHANTS BONDING COMPANY (MUTUAL) and MERCHANTS NATIONAL BONDING, INC., do hereby certify that the above and foregoing is a true and correct copy of the POWER-OF-ATTORNEY executed by said Companies, which is still in full force and effect and has not been amended or revoked.

In Witness Whereof, I have hereunto set my hand and affixed the seal of the Companies on this 18th day of February , 2025 .

MERCHANTS NATIONAL BONDING, INC. INCORPORATED -o- 2003

MERCHANTS BONDING COMPANY (MUTUAL) INCORPORATED -o- 1933

William Warner Jr.
Secretary

POA 0018 (1/24)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Otter Pharmaceuticals, LLC

Pharmacy/Wholesaler License # (if applicable) new applicant

Physical Address 100 South Saunders Road, Suite 300, RM 05

City Lake Forest State IL Zip 60045

Mailing Address (if different from physical address) 100 South Saunders Road, Suite 300, RM 05

City Lake Forest State IL Zip 60045

Telephone (224) 419-7106 Website www.assertiotx.com

Licensing Company Email otterlicensing@assertiotx.com

Section 2: Personal Information

First Sotheara Middle _____ Last Ith

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 100 S. Saunders Rd. Suite 300

City Lake Forest State IL Zip 60045

Telephone [redacted] Email sith@assertiotx.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF ILLINOIS AT CHICAGO,		08 / 10 - 12 / 14	
Address	**City**	**State**	**Zip**
1200 W Harrison St,	Chicago,	IL	60607
Diploma/Degree obtained, if any			
B.S. Biological Science			
School Name		**From - To (MM/YY – MM/YY)**	
Wheeling High School		/06 - /10	
Address	**City**	**State**	**Zip**
900 S Elmhurst Rd	Wheeling,	IL	60090
Diploma/Degree obtained, if any			
HS Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/18 to Present	[redacted]	Mundelein	IL	[redacted]
From - To (MM/YY – MM/YY)		City	State	Zip
06/03 to 06/18		Wheeling	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Otter Pharmaceuticals, LLC			From - To (MM/YY – MM/YY): 06/24 - present	
Business Address: 100 S. Saunders Rd, Suite 300		City: Lake Forest	State: Illinois	Zip: 60045
Phone: 2244197106	Title: Associate Director, Technical Operations and Manufacturing		Number of Employed Hours: 40/week	
Description of Duties: see attached resume				

Business Name: COUR Pharmaceuticals			From - To (MM/YY – MM/YY): 03/24-06/24	
Business Address:		City: Skokie	State: IL	Zip:
Phone:	Title: Principal Engineer Consultant, Operations/Technical		Number of Employed Hours: 40/week	
Description of Duties: see attached resume				

Business Name: CRISPR THERAPEUTICS			From - To (MM/YY – MM/YY): 11/21 - 11/23	
Business Address:		City: Boston	State: MA	Zip:
Phone:	Title: Engineer IV, Manufacturing Science and Technology		Number of Employed Hours: 40/weelk	
Description of Duties: see attached resume				

Business Name: NOVARTIS GENE THERAPIES			From - To (MM/YY – MM/YY): 10/19-11/21	
Business Address:		City: Libertyville	State: IL	Zip:
Phone:	Title: Supervisor, Fill-Finish		Number of Employed Hours: 40/week	
Description of Duties: See attached Resume				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:		City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

SOTHEARA ITH
[redacted]

PROFESSIONAL PROFILE

Biotech professional with extensive experience in technical operations, encompassing manufacturing, process development, and Manufacturing Science & Technology. Known for exceptional organizational skills, responsibility, effective time management, and a dedicated approach as a cross-functional team player. Proven track record of contributing to the success of biotech operations through a combination of technical proficiency and collaborative teamwork. Eager to leverage my experience and skills to drive excellence in your organization's technical and operational endeavors.

Core Competencies:

- Technology transfer
- Biotechnology start-up
- Technical document writer (SOP, deviation, protocols, reports, etc.)
- Audit and inspection readiness
- Process development
- Equipment and process validation
- Clinical and commercial manufacturing

WORK EXPERIENCE

Otter Pharmaceuticals, Lake Forest, IL — June 2024- Present

Associate Director, Technical Operations and Manufacturing

- Lead and manage the day-to-day drug substance and drug product activities with contract development, manufacturing, packaging, & testing organizations (planning, scheduling, document preparation and review).
- Oversee all biologic/small molecule drug substance/product manufacturing and process development activities at the contract organizations in the production of cGCP compliant clinical study and cGMP commercial supplies.
- Provide proactive technical expertise in process design, equipment qualification, engineering & process validation, and technical transfer activities. Investigate & troubleshoot issues and bring them to timely resolution.
- Develop optimization & life cycle support strategies to ensure continuity of high-quality supplies to meet sales/marketing demands as well as internal objectives for the Assertio product portfolio.
- Initiate and manage change controls and deviations related to Assertio's products within the Trackwise quality management system.

COUR Pharmaceuticals, Skokie, IL — Mar 2024 – June 2024

Principal Engineer Consultant, Operations/Technical Development (Contract)

Supports plant start-up activities such as authoring process related documents (batch records, and SOP's) for downstream processes. Supports technology transfer of the processes from development to stage to GMP scale and optimize the processes for robustness.

CRISPR THERAPEUTICS, Boston, MA — November 2021 – November 2023

Engineer IV, Manufacturing Science and Technology

Managed CDMOs for critical starting materials such as Cas9, guides RNA, AAV, and plasmids for cell therapy manufacturing. Supported all aspects of clinical and commercial manufacturing, process development, technology transfer, and process validation for cell therapy products such as Casgevy and others.

- Authored technical documents such as historical batch report, process description, process control strategy, process failure mode and effects analysis (PFMEA), validation master plan, sampling plan, validation supporting studies protocols and reports (mixing, freeze-thaw, and hold-time), homogeneity protocol and report, extractables and leachables assessment report, PPQ protocol, number of runs justification report, PPQ report, shipping report, comparability protocol and report, stability protocol, and continued process verification (CPV) plan.

- Supported EMA and FDA audits for Casgevy critical components, Cas9 and guide RNA.
- Collaborated with CDMO to implement process changes to optimize a robust process.
- Managed production activities at CDMO as needed to meet business needs.
- Coordinated with CDMO for material shipments to testing labs and other CDMO.
- Person-in-plant (PIP) to oversee tech transfer and PPQ batches.
- Led AAV process risk assessment for DOE studies.
- Authored validation protocol and executed validation of Skyland PIMS, a cloud-based data management with analytics tools.

NOVARTIS GENE THERAPIES, Libertyville, IL October 2019 – November 2021

Supervisor, Fill-Finish

Managed a team of seven bioprocess engineers, overseeing fill-finish operations such as sterile filtration, sterile fill, vial serialization, visual inspection, labeling, and packaging. Delivered effective task assignments and scheduling to ensure timely execution in alignment with business needs. Collaborated seamlessly with QA, QC, and warehouse teams to facilitate batch record issuance and room clearance, ADHOC sample submissions, material issuance for the batch, and shipping related activities, enabling swift turnarounds and maintaining a seamless workflow.

- Reviewed executed batch records, protocols, logbooks, etc.
- Wrote and initiated deviations, CAPAs, and change controls.
- Supported Zolgensma launches for Japan, EU, Brazil, Israel, Canada, Taiwan, and Argentina.
- Implemented 5S pillars into manufacturing processes for cost savings, Lean process, and time efficiency.
- Identified as an SME for the fill-finish processes in audits for HPRA and Ministry of Health of the Russian Federation.
- Collaborated with MSAT as SME to tech-transfer fill-finish process to Novartis Gene Therapies site in North Carolina.

AVEXIS INC., Libertyville, IL May 2017– September 2019

Senior BioProcess Engineer, Manufacturing and Technical Operations (2018 – 2019)

Developed and established commercial fill-finish manufacturing processes while leading operations with a solid focus on performance excellence and continuous improvement, leading to the approval of Zolgensma.

- Executed Bosch filling machine batch reporting validation.
- Executed TFF and Ultracentrifugation studies to support deviation closure.
- Worked with vendors to create assemblies and manifolds to close processes.
- SME for the fill-finish processes in audits for HPRA, FDA, and PMDA.
- Initiated change controls and CAPAs to optimize process improvements.
- Optimized downstream and fill-finish sampling plans to increase 4% theoretical yield.
- Person-in-plant (PIP) to oversee clinical processes at CDMO.

BioProcess Engineer, Manufacturing and Technical Operations (February 2017 – May 2018)

Supported all aspects of a plant start-up such as authoring process and equipment related documents. Commissioned and qualified equipment and production suites to operational standards. Supported technology transfer of the Zolgensma process.

- Authored startup batch records, SOPs, and validation protocols.
- Equipment validation: SAT (Site Acceptance Test), IQ/OQ on Bosch Filler, Spectrum TFF system, Millipore TFF skid, Millipore Chromatography skid, Pall TFF Skid, Beckman Coulter Ultracentrifuge.
- Performed smoke studies for filling suite.
- Successfully brought unclassified fill suite to ISO 5/6 classification.
- Tech transfer downstream process from CDMO to internal manufacturing.
- Processed performance qualification runs for downstream and drug product processes.

ADELLO BIOLOGICS, Chicago, IL May 2015 – February 2017

Manufacturing Associate II, Manufacturing

Supported all three phases of biologics manufacturing: upstream, downstream, and drug product. Led the technology transfer of the fill-finish process to a CMO.

- Drug product manufacturing: buffer preparation, sterilization of sterile filling parts, sterile filtration, filling of vials and syringes, visual inspection, and packaging.

- Drug substance manufacturing:
  - Upstream: cell bank, cell expansion (flasks to wave bag to bioreactor), cell high pressure homogenizer (cell lysis), and cell harvesting.
  - Downstream: clarification of harvested cells, chromatography using AKTA process system, chromatography column packing, tangential flow filtration, and buffer preparation.
- Reviewed executed documents: batch records, protocols, and logbooks.
- Updated batch records and SOPs, initiated deviations, CAPAs, and work orders.
- Led tech transfer of the fill-finish process to CMO.

EDUCATION

Bachelor of Science, Biological Sciences, UNIVERSITY OF ILLINOIS AT CHICAGO, Chicago, IL

PROFESSIONAL DEVELOPMENT & CERTIFICATION

- Coaching and Mentoring for Leadership, Skill Path (August 2019)

- KENX Validation University Certification (March 2022)

- Biomanufacturing World Summit for Cell and Gene Therapy (February 2023)

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Sotheara Ith, **certify that as the designated representative for**

Otter Pharmaceuticals, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SI I am at least 21 years of age;
3. SI I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SI I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SI I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SI I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SI I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sotheara Ith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/20/2024

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sotheara Ith

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

08/20/2024

Date

Please have this section completed in the presence of a Notary Public.

State of ILLINOIS, ss. County of LAKE

I, Sotheara Ith, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

08/20/2024

Date

Subscribed and Sworn to before me this 20 day of August 2024

Michelle L Victorine

Notary Public Signature

MICHELLE L VICTORINE
Official Seal
Notary Public - State of Illinois
My Commission Expires Apr 19, 2025

(Seal)

PAYROLL LAST NAME	PAYROLL FIRST NAME	PRIMARY ADDRESS - CITY	STATE
Bruce	John P	Wauconda	IL
Fox	Vanessa C	Lake Bluff	IL
Henning	Julie A	Long Grove	IL
Honda	Dorothy	Chicago	IL
Iskos	Vasilios H	Chicago	IL
Ith	Sotheara	Mundelein	IL
Jacyniewicz	Nelya	Prospect Heights	IL
Langner	Ryan	Mundelein	IL
Dir	Molly Ann	Mundelein	IL
Ngo	Jill Elizabeth	Lake Zurich	IL
O'Connor	John	Lake Forest	IL
O'Grady	Brendan	Edgewater	FL
Patel	Ajaykumar	Des Plaines	IL
Patel	Nidhi	Chicago	IL
Ramos	Edilberto	Hoffman Estates	IL
Schabdach	Brian	Chicago	IL
Schwichtenberg	Paul	Hawthorn Woods	IL
Swiercz	Justin	Hoffman Estates	IL
Troester	John Henry	Libertyville	IL
Victorine	Michelle	Lindehurst	IL
Wootton	Nicole	Park Ridge	IL
Barrientes	John	Glen Ellyn	IL
Schlessinger	Sam	Arlington Heights	IL

WHOLESALE DRUG DISTRIBUTOR INSPECTION

BUSINESS NAME: Otter Pharmaceuticals LLC			INSPECTION NUMBER:
ADDRESS: 100 Saunders Rd Ste 300 RMPS			LICENSE NUMBER: 004.005240
CITY: Lake Forest	COUNTY: Lake	TELEPHONE NUMBER (Include Area Code): (847) 727-6125	DATE: 10/4/23
ICSA LICENSE:	EXPIRATION DATE:	FAX NUMBER (Include Area Code): (510) 744-8001	INSPECTOR ID: 871
DEA LICENSE: ~~pending~~ QS NA	EXPIRATION DATE: ~~pending~~ QS NA	TYPE OF LICENSE: WDD - virtual man (broker)	
PERSON(S) RESPONSIBLE FOR DRUGS: Ryan Langner		EMERGENCY TELEPHONE NUMBER: (847) 727-6125 ( )	

	VIOLATIONS	YES	NO
8301.25(a)	All wholesale distributors must have valid license.		✓
1510.50(i)	Must comply with all Federal, State & Local laws.		✓
8301.25(e)(1)	Acceptable storage & handling conditions and standards.		✓
1510.50(a)	(1) Facility is of suitable size (2) Storage area meets requirements (3) Quarantine area is separate, distinct from general area (4) Maintained in clean & orderly condition (5) Free from infestation by insects, rodents, birds or vermin		✓
1510.50(c)	Drugs are stored under proper temperature and humidity conditions. (1) Room temperature is controlled (2) Temperature& humidity equipment to document storage conditions.		✓
8301.25(e)(2)	Minimum liability and other insurance.		✓
8301.25(e)(3)	Must have acceptable security system.		✓
1510.50(b)(1)	Secure from unauthorized entry. (a) Limited& well-controlled access from outside the premises. (b) Outside perimeter is well-lighted. (c) Prescription drug area limited to authorized personnel. (2) Alarm system to detect after hour entry. (3) Protection against theft & diversion.		✓
8301.25(e)(4)	Records shall be maintained for 2 years.		✓
1510.50(f)	(1) Records& inventories for receipt, distribution, disposal. (a) Source of drugs & location from where shipped.		✓
	(b) Identify & quantity of drugs received, distributed, disposed of. (c) Dates of receipt, distribution, disposal. (2) Inventories & records area available for inspection and copying. (3) Records are stored at site off-site location		✓
8301.25(e)(5)	Personnel must be qualified.		✓
1510.50(h)	List of persons responsible & duties is maintained.		✓
8301.25(e)(7)	Written Policies& procedures are maintained.		✓
1510.50(g)(1)	(1) Procedure to rotate stock. (2) Procedure for recalls & withdrawals of drugs. (a) FDA or other law enforcement action. (b) Manufacturer recall. (c) Replacement action. NA (3) Procedures for crisis (fire, flood, etc.) (4) Procedures to remove, segregate & document disposition of outdates. (e) (1) Drugs are quarantined & physically separated (outdates, damaged, etc.) (2) Drugs are quarantined that have been used or are open.		
8301.25(e)(8)	Inspection procedures for all incoming and outgoing drug shipments. NA		
1510.50(d)	(1) Visual examination upon receipt for damage. (2) Outgoing shipments are inspected to prevent outdates or deteriorated. (3) Records are maintained. NA		

INVESTIGATOR'S SIGNATURE	LICENSEE'S SIGNATURE	SUPERVISOR'S SIGNATURE AND DATE
10/4/23	10/4/23	Steven Smith 10-5-23

IL486-1777 3/96(ENF)

WHOLESALE DRUG DISTRIBUTOR INSPECTION (NARRATIVE)

BUSINESS NAME			INSPECTION NUMBER
Otter Pharmaceutical LLC			
ADDRESS			LICENSE NUMBER
100 Saunders Rd Ste 300 RM05			004.005240
CITY	COUNTY	TELEPHONE NUMBER (Include Area Code)	DATE
Lake Forest	Lake	(847) 727-6125	10/4/23
ICSA LICENSE	EXPIRATION DATE	FAX NUMBER (Include Area Code)	INSPECTOR ID
NA	NA	(510) 744-8001	871

New WDD virtual man. (broker). Works with CIV - 2 drugs at this time.

Entity uses Cardinal Health SPS - (3PL)
DEA license # RC0229965 ex. 5/21/24

Safe with key for potential product. over 400lbs.

Please see questionnaire for additional information. (e-file)

10/4/23 | 10/4/23 | Steven Smith 10-5-23

4NN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* Grandparent ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH01651	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: PAI Holdings, LLC d/b/a PAI Pharma

Physical Address: 1700 Perimeter Road

City: Greenville State: SC Zip: 29605

Mailing Address (if different from physical address): c/o State License Servicing, 225 Dolson Avenue, 4th floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.paipharma.com

Name of Designated Representative (DR): Ivan Cartagena Salaverris

Licensing Company Email: PAIP@slsny.com DR Email: icartagena@paipharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☒ Controlled Substances	☐ Repacker
☒ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others: OTC Drugs	☐ Warehouse
☐ Veterinarians		☒ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	X	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2/5/2009	2/5/2009	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2009-2208	Colorado State Board of Pharmacy

Reason/Charge
Cease and Desist Order

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
PAI Holdings, LLC dba PAI Pharma	Cease and Desist Order

Name of Business/Industry/Entity
PAI Holdings, LLC dba PAI Pharma

Provide explanation below:

Pharmaceutical Associates was issued a Cease and Desist Order for not being registered to distribute prescription drugs or controlled substances in CO

Original Signature (electronic, copies or stamps not accepted)

13 MARCH 2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
2/24/2009	2/24/2009	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2009-2546	Colorado State Board of Pharmacy

Reason/Charge
Unprofessional Conduct - Grounds for Discipline

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
PAI Holdings, LLC dba PAI Pharma	Unprofessional Conduct - Grounds for Discipline

Name of Business/Industry/Entity
PAI Holdings, LLC dba PAI Pharma

Provide explanation below:

Pharmaceutical Associates, Inc. was issued a stipulation and final agency order and had to pay a fee of $5,750.00 for doing business without a license.

Original Signature (electronic, copies or stamps not accepted)

13 MARCH 2025

Date

CO-Resolved

RECEIVED
FEB 13 2009 K.H.
DIVISION OF REGISTRATIONS

BEFORE THE STATE BOARD OF PHARMACY
STATE OF COLORADO

Case No. 2009-2546

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE LICENSE TO PRACTICE AS A OUT-OF-STATE WHOLESALER IN THE STATE OF COLORADO OF **PHARMACEUTICAL ASSOCIATES, INC.,**

Wholesaler Applicant.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and Pharmaceutical Associates, Inc. ("Wholesaler Applicant") to resolve all matters pertaining to Board Case Number 2 009-2546 as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Wholesaler Applicant, its application for registration as an out-of-state wholesaler and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Wholesaler Applicant admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

3. On December 1, 2008, Wholesaler Applicant distributed prescription drugs to into Colorado without having first registered as an out-of-state wholesaler in the State of Colorado.

4. Wholesaler Applicant's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes:

Colorado Revised Statutes

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drugs.

12-22-125.2. Disciplinary actions. (1) The board may deny or discipline an applicant, licensee, or registrant when the board determines that such applicant, licensee, or registrant has engaged in activities that are grounds for discipline.

* * *

12-22-802. Wholesaler license requirements. (1) A wholesaler that resides in this state shall be licensed by the board. A wholesaler that does not reside in this state shall be licensed in this state prior to engaging in the wholesale distribution of prescription drugs in this state. The board shall exempt a manufacturer and that manufacturer's third-party logistics providers to the extent involving that manufacturer's drugs under contract from any licensing qualifications and other requirements, including the requirements in subparagraphs (VI) and (VII) of paragraph (a) of subsection (3) of this section, subsections (4) to (6) of this section, and section 12-22-803, to the extent the requirements are not required by federal law or regulation, unless the particular requirements are deemed necessary and appropriate following rulemaking by the board.

* * *

5. On August 11, 2008, Wholesaler Applicant submitted an out-of-state wholesaler application, which application was denied by the Board.

6. The Board finds and concludes, and Wholesaler Applicant agrees, that based upon Wholesaler Applicant's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances as a condition of its registration as an out-of-state wholesaler.

DISPOSITION

Conditional Registration;
$5,000.00 Fine and Terms

7. **Conditional Registration.** Wholesaler Applicant shall be granted a registration as an out-of-state wholesaler upon execution of this Final Agency Order and satisfaction of the terms and conditions set forth herein.

8. **Fine with Surcharge.** Wholesaler Applicant accepts the following discipline: Pursuant to §12-22-125.2(5), C.R.S., Wholesaler Applicant shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Wholesaler Applicant understands and acknowledges, pursuant to §24-34-108, C.R.S., that the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 15% of this fine. Wholesaler Applicant shall therefore pay a total amount of Five Thousand, Seven Hundred Fifty Dollars and No Cents ($5,750.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Wholesaler Applicant submits this signed Final Agency Order to the Board.

9. **Compliance.** Wholesaler Applicant shall at all times remain in compliance with §§12-22-801, *et seq.* C.R.S. and shall not at any time distribute prescription drugs into Colorado without being registered as an out-of-state wholesaler in the State of Colorado at the time of distribution.

10. **Advisements and Waivers.** Wholesaler Applicant enters into this Final Agency Order freely and voluntarily, whether or not Wholesaler Applicant has consulted with legal counsel. Wholesaler Applicant acknowledges its understanding that it has the following rights:

    a. To have a formal notice of hearing and charges served upon it;
    b. To respond to said formal notice of charges;
    c. To have a formal disciplinary hearing pursuant to §12-22-125, C.R.S.; and
    d. To appeal this Board order.

    Wholesaler Applicant freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for Board's limiting the action taken against it to the sanctions imposed herein.

11. **Acknowledgments.** The undersigned authorized agent of Wholesaler Applicant has read this Final Agency Order in its entirety and acknowledges, whether or not Wholesaler Applicant has consulted with legal counsel, that Wholesaler Applicant understands the legal consequences and agrees that none of the terms or conditions herein are unconscionable.

12. **Violations.** Time is of the essence to this Final Agency Order. It is the responsibility of Wholesaler Applicant to take all appropriate steps to comply fully with this Final Agency Order. Wholesaler Applicant acknowledges and agrees that any violation of this Final Agency Order may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of its registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Wholesaler Applicant to comply with all terms and conditions of this Final Agency Order.

13. **Integration and Severability**. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

14. **Public Record**. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

15. **Effective Date**. This Final Agency Order shall become effective upon signature of a Board member or representative.

ACCEPTED AND AGREED BY

Jane C. Hicks — Dated: 2/16/09

Authorized Agent of Wholesaler Applicant

Subscribed and sworn to by Jane C. Hicks, in his/her capacity as an authorized agent of Pharmaceutical Associates, Inc., before me in the County of Greenville, State of South Carolina this 16th day of February, 2009.

Notary Public

My commission expires:

October 19, 2015

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 24th day of February, 2009.

State Board of Pharmacy

BY: Wendy Anderson

Wendy Anderson
Program Director

CO- Resolved

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2009-2208

CEASE AND DESIST ORDER

IN THE MATTER OF THE UNAUTHORIZED AND UNLAWFUL DISTRIBUTION OF PRESCRIPTION DRUGS IN COLORADO BY **PHARMACEUTICAL ASSOCIATES,**

Respondent.

Pursuant to guidance established by the Colorado State Board of Pharmacy ("Board") at its January 15, 2009 meeting, documentation has beeen considered, including, but not limited to, the written complaint dated January 9, 2009, in the above-captioned matter.

Based upon this review, the Board hereby finds that it has jurisdiction over Respondent and the subject matter herein, and that there exists credible evidence that Respondent has acted without the required license, in violation of §§12-22-126 and/or 12-22-127, C.R.S.

The Board finds as follows:

1. Respondent is not registered to distribute prescription drugs or controlled substances in the State of Colorado.

2. On or around December 1, 2008, Respondent distributed prescription drugs to a prescription drug wholesaler in the State of Colorado.

3. Respondent's conduct constitutes the unlawful distribution of prescription drugs and in the State of Colorado, in violation of §§12-22-802(1), C.R.S.

4. WHEREFORE, pursuant to §12-22-125.2(9), C.R.S., the Board hereby ORDERS that Respondent immediately CEASE AND DESIST in engaging in the unlawful distribution of prescription drugs in the State of Colorado, in violation of §§12-22-802(1), C.R.S.

Within ten days after service of this order to cease and desist, Respondent may request a hearing on whether such acts or practices in violation of Part 1 of Article 22 of Title 12, C.R.S. have occurred. Such hearing shall be conducted pursuant to §§ 24-4-104 and 24-4-105, C.R.S.

The Board authorized the undersigned representative to sign this Cease and Desist Order on its behalf.

DATED this 5th day of February 2009.

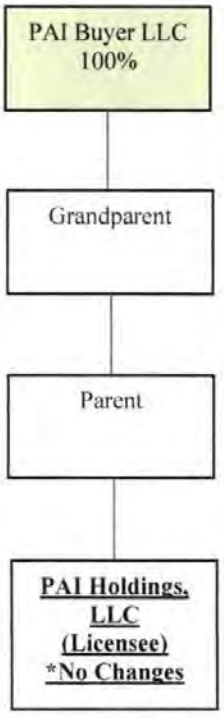
STATE BOARD OF PHARMACY

BY: Wendy Anderson

Wendy Anderson
Program Director
1560 Broadway, Suite 1300
Denver, Colorado 80202

ownership chart

Post-Closing Organization Structure



Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Abbot Laboratories Limited
Address: 74 Boul City: Victoriaville State: QC Zip: G6P 6S9

Name: Siegfield USA, LLC
Address: 33 industrial Park Road City: Pennsville State: NJ Zip: 08070

Name: Henry Pak Inc.
Address: PO Box 941 City: Simpsonville State: SC Zip: 29681

Name: ACIC Pharmaceuticals Inc.
Address: B211-325 West Street City: Brant ford State: Ont Zip: N3R 3VR

Section 4: Publicly Traded Corporation

N/A

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: SC
Parent Company (if any): PAI Middle Tier, LLC
Corporation/Organization Name: PAI Holdings, LLC d/b/a PAI Pharma
Mailing Address: c/o State License Servicing, 225 Dolson Avenue, 4th floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: PAIP@slsny.com
Contact Person Name: Christine Cannon

Section 6: Partnership

N/A

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

N/A

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	X	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

PAI Holdings, LLC d/b/a PAI Pharma

Facility Name

Kurt J Orlofski

Print Name of Authorized Person Submitting Application

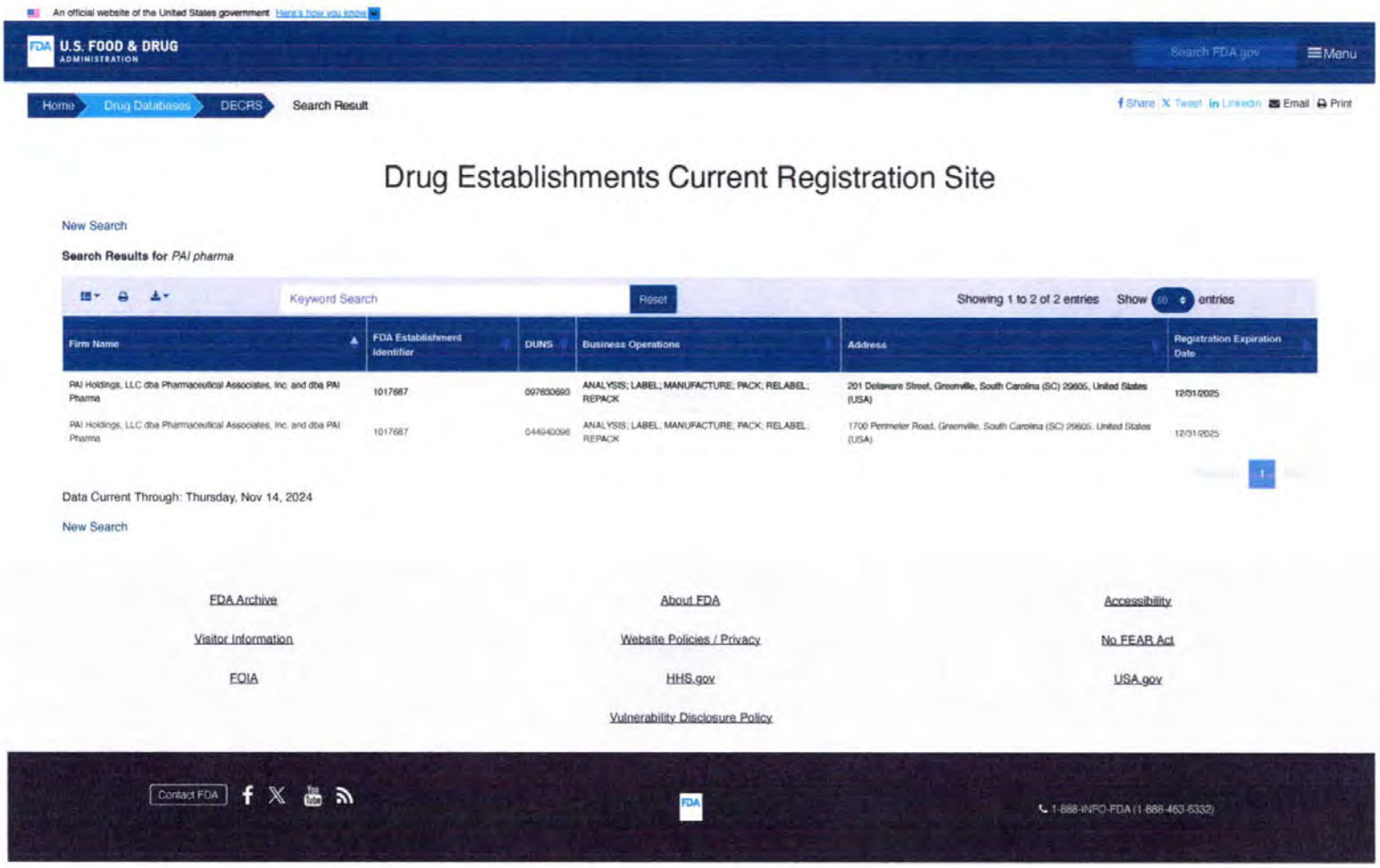
Original signature of Authorized Person (copies or stamps not accepted)

13 MARCH 2025

Date

Board Use Only	Date Received: 3/17/25	Amount: $1000.00 CK # 2905

FDA


An official website of the United States government Here's how you know
U.S. FOOD & DRUG ADMINISTRATION
Search FDA.gov
Menu
Home
Drug Databases
DECRS
Search Result
Share
Tweet
LinkedIn
Email
Print
Drug Establishments Current Registration Site
New Search
Search Results for PAI pharma
Keyword Search
Reset
Showing 1 to 2 of 2 entries
Show 50 entries
Firm Name
FDA Establishment Identifier
DUNS
Business Operations
Address
Registration Expiration Date
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma
1017687
097630693
ANALYSIS; LABEL; MANUFACTURE; PACK; RELABEL; REPACK
201 Delaware Street, Greenville, South Carolina (SC) 29605, United States (USA)
12/31/2025
PAI Holdings, LLC dba Pharmaceutical Associates, Inc. and dba PAI Pharma
1017687
044940096
ANALYSIS; LABEL; MANUFACTURE; PACK; RELABEL; REPACK
1700 Perimeter Road, Greenville, South Carolina (SC) 29605, United States (USA)
12/31/2025
Data Current Through: Thursday, Nov 14, 2024
New Search
FDA Archive
About FDA
Accessibility
Visitor Information
Website Policies / Privacy
No FEAR Act
FOIA
HHS.gov
USA.gov
Vulnerability Disclosure Policy
Contact FDA
1-888-INFO-FDA (1-888-463-6332)

PAI Holdings, LLC
d/b/a PAI Pharma

Corporate Address: 20 Waterview Boulevard, 3rd Floor, Parsippany, NJ 07054 USA
FEIN: 57-0511073
www.paipharma.com

Drug Labeler Code: 0121
Incorporation State: SC
Incorporation Date: 07/25/1968

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
PMT	1700 Perimeter Road Greenville, SC 29605 County: Greenville	1017687	RP0569840 & RP0569838, RP0569826 (Analytical Lab DEA) RP0653685 RP0653750		Yes	(864) 277-7282	(864) 236-0116

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Robin Lever Fedina	[redacted]	Senior Quality Director	No	[redacted]		
Ivan Cartagena Salaverris		Designated Representative				
Glen Micheal Ross		Designated Representative				

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
PAI Middle Tier, LLC	20 Waterview Blvd Suite 303 Parsippany, NJ 07054	N/A	100%	N/A	84-3275742	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Kurt J Orlofski	[redacted]	Chief Executive Officer		[redacted]		
Brandon M Rockwell		Chief Operations Officer				
Domenico Ciarico		Chief Commercial Officer				
Debra G Cesard		Chief Financial Officer	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
CT Corporation			

Company Particulars

Good Standing

The State of South Carolina

Office of Secretary of State Mark Hammond

Certificate of Existence

I, Mark Hammond, Secretary of State of South Carolina Hereby Certify that:

PAI Holdings, LLC, a limited liability company duly organized under the laws of the State of South Carolina on July 25th, 1968, with a duration that is at will, has as of this date filed all reports due this office, paid all fees, taxes and penalties owed to the State, that the Secretary of State has not mailed notice to the company that it is subject to being dissolved by administrative action pursuant to S.C. Code Ann. §33-44-809, and that the company has not filed articles of termination as of the date hereof.

Given under my Hand and the Great Seal of the State of South Carolina this 4th day of February, 2025.

Mark Hammond

Mark Hammond, Secretary of State

Homestate License

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

PAI Holdings, LLC
1700 Perimeter Rd
Greenville, SC 29605

PY .19223 PWD
Wholesale/Distributor

Heather C. Harris
Heather C. Harris, Board Chair

Archie "Artie" McKnight, Vice Chair

License Expires on
06/30/2025

Effective Date
04/30/2024

Traci Collier
Traci Collier, Board Administrator

South Carolina Department of Labor, Licensing and Regulation

Board of Pharmacy

PAI Holdings, LLC
PAI Pharma
1700 Perimeter Road
Greenville, SC 29605

PY .21981 PMR

Manufacturer/Repackager

License Expires on
06/30/2025

Heather C. Harris, Board Chair

Archie "Artie" McKnight, Vice Chair

Effective Date
04/30/2024

Traci Collier, Board Administrator

To verify current license status, go to http://verify.llronline.com/LicLookup/LookupMain.aspx

License must be displayed publicly.

DEA
(distributor)

Registrant Verification For

PAI HOLDINGS, LLC

DEA Number:	RP0569840
Expiration Date:	03/31/2025
Additional Company Info:	D/B/A PAI PHARMA
Registered Address:	1700 PERIMETER RD
	BLDG A
City:	GREENVILLE
State:	SC
Zip Code:	29605
Business Activity:	DISTRIBUTOR
DEA Schedules:	2 2N 3 3N 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	02/19/2025

This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

Drug Enforcement Administration • Diversion Control Division • 75 Morrissette Dr, Springfield, VA 22152

DEA (manufacturer)

Registrant Verification For
PAI HOLDINGS, LLC

DEA Number:	RP0569838
Expiration Date:	03/31/2025
Additional Company Info:	D/B/A PAI PHARMA
Registered Address:	1700 PERIMETER RD
	BLDG B
City:	GREENVILLE
State:	SC
Zip Code:	29605
Business Activity:	MANUFACTURER
DEA Schedules:	2 3 4 5
Payment Indicator:	Paid
Registration Status:	ACTIVE
Date of Verification:	02/19/2025

Drug Codes:
9050 9193 9300 9143 9250

This Primary Source Verification was obtained from the Drug Enforcement Administration's Controlled Substance Act Registrant Database.

Drug Enforcement Administration • Diversion Control Division • 75 Morrissette Dr, Springfield, VA 22152

Bond

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. POA1002533

Application/License No. _____

PAI Holdings, LLC dba Pharmaceutical Associates, Inc., doing or intending to do business as a
(Applicant/Principal)
pharmaceutical wholesaler, whose address for purposes of service is
1700 Perimeter Road, Greenville, SC 29605, as
(Address of Applicant/Principal)
PRINCIPAL, and Seneca Insurance Company, Inc., a
(Surety Company)
corporation organized under the laws of the state of New York
(State of Incorporation)
and authorized to transact a general surety business in the State of
Nevada, whose address for purposes of service is
160 Water Street, New York, NY 10038-4922 as
(Address of Surety)
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 2nd, 2020.
(Effective Date)

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 2nd day of April, 2020.

APPLICANT/PRINCIPAL

COMPANY
PAI Holdings, LLC dba Pharmaceutical Associates, Inc.

Authorized Representative

SURETY

Seneca Insurance Company, Inc.

Joshua Sanford
Digitally signed by Joshua Sanford
Date: 2020-04-02 14:43:45

Surety Company's Representative

Joshua Sanford, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Aimee R Perondine
Digitally signed by Aimee R Perondine
Date: 2020-04-02 14:39:42

Witness Aimee R. Perondine

Tanya Nguyen
Digitally signed by Tanya Nguyen
Date: 2020-04-02 14:36:12

Witness Tanya Nguyen

CATERINA GULYAS
NOTARY PUBLIC OF NEW JERSEY
COMMISSION # 2393142
MY COMMISSION EXPIRES 02/05/2025

Countersigned by: Donna M. Planeta

Donna M Planeta
Digitally signed by Donna M Planeta
Date: 2020-04-02 14:33:18

Nevada Resident Agent License No. 3158296
Non Resident

POWER OF ATTORNEY
SENECA INSURANCE COMPANY, INC.
PRINCIPAL OFFICE, NEW YORK, NEW YORK

92001

KNOW ALL MEN BY THESE PRESENTS: That SENECA INSURANCE COMPANY, INC., a corporation duly organized and existing under the laws of the State of New York, has made, constituted and appointed, and does hereby make, constitute and appoint:

Aimee R. Perondine, Aiza Anderson, Bethany Stevenson, Danielle D. Johnson, Donna M. Planeta, Jenny Rose Belen Phothirath, Joshua Sanford Mercedes Phothirath Samuel E. Begun, Melissa J. Stanton, Lorina Monique Garcia, Nicholas Turecamo, Michelle Anne McMahon

each, its true and lawful Attorney(s)-In-Fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver: Any and all bonds and undertakings of surety and other documents that the ordinary course of surety business may require, and to bind the Corporation thereby as fully and to the same extent as if such bonds or undertakings had been duly executed and acknowledged by the regularly elected officers of the Corporation at its principal office, in amounts or penalties not exceeding: Fifty Million Dollars ($50,000,000).

This Power of Attorney limits the act of those named therein to the bonds and undertakings specifically named therein, and they have no authority to bind the Company except in the manner and to the extent therein stated.

This Power of Attorney revokes all previous Powers of Attorney issued on behalf of the Attorneys-In-Fact named above and expires on 31 day, of January month, 2021 year.

This Power of Attorney is granted pursuant to unanimous written consent passed the 19th day of September 2011 by the directors of Seneca Insurance Company, Inc. in accordance with Article II, Section 12 of the By-Laws of Seneca Insurance Company, Inc.

Resolved that the President, Vice President, Secretary and Treasurer and each of them hereby is authorized to execute powers of attorney, and such authority can be executed by use of facsimile signatures, which may be attested or acknowledged by any officer or attorney of the Company, qualifying the attorney or attorneys named in the given power of attorney to execute on behalf of, and acknowledge as the act and deed of the Company, all bond undertakings and contracts of suretyship, and to affix the corporate seal thereto.

IN WITNESS WHEREOF, SENECA INSURANCE COMPANY, INC. has caused these presents to be signed and attested by its appropriate officer and its corporate seal hereunto affixed this 11th day of March, 2019.

Corporate Seal:

SENECA INSURANCE COMPANY, INC.

By _____
Daniel Sussman
Senior Vice President

Attest: _____
Laura Schneider
Senior Vice President

STATE OF NEW JERSEY,
ss.:
COUNTY OF MORRIS

On this 11th day of March, 2019 before me, a Notary Public, personally appeared the above named officers, Daniel Sussman and Laura Schneider, who, being duly sworn, acknowledged that they signed the above Power of Attorney as Senior Vice President and Vice President of the said SENECA INSURANCE COMPANY, INC. and acknowledged said instrument to be the voluntary Act and Deed of said Company. They are both personally known to me.

Sonia Scala, Notary Public

SONIA SCALA
NOTARY PUBLIC OF NEW JERSEY
MY COMMISSION EXPIRES 3/25/2024
No. 2163686

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal of Seneca Insurance Company, Inc. on the 2nd day of April ,20 20

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: PAI Holdings, LLC d/b/a PAI Pharma

Pharmacy/Wholesaler License # (if applicable): WH01651

Physical Address: 1700 Perimeter Road

City: Greenville State: SC Zip: 29605

Mailing Address (if different from physical address): c/o State License Servicing 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.paipharma.com

Licensing Company Email: PAIP@slsny.com

Section 2: Personal Information

First: Ivan Middle: Last: Cartagena Salaverris

Alias(es, nicknames, name changes, etc.): Ivan Cartagena

Date of Birth: [redacted] SSN or ITIN: Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Greenville State: SC Zip: [redacted]

Telephone: [redacted] Email: icartagena@paipharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Turabo University		08/1986 - 05/19992	
Address	City	State	Zip
6XRV+Q6H, Rio Grande Road, Juncos	Caguas, 00777, Puerto Rico		
Diploma/Degree obtained, if any			
Master in Business Administration, Industrial Management			
School Name		From - To (MM/YY – MM/YY)	
University of Puerto Rico		08/1980 - 05/1985	
Address	City	State	Zip
259 Av. Alfonso Valdés Cobián	Mayagüez, Puerto Rico		00680
Diploma/Degree obtained, if any			
BS Mechanical Engineer			
School Name		From - To (MM/YY – MM/YY)	
Colegio Bautista		09/1976 - 06/1980	
Address	City	State	Zip
PR-784	Caguas	PR	00727
Diploma/Degree obtained, if any			
High School Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2023 - Present	[redacted]	Greenville	SC	[redacted]
02/2020 - 09/2023		Wesley Chapel	FL	
05/2019 - 05/2020		Wesley Chapel	FL	
07/2011 - 05/2020		Wesley Chapel	FL	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PAI Holdings, LLC d/b/a PAI Pharma			09/2023-Present	
Business Address		**City**	**State**	**Zip**
1700 Perimeter Road		Greenville	SC	29605
Phone	**Title**		**Number of Employed Hours**	
(864) 277-7282	Designated Representative		~ 3,080 Hours	
Description of Duties				
Responsible for providing leadership, strategic direction and directing all manufacturing and administrative activities in a pharmaceutical manufacturing and distribution operation. Responsible to manage an operating budget of $52MM with approximately 525 exempt and non-exempt employees.				

Business Name			From - To (MM/YY – MM/YY)	
Vista Pharm, LLC, Division of PAI Pharma			07/2022 – 08/2023	
Business Address		**City**	**State**	**Zip**
13707 66th St N		Largo	FL	33771
Phone	**Title**		**Number of Employed Hours**	
(727) 530-1633	General Manager		~ 2,240 Hours	
Description of Duties				
Responsible for providing leadership, strategic direction and directing all manufacturing and administrative activities in a pharmaceutical manufacturing and distribution operation. Responsible to manage an operating budget of $34MM with approximately 197 exempt and non-exempt employees.				

Business Name			From - To (MM/YY – MM/YY)	
Vista Pharm, Inc. Division of Vertice Pharma			02/2017 - 07/2022	
Business Address		**City**	**State**	**Zip**
13707 66th St N		Largo	FL	29605
Phone	**Title**		**Number of Employed Hours**	
(727) 530-1633	Vice President Technical Operations		~ 11,280 Hours	
Description of Duties				
Responsible for providing leadership, strategic direction and directing all manufacturing and administrative activities in a pharmaceutical manufacturing and distribution operation. Responsible to manage an operating budget of $34MM with approximately 197 exempt and non-exempt employees.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Ivan Cartagena Salaverris, **certify that as the designated representative for**

PAI Holdings, LLC d/b/a PAI Pharma,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. IC I am at least 21 years of age;
3. IC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. IC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. IC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. IC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. IC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ivan Cartagena Salaverris

Print Name (First, Last)

Iván Cartagena Salaverris 13-MAR-2025

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ivan Cartagena Salaverris

Print Name (First, Last)

Ivan Cartagena Salaverris

Original Signature (electronic, copies or stamps not accepted)

13-MAR-2025

Date

Please have this section completed in the presence of a Notary Public.

State of South Carolina, ss. County of Greenville

I, LaKenya C. Hagood, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ivan Cartagena Salaverris

Original Signature

Ivan Cartagena Salaverris

13-MAR-2025

Date

Subscribed and Sworn to before me this 13 day of March 2025

LaKenya C. Hagood

Notary Public Signature

LaKenya C. Hagood
Notary Public - State of South Carolina
My Commission Expires
August 23, 2031

(Seal)

List of employees

Last Name	First Name
Fox	Rita
Sherman	Joann
Rodgers	Lisa
Gambrell	Gloria
Brockman	Karen
Platt	Tammy
Knobloch	Tiffanie
Allen	Jeffrey
Scott	Darren
Carriker	Jennifer
Brock	Demorris
Persaud	Sheron
Bishop	Derek
Manley	Meredith
Wolff	Todd
Chandler	Michael
Phares	Stacey
Arellano	Maria
Ledford	Taylor
Vega	Gamaliel
Ledford	Audie
Muratore	Elvia
Morton	Debra
Chapin	Amanda
Hatch	Michael
Chambers	Nancy
Hall	Kristianna
Patel	Pravin
Leverette	Leslie
Keltner	Jason
Perrin	Cynthia
Williams	Rebecca
Davis	Eric
Harris	Patricia
Harris	Jeremy
Burket	Darin
Fowler	Robert
Banihani	Michael
Morris	James
Rogers	Anthony
Couch	Stephen
Wenner	Daniel
Eppes	Wade
Wright	Emma
Turner	Connie
Westmoreland	Brenda
Revis	Charles

McClellion	Holly
Miller	Jack
Miller	Matthew
Darby	Brandi
Gaffney	Ann
Harmon	Alfred
Barksdale	Leon
Graves	Kimberly
Mills	Ronald
Shull	Patricia
Cochran	Jonathan
Dodson	Windy
Abbott	Andrea
Watson	Molly
Fowler	Patsy
Carlson	Adam
Bennett	Kimberly
Evans	Allison
Abbott	Robert
Williams	Barbara
Wofford	Tracy
Roberts	Ronald
McKinney	Amanda
Hays	Brentt
Taylor	Landa
McRae	Chadwick
Martin	Craig
Caudle	Kelly
West	Jeffrey
Moore	Jimmy
Miller	Christopher
Schenkel	Miranda
Rogers	Andrew
Bolin	Bruce
Rojas	Dilber
Kakaras	Julie
Wright	Tammy
Brissey	Joey
Sutton	William
Collins	Valerie
Crosby-Sheppard	Patricia
Freeman	Shontavia
Lindler	Amy
Donahue	Byrne
Scott	Shereco
Smith	Mark
Simmons	Maurice
Smith	Patrick

Young	Steve
King	Zachary
Key	Penny
Johnson	Katherine
Carter	Kimberly
Drummond	Calvert
Lark	Ricky
Goins	Lakeisha
Alonso	Hugo
Hannah	Michael
Olmsted	Frederick
Hankston	Marvin
Russell	Nicole
Smith	Nicole
Martin	Dana
Vance	Daniel
Stancell	Ruth
Williams	Tyrone
Dawson	Charles
Bolt	Robert
Rodgers	Diane
Macri	Nancy
Keeler	Cynthia
Orlofski	Kurt
Gulyas	Caterina
Winch	Mitchell
Shumaker	Kelly
Chastain	Jeremy
Gill	Grayson
Langston	Darby
Smith	Robin
Baldeo	Nalini
Lashway	Jaclyn
Holcombe	Letitia
Leister	David
Johnson	Patrice
Bostic	Vicki
Padilla	James
Sufczynski	Christopher
Bennett	Amanda
Shumate	Jacobie
Pringle	Paula
Stringer	Ashley
McCoy	Andrea
Dacus	Tyler
Griffin	Sharon
Cavanaugh	Charles
Fisher	Michael

Syracuse	Alicia
Blount	William
Fox	Frank
Miller	Christie-Ann
Chen	George
Versele	Laurie
Johnson	Juvelle
ODea	Laura
Burdick	Brian
Fedina	Robin
McAntyre	James
Zolnai	Nancy
Morris	Lorrie
Ratchford	Susanne
Spencer	Roxane
Bolin	Rachel
THOMPSON	ROBERT
Liegey	Nittie
Grier	Kaitlyn
Williams	Parry
Brinkley	Michael
Wardlaw	Brandon
LoGrippo	Matthew
Blyther II	Thomas
Lee	Julia
Tucker	Frennie
Blakley	Carol
Seibles	India
Evans	Jennifer
Thompson	Jonathan
Owens	Bobby
GOLDEN	BRIAN
Suber	Mary
Cannon	Nakesha
Lupse	Corina
Eppes	Jolie
Cochran	Taylor
Barber	Rachel
Floyd Gambrell	Sadeirya
SLOAN	TRACIE
Mazuera	Juliette
Hassler	Brian
Turner	James
Tchetgna	Laetitia
DuBose	Andre
Henry	Samari
Wagner	Harold
Wedge	Ashlee

Allen	Jessica
Ollison	Darius
Carter	Kesley
Powell	Kimberley
Jackson	Hunter
Poore	Lauren
Hine	Jordan
Gysin	Davis
Taylor-Farley	Jeremy
LaGuardia	Emily
Harward	Brisco
Finley	Brandon
Menigoz	Scott
Rodriguez Zamora	Sigfredo
Adams	James
Reid	Cody
Brulato	Amanda
Requena	Jose
Kaplan	Rebecca
Gelinas	Amalia
Rogerson	Jordan
Christopher Daniel	Loree
Yeargin	Deborah
Cabanillas	Ashleigh
van der Heyden	Kai
Ng	Bryant
Davenport	Debra
Davidson	Robert
Lewis	Michael
Behnert	Klaus
Turner	William
Hester	Misty
Dixon	Thomas
Copeland	Latonia
Kennedy	Ashley
Mixon	Christina
Fort	John
Wilson	Janet
Hickey	James
Etwaru	Chandra
McMahan	Jacob
Lisenby	Julie
Geer	Briana
Mathews	Kevin
Rhodes	Scott
Little	Brooke
Ciarico	Domenico
Rockwell	Brandon

Williams	Trenton
Covington	David
Ricaurte	Diana
Freeman	Tangie
Rengasawmy	Sarah
Vaughn	Cindy
Norton Teamer	Sedrika Lavatta
Dixon	Nathan
Durkin	Erin
Lanford	Terry
Underwood	Aaron
Sanghvi	Suketu
Power	Brittany
Baker	Laura Jean
Blake	Genae
Bolton	Sarah
Revis	Rhonda
Thompson	Willie
Dawson	Anthony
Phelps	Sean
Spinoso	Nicholas
Allen	Jacob
Hester	Sherrie
Scott	Michael
Stewart	Candace
Keller	Matthew
Maddi	Kranthi kumar
Bell	Lakeitha
Holsen	Andrew
Brown	Shannon
Craig	Gabriel
Ruiz Zaia	Lina
Taylor	Trevor
Bodjona	Essotolom
Davenport	William
Bishop	Travis
McCullough	Vincent
Johnson	Marleah
Durham	Cassandra
Martori	Jessica
Ramirez Ramirez	LIZETT
Orta	Ninva
Orta	Emilio
Terzakis	Donna
Collins	Amanda
Jambula	Sneha Reddy
Lee	Jessica
Stover	James

Rock	Abigail
Tarrant	Regina
Patel	Jigna
McBride	Keenan
Sullivan	Stanise
Beeler	Paul
Haus	Kiera
Kody	Michael
Wilkinson	Joseph
Rivera Gonzalez	Angel
Daniels	Randall
Brock	Claudia
Thomas	Bridgett
Higgs	Caldin
Pitts	Candace
Robbs	Sammerah
Greer	Cody
Farrar	Kasey
Latham	Andrew
Dardaine	Polly-Ann
Ingram	Aunyae
Minnick	Bryan
Sharpe	Ansley
Davis	Anna
Holmes	Travis
Purcell	Tyler
Alvarez	Onofre
Renz	Robert
Dixon	Zackery
Patel	Jalit
Potlow	Sandra
Allston	Richard
Howell	Virginia
Cody	Carl
Shelton	Carmen
Wilson	Shynese
Figueredo	Madelyne
Ko	Emily
Pitt	Shawna
Ford	Gerald
Aufderheide	Nathan
Tazuma	Kyle
Ross	Ryan
Miller	Roger
Campbell	Joseph
Anand	Sunil
Mitchell	Marissa
Moseley III	Charles

Watson	Shavor
Stovall	Jeffrey
Bing	TedDrika
White	Devon
Thomas	Charles
Lyda	Kevin
Hutchinson	Brandon
Zheng	Yitong
Prioleau	Chauncey
Wallen	Brandon
Trimmer	Craig
Spence	Donald
Hunter	David
Goodwin	Antionette
Miles	Jermaine
Jameson	Brandon
Ikanovic	Kasim
Sumeral	Justin
Fabregas	Edgardo
COLEMAN	DARIUS
Edwards	Aiyana
Culbertson	Kalea
Pereiro	Stephen
Andrews	Kaseem
Wells	Joyseptia
Kincaid	Brittany
Young	Ajia
Nelson	Lakecia
Eskew	Kevin
Mcdowell	Kareem
Stevenson	Braydon
Mcentyre	Kayla
Clarkson	Genobia
Johnson	Debbie
Hagood	Queenie
Pitts	Aneya
morgan	trinity
Henderson	Krystal
Eskew	Ricky
Healy	Liam
Harrison	Tessish
Dirton	Shirnasha
Jackson	Terrail
Whisonant	Megan
Hicks	Tracy
Edwards	Erica
Dixon	Sherdell
Shell	Donald

McDowell	Anthony
Coleman	Harold
Bosier	Latoya
Fant	Vanessa
Slater	Shametris
Hicks	Dineene
Cunningham	James
Thompson	Chauncey
Burnside	Claudette
Williams	Ricky
Williams	Tavares
Killingsworth	Rachel
Hutcherson	Lisa
Miles	Jasmine
Grzejdziak	Igor
Thomason	Audrey

400

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Philips Ultrasound LLC

Physical Address: 1 Echo Drive

City: Reedsville State: PA Zip: 17084

Mailing Address (if different from physical address): 1 Echo Drive, ATTN: Alysia S. Middaugh

City: Reedsville State: PA Zip: 17084

Telephone: (717) 667-5000 Website: https://www.usa.philips.com/

Name of Designated Representative (DR): Alysia S. Middaugh

Licensing Company Email: statelicense@philips.com DR Email: alysia.middaugh@philips.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☑ [a]Medical devices, equipment, supplies, ~~gases~~	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Manufacturers, Distributors		☑ Others: Distributor

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A
Original Signature (electronic, copies or stamps not accepted)

N/A
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: N/A - No pharmaceutical products are handled or sold. See Attachment A.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded ~~Corporation or~~ Company Limited Liability Company

State of Incorporation/Organization: Washington

Parent Company (if any): ATL Ultrasound, Inc.

Corporation/Organization Name: Philips Ultrasound LLC

Mailing Address: 1 Echo Drive, ATTN: Alysia S. Middaugh

City: Reedsville State: PA Zip: 17084

Telephone: (717) 667-5000 Email: statelicense@philips.com

Contact Person Name: Alysia S. Middaugh

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

N/A

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment D		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - wholly owned by parent company		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment I	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment J	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

N/A - See Attachment B

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Philips Ultrasound LLC

Facility Name

Alysia S. Middaugh

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

03/21/2025

Date

Board Use Only	Date Received: 4/2/25	Amount: $1000 - CK 2425

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✔	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

N/A

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment D		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - wholly owned by parent company		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ See Attachment I	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). See Attachment J	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

N/A - See Attachment B

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search

Back To Search Results

Establishment:
Philips Ultrasound LLC
Business Trade Names:
(1) Philips (2) Philips Healthcare (3) Philips Medical Systems

1 Echo Dr
Reedsville, PA 17084
Registration Number: 2518586
FEI Number*: 2518586
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Philips Medical Systems International BV[6]
Veenpluis 6
Best, NL 5684PC
Owner/Operator Number: 1217116[7]

Official Correspondent:
Sunny Yi
22100 Bothell Everett Hwy
Bothell, WA 98021
Phone: 1-657-2195441

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 02/10/2025

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Silver Spring, MD 20993
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Attachment A

Nature of Business

Philips Ultrasound, LLC (Ultrasound) is a manufacturer and distributor of prescription and non-prescription medical devices. Ultrasound's Reedsville, PA location manufactures scanning products. This facility manufactures and ships products nationwide. All products are invoiced by the facility in Bothell. Provided below are the manufacturing and distributing locations:

Manufacturing Locations:

Philips Ultrasound LLC
1 Echo Drive
Reedsville, PA 17084

Philips Ultrasound (Shanghai) Co., Ltd
3000 Longdong Blvd., Building 5, Suite 203
SHANGHAI, Shanghai, 201203, China
FDA Registration #: 3005403518

Distributing Location:

Philips Ultrasound LLC
1 Echo Drive
Reedsville, PA 17084

FedEx Supply Chain, Inc.
2901 Black Bridge Road
York, PA 17406

Selling Location:

Philips Ultrasound LLC
22100 Bothell Everett Hwy
Bothell, WA 98021

Attachment D

LLC Information

Philips Ultrasound LLC

Philips Ultrasound LLC is wholly-owned by its parent company, ATL Ultrasound, Inc.

Jeffrey M. Cohen
President/General Manager

Leonardus Ammerlaan
Vice President and Treasurer

Joseph E. Innamorati
Vice President and Secretary

Paul Cavanaugh
Vice President

Irma I. Gomez
Assistant Secretary

UNITED STATES OF AMERICA

The State of Washington

Secretary of State

I, STEVE R. HOBBS, Secretary of State of the State of Washington and custodian of its seal, hereby issue this

CERTIFICATE OF EXISTENCE

OF

PHILIPS ULTRASOUND LLC

I CERTIFY that the records on file in this office show that the above named entity was formed under the laws of the State of Washington and that its public organic record was filed in Washington and became effective on 03/14/1973.

I FURTHER CERTIFY that the entity's duration is Perpetual, and that as of the date of this certificate, the records of the Secretary of State do not reflect that this entity has been dissolved.

I FURTHER CERTIFY that all fees, interest, and penalties owed and collected through the Secretary of State have been paid.

I FURTHER CERTIFY that the most recent annual report has been delivered to the Secretary of State for filing and that proceedings for administrative dissolution are not pending.

Issued Date: 03/07/2025
UBI Number: 600 094 395

Given under my hand and the Seal of the State of Washington at Olympia, the State Capital

Steve R. Hobbs, Secretary of State

Date Issued: 03/07/2025

Pennsylvania
Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

Philips Ultrasound, LLC 1 Echo Drive; Reedsville, PA 17084
Certificate(s): **6000008162** issued: 07/23/2012 expires: 9/30/2025

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version 4.0.0.0

Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

1911

Certificate of Registration

Certificate No. 6003008162
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Drug & Device Registration
2525 North 7th Street
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

Category:

Devices

PHILIPS ULTRASOUND, LLC
1 ECHO DRIVE
REEDSVILLE, PA 17084

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: July 23, 2012
Expiration Date: The Last Day of September, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/28/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
MARSH USA, LLC.
1166 Avenue of the Americas
New York, NY 10036
Attn: NewYork.Certs@marsh.com Fax: 212-948-0500

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS:

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : National Union Fire Insurance Company of Pittsburgh,	19445
INSURER B : Safety National Casualty Corp.	15105
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
Philips North America LLC
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

COVERAGES **CERTIFICATE NUMBER:** NYC-011250033-22 **REVISION NUMBER:** 7

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS		
A	X COMMERCIAL GENERAL LIABILITY			536-18-48	12/31/2024	12/31/2025	EACH OCCURRENCE	$	2,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$	3,000,000
							MED EXP (Any one person)	$	10,000
							PERSONAL & ADV INJURY	$	2,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$	5,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$	5,000,000
	OTHER:							$	
B	AUTOMOBILE LIABILITY			CA6675481	12/31/2024	12/31/2025	COMBINED SINGLE LIMIT (Ea accident)	$	2,000,000
	X ANY AUTO						BODILY INJURY (Per person)	$	
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$	
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$	
								$	
A	X UMBRELLA LIAB X OCCUR			041233800	12/31/2024	12/31/2025	EACH OCCURRENCE	$	5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$	5,000,000
	DED RETENTION $							$	
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY			LDS4047559 (AOS)	12/31/2024	12/31/2025	X PER STATUTE OTH-ER		
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH)	N/A		PS4047560 (WI)	12/31/2024	12/31/2025	E.L. EACH ACCIDENT	$	2,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$	2,000,000
							E.L. DISEASE - POLICY LIMIT	$	2,000,000
A	CYBER LIABILITY			39325976 'Subject to a policy deductible'	12/31/2024	12/31/2025	Per Occurrence Limit:		10,000,000
							Aggregate Limit:		10,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
Evidence of coverage
This certificate applies to all employees of the named Insured's who are applying for vendor access at medical facilities. All operations in the United States and Canada (see attached). The Certificate Holder named below is Additional Insured where required by written contract or agreement under the Vendors' Broad Form referenced on the attached. Coverage includes Host Liquor Liability.

CERTIFICATE HOLDER
Philips North America LLC
(See additional page for other Insureds)
222 Jacobs Street, 3rd Floor
Cambridge, MA 02141

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Marsh USA LLC

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA, LLC.	Philips North America LLC (See additional page for other Insureds) 222 Jacobs Street, 3rd Floor, Cambridge, MA 02141
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Named Insured Includes:
370 West Trimble Road LLC
AllParts Medical, LLC
BioTelemetry, Inc.
BioTel Holter Direct, LLC
BioTel Research, LLC
BioTelemetry Care Management, LLC
Telcare Medical Supply, LLC
Telcare, LLC
Braemar Manufacturing, LLC
Cardiac Monitoring Holding Company, LLC
LifeWatch Corp.
LifeWatch Services, Inc.
Cardiologs Technologies Inc.
CardioNet, LLC
BioTel INR, LLC
Geneva Healthcare, LLC
VirtualScopics, LLC
Blue Willow Systems LLC
Discus Holdings, LLC
Discus Dental, LLC
Discus International, LLC
Discus Dental Canada, LLC
Electrical Geodesics LLC
Cerebral Data Systems, Inc. (CDS)
Intact Vascular, Inc.
Philips CS Corporation (formerly "Vita Topco, Inc." and "Philips Capsule Corporation")
Capsule Technologies, Inc.
CapsuleTech, Inc.
Philips Healthcare Informatics, Inc.
Philips Image Guided Therapy Corporation
Cardioprolific Inc.
Crux Biomedical, LLC
Spectranetics LLC
Angioscore LLC
Volcano Atheromed, Inc.
Philips Medical Systems (Cleveland), Inc.
Philips Medical Systems MR, Inc.
Philips DS North America LLC
Philips North America, LLC
Philips North America, LLC D/B/A Philips Healthcare
Philips Oral Healthcare, LLC
Philips RS North America Holding Corporation
Philips RS North America LLC
Respironics California, LLC
Respironics Colorado, Inc.
Respironics Logistics Services, LLC
Respironics Novametrix, LLC
Philips Semiconductors Inc.

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AGENCY CUSTOMER ID: CN101736188
LOC #: New York

ACORD®

ADDITIONAL REMARKS SCHEDULE

AGENCY	NAMED INSURED
MARSH USA, LLC.	Philips North America LLC (See additional page for other Insureds) 222 Jacobs Street, 3rd Floor, Cambridge, MA 02141
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,
FORM NUMBER: 25 FORM TITLE: Certificate of Liability Insurance

Remote Diagnostics Technologies LLC
Respiratory Technologies, Inc.
Tomtec Corporation
TR Management Company, LLC
U.S. Philips Corporation
Vesper Medical, Inc.
VISICU, Inc.
VitalHealth Software Corp.
Wellcentive LLC (formerly "Wellcentive, Inc.")
Wellcentive QR, LLC
American Color & Chemical, L.L.C.
ATL Ultrasound, Inc.
Philips Ultrasound LLC (formerly "Philips Ultrasound, Inc.")
ATL International LLC
Philips Electronics North America Foundation
Philips Electronics Realty, LLC
Philips Medical Systems Export, Inc
Philips MPEG Inc.
Philips Project Management, LLC

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CHANGE RIDER

To be attached to and form a part of Bond No. 30185503

in the amount of $25,000.00 issued by Western Surety Company

on behalf of **See attached list of principals

in favor of Nevada State Board of Pharmacy

It is understood and agreed that the bond described above is hereby modified so as to

Add the Principal:

Philips Ultrasound LLC, 1 Echo Drive, Reedsville, PA 17084

It is further expressly understood and agreed that the aggregate liability of the Western Surety Company under said bond to the obligee herein mentioned shall not exceed the amount stated above.

Nothing herein contained shall be held to vary, alter, waive, or extend any of the terms, agreements, conditions or limitations of the above-mentioned bond, other than as above stated.

Signed, sealed and dated this 14th day of March, 2025.

Western Surety Company

BY: Kristin S. Bender Attorney-in-Fact

Nevada Non-Resident Producer License No. 829075

LMS-14173 02/98

APPLICANT/PRINCIPALS:

AllParts Medical, LLC, 400 Brick Church Park Drive, Nashville, TN 37207
Discus Dental, LLC, 1700 A South Baker Ave., Ontario, CA 91761
Philips Healthcare Informatics, Inc., 4430 Rosewood Drive, Suite 200, Pleasanton, CA 94588
Philips Healthcare, a division of Philips North America LLC, 22100 Bothell Everett Hwy, Bothell,WA 98021
Philips Healthcare, a division of Philips North America LLC, 222 Jacobs Street, Cambridge, MA 02141
Philips Ultrasound LLC, 22100 Bothell Everett Highway, Bothell, WA 98021
Philips Image Guided Therapy Corporation, 3721 Valley Center Drive, Suite 500, San Diego, CA 92130
Philips Image Guided Therapy Corporation, 2451 Mercantile Drive, Rancho Cordova, CA 95742
Spectranetics LLC, 9965 Federal Drive, Colorado Springs, CO 80921
Visicu, Inc., 217 E. Redwood Street, Suite 1900, Baltimore, MD 21202
Philips RS North America LLC, 1010 Murry Ridge Lane, Murrysville, PA 15668
Philips RS North America LLC, 174 Tech Center Drive, Suite 100, Mt. Pleasant, PA 15666
Respironics Logistics Services, LLC, 174 Tech Center Drive, Suite 200, Mt. Pleasant, PA 15666
Respironics Novametrix, LLC, 3000 Minuteman Road, Andover MA 01810

Western Surety Company

POWER OF ATTORNEY APPOINTING INDIVIDUAL ATTORNEY-IN-FACT

Know All Men By These Presents, That WESTERN SURETY COMPANY, a South Dakota corporation, is a duly organized and existing corporation having its principal office in the City of Sioux Falls, and State of South Dakota, and that it does by virtue of the signature and seal herein affixed hereby make, constitute and appoint

Kristin S. Bender

, Individually

of Morristown, NJ, its true and lawful Attorney(s)-in-Fact with full power and authority hereby conferred to sign, seal and execute for and on its behalf bonds, undertakings and other obligatory instruments of similar nature

- In Unlimited Amounts -

Surety Bond Number: 30186503
Principal: see attached list or principals
Obligee: Nevada State Board of Pharmacy

and to bind it thereby as fully and to the same extent as if such instruments were signed by a duly authorized officer of the corporation and all the acts of said Attorney, pursuant to the authority hereby given, are hereby ratified and confirmed.

This Power of Attorney is made and executed pursuant to and by authority of the By-Laws and Resolutions printed below, duly adopted, as indicated, by the shareholders of the corporation.

In Witness Whereof, WESTERN SURETY COMPANY has caused these presents to be signed by its Vice President and its corporate seal to be hereto affixed on this 13th day of March, 2024.

WESTERN SURETY COMPANY

Larry Kasten, Vice President

State of South Dakota }
County of Minnehaha } ss

On this 13th day of March, 2024, before me personally came Larry Kasten, to me known, who, being by me duly sworn, did depose and say: that he resides in the City of Sioux Falls, State of South Dakota; that he is the Vice President of WESTERN SURETY COMPANY described in and which executed the above instrument; that he knows the seal of said corporation; that the seal affixed to the said instrument is such corporate seal; that it was so affixed pursuant to authority given by the Board of Directors of said corporation and that he signed his name thereto pursuant to like authority, and acknowledges same to be the act and deed of said corporation.

My commission expires

March 2, 2026

M. BENT
NOTARY PUBLIC
SOUTH DAKOTA

M. Bent, Notary Public

CERTIFICATE

I, Paula Kolsrud, Assistant Secretary of WESTERN SURETY COMPANY do hereby certify that the Power of Attorney hereinabove set forth is still in force, and further certify that the By-Laws and Resolutions of the corporation printed below are still in force. In testimony whereof I have hereunto subscribed my name and affixed the seal of the said corporation this 14th day of March, 2025

WESTERN SURETY COMPANY

Paula Kolsrud, Assistant Secretary

Authorizing By-Laws and Resolutions

ADOPTED BY THE SHAREHOLDERS OF WESTERN SURETY COMPANY

This Power of Attorney is made and executed pursuant to and by authority of the following By-Law duly adopted by the shareholders of the Company.

Section 7. All bonds, policies, undertakings, Powers of Attorney, or other obligations of the corporation shall be executed in the corporate name of the Company by the President, Secretary, and Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or agents who shall have authority to issue bonds, policies, or undertakings in the name of the Company. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the corporation. The signature of any such officer and the corporate seal may be printed by facsimile.

This Power of Attorney is signed by Larry Kasten, Vice President, who has been authorized pursuant to the above Bylaw to execute power of attorneys on behalf of Western Surety Company.

This Power of Attorney may be signed by digital signature and sealed by a digital or otherwise electronic-formatted corporate seal under and by the authority of the following Resolution adopted by the Board of Directors of the Company by unanimous written consent dated the 27th day of April, 2022:

"RESOLVED: That it is in the best interest of the Company to periodically ratify and confirm any corporate documents signed by digital signatures and to ratify and confirm the use of a digital or otherwise electronic-formatted corporate seal, each to be considered the act and deed of the Company."

Form F4280-2/2024

WESTERN SURETY COMPANY
Sioux Falls, South Dakota
Statement of Net Admitted Assets and Liabilities
December 31, 2023

ASSETS

Bonds	$ 1,935,600,431
Stocks	15,281,696
Cash, cash equivalents, and short-term investments	36,335,353
Receivables for securities	14,770,000
Investment income due and accrued	18,185,645
Premiums and considerations	70,728,009
Amounts recoverable from reinsurers	4,459,042
Net deferred tax asset	18,202,272
Receivable from parent, subsidiaries, and affiliates	12,895,815
Other assets	157,742
Total Assets	$ 2,126,616,005

LIABILITIES AND SURPLUS

Losses	$ 247,328,673
Loss adjustment expense	56,340,495
Commissions payable, contingent commissions and other similar charges	13,245,319
Taxes, License and fees (excluding federal and foreign income taxes)	5,075,390
Federal and foreign income taxes payable	829,556
Unearned premiums	316,760,881
Advance premiums	6,183,112
Ceded reinsurance premiums payable (net of ceding commissions)	4,347,066
Amounts withheld or retained by company for account of others	3,094,680
Provision for reinsurance	157,388
Payable to parent, subsidiaries and affiliates	9,464
Other liabilities	(6,171)
Total Liabilities	$ 653,365,853

Surplus Account:		
Common stock	$ 4,000,000	
Gross paid in and contributed surplus	286,896,195	
Unassigned funds	1,182,353,957	
Surplus as regards policyholders		$ 1,473,250,152
Total Liabilities and Capital		$ 2,126,616,005

I, Julie Lee, Vice President of Western Surety Company hereby certify that the above is an accurate representation of the financial statement of the Company dated December 31, 2023, as filed with the various Insurance Departments and is a true and correct statement of the condition of Western Surety Company as of that date.

WESTERN SURETY COMPANY

By Julie Lee
Vice President, Accounting Policy & External Reporting

Subscribed and sworn to me this 14th day of March, 2024.

My commission expires:

YOLANDA JIMENEZ
OFFICIAL SEAL
Notary Public - State Of Illinois
My Commission Expires
September 24, 2025

By Yolanda Jimenez
Notary Public

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Philips Ultrasound LLC — MDEG License # (if applicable): N/A

Physical Address: 1 Echo Drive

City: Reedsville — State: PA — Zip: 17084

Mailing Address (if different from physical address): 1 Echo Drive, ATTN: Alysia S. Middaugh

City: Reedsville — State: PA — Zip: 17084

Telephone: (717) 667-5000 — Website: https://www.usa.philips.com/

Licensing Company Email: statelicense@philips.com

Section 2: Personal Information

First: Alysia — Middle: Sue — Last: Middaugh

Alias(es, nicknames, name changes, etc.): Alysia Sue Fleisher

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ■ F ☐ X

Mailing Address: 1 Echo Drive, ATTN: Alysia S. Middaugh

City: Reedsville — State: PA — Zip: 17084

Telephone: [redacted] — Email: alysia.middaugh@philips.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		08/03 - 06/06	
Address	City	State	Zip
4025 S Riverpoint Parkway, Suite 100	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Bachelor of Science in Information Technology			

School Name		From - To (MM/YY – MM/YY)	
Penn State University		08/01 - 06/03	
Address	City	State	Zip
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Elizabethtown College		09/87 - 01/90	
Address	City	State	Zip
1 Alpha Drive	Elizabethtown	PA	17022
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Lewistown Area High School		08/83 - 06/87	
Address	City	State	Zip
2 Manor Drive	Lewistown	PA	17044
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2006 - Present	[redacted]	Lewistown	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Philips Ultrasound LLC			08/90 - Present	
Business Address		**City**	**State**	**Zip**
1 Echo Drive		Reedsville	PA	17084
Phone	**Title**		**Number of Employed Hours**	
(717) 667-5000	Sr. Manufacturing Manager		40 hours per week	
Description of Duties				
Supply Chain Manager in Ultrasound Transducers of 160 people including Stockroom, Shipping, Receiving, and Manufacturing.				

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

N/A **Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.**

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A _____ N/A _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Alysia Middaugh, **certify that as the MDEG Administrator for**

Philips Ultrasound LLC,

that I (initial that you have read and meet the following requirements):

1. ASM Have a high school diploma or its equivalent;
2. ASM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. ASM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ASM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alysia Middaugh
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/21/2025
Date

Board Use Only	Date Received: 4/2/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Philips Ultrasound LLC

Pharmacy/Wholesaler License # (if applicable): Pending

Physical Address: 1 Echo Drive

City: Reedsville State: PA Zip: 17084

Mailing Address (if different from physical address): 1 Echo Drive, ATTN: Alysia S. Middaugh

City: Reedsville State: PA Zip: 17084

Telephone: (717) 667-5000 Website: https://www.usa.philips.com/

Licensing Company Email: statelicense@philips.com

Section 2: Personal Information

First: Alysia Middle: Sue Last: Middaugh

Alias(es, nicknames, name changes, etc.): Alysia Sue Fleisher

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☐ M ■ F ☐ X

Mailing Address: 1 Echo Drive, ATTN: Alysia S. Middaugh

City: Reedsville State: PA Zip: 17084

Telephone[redacted] Email: alysia.middaugh@philips.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Phoenix		08/03 - 06/06	
Address	City	State	Zip
4025 S Riverpoint Parkway, Suite 100	Phoenix	AZ	85040
Diploma/Degree obtained, if any			
Bachelor of Science in Information Technology			

School Name		From - To (MM/YY – MM/YY)	
Penn State University		08/01 - 06/03	
Address	City	State	Zip
201 Old Main	University Park	PA	16802
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Elizabethtown College		09/87 - 01/90	
Address	City	State	Zip
1 Alpha Drive	Elizabethtown	PA	17022
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Lewistown Area High School		08/83 - 06/87	
Address	City	State	Zip
2 Manor Drive	Lewistown	PA	17044
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
Sept 2006 Present	[redacted]	Lewistown	PA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Philips Ultrasound LLC			08/90 - Present	
Business Address		**City**	**State**	**Zip**
1 Echo Drive		Reedsville	PA	17084
Phone	**Title**		**Number of Employed Hours**	
(717) 667-5000	Sr. Manufacturing Manager		40 hours per week	
Description of Duties				
Supply Chain Manager in Ultrasound Transducers of 160 people including Stockroom, Shipping, Receiving, and Manufacturing.				

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Alysia Middaugh, **certify that as the designated representative for**

Philips Ultrasound LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ASM I am at least 21 years of age;
3. ASM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, ~~prescription drugs~~ medical devices. ASM 3/21/2025
4. ASM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ASM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ASM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ASM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Alysia Middaugh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/21/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Alysia Middaugh

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/21/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Mifflin

I, Alysia Middaugh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/22/2025

Date

Subscribed and Sworn to before me this 22nd day of March 2025

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Amber M. Kauffman, Notary Public
Mifflin County
My commission expires November 10, 2026
Commission number 1286731
Member, Pennsylvania Association of Notaries

(Seal)

First Name	Last Name	Active Status	Worker Type	Location Address
Elizabeth	Hartley	Yes	Employee	Reedsville
Dustin	Shinn	Yes	Employee	Reedsville
Kayla	Lefevre	Yes	Employee	Reedsville
Dalton	Byers	Yes	Employee	Reedsville
Pati	Moore	Yes	Employee	Reedsville
Robert	Slemons	Yes	Employee	Reedsville
Alexandra	Stauffer	Yes	Employee	Reedsville
Nick	Beaston	Yes	Employee	Reedsville
Jeremy	Henry	Yes	Employee	Reedsville
Nicolas	Winkles	Yes	Employee	Reedsville
Ethan	Bradley	Yes	Employee	Reedsville
Brennan	Specht	Yes	Employee	Reedsville
Caitlin	Bullman	Yes	Employee	Reedsville
Jada	Navedo	Yes	Employee	Reedsville
Donald	Brittain	Yes	Employee	Reedsville
Christopher	Ferguson	Yes	Employee	Reedsville
Ethan	Shawver	Yes	Employee	Reedsville
Thomas	Maloney	Yes	Employee	Reedsville
Tylyn	Ritter	Yes	Employee	Reedsville
Kelsey	Yeater	Yes	Employee	Reedsville
Donna	Robertson	Yes	Employee	Reedsville
Crystal	wise	Yes	Employee	Reedsville
Janelle	Shawver	Yes	Employee	Reedsville
Brynn	Kibe	Yes	Employee	Reedsville
Heather	Kreitzer	Yes	Employee	Reedsville
Joseph	Moschetto	Yes	Employee	Reedsville
Brandon	Vogt	Yes	Employee	Reedsville
Josh	Barger	Yes	Employee	Reedsville
Michele	Condon	Yes	Employee	Reedsville
Sandy	Sheeler	Yes	Employee	Reedsville
Monaca	Hoffman	Yes	Employee	Reedsville
Sam	Bowes	Yes	Employee	Reedsville
Chloe	Jackson	Yes	Employee	Reedsville
Rosevel	Kahley	Yes	Employee	Reedsville
Susan	Singer	Yes	Employee	Reedsville
Morgan	Kauffman	Yes	Employee	Reedsville
Jenna	Yeater	Yes	Employee	Reedsville
Cody	Romanoskie	Yes	Employee	Reedsville
Joseph	Haines	Yes	Employee	Reedsville
Ashlynn	Jackson	Yes	Employee	Reedsville
Madison	Stringfellow	Yes	Employee	Reedsville
Andrew	Bergeron	Yes	Employee	Reedsville
Andrew	Fike	Yes	Employee	Reedsville
Zachary	Neff	Yes	Employee	Reedsville
Chadd	Dexter	Yes	Employee	Reedsville
Noah	Kahley	Yes	Employee	Reedsville
Amy	Thomas	Yes	Employee	Reedsville
Lindsey	Adams	Yes	Employee	Reedsville

Kinsley	Kukurender	Yes	Employee	Reedsville
Natalie	Norman	Yes	Employee	Reedsville
Charity	Stuck	Yes	Employee	Reedsville
Barry	Osborne	Yes	Employee	Reedsville
Destiney	Gardner	Yes	Employee	Reedsville
Brady	Specht	Yes	Employee	Reedsville
Kolby	Fry	Yes	Employee	Reedsville
Charlie	Laughlin	Yes	Employee	Reedsville
Kevin	Fultz	Yes	Employee	Reedsville
Kayla	Marr	Yes	Employee	Reedsville
Carson	Pedaci	Yes	Employee	Reedsville
Janee	Lim	Yes	Employee	Reedsville
Wendy	Price	Yes	Employee	Reedsville
Levi	Baumgardner	Yes	Employee	Reedsville
Derek	Romig	Yes	Employee	Reedsville
Christopher	Hatch	Yes	Employee	Reedsville
Andrew	Ostovich	Yes	Employee	Reedsville
Brandon	Shumaker	Yes	Employee	Reedsville
Becky	Yeater	Yes	Employee	Reedsville
Diana	Hipple	Yes	Employee	Reedsville
Ann	Shirk	Yes	Employee	Reedsville
Jacob	Fultz	Yes	Employee	Reedsville
Cody	Yetter	Yes	Employee	Reedsville
Alec	Brindle	Yes	Employee	Reedsville
Linzee	Deamer	Yes	Employee	Reedsville
Nathaniel	Swineford	Yes	Employee	Reedsville
Denise	Freed	Yes	Employee	Reedsville
Mike	Hosterman	Yes	Employee	Reedsville
Marlene	Haubrick	Yes	Employee	Reedsville
Kottie	Groce	Yes	Employee	Reedsville
Clair	Diven	Yes	Employee	Reedsville
Nancy	Wilt	Yes	Employee	Reedsville
Stacy	Wagner	Yes	Employee	Reedsville
Lisa	Specht	Yes	Employee	Reedsville
Kevin	Fisher	Yes	Employee	Reedsville
Justin	Hower	Yes	Employee	Reedsville
Morgan	Daddario	Yes	Employee	Reedsville
Dane	Collins	Yes	Employee	Reedsville
Bradley	Kensinger	Yes	Employee	Reedsville
Michael	Lukens	Yes	Employee	Reedsville
Dakota	Dillree	Yes	Employee	Reedsville
Jacki	Rittenhouse	Yes	Employee	Reedsville
Courtney	Neal	Yes	Employee	Reedsville
Shaylee	Gardner	Yes	Employee	Reedsville
Cynthia	Liddick	Yes	Employee	Reedsville
Cody	Carlson	Yes	Employee	Reedsville
Peggy	Morrow	Yes	Employee	Reedsville
Tammy	Walker	Yes	Employee	Reedsville
Amber	Shumaker	Yes	Employee	Reedsville

Stephanie	Freed	Yes	Employee	Reedsville
Scott	Campbell	Yes	Employee	Reedsville
Louie	Griffith	Yes	Employee	Reedsville
Brooke	Stuck	Yes	Employee	Reedsville
Kathryn	Myers	Yes	Employee	Reedsville
Melissa	Coleman	Yes	Employee	Reedsville
Ron	Mills	Yes	Employee	Reedsville
Dennis	Yetter	Yes	Employee	Reedsville
Sydney	Forshey	Yes	Employee	Reedsville
Skylar	Rittle	Yes	Employee	Reedsville
Lori	Saylor	Yes	Employee	Reedsville
Robert	Kirchoff	Yes	Employee	Reedsville
Consuelo	Wertz	Yes	Employee	Reedsville
Angela	Moist	Yes	Employee	Reedsville
Jesse	Kelley	Yes	Employee	Reedsville
Elijah	Bunting	Yes	Employee	Reedsville
Todd	Thomas	Yes	Employee	Reedsville
Gloria	Michaels	Yes	Employee	Reedsville
Sherri	Scheffel	Yes	Employee	Reedsville
Toni	Thomas	Yes	Employee	Reedsville
Rachel	Diven	Yes	Employee	Reedsville
Tiara	Rhodes	Yes	Employee	Reedsville
Cindy	Roycroft	Yes	Employee	Reedsville
Amanda	Robertson	Yes	Employee	Reedsville
Vicky	Conner	Yes	Employee	Reedsville
Tory	Mcconaughey	Yes	Employee	Reedsville
Evan	Kinzer-Howell	Yes	Employee	Reedsville
Tony	Arzamendi	Yes	Employee	Reedsville
Milynda	Campbell	Yes	Employee	Reedsville
Richard	Lewis	Yes	Employee	Reedsville
Lori	Specht	Yes	Employee	Reedsville
Lacey	Morder	Yes	Employee	Reedsville
Paul	Crater	Yes	Employee	Reedsville
Chris	Smyers	Yes	Employee	Reedsville
Beth	McCombie	Yes	Employee	Reedsville
Ruth	Hartman	Yes	Employee	Reedsville
Brett	Mann	Yes	Employee	Reedsville
Jenna	Rhoads	Yes	Employee	Reedsville
Robert	Youngman	Yes	Employee	Reedsville
Kirsten	Monihen	Yes	Employee	Reedsville
Larry	Pannebaker	Yes	Employee	Reedsville
Michael	Bailey	Yes	Employee	Reedsville
barry	hesser	Yes	Employee	Reedsville
Ivy	Varner	Yes	Employee	Reedsville
Lauren	Fleegal	Yes	Employee	Reedsville
Lisa	Stroup	Yes	Employee	Reedsville
Kellie	Baker	Yes	Employee	Reedsville
Vicki	Smyers	Yes	Employee	Reedsville
Austin	Koch	Yes	Employee	Reedsville

Mackenzie	Riden	Yes	Employee	Reedsville
Eric	Barton	Yes	Employee	Reedsville
Eric	Simonetti	Yes	Employee	Reedsville
Trenton	Pollock	Yes	Employee	Reedsville
Gavi	Dennison	Yes	Employee	Reedsville
Christine	Crownover	Yes	Employee	Reedsville
Dennis	Patterson	Yes	Employee	Reedsville
Kelly	Banks	Yes	Employee	Reedsville
Timothy	Hertzog	Yes	Employee	Reedsville
Dennis	Dippery	Yes	Employee	Reedsville
Mary	Sine-	Yes	Employee	Reedsville
Kassondra	Walters	Yes	Employee	Reedsville
Francine	Bookwalter	Yes	Employee	Reedsville
Brian	Settle	Yes	Employee	Reedsville
Gabe	Simonetti	Yes	Employee	Reedsville
Jessica	Henry	Yes	Employee	Reedsville
Justin	Deppen	Yes	Employee	Reedsville
Buffy	Butcher	Yes	Employee	Reedsville
Michael	Wilson	Yes	Employee	Reedsville
Barbara	Haubrick	Yes	Employee	Reedsville
Tony	Shearer	Yes	Employee	Reedsville
Crystal	Auman	Yes	Employee	Reedsville
Cody	Kipp	Yes	Employee	Reedsville
Walter	Kennedy	Yes	Employee	Reedsville
Kacie	Bearley	Yes	Employee	Reedsville
Conner	Henry	Yes	Employee	Reedsville
Chad	Spickler	Yes	Employee	Reedsville
Amy	Stauffer	Yes	Employee	Reedsville
Adam	Geissinger	Yes	Employee	Reedsville
Lewis	Hartman	Yes	Employee	Reedsville
Roberta	Krepps	Yes	Employee	Reedsville
Brian	Bohn	Yes	Employee	Reedsville
Dottie	Thompson	Yes	Employee	Reedsville
Tasha	Shoop	Yes	Employee	Reedsville
Karen	Moore	Yes	Employee	Reedsville
Justin	Schmidt	Yes	Employee	Reedsville
Myra	Kline	Yes	Employee	Reedsville
Trish	Wilson	Yes	Employee	Reedsville
Nick	Carolus	Yes	Employee	Reedsville
Garett	Gorby	Yes	Employee	Reedsville
Franklin	Stevens	Yes	Employee	Reedsville
Joe	Ryan	Yes	Employee	Reedsville
Tyler	Stein	Yes	Employee	Reedsville
Betty Jo	Johnson	Yes	Employee	Reedsville
Michelle	Wilson	Yes	Employee	Reedsville
Jenna	Bagrosky	Yes	Employee	Reedsville
Heather	Griffith	Yes	Employee	Reedsville
Nate	Yetter	Yes	Employee	Reedsville
Zachary	Goss	Yes	Employee	Reedsville

Bella	Goss	Yes	Employee	Reedsville
Douglas	Wilson	Yes	Employee	Reedsville
Cathy	Crownover	Yes	Employee	Reedsville
Tiffany	Swanger	Yes	Employee	Reedsville
Shannon	Gramley	Yes	Employee	Reedsville
Mark	Yoder	Yes	Employee	Reedsville
Joshua	Frampton	Yes	Employee	Reedsville
William	Mcnemar	Yes	Employee	Reedsville
Justin	Pandel	Yes	Employee	Reedsville
Billie Jo	Stringfellow	Yes	Employee	Reedsville
Brian	Kibe	Yes	Employee	Reedsville
Adam	Swanger	Yes	Employee	Reedsville
Ally	McMullen	Yes	Employee	Reedsville
Suzanne	Ritter	Yes	Employee	Reedsville
Beverly	Williams	Yes	Employee	Reedsville
Taylor	DeArment	Yes	Employee	Reedsville
Cole	Middaugh	Yes	Employee	Reedsville
Lori	Wilson	Yes	Employee	Reedsville
Catherine	Paige	Yes	Employee	Reedsville
Melanie	Harshbarger	Yes	Employee	Reedsville
Tracy	Williams	Yes	Employee	Reedsville
Carrie	Kauffman	Yes	Employee	Reedsville
Stacy	Parks	Yes	Employee	Reedsville
Christopher	Soccio	Yes	Employee	Reedsville
Leslie	Stimely	Yes	Employee	Reedsville
Kerry	Pennebaker	Yes	Employee	Reedsville
Brandy	Peterson	Yes	Employee	Reedsville
Stefanie	Rhodes	Yes	Employee	Reedsville
Dustin	Lepley	Yes	Employee	Reedsville
Angela	Beckenbaugh	Yes	Employee	Reedsville
April	Walker	Yes	Employee	Reedsville
Amber	Welch	Yes	Employee	Reedsville
Jason	Franklin	Yes	Employee	Reedsville
Brian	Harpster	Yes	Employee	Reedsville
Austen	Bingaman	Yes	Employee	Reedsville
Brian	Shawver	Yes	Employee	Reedsville
Cynthia	Kepner	Yes	Employee	Reedsville
Sheila	Earnest	Yes	Employee	Reedsville
Rachele	Ettinger	Yes	Employee	Reedsville
Stephanie	Wagner	Yes	Employee	Reedsville
Brian	Hill	Yes	Employee	Reedsville
Amber	Frymyer	Yes	Employee	Reedsville
Carla	Knapp	Yes	Employee	Reedsville
Lori	Wilson	Yes	Employee	Reedsville
Patricia	Mowery	Yes	Employee	Reedsville
Julie	Metzger	Yes	Employee	Reedsville
Tracy	Aumiller	Yes	Employee	Reedsville
Tina	Kuhns	Yes	Employee	Reedsville
Mark	McKnight	Yes	Employee	Reedsville

Kelly	Huff	Yes	Employee	Reedsville
Rosemary	Bilger	Yes	Employee	Reedsville
Margaret	Phillips	Yes	Employee	Reedsville
Sharon	Lash	Yes	Employee	Reedsville
Kyle	Brackbill	Yes	Employee	Reedsville
Shannon	Miller	Yes	Employee	Reedsville
Kristin	Wilt	Yes	Employee	Reedsville
Dan	Solomon	Yes	Employee	Reedsville
Samantha	Nale	Yes	Employee	Reedsville
Catherine	Fleegal	Yes	Employee	Reedsville
Jamie Ann	Smith	Yes	Employee	Reedsville
Wendy	Cooper	Yes	Employee	Reedsville
Carolyn	McKnight	Yes	Employee	Reedsville
Marla	Wright	Yes	Employee	Reedsville
Tymberli	Stover	Yes	Employee	Reedsville
Roberta	Deavor	Yes	Employee	Reedsville
Lisa	Barger	Yes	Employee	Reedsville
Steven	Marker	Yes	Employee	Reedsville
Michael	Weber	Yes	Employee	Reedsville
Robert	Aultz	Yes	Employee	Reedsville
Margaret	Smith	Yes	Employee	Reedsville
Yvette	Crain	Yes	Employee	Reedsville
Emily	Atherton	Yes	Employee	Reedsville
Huyen	Vu	Yes	Employee	Reedsville
Heather	Ughetto	Yes	Employee	Reedsville
Caleb	Breneman	Yes	Employee	Reedsville
Kelly	Betlyon	Yes	Employee	Reedsville
Lauren	Bachman	Yes	Employee	Reedsville
Lisa	Shirk	Yes	Employee	Reedsville
Jennifer	Kratzer	Yes	Employee	Reedsville
Leisle	Kauffman	Yes	Employee	Reedsville
Donna	Sheetz	Yes	Employee	Reedsville
Danielle	Dietrich	Yes	Employee	Reedsville
Mae	Shirey	Yes	Employee	Reedsville
Steven	Kitting	Yes	Employee	Reedsville
Sue	Kibe	Yes	Employee	Reedsville
Tina	Brownsberger	Yes	Employee	Reedsville
Damian	Yetter	Yes	Employee	Reedsville
Ian	Nichols	Yes	Employee	Reedsville
Jayme	Tozer	Yes	Employee	Reedsville
Kelly	Arentz	Yes	Employee	Reedsville
Betty	Stout	Yes	Employee	Reedsville
Jeremy	Fisher	Yes	Employee	Reedsville
Daren	Mauck	Yes	Employee	Reedsville
Kodi	Monroe	Yes	Employee	Reedsville
Rachelle	Brackbill	Yes	Employee	Reedsville
Martha	Keller	Yes	Employee	Reedsville
Dylan	Kepner	Yes	Employee	Reedsville
Sean	Spigelmyer	Yes	Employee	Reedsville

Kenneth	Gutshall	Yes	Employee	Reedsville
Mackenzie	Wilson	Yes	Employee	Reedsville
Caleb	Diven	Yes	Employee	Reedsville
Christian	Yoder	Yes	Employee	Reedsville
Jerry	Gramley	Yes	Employee	Reedsville
Mark	Kosman	Yes	Employee	Reedsville
Glenn	Brown	Yes	Employee	Reedsville
Margaret	O'Donnell	Yes	Employee	Reedsville
Paitin	Eslinger	Yes	Employee	Reedsville
Westan	Feather	Yes	Employee	Reedsville
Ron	Stong	Yes	Employee	Reedsville
Chris	Sulouff	Yes	Employee	Reedsville
Jennifer	Wilson	Yes	Employee	Reedsville
Thomas	Dobson	Yes	Employee	Reedsville
Dalton	Long	Yes	Employee	Reedsville
Sue	Heister	Yes	Employee	Reedsville
Kevin	Bratton	Yes	Employee	Reedsville
Morgan	Snyder	Yes	Employee	Reedsville
Brian	Rothrock	Yes	Employee	Reedsville
Toré	Forshey	Yes	Employee	Reedsville
Keri	Gardner	Yes	Employee	Reedsville
Steve	Carter	Yes	Employee	Reedsville
Jason	Gaisior	Yes	Employee	Reedsville
Cullen	Smith	Yes	Employee	Reedsville
Ronald	Yoder	Yes	Employee	Reedsville
Justin	Lewis	Yes	Employee	Reedsville
Robert	Shelly	Yes	Employee	Reedsville
Wayne	Harshbarger	Yes	Employee	Reedsville
John	Brumbaugh	Yes	Employee	Reedsville
Brad	Stimely	Yes	Employee	Reedsville
Brett	Carper	Yes	Employee	Reedsville
Matt	Rearick	Yes	Employee	Reedsville
Rebecca	Cramer	Yes	Employee	Reedsville
Spencer	Weaver	Yes	Employee	Reedsville
Robert	McCalips	Yes	Employee	Reedsville
Bradley	Renninger	Yes	Employee	Reedsville
Chad	Campbell	Yes	Employee	Reedsville
Scott	Lewis	Yes	Employee	Reedsville
Charles	Hackenberry	Yes	Employee	Reedsville
Anthony	Young	Yes	Employee	Reedsville
Nathan	Shirk	Yes	Employee	Reedsville
Josh	Varner	Yes	Employee	Reedsville
Thomas	Flaherty	Yes	Employee	Reedsville
Josh	Yoder	Yes	Employee	Reedsville
Gregory	Baumgardner	Yes	Employee	Reedsville
Jamie	Fultz	Yes	Employee	Reedsville
Jason	Buffington	Yes	Employee	Reedsville
Amber	Reish	Yes	Employee	Reedsville
April	Guthridge	Yes	Employee	Reedsville

Brian	Trinclisti	Yes	Employee	Reedsville
Christina	Kerstetter	Yes	Employee	Reedsville
Susan	Gecht	Yes	Employee	Reedsville
Todd	Metzger	Yes	Employee	Reedsville
Noah	Heimbaugh	Yes	Employee	Reedsville
Natalie	Thompson	Yes	Employee	Reedsville
Jonathan	Jones	Yes	Employee	Reedsville
Arantza	Ruiz Aguirre	Yes	Employee	Reedsville
Gretta	Yener	Yes	Employee	Reedsville
Meghan	O'Reilly	Yes	Employee	Reedsville
Adam	Johnson	Yes	Employee	Reedsville
Andrew	Galetta	Yes	Employee	Reedsville
Jacob	McMaster	Yes	Employee	Reedsville
Eli	Hannon	Yes	Employee	Reedsville
Lauren	Wysocki	Yes	Employee	Reedsville
Seth	Harpster	Yes	Employee	Reedsville
Kelli	Hale	Yes	Employee	Reedsville
Julie	Ayers	Yes	Employee	Reedsville
Justin	Hartley	Yes	Employee	Reedsville
Will	Myers	Yes	Employee	Reedsville
Justin	Thomassen	Yes	Employee	Reedsville
Sara	Almasy	Yes	Employee	Reedsville
Lauren	Wilson	Yes	Employee	Reedsville
Jess	Kaiser	Yes	Employee	Reedsville
Hannah	Shank	Yes	Employee	Reedsville
Amelia	Wellmon	Yes	Employee	Reedsville
Sherman	Johnson	Yes	Employee	Reedsville
Holly	Umbenhour	Yes	Employee	Reedsville
Trevor	Nearhood	Yes	Employee	Reedsville
Mike	Tozer	Yes	Employee	Reedsville
Whitney	Snook	Yes	Employee	Reedsville
Cierra	Beaston	Yes	Employee	Reedsville
Derrick	Fellows	Yes	Employee	Reedsville
Danielle	Yetter	Yes	Employee	Reedsville
Levi	Spigelmyer	Yes	Employee	Reedsville
Selene	McCaffrey	Yes	Employee	Reedsville
Tanya	Hoover	Yes	Employee	Reedsville
Heather	Betlyon	Yes	Employee	Reedsville
Kaylene	Killeen	Yes	Employee	Reedsville
Marshall	Hill	Yes	Employee	Reedsville
Douglas	Merritts	Yes	Employee	Reedsville
Brent	Erb	Yes	Employee	Reedsville
Micha	Mills	Yes	Employee	Reedsville
Mark	Riley	Yes	Employee	Reedsville
Matt	Cooper	Yes	Employee	Reedsville
Greg	Rupp	Yes	Employee	Reedsville
Jason	Stout	Yes	Employee	Reedsville
Scott	Snook	Yes	Employee	Reedsville
Omar	Fernandes	Yes	Employee	Reedsville

Brian	Moist	Yes	Employee	Reedsville
Clayton	Hoover	Yes	Employee	Reedsville
Nathaniel	Moore	Yes	Employee	Reedsville
Steve	Ake	Yes	Employee	Reedsville
Ethan	Fultz	Yes	Employee	Reedsville
Jennifer	Creighton	Yes	Employee	Reedsville
Matt	Morrison	Yes	Employee	Reedsville
John	Gailey	Yes	Employee	Reedsville
Jordan	Baker	Yes	Employee	Reedsville
Allison	Couch	Yes	Employee	Reedsville
Tejohanish	Mulpuru	Yes	Employee	Reedsville
Danielle	Crawford	Yes	Employee	Reedsville
Regina	Incarnato	Yes	Employee	Reedsville
Michael	Overdorf	Yes	Employee	Reedsville
Brandy	Shearer	Yes	Employee	Reedsville
Dan	Baker	Yes	Employee	Reedsville
Steven	Stringfellow	Yes	Employee	Reedsville
David	Aldinger	Yes	Employee	Reedsville
James	Fitzgerald	Yes	Employee	Reedsville
Joshua	Looney	Yes	Employee	Reedsville
Cody	Zong	Yes	Employee	Reedsville
Jon	Vargas	Yes	Employee	Reedsville
Sam	Peters	Yes	Employee	Reedsville
Stephanie	Wilson	Yes	Employee	Reedsville
Jake	Burnside	Yes	Employee	Reedsville
Alysia	Middaugh	Yes	Employee	Reedsville
Chad	Picketts	Yes	Employee	Reedsville
Ben	Stover	Yes	Employee	Reedsville
Timothy	Mcgarry	Yes	Employee	Reedsville
Frederick	Davis	Yes	Employee	Reedsville
David	Becker	Yes	Employee	Reedsville
Crist	Eckley	Yes	Employee	Reedsville
Cody	Reid	Yes	Employee	Reedsville
Matthew	Benner	Yes	Employee	Reedsville
John	Myers	Yes	Employee	Reedsville
Dominic	Giannangeli	Yes	Employee	Reedsville
Chloe	Melnick	Yes	Employee	Reedsville
Tom	Burtnett	Yes	Employee	Reedsville
Tyler	Rupp	Yes	Employee	Reedsville
Taylor	Swan	Yes	Employee	Reedsville
Misty	Schilling	Yes	Employee	Reedsville
Zhi	Zhou	Yes	Employee	Reedsville
Nick	Petrunyak	Yes	Employee	Reedsville
Albert	Foster	Yes	Employee	Reedsville
Derek	Jones	Yes	Employee	Reedsville
Austin	Lanning	Yes	Employee	Reedsville
James	Taylor	Yes	Employee	Reedsville
Haifeng	Wang	Yes	Employee	Reedsville
Victor	Hagerstrom	Yes	Employee	Reedsville

Jian	Jiao	Yes	Employee	Reedsville
Ellie	Jafarigol	Yes	Employee	Reedsville
Megan	Romanoskie	Yes	Employee	Reedsville
Zachary	McCoy	Yes	Employee	Reedsville
Sara	Kron	Yes	Employee	Reedsville
Hakan	Toykoc	Yes	Employee	Reedsville
Guy	Roszel	Yes	Employee	Reedsville
Smitha	Shetty	Yes	Employee	Reedsville
Angela	Price	Yes	Employee	Reedsville
Brett	Corl	Yes	Employee	Reedsville
Jeffrey	Hart	Yes	Employee	Reedsville
Reid	Hannon	Yes	Employee	Reedsville

4PP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application
Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☒ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ☒ Ownership Change* ☒ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH WH02543	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Premier Dental Products Company, LLC

Physical Address: 1710 Romano Drive

City: Plymouth Meeting State: PA Zip: 19462

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (845) 544-2482 Website: www.premierdentalco.com

Name of Designated Representative (DR): Robert Warren Sutherland

Licensing Company Email: PDL@SLSNY.COM DR Email: rsutherland@premierdentalco.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☒ Others: List One Chemical Precursors, Finished Dosage Form	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Diversified Chemical Products
Address: 60 Germay Dr. City: Wilmington State: DE Zip: 19804

Name: Medical Product Laboratories Inc.
Address: 9990 Global Rd City: Phila State: PA Zip: 19115

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PA
Parent Company (if any): Premier Dental Buyer LLC
Corporation/Organization Name: Premier Dental Products Company, LLC
Mailing Address: c/o State License Servicing, 1751 State Route 17A, Suite 3
City: Florida State: NY Zip: 10921
Telephone: (845) 544-2482 Email: PDL@SLSNY.COM
Contact Person Name: Christine Cannon

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA #: 2511556	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Premier Dental Products Company, LLC

Facility Name

Perry Scott Lowe

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2/6/2025

Date

Board Use Only	Date Received: 3/12/25	Amount: $1,000 CK# 178

FDA

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
PREMIER DENTAL PRODUCTS CO.
1710 ROMANO DR.
PLYMOUTH MEETING, PA 19462
Registration Number: 2511556
FEI Number*: 2511556
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:

Premier Dental Products Company[6]
1710 ROMANO DR.
Plymouth Meeting, PA US 19462
Owner/Operator Number: 2511556[7]

Official Correspondent:
Jessica Huang
1710 ROMANO DR.
Plymouth Meeting, PA 19462
Phone: 1-610-2396069

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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Page Last Updated: 12/16/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

Combination Products Advisory Committees Science & Research Regulatory Information Safety Emergency Preparedness International Programs News & Events Training and Continuing Education Inspections/Compliance State & Local Officials Consumers Industry Health Professionals FDA Archive Vulnerability Disclosure Policy

U.S. Department of **Health & Human Services**

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7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=2511556&OwnerOperatorName

Company Particulars

Premier Dental Products Company, LLC

Corporate Address: 1710 Romano Drive, Plymouth Meeting PA 19462 USA
FEIN: 23-1567035
www.premierdentalco.com

Drug Labeler Code: 48783
Incorporation State: PA
Incorporation Date: 12/31/1959

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
PPA	1710 Romano Drive Plymouth Meeting, PA 19462 County: Montgomery	2511556	006835PMY	014789863	No	(610) 239-6000	(484) 681-9389

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Michael Hornberger	[redacted]	Warehouse Manager	No	[redacted]		
Robert Warren Sutherland	[redacted]	Designated Representative	No	[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
Premier Dental Buyer LLC	1209 Orange Street Wilmington DE 19801	N/A	100	N/A	33-2271660	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Perry Scott Lowe	[redacted]	CEO	No	[redacted]		
Steven D Hayman		Chief Financial Officer	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Corporation Service Company			

Good Standing

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	Premier Dental Products Company, LLC
Request Type:	Subsistence Certificate
Request No.:	050695519
Receipt No.:	001435233
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	December 31, 1959
Status:	Active

Issuance Date: February 07, 2025
File No.: 0000290079

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

Premier Dental Products Company, LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

Home State Licence

Pennsylvania Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

- **Premier Dental Products Company, LLC** 1710 Romano Drive; Plymouth Meeting, PA 19462
  Certificate(s): **3000010714** issued: 01/23/2025 expires: 2/28/2026; **8000003213** issued: 01/23/2025 expires: 2/28/2026

Back to DD&C Home

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Assembly Version 4.0.0.0

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VOL

Date: 2/4/2025

To: Nevada Licensing or Registering Board or Agency:
(Name of State or Agency)

Name of Facility: Premier Dental Products Company, LLC

Facility Address : 1710 Romano Drive Plymouth Meeting, PA 19462

PA. Facility License, Registration, or Record number : 3000010714 / 800000 3213

The information below is to be completed only by a Pennsylvania state Licensing or Registering Agency. Must have State seal to be valid.

pennsylvania
DEPARTMENT OF HEALTH

www.health.pa.gov
www.health.state.pa.us/ddc

Drug Device and Cosmetic (DDC) Program
2525 N. 7th Street, Suite 210D
Harrisburg, PA 17110
Ph: 717-787-4779 Email: ra-ddc@pa.gov

Current Status: Active ☑ Yes ☐ No
Location: ☑ In state ☐ Out of State/Nonresident*
Type of Facility: Wholesale Distributor
Issue Date: 1/23/2025
Expiration Date: 2/28/2026

☒ The above facility is in good standing and has not had any formal disciplinary action under the above registration/license/record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program.

☐ The above facility has had any formal disciplinary action under the above registration/license record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program. Please explain:

Jessica Waller-Administrative Assistant — DDC Program Staff- Name
Jessica Waller — Signature

STATE SEAL:

*Interested parties are encouraged to verify status/standing with entity's home state or FDA if applicable.

VOL

Date: 2/4/2025

To: Missouri Licensing or Registering Board or Agency:
(Name of State or Agency)

Name of Facility: Premier Dental Products Company, LLC

Facility Address : 1710 Romano Drive Plymouth Meeting, PA 19462

PA. Facility License, Registration, or Record number : 30000107l4 / 80000003213

The information below is to be completed only by a Pennsylvania state Licensing or Registering Agency. Must have State seal to be valid.

pennsylvania
DEPARTMENT OF HEALTH

www.health.pa.gov
www.health.state.pa.us/ddc

Drug Device and Cosmetic (DDC) Program
2525 N. 7th Street, Suite 210D
Harrisburg, PA 17110
Ph: 717-787-4779 Email: ra-ddc@pa.gov

Current Status: Active ☑ Yes ☐ No
Location: ☑ In state ☐ Out of State/Nonresident*
Type of Facility: Wholesale Distributor
Issue Date: 1/23/2025
Expiration Date: 2/28/2026

☒ The above facility is in good standing and has not had any formal disciplinary action under the above registration/license/record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program.

☐ The above facility has had any formal disciplinary action under the above registration/license record number administered or issued by the Commonwealth of Pennsylvania Department of Health DDC Program. Please explain:

Jessica Waller-Administrative Assistant — DDC Program Staff- Name

Jessica Waller — Signature

STATE SEAL:

*Interested parties are encouraged to verify status/standing with entity's home state or FDA if applicable.

PREMDEN-01 MELISSACLARKE

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 2/4/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER NFP Property & Casualty Services, Inc. 1307 White Horse Road Building C Voorhees, NJ 08043	CONTACT NAME: PHONE (A/C, No, Ext): (856) 784-0707 FAX (A/C, No): E-MAIL ADDRESS:	
	INSURER(S) AFFORDING COVERAGE	NAIC #
INSURED Premier Dental Products Company, LLC 1710 Romano Drive Plymouth Meeting, PA 19462	INSURER A : Travelers Indemnity Company	25658
	INSURER B : Travelers Property Casualty Company of America	25674
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES CERTIFICATE NUMBER: REVISION NUMBER:

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY						EACH OCCURRENCE	$ 1,000,000
	CLAIMS-MADE X OCCUR			H-630-5617P754-IND-25	2/1/2025	2/1/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 300,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$
	OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						PER STATUTE / OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N / A						E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
B	Products Liability			ZPP-12S27398	2/1/2025	2/1/2026	SEE BELOW	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)
** Products Completed Operations is a separate policy - Limit $20,000,000 Each Occurrence/$20,000,000 Aggregate, the Excess Liability does not sit over the Products Completed Operations Policy. Products Liability coverage is written on a Claims Made form with a Retroactive Date of 02/01/10 and Subject to a $10,000 deductible.

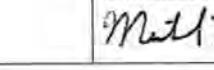
CERTIFICATE HOLDER

Premier Dental Products Company, LLC
1710 Romano Drive
Plymouth Meeting, PA 19462

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE



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Bond Rider

THE HARTFORD

Nevada State Board of Pharmacy
431 W Plumb Lane
RENO, NV 89509

RIDER

Attached to and forming part of Bond # 13BSBHZ5746 ,
on behalf of Premier Dental Products Company
of 1710 Romano Drive, Plymouth Meeting, PA 19462
in favor of Nevada State Board of Pharmacy
and in the amount of One Hundred Thousand ($100,000.00) Dollars.

It is understood and agreed that effective January 31, 2025
The Principal Name Change shall be changed
from Premier Dental Products Company
to Premier Dental Products Company and Premier Dental Products Company, LLC

All other conditions and terms remain as originally written.

Signed, Sealed, and Dated January, 8th , 2025

Hartford Fire Insurance Company

By: Joelle L LaPierre , Attorney-in-Fact

Form GENCNG-A (Rev. 07/01/22)

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call. **888-266-3488** *or fax.* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: NFP PROPERTY & CASUALTY SVCS INC
Agency Code: 13-657207

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Joelle L LaPierre
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 13BSBHZ5746
Naming Premier Dental Products Company and Premier Dental Products Company, LLC as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } ss. Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Marluz Arce

Marluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of January 8, 2025.

Signed and sealed in Lake Mary, Florida.

Keith Dozois

Keith D. Dozois, Assistant Vice President

Revised: July 31, 2013

Bond

NEVADA STATE BOARD OF PHARMACY
431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 13BSBHZ5746

Application/License No. _____

Premier Dental Products Company (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 1710 Romano Drive, Plymouth Meeting, PA 19462 (Address of Applicant/Principal), as PRINCIPAL, and Hartford Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of Connecticut (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 1 Hartford Plaza, Hartford, CT 06155 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on October 3, 2018 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

13BSBHZ5746

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 4th day of October, 2018.

APPLICANT/PRINCIPAL

Premier Dental Products Company

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Dottie Ready

Surety Company's Representative

Dottie Ready, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Rebecca Cavrak

Witness

Loretta Kephart

Witness

Countersigned by:

Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries/Claims to:
THE HARTFORD
BOND, T-12
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call **888-266-3488** *or fax* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: NFP PROPERTY & CASUALTY SVCS INC
Agency Code: 13-657207

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Underwriters Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Twin City Fire Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of Illinois**, a corporation duly organized under the laws of the State of Illinois
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Insurance Company of the Southeast**, a corporation duly organized under the laws of the State of Florida

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Dottie Ready

its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by , and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:
Bond No. 13BSBHZ5746
Naming Premier Dental Products Company as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 6, 2015 the Companies have caused these presents to be signed by its Senior Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

John Gray, Assistant Secretary

M. Ross Fisher, Senior Vice President

STATE OF CONNECTICUT
COUNTY OF HARTFORD } ss. Hartford

On this 5th day of January, 2018, before me personally came M. Ross Fisher, to me known, who being by me duly sworn, did depose and say: that he resides in the County of Hartford, State of Connecticut; that he is the Senior Vice President of the Companies, the corporations described in and which executed the above instrument; that he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals, that they were so affixed by authority of the Boards of Directors of said corporations and that he signed his name thereto by like authority.

Kathleen T. Maynard
Notary Public
My Commission Expires July 31, 2021

CERTIFICATE

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of October 4, 2018.
Signed and sealed at the City of Hartford.

Kevin Heckman, Assistant Vice President

premier. Inspired solutions for daily dentistry

March 24, 2025

State of Nevada
Board of Pharmacy

RE: Premier Dental Products Company, LLC – Designated Representative

Dear Sir/Madam:

I confirm that I am physically present at the Premier Dental Products Company, LLC facility during regular business hours, except when my absence is authorized, including sick leave, vacation leave and other authorized absences.

Thank you for your attention to this matter.

Very truly yours

Robert Sutherland III
Designated Representative
Premier Dental Products Company, LLC

Premier® Dental Products Company, LLC | 1710 Romano Drive | Plymouth Meeting, PA
19462 P 610.239.6000 888.773.6872 | F 610.239.6171 | www.premusa.com

THE PREMIER Promise EVERY TIME

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Premier Dental Products Company, LLC

Pharmacy/Wholesaler License # (if applicable): WH02543

Physical Address: 1710 Romano Drive

City: Plymouth Meeting State: PA Zip: 19462

Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3

City: Florida State: NY Zip: 10921

Telephone: (610) 239-6000 Website: www.premierdentalco.com

Licensing Company Email: PDL@SLSNY.COM

Section 2: Personal Information

First: Robert Middle: Warren Last: Sutherland

Alias(es, nicknames, name changes, etc.): Rob Sutherland

Date of Birth: [redacted] SSN or ITI[redacted] Sex: ■ M ☐ F ☐ X

Mailing Addres[redacted]

City: Middletown State: NY Zip: [redacted]

Telephone: (610) 239-6075 Email: rsutherland@premierdentalco.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Iona University		08/2002 - 05/2004	
Address: 715 North Ave	City: New Rochelle	State: NY	Zip: 10804
Diploma/Degree obtained, if any: MBA, Information & Decision Technology Management			

School Name		From - To (MM/YY – MM/YY)	
United States Naval Academy		08/1988 -05/1992	
Address: 121 Blake Rd	City: Naval Academy	State: MD	Zip: 21402
Diploma/Degree obtained, if any: Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Mt. Vernon High School		09/84 - 06/88	
Address: 731 Possum Rd SW	City: Mt. Vernon	State: IA	Zip: 52314
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2001 - Present	[redacted]	Middletown	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Premier Dental Products Company, LLC			09/2021 - Present	
Business Address		**City**	**State**	**Zip**
1710 Romano Drive		Plymouth Meeting	PA	19462
Phone	**Title**		**Number of Employed Hours**	
(610) 239-6000	Chief Operating Officer		~ 7,160 hours	
Description of Duties				
20+ years of experience in leadership, supply chain operations & systems, industrial automation, manufacturing, analytics and consulting. COO scope of of responsibility includes manufacturing, warehousing, customer experience and regulatory functions. Improvements achieved through targeted SG&A and COGS improvement in projects in manufacturing, purchasing, fulfillment, and revenue operations.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Robert Warren Sutherland, **certify that as the designated representative for**

Premier Dental Products Company, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RS I am at least 21 years of age;
3. RS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Warren Sutherland
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/21/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Warren Sutherland

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/25

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Montgomery

I, Robert Warren Sutherland, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/11/25

Date

Subscribed and Sworn to before me this 11 day of February, 2025

Karen Giannone

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Karen Giannone, Notary Public
Montgomery County
My commission expires June 13, 2025
Commission number 1058129
(Seal)
Member, Pennsylvania Association of Notaries

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Premier Dental Products Company, LLC — MDEG License # (if applicable): WH02543
Physical Address: 1710 Romano Drive
City: Plymouth Meeting — State: PA — Zip: 19462
Mailing Address (if different from physical address): c/o State License Servicing, 1751 State Route 17A, Suite 3
City: Florida — State: NY — Zip: 10921
Telephone: (610) 239-6000 — Website: www.premierdentalco.com
Licensing Company Email: PDL@SLSNY.COM

Section 2: Personal Information

First: Robert — Middle: Warren — Last: Sutherland
Alias(es, nicknames, name changes, etc.): Rob Sutherland
Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☒ M ☐ F ☐ X
Mailing Address: [redacted]
City: Middletown — State: NY — Zip: [redacted]
Telephone: (610) 239-6000 — Email: rsutherland@premierdentalco.com
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	X	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Iona University		08/2002 - 05/2004	
Address	**City**	**State**	**Zip**
715 North Ave	New Rochelle	NY	10804
Diploma/Degree obtained, if any			
MBA, Information & Decision Technology Management			

School Name		From - To (MM/YY – MM/YY)	
United States Naval Academy		08/1988 -05/1992	
Address	**City**	**State**	**Zip**
121 Blake Rd	Naval Academy	MD	21402
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Mt. Vernon High School		09/84 - 06/88	
Address	**City**	**State**	**Zip**
731 Pobisgvidge Rd.	Mt. Vernon	IA	52314
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2001 - Present	[redacted]	Middletown	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Premier Dental Products Company, LLC			09/2021 - Present	
Business Address		**City**	**State**	**Zip**
1710 Romano Drive		Plymouth Meeting	PA	19462
Phone	**Title**		**Number of Employed Hours**	
(610) 239-6000	Chief Operating Officer		~ 7,160 hours	

Description of Duties

20+ years of experience in leadership, supply chain operations & systems, industrial automation, manufacturing, analytics and consulting. COO scope of of responsibility includes manufacturing, warehousing, customer experience and regulatory functions. Improvements achieved through targeted SG&A and COGS improvement in projects in manufacturing, purchasing, fulfillment, and revenue operations.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Robert Warren Sutherland, **certify that as the MDEG Administrator for**

Premier Dental Products Company, LLC,

that I (initial that you have read and meet the following requirements):

1. RS Have a high school diploma or its equivalent;
2. RS Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RS Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RS Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Warren Sutherland
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/11/25
Date

Board Use Only	Date Received: 3/12/25

Employee List

premier Inspired solutions for daily dentistry

Employee List - PDPC, Plymouth Meeting, PA

EE #	Last Name	Preferred/First Name	Department Description
154	Braslow	Cara	Corporate
462	Lowe	Perry	Corporate
553	Pranitis	Leo	Corporate
567	Reed	Shaun	Cust Service Exempt
694	Zettlemoyer	Thaddeus	Cust Service Exempt
202	Bryant	Susan	Cust Service Hourly
300	Gillespie	Mary	Cust Service Hourly
474	Marchozzi	Dominique	Cust Service Hourly
482	Marchozzi	Nicole	Cust Service Hourly
506	Morales	Iris	Cust Service Hourly
627	Spinelli	Mary	Cust Service Hourly
659	Varrone	Patricia	Cust Service Hourly
113	Armstrong	Benjamin	Distribution Hourly
342	Hornberger	Michael	Distribution Exempt
236	Dolby	David	Distribution Hourly
240	Feaster	Doyle	Distribution Hourly
252	Fleming	Jesse	Distribution Hourly
304	Gooden	Teresa	Distribution Hourly
450	Kunnmann	Jared	Distribution Hourly
456	Lewis	Faith	Distribution Hourly
458	Loughin	Donald	Distribution Hourly
526	Ozga	John	Distribution Hourly
568	Rivera	Elisa	Distribution Hourly
574	Rowland	James	Distribution Hourly
116	Barthold	Charles	Finance Exempt

203	Carcaci	Brenda	Finance Exempt
207	Chand	Avtar	Finance Exempt
223	Cooper	Jay	Finance Exempt
297	Gillard	Amy	Finance Exempt
337	Hayman	Steven	Finance Exempt
513	Muhammad	Nauman Noor	Finance Exempt
348	Hughes	Lisa	Intl Admin Exempt
232	Davenport	Teresa	Marketing Exempt
237	Ernst	Tim	Marketing Exempt
425	Korchak	Judy	Marketing Exempt
674	Whitner	John	Marketing Exempt
677	Wilk	Debra	Marketing Exempt
684	Zerr	Diane	Marketing Exempt
311	Hamilton	Rachel	Marketing Hourly
444	Kunnmann	Mary Kate	Marketing Hourly
165	Brown	Kevin	Med Sales Exempt
6	Scott	Erica	Med Sales Exempt
471	Lukov	Frida	MIS Exempt
516	Neville	Benjamin	MIS Exempt
634	Srinivasa Reddy	Supriya	MIS Exempt
387	Kaplan	Emma	Officers Hourly
412	Kita	Patricia	Officers Hourly
274	Giannone	Karen	Operations Exempt
639	Sutherland III	Robert	Operations Exempt
114	Barthol	Tiffany	Product Development
225	Coyne	Ann	Product Development
301	Goodchild	Jason	Product Development
367	Jones	David	Product Development
4	Kerr	Sean	Product Development
520	Neyer	Erika	Product Development
55	Pijanowski	Lawrence	Product Development
610	Shabazz	Akil	Product Development

624	Shtessel-Nemzer	Victoriya	Product Development
208	Chou	Ming Chin	Regulatory
3448	Huang	Jessica	Regulatory
356	Hunt	Devan	Regulatory
472	Madras Raja Reddy	Chetan	Regulatory
587	Ryan	Allison	Regulatory
233	Dawson	Laura	Salesforce Mgt Exempt
235	D'Errico	Michael	Salesforce Mgt Exempt
521	O'Halloran	Sean	Salesforce Mgt Exempt

4QQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☑ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH Pending	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Progenics Pharmaceuticals, Inc.

Physical Address: 201 Burlington Road, Suite PGX-01

City: Bedford State: MA Zip: 01730

Mailing Address (if different from physical address): Same as Physical Address above.

City: State: Zip:

Telephone: (800) 362-2668 Website: www.lantheus.com

Name of Designated Representative (DR): James B. Bradosky

Licensing Company Email: James.bradosky@lantheus.com DR Email: James.bradosky@lantheus.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☑ Dangerous Drugs	☑ Manufacturer (Virtual)
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☑ Others: Radiopharmacies		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment A

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Lantheus Medical Imaging, Inc.

Corporation/Organization Name: Progenics Pharmaceuticals, Inc.

Mailing Address: 201 Burlington Road, Suite PGX-01

City: Bedford State: MA Zip: 01730

Telephone: (800) 362-2668 Email: James.bradosky@lantheus.com

Contact Person Name: James B. Bradosky

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		N/A
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachment D		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by Lantheus Medical Imaging, Inc.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment D	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment G	✓	✓	✓	✓
N/A • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
N/A • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
N/A - See Attachment B • **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Progenics Pharmaceuticals, Inc.

Facility Name

James B. Bradosky

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

25 Feb 2025

Date

Board Use Only	Date Received: 3/27/25	Amount: $1,000.00

Attachment A

Nature of Business

Progenics Pharmaceuticals, Inc. (Progenics) is focused on developing innovative nuclear medicines and other technologies to target and treat cancer. The company is headquartered in Massachusetts. Products are sold by the Bedford, MA location and manufactured at positron emission tomography (PET) Manufacturing Facilities. Due to a short half-life, the products are then shipped by a common carrier, to the treatment center for a specific patient. **As the Progenics product is radioactive, it does not utilize traditional contract manufacturers, third party logistics providers, or wholesalers for product distribution.**

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
PROGENICS PHARMACEUTICALS, INC.
201 Burlington Road
South Building
Bedford, MA 01730
Registration Number: 3013080312
FEI Number*: 3013080312
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types.
Please Review Listings For Further Information.
Date Of Registration Status: 2025

Owner/Operator:
Progenics Pharmaceuticals, Inc.[6]
201 Burlington Road
South Building
Bedford, MA US 01730
Owner/Operator Number: 10061306[7]

Official Correspondent:
Joanne Magnotta
201 Burlington Road
South Building
Bedford, MA 01730
Phone: 978-6718848

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10061306&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10061306&OwnerOperatc

Page Last Updated: 11/18/2024

Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsc | 日本語 | فارسی | English

Accessibility Contact FDA Careers FDA Basics FOIA No FEAR Act Nondiscrimination Website Policies / Privacy

FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

For Government For Press

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U.S. Department of **Health & Human Services**

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=&RegNum=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10061306&OwnerOperatc

An official website of the United States government Here's how you know

FDA

Current through December 10, 2024

You have searched Finished drug products

Search Results: *'Progenics Pharmaceuticals, Inc.'*

Back to Search Page

Keyword Search Reset Showing 1 to 1 of 1 entries Show All entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Product Type Name	Start Marketing Date	End Marketing Date	Market Category	Package Description
PYLARIFY	71258-022-01	80mCi/mL	INJECTION	INTRAVENOUS	NDA214793	Progenics Pharmaceuticals, Inc.	71258-022	PIFLUFOLASTAT F-18	PIFLUFOLASTAT F-18	HUMAN PRESCRIPTION DRUG	05/26/2021	N/A	NDA	50 mL in 1 VIAL, MULTI-DOSE (71258-022-01)

Previous 1 Next

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration
Center for Drug Evaluation and Research
Division of Data Management and Services

Attachment D

Corporation Information

Progenics Pharmaceuticals, Inc.

Progenics Pharmaceuticals, Inc. is wholly-owned by its parent company, Lantheus Medical Imaging, Inc.

Corporate Officers:

Brian A. Markison
Chief Executive Officer

Paul M. Blanchfield
President

Daniel M. Niedzwiecki
Chief Administrative Officer & General Counsel

Robert J. Marshall Jr.
Chief Financial Officer & Treasurer

Designated Representative:

James B. Bradosky
Vice President EHS & RPO

Enclosed please find a list of site employees.

Attachment E

Delaware Certificate of Good Standing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "PROGENICS PHARMACEUTICALS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-EIGHTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "PROGENICS PHARMACEUTICALS, INC." WAS INCORPORATED ON THE FIRST DAY OF DECEMBER, A.D. 1986.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

2109273 8300

SR# 20250822963

Authentication: 203045893

Date: 02-28-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE COMMONWEALTH OF MASSACHUSETTS

DEPARTMENT OF PUBLIC HEALTH, DRUG CONTROL PROGRAM

Massachusetts Controlled Substance Registration

In accordance with the provision of Massachusetts General Laws, Chapter 94C, issues the registration of Virtual Drug Manufacturer or Virtual Drug Distributor Controlled Substance Registration to:

Progenics Pharmaceuticals, Inc.
201 Burlington Road, Suite PGX-01
Bedford, MA 01730

Robert Goldstein, MD, PhD
Commissioner - Department of Public Health

Registration Number: VIR200119

Type: Virtual Manufacturer

Issue Date: 01/28/2025

Expiration Date: 01/28/2026

COMMONWEALTH OF MASSACHUSETTS
DEPARTMENT OF PUBLIC HEALTH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 800005920

Application/License No. _____

Progenics Pharmaceuticals, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 201 Burlington Road, Bedford, MA 01730 (Address of Applicant/Principal), as PRINCIPAL, and Atlantic Specialty Insurance Company (Surety Company), a corporation organized under the laws of the state of New York (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 605 Highway 169 North, Suite 800, Plymouth, MN 55441 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 20, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 19th day of March, 2025.

APPLICANT/PRINCIPAL
Progenics Pharmaceuticals, Inc.

Authorized Representative

SURETY COMPANY
Atlantic Specialty Insurance Company

Surety Company's Representative

April D. Perez, Attorney-in-fact
print name
NV Non-Resident License #722132

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness Annette Audinot

Witness Jessica Iannotta

Countersigned by:

n/a
Nevada Resident Agent

Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
December 04, 2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Progenics Pharmaceuticals, Inc.

Pharmacy/Wholesaler License # (if applicable): VIR200119

Physical Address: 201 Burlington Road, Suite PGX-01

City: Bedford State: MA Zip: 01730

Mailing Address (if different from physical address): Same as Physical Address above.

City: State: Zip:

Telephone: (800) 362-2668 Website: www.lantheus.com

Licensing Company Email: James.bradosky@lantheus.com

Section 2: Personal Information

First: James Middle: Billings Last: Bradosky

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 201 Burlington Road, Suite PGX-01

City: Bedford State: MA Zip: 01730

Telephone: [redacted] Email: James.bradosky@lantheus.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Massachusetts at Lowell		09/12 - 05/16	
Address	**City**	**State**	**Zip**
1 University Avenue	Lowell	MA	01854
Diploma/Degree obtained, if any			
Master of Science (MSc), Occupational and Environmental Hygiene			
School Name		**From - To (MM/YY – MM/YY)**	
US Army Chemical School		05/02 - 07/02	
Address	**City**	**State**	**Zip**
1121 112TH Avenue South	FT Leonard Wood	MO	98444
Diploma/Degree obtained, if any			
Chemical, Biological, Radiological and Nuclear Operations School (CBRN)			
School Name		**From - To (MM/YY – MM/YY)**	
University of Massachusetts Amherst		09/96 - 05/10	
Address	**City**	**State**	**Zip**
243 Whitmore Admin. Building, 181 Presidents Dr.	Amherst	MA	01003
Diploma/Degree obtained, if any			
Bachelor of Arts			
School Name		**From - To (MM/YY – MM/YY)**	
Marian High School		09/89 - 06/93	
Address	**City**	**State**	**Zip**
273 Union Ave	Framingham	MA	01702
Diploma/Degree obtained, if any			
HS Diploma			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/15 - Present	[redacted]	Medway	MA	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Progenics Pharmaceuticals, Inc.			10/18 - Current
Business Address	**City**	**State**	**Zip**
201 Burlington Road, Suite PGX-01	Bedford	MA	01730
Phone	**Title**	**Number of Employed Hours**	
(800) 362-2668	Vice President EHS & RPO	40 hours per week	
Description of Duties			
Experienced Environment Health Safety Leader with a demonstrated history of working in the biotechnology, pharmaceutical and manufacturing industries over 11 years.			

Business Name			From - To (MM/YY – MM/YY)
Lantheus Medical Imaging, Inc.			10/18 - Current
Business Address	**City**	**State**	**Zip**
331 Treble Cove Road	N. Billerica	MA	01862
Phone	**Title**	**Number of Employed Hours**	
978-436-7387	VP; Sr. Director EHS RPO; Assoc. Director EHS	40 hours per week	
Description of Duties			
Experienced Environment Health Safety Leader with a demonstrated history of working in the biotechnology, pharmaceutical and manufacturing industries over 11 years.			

Business Name			From - To (MM/YY – MM/YY)
Amgen, Inc.			05/15 - 10/18
Business Address	**City**	**State**	**Zip**
360 Binney Street	Cambridge	MA	02142
Phone	**Title**	**Number of Employed Hours**	
(617) 444-5000	Manager EHS & Sustainability	40 hours per week	
Description of Duties			
Construction Safety Manager for 20MM manufacturing facility upgrade.			

Business Name			From - To (MM/YY – MM/YY)
AstraZeneca Pharmaceuticals			10/13 - 05/15
Business Address	**City**	**State**	**Zip**
35 Gatehouse Drive	Waltham	MA	02451
Phone	**Title**	**Number of Employed Hours**	
(781) 839-4000	Manager Safety Health & Environment	40 hours per week	
Description of Duties			
Chemical Hygiene Officer supporting all site functional innovative medicines R&D groups including Infection, Oncology, DMPK, Analytical, Compound Management and vivarium operations.			

Business Name			From - To (MM/YY – MM/YY)
			/-/
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

N/A

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

N/A

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, James B. Bradosky, **certify that as the designated representative for**

Progenics Pharmaceuticals, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JB I am at least 21 years of age;
3. JB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James Bradosky

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

25 Feb 2020

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Bradosky

Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

25 Feb 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Commonwealth Massachusetts, ss. County of Middlesex

I, James Bradosky, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

25 Feb 2025

Date

Subscribed and Sworn to before me this 25th day of February 2025

Notary Public Signature

Jill M. Corbett
Notary Public
COMMONWEALTH OF MASSACHUSETTS
My Commission Expires
December 04, 2026

(Seal)

Employee Name		
Abesamra, Michael	Connolly, Tamara J.	Harper, Susan M.
Abril, Shaun A.	Cook, Andrew P.	Hasegawa, Brian
Alpatov, Roman	Crabb, Stephen J.	Hawks, Dustin K.
Anastasiou, Peter	Dalal, Fenil P.	Hayat, Ali A.
Arami, Robine	Davison, Courtney	Hehir, Brandon
Arnold, Austin M.	Dentino, Dave A.	Hemenway, Angela
Ashworth, Margo M.	Devost, Jeffrey J.	Heng, Paul
Aulson, Molly	Dogu Tumer, Sinem	Holland, Neil
Ball, Cheryl	Domenici-Bell, Carla A.	Howe, Lee Anne A.
Bandani, Bijan	Donohoe, Stacy D.	Hurley, Diana
Bangalore, Raghu	Douglas, Diah A.	Huseinovic, Neda
Barr-Potty, Dorothy	Driscoll, Kelsey R.	Hutchinson, Samuel R.
Barros, Angela	Duffy, Jillian C.	Infanger, Julie A.
Bartlett, Susan	Dufur, Becky M.	Ingram, Melissa L.
Bermudez, Christian J.	Dumas, Robert W.	Insixiengmay, Lanita
Bhatlapenumarthy, Raghav	Dumouchel, Darin	Irvine-Salvi, Holly Irvine E.
Biskup, Courtney	Dwivedi, Abhishek	Iyer, Siva C.
Blanchfield, Paul M.	Fayyoumi, Waleed K.	Janeczko, Tom
Boland, Martha M.	Fearon, Maeve M.	Jastive, Mark
Bond, Susan	Ferencsik, Michael R.	JeBailey, Lellean J.
Bowie, Tyler P.	Folwell, Kate H.	Kell, Richard B.
Boyle, Sean	Forrester, Melissa E.	Kerwin, Thomas
Bradosky, James B.	Frank, Ashley M.	Kinarney, Mark
Brauneis, James R.	Fraumeni, Rosemarie	Kirby, Nicholas M.
Brown, Kim A.	Gac, Jayne P.	Kolanda, Kenan J.
Burke, Rayna L.	Gamel, Laura M.	Kosmidis, Chantal V.
Burke, Tim W.	Garg, Payal	Krishnatry, Bhavna
Burrington, Carson S.	Gharat, Abhishek	Kulacz, Cheryl L.
Carlson, Jennifer M.	Gilbert Jr., Tom D.	Lane, Mike M.
Carney, Melissa	Goldman, Ira N.	Langston, Jacqueline G.
Castillo, Kiana D.	Goodstal, Sam M.	Lau, Shing N.
Cavanaugh, Mollie M.	Grasso, Brittany M.	Leary, Kate E.
Clark, Kevin R.	Green, Eric	Leary, Kristin E.
Clement, Mike J.	Halsey, Anne M.	Lennox, Linda
Cogswell III, Larry P.	Han, Edward	Li, June J.

Employee Name		
Lichter, Sam	Niedzwiecki, Dan	Tao, Meng
Loblundo, Chris	O'Brien, Ken	Thompson, Diana S.
Lovequist, Mel	O'Neill, Denise C.	Tracey, Amber
MacNeil, Stephen	O'Neill, Jillian L.	Tremblay, Amy E.
Magliozzi, Deana L.	Olcott, Christopher	Tremont, Jennifer A.
Maharjan, Poonam	Passamonti, Luca	Trexler, Brandy L.
Maione, Vanessa	Perault, Thomas J.	Tso, Ben
Mara, Bryanne L.	Plourde, Laura K.	Tuttle, Lauren G.
Margolin, Lauren P.	Popoloski, Emery A.	Uppara, Vijaya Kumar
Marino, Courtney	Quirk, TJ	Upputuri, Chiranjeevi
Marino, Donna	Reilly, Sarah	Valkenburg, Jessica A.
Markison, Brian A.	Reinhardt, Katy E.	Vanstone, Darlene A.
Marlin, Julia H.	Ricci, Steve M.	Verlinden, Matt C.
Marshall, Bob	Richmond, Will	Wagner, Cynthia W.
Matthews, Rebecca K.	Riley, Cathleen M.	Waingortin, Lauren
Matys, Ben	Rumrill, Sarah	Walker, Carol
May, Molly J.	Ryan, Peg	Wang, Chao
McCabe, Sean R.	Sabens, Andrea	Wang, Elaine B.
McClure, Liz T.	Salmo, Mia B.	Wang, Zemin
McDonough, Maura A.	Sangenario, Jennifer L.	Warwick, Cindy
McLaughlin, Jeffrey J.	Sannie, Tiffany N.	Whitaker Sayre, Ashley F.
Mellace, Timothy	Sapp, Kevin	Whitney, Ian
Melvin, Carrie L.	Schnebly, Keith G.	Wiggins, John
Merrill, Raymond	Shah, Vishwal	Williams, Wayne
Miller, Shane W.	Shahid, Muhammad	Wisniewski, Julie C.
Mitchell, Lindsye L.	Shamani, Mehek	Wong, Lok
Mitchell, Terri	Sherman, Rob S.	Wooten, Carson R.
Mockler, Matt R.	Shultz, Cliff J.	Zanengo, Zachary A.
Morrison, Cameron A.	Simone, Vince M.	
Murphy, Meara K.	Sitthirath, Keo	
Murray-Pietsch, Helene	Smith, Benjamin	
Nadkarni, Shirish S.	Song, Ying	
Nestor, Joann S.	Spaeth, Jamie L.	
Nezafat, Maryam	Srivastava, Amit	
Nguyen, Quang-De	Stow, Lisa R.	

4RR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 02615	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Sagent Pharmaceuticals

Physical Address: 1515 E Woodfield Road, Ste 1100

City: Schaumburg State: IL Zip: 60173

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (847) 908-1600 Website: www.sagentpharma.com

Name of Designated Representative (DR): James Horger

Licensing Company Email: adetweiler@sagentpharma.com DR Email: jhorger@sagentpharma.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
■ Hospitals	☐ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: Virtual Manufacturer

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Please see attached.

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Wyoming

Parent Company (if any): Ellimist Singapore Pte. Ltd.

Corporation/Organization Name: Sagent Pharmaceuticals

Mailing Address: 1515 East Woodfield Road, Ste 1100

City: Schaumburg State: IL Zip: 60173

Telephone: (847) 908-1600 Email: jhorger@sagentpharma.com

Contact Person Name: James Horger

Section 6: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✔" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✔	✔		
• **List the top four corporation shareholders and their percent ownership.**	✔			
• **List of all corporation shareholders and their percent ownership.**		✔		
• **List of all partners and their percent ownership.**			✔	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✔	✔	✔	✔
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✔	✔	✔
• **Copy of DEA certificate if handling controlled substances**	✔	✔	✔	✔
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✔			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✔	✔	✔	✔
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✔	✔	✔	✔
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✔	✔	✔	✔
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✔	✔	✔	✔
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✔	✔	✔
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✔	✔	✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Sagent Pharmaceuticals

Facility Name

Jeffrey Greve

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/25/25.

Date

Board Use Only	Date Received: 3/31/25	Amount: $1000 CK 49705

Labeler - Sagent Pharmaceuticals (080579617) NDC Labeler Code: 25021

Contact	Address	Telephone Number	Email Address
Rebecca Simpson	Address: 1901 N Roselle Rd Ste 450 City, State, Zip: Schaumburg, IL, 60195 Country: USA	+1-847-908-1632	rsimpson@sagentpharma.com

Labeler Detail

Name	Address	ID/FEI	Business Operations
Sagent Pharmaceuticals	Address: 1901 N Roselle Rd Ste 450 City, State, Zip: Schaumburg, IL, 60195 Country: USA	080579617	Distributes drug products under own private label(Distributes human prescription drug products)

Revised: 4/2023

APPROVED
By Rebecca Simpson at 3:25 pm, Apr 17, 2023

Sagent Pharmaceuticals

Verified 4/3/25 MH

sagent

Sagent Pharmaceuticals' Ownership Hierarchy
pre-Change of Ownership: March 31, 2025

Gland Celsus Bio Chemicals Private Limited (24.92%)
6-3-865 ½, Flat No.: 204
Greenlands, Ameerpet, Hyderabad
Telangana, India 500016

K P Advisory Services LLP (75.08%)
6-3-865 ½, Flat No.: 203
Greenlands, Ameerpet, Hyderabad
Telangana, India 500016

Ellimist Singapore Pte. Ltd. (100%)
UEN: 201904985H
8 Cross St, #24-03/24
Manulife Tower, Singapore

Que Pharma, Inc. (100%)
FEIN: 92-2844630, DE 2023
251 Little Falls Drive
Wilmington, DE USA 19808

Sagent Pharmaceuticals
FEIN: 20-5522946, WY 2006
1515 E. Woodfield Road, Suite 1100
Schaumburg, IL USA 60173

sagent

Sagent Pharmaceuticals' Ownership Hierarchy post-Change of Ownership: March 31, 2025

Gland Celsus Bio Chemicals Private Limited (24.92%)
6-3-865 ½, Flat No.: 204
Greenlands, Ameerpet, Hyderabad
Telangana, India 500016

K P Advisory Services LLP (75.08%)
6-3-865 ½, Flat No.: 203
Greenlands, Ameerpet, Hyderabad
Telangana, India 500016

Ellimist Singapore Pte. Ltd. (100%)
UEN: 201904985H
8 Cross St, #24-03/24
Manulife Tower, Singapore

Sagent Pharmaceuticals
FEIN: 20-5522946, WY 2006
1515 E. Woodfield Road, Suite 1100
Schaumburg, IL USA 60173

1515 E. Woodfield Road, Suite 1100, Schaumburg, IL 60173
847.908.1600 | www.SagentPharma.com

VIRTUAL MANUFACTURER STATEMENTS

Facility Description
Sagent Pharmaceuticals is a virtual pharmaceutical manufacturer. As a virtual manufacturer, Sagent Pharmaceuticals utilizes contract manufacturing organizations and a third-party logistics provider to manufacture, store and distribute Sagent's products. No pharmaceutical products are located, stored, or distributed from Sagent's facility: a corporate and administrative office operating from the 11th floor of the Schaumburg Corporate Center office building located at 1515 E. Woodfield Road, Schaumburg, Illinois.

Food & Drug Administration Registration
FDA Establishment Identification #: 3006167046 (Distributor only)
FDA Labeler Code: 25021
DUNS #: 080579617

Drug Enforcement Agency Registration
Sagent Pharmaceuticals is a virtual manufacturer and is not required to hold a DEA Registration Certificate. As a virtual manufacturer, Sagent Pharmaceuticals utilizes contract manufacturing organizations and a third-party logistics provider to manufacture, store and distribute Sagent's controlled substance products. No controlled substance products are located, stored, distributed or received at Sagent's facility. Sagent's controlled substances are managed under Sagent's third-party logistics provider's DEA Registration Certificate.

Third Party Logistics Provider
Eversana Life Science Services, LLC
4580 S Mendenhall Road
Memphis, TN 38141

FDA #: 15096257322
DEA #: RD0205333

1515 E. Woodfield Road, Suite 1100, Schaumburg, IL 60173
847.908.1600 | www.SagentPharma.com

SAGENT PHARMACEUTICALS CORPORATE OFFICERS

(Wyoming) FEIN: 20-5522946

Officer	Name	Business Address (effective January 1, 2025)	Home Address	SSN/DoB/DL
Chief Executive Officer	Viswanath Chebrol	Sagent Pharmaceuticals 1515 East Woodfield Road, Suite 1100 Schaumburg, IL 60173	[redacted]	
Corporate Secretary & General Counsel	Brennan Bolt	Sagent Pharmaceuticals 1515 East Woodfield Road, Suite 1100 Schaumburg, IL 60173		
Chief Financial Officer	Jeffrey Greve	Sagent Pharmaceuticals 1515 East Woodfield Road, Suite 1100 Schaumburg, IL 60173		
EVP Sales & National Accounts	Don Bullock	Sagent Pharmaceuticals 1515 East Woodfield Road, Suite 1100 Schaumburg, IL 60173		
Controller	Kara Venegas	Sagent Pharmaceuticals 1515 East Woodfield Road, Suite 1100 Schaumburg, IL 60173		

Parent Company: Ellimist Singapore Pte. Ltd. (Singapore) UEN: 201904985H **effective: March 31, 2025**

Filing Information

Please note that this form CANNOT be submitted in place of your Annual Report.

Name	**Sagent Pharmaceuticals**
Filing ID	**2006-000514030**
Type	Profit Corporation
Status	Active

Most Recent Annual Report Information

Type	Original			AR Year	2024
License Tax	$60.00	AR Exempt	N	AR ID	10178849
AR Date	7/17/2024 5:18 PM				
Web Filed	Y				

Officers / Directors

Type	Name / Organization / Address
Director	Jeffrey Greve 1901 N Roselle, Schaumburg, IL 60195
President	Viswanath Chebrol 1901 N Roselle, Schaumburg, IL 60195
Secretary	Brennan Bolt 1901 N Roselle, Schaumburg, IL 60195
Treasurer	Kara Venegas Suite 450 1901 N. Roselle Road, Schaumburg, IL 60195

Principal Address

1901 N. Roselle Road Ste. 450
Schaumburg, IL 60195

Mailing Address

1901 N. Roselle Road Ste. 450
Schaumburg, IL 60195

Annual Report History

Num	Status	Date	Year	Tax
00775272	Original	05/03/2007	2007	$50.00
00884960	Original	05/06/2008	2008	$50.00
01010586	Original	05/06/2009	2009	$50.00

Principal Address 1 Changed From: Registered Agency Services Inc. To: 1901 N Roselle Rd Ste 700
Principal Address 2 Changed From: 2120 Carey Ave To: No value
Principal City Changed From: Cheyenne To: Schaunburg
Principal State Changed From: WY To: IL
Principal Postal Code Changed From: 82001 To: 60195

01126646	Original	03/02/2010	2010	$50.00
01323536	Original	04/22/2011	2011	$50.00
01527937	Original	04/24/2012	2012	$50.00
01824627	Original	04/18/2013	2013	$50.00

Principal Address 1 Changed From: 2120 Carey Ave Ste 300 To: 1901 N. Roselle Road
Principal Address 2 Changed From: No value To: Ste. 700
Principal City Changed From: Cheyenne To: Schaumburg
Principal State Changed From: WY To: IL
Principal Postal Code Changed From: 82001 To: 60195

2015

STATE OF WYOMING * SECRETARY OF STATE
BUSINESS DIVISION

Herschler Bldg East, Ste.100 & 101, Cheyenne, WY 82002-0020
Phone: 307-777-7311 · Website: https://sos.wyo.gov · Email: business@wyo.gov

Filing Information



Please note that this form CANNOT be submitted in place of your Annual Report.

Name	**Sagent Pharmaceuticals**
Filing ID	**2006-000514030**
Type	Profit Corporation
Status	Active

General Information

Old Name		Sub Status	Current
Fictitious Name		Standing - Tax	Good
		Standing - RA	Good
Sub Type		Standing - Other	Good
Formed in	Wyoming	Filing Date	05/05/2006 12:00 AM
Term of Duration	Perpetual	Delayed Effective Date	
		Inactive Date	

Share Information

Common Shares	10,000	Preferred Shares		Additional Stock	N
Par Value	0.0100	Par Value	0.0000		

Principal Address

1901 N. Roselle Road Ste. 450
Schaumburg, IL 60195

Mailing Address

1901 N. Roselle Road Ste. 450
Schaumburg, IL 60195

Registered Agent Address

Corporation Service Company
1821 Logan Ave
Cheyenne, WY 82001

Parties

Type	Name / Organization / Address

Notes

Date	Recorded By	Note

2016

Filing Information

Please note that this form CANNOT be submitted in place of your Annual Report.

Name	**Sagent Pharmaceuticals**
Filing ID	**2006-000514030**
Type	Profit Corporation
Status	Active

02026158	Original	04/30/2014	2014	$50.00
02231911	Original	04/30/2015	2015	$50.00
Principal Address 1 Changed From: 1901 N. Roselle Road To: 1901 N. Roselle Road Ste. 700				
02471964	Original	04/08/2016	2016	$50.00
02795353	Original	04/30/2017	2017	$50.00
03474056	Original	04/09/2018	2018	$50.00
04454023	Original	04/22/2019	2019	$50.00
05678705	Original	04/07/2020	2020	$50.00
06209644	Original	04/26/2021	2021	$50.00
07218827	Original	04/29/2022	2022	$60.00
Principal Address 1 Changed From: 1901 N. Roselle Road Ste. 700 To: 1901 N. Roselle Road Ste. 450				
08483200	Original	05/01/2023	2023	$60.00
08879481	Amendment	07/31/2023	2023	$0.00
10178849	Original	07/17/2024	2024	$60.00

Amendment History

ID	Description	Date
2024-005187891	Reinstatement - Tax	07/17/2024
Filing Status Changed From: Inactive - Administratively Dissolved (Tax) To: Active		
2024-005167274	Dissolution / Revocation - Tax	07/09/2024
Filing Status Changed From: Active To: Inactive - Administratively Dissolved (Tax)		
Inactive Date Changed From: No Value To: 07/09/2024		
2024-004738909	Delinquency Notice - Tax	05/02/2024
2016-001907410	Change of Agent	05/24/2016
Registered Agent # Changed From: 0188376 To: 0173386		
Registered Agent Organization Name Changed From: Incorp Services, Inc. To: Corporation Service Company		
Registered Agent Physical Address 1 Changed From: 1910 Thomes Ave To: 1821 Logan Ave		
2016-001892303	RA Address Change	05/06/2016
2014-001630474	Change of Agent	06/27/2014
Registered Agent # Changed From: 0183311 To: 0188376		
Registered Agent Organization Name Changed From: FRONTIER REGISTERED AGENCY SERVICES LLC To: Incorp Services, Inc.		
Registered Agent Physical Address 1 Changed From: 2120 Carey Ave To: 1621 Central Ave		
2013-001500322	RA Address Change	05/17/2013

2017

Filing Information

Please note that this form CANNOT be submitted in place of your Annual Report.

Name	**Sagent Pharmaceuticals**
Filing ID	**2006-000514030**
Type	Profit Corporation
Status	Active

2011-000945348	RA Name/Address Change	02/10/2011

Registered Agent # Changed From: No Value To: 0183311

Registered Agent Organization Name Changed From: No Agent To: FRONTIER REGISTERED AGENCY SERVI(LLC

Registered Agent Physical Address 1 Changed From: No Office To: 2120 Carey Ave Ste 300

Registered Agent Physical City Changed From: No Value To: Cheyenne

Registered Agent Physical Postal Code Changed From: No Value To: 82001

Principal Address 1 Changed From: 1901 N Roselle Rd Ste 700 To: 2120 Carey Ave Ste 300

Principal City Changed From: Schaunburg To: Cheyenne

Principal State Changed From: IL To: WY

Principal Postal Code Changed From: 60195 To: 82001

2011-000945347	RA Resignation	02/10/2011

Registered Agent # Changed From: 0138661 To: No Value

Registered Agent Organization Name Changed From: Registered Agency Services, Inc. To: No Agent

Registered Agent Physical Address 1 Changed From: 2120 Carey Ave To: No Office

Registered Agent Physical City Changed From: Cheyenne To: No Value

Registered Agent Physical Postal Code Changed From: 82001 To: No Value

2009-000752913	Delinquency Notice - Tax	05/02/2009
2008-000670780	Delinquency Notice - Tax	05/02/2008
2007-000609392	Delinquency Notice - Tax	05/01/2007
See Filing ID	Initial Filing	05/05/2006

File Number 6552-911-4

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

SAGENT PHARMACEUTICALS (INC.), INCORPORATED IN WYOMING AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON MAY 03, 2007, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 7TH *day of* MARCH *A.D.* 2025 .

SEAL OF THE STATE OF ILLINOIS
AUG. 26TH 1818

Authentication #: 2506603738 verifiable until 03/07/2026
Authenticate at: https://www.ilsos.gov

Alexi Giannoulias
SECRETARY OF STATE

2019

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
004.005364

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
12/31/2026

LICENSED WHOLESALE DRUG DISTRIBUTOR

BROKER

SAGENT PHARMACEUTICALS
JAMES F HORGER
1515 E WOODFIELD RD STE 1100
SCHAUMBURG, IL 60173-6067

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.illinois.gov

20072683

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4424493

Illinois Department of Financial and Professional Regulation

Division of Professional Regulation

JB Pritzker
Governor

Mario Treto, Jr.
Secretary

Camile Lindsay
Acting Director
Division of
Professional
Regulation

CERTIFICATION OF LICENSURE

James F Horger
1515 E Woodfield Rd Ste 1100
Schaumburg, IL 60173-6067

Licensee:	SAGENT PHARMACEUTICALS
Number:	004.005364
Profession:	LICENSED WHOLESALE DRUG DISTRIBUTOR
Date of Issuance:	07/31/2023
Expiration Date:	12/31/2026
License Status:	ACTIVE
License Method:	NON-EXAM
Disciplinary History:	Has not been disciplined

This document is a certified copy of the records maintained and kept by this department in the regular course of business as of 01/30/2025

Camile Lindsay

Camile Lindsay
Acting Director
Division of Professional Regulation

01/30/2025
Date

Refer to the Department's Web Site at IDFPR.Illinois.gov to verify professional licenses via License Look-Up.

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
SAGENT PHARMACEUTICALS	Schaumburg, IL 60173	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004005364	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	07/31/2023	10/09/2024	12/31/2026	N

Other Licenses

Other Licenses

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004005037	LICENSED WHOLESALE DRUG DISTRIBUTOR	CHANGE OF OWNERSHIP	03/05/2021	03/13/2023	12/31/2024	N
004005399	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	01/23/2024	12/04/2024	12/31/2026	N

Generated on: 3/28/2025 10:01:59 AM

2022

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970 as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RD0205333	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	08-09-2024

EVERSANA LIFE SCIENCE SERVICES, LLC
4580 S MENDENHALL RD
MEMPHIS, TN 381416700

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	0736295
For	NV Pharmaceutical Wholesaler Bond
Dated effective	09/09/2020 (MONTH, DAY, YEAR)
Executed by	Sagent Pharmaceuticals, as Principal, (PRINCIPAL)
And by	Harco National In' urance Company, as Surety, (SURETY)
And in favor of	Nevada State B ard of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Address	1901 N Roselle Rd #450 RM4032	1515 Woodfield Road, Suite 1100
Principal Zip	60195	60173

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **12/19/2024**
(MONTH, DAY, YEAR)

Signed and Sealed **12/20/2024**
(MONTH, DAY, YEAR)

Sagent Pharmaceuticals
PRINCIPAL

BY _____ EVP CFO
TITLE

Harco National Insurance Company
SURETY

BY _____
Tamara Bowser, ATTORNEY-IN-FACT

2025

POWER OF ATTORNEY

HARCO NATIONAL INSURANCE COMPANY

INTERNATIONAL FIDELITY INSURANCE COMPANY

Member companies of IAT Insurance Group, Headquartered: 4200 Six Forks Rd, Suite 1400, Raleigh, NC 27609

Bond # 0736295

Principal Sagent Pharmaceuticals

Obligee Nevada State Board of Pharmacy

KNOW ALL MEN BY THESE PRESENTS: That **HARCO NATIONAL INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of Illinois, and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, a corporation organized and existing under the laws of the State of New Jersey, and having their principal offices located respectively in the cities of Rolling Meadows, Illinois and Newark, New Jersey, do hereby constitute and appoint

Tamara Bowser

their true and lawful attorney(s)-in-fact to execute, seal and deliver for and on its behalf as surety, any and all bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof, which are or may be allowed, required or permitted by law, statute, rule, regulation, contract or otherwise, and the execution of such instrument(s) in pursuance of these presents, shall be as binding upon the said **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, as fully and amply, to all intents and purposes, as if the same had been duly executed and acknowledged by their regularly elected officers at their principal offices.

This Power of Attorney is executed, and may be revoked, pursuant to and by authority of the By-Laws of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** and is granted under and by authority of the following resolution adopted by the Board of Directors of **INTERNATIONAL FIDELITY INSURANCE COMPANY** at a meeting duly held on the 13th day of December, 2018 and by the Board of Directors of **HARCO NATIONAL INSURANCE COMPANY** at a meeting held on the 13th day of December, 2018.

"**RESOLVED**, that (1) the Chief Executive Officer, President, Executive Vice President, Senior Vice President, Vice President, or Secretary of the Corporation shall have the power to appoint, and to revoke the appointments of, Attorneys-in-Fact or agents with power and authority as defined or limited in their respective powers of attorney, and to execute on behalf of the Corporation and affix the Corporation's seal thereto, bonds, undertakings, recognizances, contracts of indemnity and other written obligations in the nature thereof or related thereto; and (2) any such Officers of the Corporation may appoint and revoke the appointments of joint-control custodians, agents for acceptance of process, and Attorneys-in-fact with authority to execute waivers and consents on behalf of the Corporation; and (3) the signature of any such Officer of the Corporation and the Corporation's seal may be affixed by facsimile to any power of attorney or certification given for the execution of any bond, undertaking, recognizance, contract of indemnity or other written obligation in the nature thereof or related thereto, such signature and seals when so used whether heretofore or hereafter, being hereby adopted by the Corporation as the original signature of such officer and the original seal of the Corporation, to be valid and binding upon the Corporation with the same force and effect as though manually affixed."

IN WITNESS WHEREOF, **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** have each executed and attested these presents on this 31st day of December, 2023

INTERNATIONAL FIDELITY INSURANCE COMPANY CORPORATE SEAL 1904 NEW JERSEY

STATE OF NEW JERSEY
County of Essex

STATE OF ILLINOIS
County of Cook

HARCO NATIONAL INSURANCE COMPANY CORPORATE SEAL 1984 ILLINOIS

Michael F. Zurcher
Executive Vice President, Harco National Insurance Company
and International Fidelity Insurance Company

On this 31st day of December, 2023, before me came the individual who executed the preceding instrument, to me personally known, and, being by me duly sworn, said he is the therein described and authorized officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY**, that the seals affixed to said instrument are the Corporate Seals of said Companies; that the said Corporate Seals and his signature were duly affixed by order of the Boards of Directors of said Companies.

CATHY CRUZ NOTARY PUBLIC STATE OF NEW JERSEY

IN TESTIMONY WHEREOF, I have hereunto set my hand affixed my Official Seal, at the City of Newark, New Jersey the day and year first above written.

Cathy Cruz a Notary Public of New Jersey
My Commission Expires April 16, 2029

CERTIFICATION

I, the undersigned officer of **HARCO NATIONAL INSURANCE COMPANY** and **INTERNATIONAL FIDELITY INSURANCE COMPANY** do hereby certify that I have compared the foregoing copy of the Power of Attorney and affidavit, and the copy of the Sections of the By-Laws of said Companies as set forth in said Power of Attorney, with the originals on file in the home office of said companies, and that the same are correct transcripts thereof, and of the whole of the said originals, and that the said Power of Attorney has not been revoked and is now in full force and effect.

IN TESTIMONY WHEREOF, I have hereunto set my hand this 20th day of December, 2024

Irene Martins, Assistant Secretary

2026

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Sagent Pharmaceuticals

Pharmacy/Wholesaler License # (if applicable) WH02615

Physical Address 1515 E Woodfield Road, Ste 1100

City Schaumburg State IL Zip 60173

Mailing Address (if different from physical address) as above

City as above State as above Zip as above

Telephone (847) 908-1600 Website www.sagentpharma.com

Licensing Company Email adetweiler@sagentpharma.com

Section 2: Personal Information

First James Middle F Last Horger

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 1515 E Woodfield Road, Ste 1100

City Schaumburg State IL Zip 60173

Telephone (847) 908-1600 Email jhorger@sagentpharma.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Iowa State University		01/1982-05/1982	
Address	City	State	Zip
2433 Union Dr	Ames	IA	50011-2042
Diploma/Degree obtained, if any			
BS Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Parkland College		1980-1982	
Address	City	State	Zip
2400 W Bradley Ave.	Champagne	IL	61821
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/21-present	[redacted]	Crystal Lake	IL	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04/16-03/21		Greenville	OH	
From - To (MM/YY – MM/YY)		City	State	
11/12-04/16		Edwardsville	IL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Sagent Pharmaceuticals			11/20-present	
Business Address		**City**	**State**	**Zip**
1515 East Woodfield Road, Ste 1100		Schaumburg	IL	60173
Phone	**Title**		**Number of Employed Hours**	
(847) 908-1600	VP of Quality and Regulatory Compliance		40+/week	
Description of Duties				
Direct the QA External disposition group for 40 CMOs (located in India, Europe, and North America)				

Business Name			From - To (MM/YY – MM/YY)	
Akorn Pharmaceuticals			02/2019 - 11/20	
Business Address		**City**	**State**	**Zip**
1222 W. Grand Ave		Decatur	IL	62522
Phone	**Title**		**Number of Employed Hours**	
1-217-423-9715	Executive Director, Quality		40+/week	
Description of Duties				
Directed a Quality group of 140 FTEs including Quality Systems, QA, QC Chemistry & Microbiology Labs.				

Business Name			From - To (MM/YY – MM/YY)	
Adare Pharmaceuticals			02/16-02/19	
Business Address		**City**	**State**	**Zip**
845 Center Drive		Vandalia	OH	45377
Phone	**Title**		**Number of Employed Hours**	
1-937-898-9669	Senior Director, Quality		40+/week	
Description of Duties				
Directed a Quality group of 40 FTEs including Quality Systems, QA, and QC Laboratory. Manage $4.1 M budget.				

Business Name			From - To (MM/YY – MM/YY)	
Covidien-Mallinckrodt Pharmaceuticals			05/12-12/15	
Business Address		**City**	**State**	**Zip**
675 James S McDonnell Blvd		Hazelwood	MO	63042
Phone	**Title**		**Number of Employed Hours**	
1-314-654-8622	Sr. Director, Corporate Quality Systems & Compliance		40+/week	
Description of Duties				
Directed a Corporate Quality Systems group of 32 FTEs; including Product Monitoring (Product Complaints), Corporate Validation, Supply Chain Quality, and a Corporate GMP Auditing group that performed internal & external audits.				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, James F. Horger, **certify that as the designated representative for**

Sagent Pharmaceuticals,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James Horger

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/26/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Horger

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/26/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Cook

I, James Horger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/26/2025

Date

Subscribed and Sworn to before me this 26 day of March.

Amy L Sorapuru

Notary Public Signature

AMY L. SORAPURU
OFFICIAL SEAL
Notary Public, State of Illinois
My Commission Expires
August 26, 2025
(Seal)

Sagent Pharmaceuticals Headcount Report: Spring 2025

Last Name	First Name	Job Title
Abraham	Victoria	Supplier Quality Auditor
Adewumi	rebecca	Sr. Ops Information Analyst, Supply Chain
Agnello	Nicole	Senior Analyst, IT
Alexander	Irene	Senior Manager, Procurement/Logistics
Anderson	Kylie	Senior Analyst, Contracting
Andersson	Elliott	Senior Accountant
Bagri	Jojhar	Manager, Commercial Business Analysis
Barouni	Eleftheria	Sr. Specialist, QA - Batch Release
Batey	Stephanie	Regional Business Manager
Bazinski	Jerri	Regional Business Manager
Beisler	Amanda	Regional Business Manager
Belen	Rey	Specialist, Quality Assurance -Change Control
Bellino	Kristina	Director, Alliance Management
Bizhga	Eliot	Specialist, Quality Assurance - Batch Release
Bjork	Jay	Urology Business Manager
Black	Randell	Regional Business Manager
Blasey	Brian	Dir, Op Excellence & Supply Chain Security
Blasik	Matthew	National Sales Director - Urology
Bolt	Brennan	General Counsel
Brahmbhatt	Rushi	Sr. Associate, Regulatory Affairs -Publishing
Bruschuk	Claudette	Mgr, Quality Systems & Regulatory Compliance
Buird	Brian	Regional Business Manager
Bullock	Donald	EVP, Commercial Operations
Caldwell	Iwona	Director, Accounting
Conrad	Kimberly	HR Assistant/Receptionist
Cook	Benjamin	Urology Business Manager
Craparo	Olivia	Regional Business Manager
Cudia	Joyce	Analyst, Supply Chain - Outbound
Decowski	Peter	Business Intelligence Administrator/Developer
Dhingra	Priyanka	Sr Manager Medical Affairs
Eames	Kevin	Urology Business Manager
Ebenstein	Denise	Inside Sales Support Specialist
Eisele	Janell	Senior Director, National Accounts
Ekstrom	Austin	Regional Business Manager
Elakatt	Jumey	Sr Specialist, Quality Systems
Emling	Timothy	Sr. Director, Regional Sales- East
Farrar	Nicholas	Regional Business Manager
Fox	Chad	Manager, National Accounts
Fox	Thomas	Urology Business Manager
Fusha	Jana	Validated Systems Analyst, IT
Gajera	Ronakkumar	Manager, QA - Change Control
Gehrig	Kathleen	Senior Executive Assistant
Gibson	Amy	Senior Manager, Sales Operations
Greve	Jeffrey	EVP, Chief Financial Officer
Gwizdz	Natalie	Specialist, Quality Assurance -Change Control
Hagmann	Madeline	Urology Business Manager
Hansen	Elene	Manager, RA - Labeling Design

Herman	Robert	Regional Business Manager
Hoehn	Kara	Director, Human Resources
Horger	James	VP, Quality and Regulatory Affairs
Hubbard II	Charles	Seasonal Finance Associate
Hussaini	Khudija	Senior Manager, RA - Publishing
Iuni	Gina	Urology Business Manager
Jackson	Brynn	National Account Manager
Johnson	Michelle	Financial Systems Analyst, IT
Johnston	Clayton	Regional Business Manager
Katragadda	Anitha	Sr. Manager, RA - Product Dev & Post Approval
Kean	James	Regional Business Manager
Keilhack	Thomas	Director, Tax
Kemov	Stanislav	Optimization Analyst, Supply Chain
Kessenich	Charles	Regional Business Manager
Khan	Lamisah	Associate, Regulatory Affairs - Publishing
Knudson	Elizabeth	Sr Specialist, QA - Change Control + Training
Kupisch	Jason	Inside Sales Support Specialist
Lewis	Megan	Senior Manager, Regional Sales Training
Lim	Douglas	Software Engineer
Lockhart	Angela	Urology Business Manager
Lope	Amy	Senior Manager, Marketing Communications
Love	Michael	Regional Business Manager
Luke	Brandon	Regional Business Manager
Mack	Walker	Director, FP&A
McBee	Austin	Regional Business Manager
McCasland	Craig	Seasonal Operations Associate
McClellan	Katherine	Sr Specialist, Quality Systems
McClory	Amy	Sr Director, Marketing
McCoy	Sarah	Seasonal Operations Associate
McKenny	Wanda	VP, Human Resources
Michalik	Mariusz	Trade Relations Support Specialist
Morano	John	Mgr, IT Infrastructure, Strategy and Delivery
Morrison	Mary	Manager, Regional Sales - Central
Murray	Dale	Network Engineer
Orr	Michael	Senior Analyst, Finance
Ortmann	Brad	Senior Manager, Financial Planning
Pabis	Magdalena	Sr Associate, RA - Post Approval
Parker	Wonderlyn	Associate Director, Contracting
Patel	Dhruviben	Specialist, Quality Systems
Patel	Komal	Sr. Specialist, QA - Batch Release
Patel	RIMABEN	Specialist, Quality Assurance - Batch Release
Perez	Anali	Coordinator, Contracts
Perez	Penny	Urology Business Manager
Peterman	Richard	Sr. Director Contracting, Pricing & Analytics
Petzke	Jennifer	Regional Business Manager
Pfeiffer	Michael	Project Manager, Commercial
Rahman	Sajid	Director, Regulatory Affairs
Ram	Edward	Senior Director, Supply Chain
Rasheed	Andleeb	Pharmacovigilance/Medical Information Special
Rivera	Yolanda	Coordinator, Accounts Payable

Rogers	Matthew	Senior Analyst, Tax
Santiago	Vanessa	Area Sales Manager
Sarkisian	Grant	Associate Director, Program Management
Schier	Eric	Senior Director, Regional Sales West
Schwartz	Renee	Specialist, Quality Assurance - Batch Release
Simms	Cynthia	Administrator, IT Support
Simpson	Rebecca	Director, RA - Labeling
Smith	Paul	Senior Analyst, Finance
Sorapuru	Amy	Senior Specialist, Payroll
Stone	Stephen	VP, Trade Relations
Szurgot	Robert	VP, Specialty Pharmaceuticals
Szwec	Janice	Director, Quality Assurance
Tart	Benny	Regional Business Manager
Tinkoff	Cynthia	Seasonal Medical Affairs Associate
Trusler	Jason	Regional Business Manager
Varughese	Bindu	Sr. Associate, Regulatory Affairs - Labeling
Venegas	Kara	VP, Finance and Controller
Welch	Susan	Regional Business Manager
Wilburth	John	Urology Business Manager

4SS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☒ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☒ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: ECS Opco 1, LLC d/b/a Spectrum Vascular

Physical Address: 50 Main Street, Suite 1000

City: White Plains State: NY Zip: 10606

Mailing Address (if different from physical address): c/o State License Servicing, Inc., 225 Dolson Avenue, 4th floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.spectrumvascular.com

Name of Designated Representative (DR): Sharon W Klugewicz

Licensing Company Email: ECS@SLSNY.COM DR Email: sklugewicz@spectrumvascular.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☐ Pharmacies	☐ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☒ Hospitals	☒ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☒ Others: US Government		☒ Others: Manufacturer - Virtual

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Angio Dnamics
Address: 14 Plaza Dr City: Lathem State: NY Zip: 12110
Name: Cook Medical
Address: 750 Daniels Way City: Bloomington State: IN Zip: 47402
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

N/A

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE
Parent Company (if any): ECS Holdco 1, LLC
Corporation/Organization Name: ECS Opco 1, LLC d/b/a Spectrum Vascular
Mailing Address: c/o State License Servicing, Inc. 225 Dolson Avenue, 4th floor
City: Middletown State: NY Zip: 10940
Telephone: (845) 544-2482 Email: ECS@SLSNY.COM
Contact Person Name: Christine Cannon

N/A

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

N/A

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		X
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide: FDA # 3030714660	X	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

ECS Opco 1, LLC d/b/a Spectrum Vascular

Facility Name

Keith E Bernius

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/28/25

Date

Board Use Only	Date Received: 4/8/25	Amount: $1000 Ck 34645

Establishment Registration & Device Listing

Establishment:
SPECTRUM VASCULAR
Business Trade Name:
ECS Opco 1 Dba Spectrum Vascular

50 Main St. Suite 1000
White Plains, NY 10606
Registration Number: 3030714660
FEI Number*: 3030714660
Status: Active
Date Of Registration Status: 2025

Owner/Operator:
Spectrum Vascular
50 Main St. Suite 1000
White Plains, NY US 10606
Owner/Operator Number: 10090343

Official Correspondent:
Sharon Klugewicz
50 Main St. Suite 1000
White Plains, NY 10606
Phone: 1-914-6392410

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

Page Last Updated: 03/17/2025
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.
Language Assistance Available: Español | 繁體中文 | Tiếng Việt | 한국어 | Tagalog | Русский | العربية | Kreyòl Ayisyen | Français | Polski | Português | Italiano | Deutsch | 日本語 | فارسی | English

FDA

New York State
EDUCATION DEPARTMENT
Office of the Professions

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Registration Renewal

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Home State (NY) No official VOL - online only

Home State NY license verification

ECS OPCO 1, LLC

GENERAL INFO | ENFORCEMENT ACTIONS

Type	Manufacturer
Legal Name	ECS OPCO 1, LLC
Trade Name	SPECTRUM VASCULAR
Street Address	50 MAIN ST. SUITE 1000 WHITE PLAINS NY 10606
Registration No	041154
Date First Registered	February 12, 2025
Registration Begins	February 12, 2025
Registered Through	January 31, 2028
Supervisor	KLUGEWICZ SHARON
Establishment Status	Active
Successor	NONE

April 4, 2025 10:49 AM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=041154&professionCode=020

Home State NY -
No discipline

ECS OPCO 1, LLC

GENERAL INFO | ENFORCEMENT ACTIONS

Registration No: 041154

No Enforcement Actions Found

April 4, 2025 10:49 AM (ET)
https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=041154&professionCode=020

ECS Opco 1, LLC
d/b/a Spectrum Vascular

Corporate Address: 50 Main Street, Suite 1000, White Plains, NY 10606 USA
FEIN: 92-3735547
www.spectrumvascular.com

Drug Labeler Code: N/A
Incorporation State: DE
Incorporation Date: 4/13/2023

FACILITY INFORMATION

Code	Address	FDA	DEA	DUNS	VAWD	Phone	Fax
WPNY	50 Main Street Suite 1000 White Plains, NY 10606 County: Westchester	3030714660	N/A - No CS	119212396	No	(914) 639-2410	N/A

FACILITY DESIGNATED REPRESENTATIVES

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Sharon W Klugewicz	[redacted]	Designated Representative		[redacted]		

OWNERSHIP

Name	Address	Title	Percent of Ownership	Prescribing Authority	FEIN/SSN	DOB	Driver's License
ECS Holdco 1, LLC	50 Main Street 1000 White Plains, NY 10606	N/A	100	N/A	92-3722466	N/A	N/A

LIST OF OFFICERS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
Keith E Bernius	[redacted]	Chief Financial Officer		[redacted]		
Richard Fay		Chief Executive Officer	No			
Christopher Kenji Yamamoto		President & Secretary	No			

REGISTERED AGENT IN ALL APPLICABLE STATES

Name	SSN	DOB	Driver's License
Incorp Services, Inc.			

3PLS

Name	Address	Title	Prescribing Authority	SSN	DOB	Driver's License
LifeScience Logistics, LLC	1105 E. Northfield Dr. Brownsburg, IN 46112					

Company Particulars

Good Standing

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "ECS OPCO 1, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE FOURTEENTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "ECS OPCO 1, LLC" WAS FORMED ON THE THIRTEENTH DAY OF APRIL, A.D. 2023.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 202944250

Date: 02-14-25

7404974 8300

SR# 20250524674

You may verify this certificate online at corp.delaware.gov/authver.shtml

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2025-28

NAME OF SUPERVISOR
SHARON KLUGEWICZ

THIS IS TO CERTIFY

ECS OPCO 1, LLC
50 MAIN ST.
SUITE 1000
WHITE PLAINS, NY 10606

is duly recorded as a

REGISTERED MANUFACTURER OF DRUGS AND/OR DEVICES

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE TWELFTH DAY OF FEBRUARY, 2025.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF JANUARY, 2028.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER

041154

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

HS License

Liability Ins.

ACORD

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 07/15/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Willis Towers Watson Northeast, Inc. c/o 26 Century Blvd P.O. Box 305191 Nashville, TN 372305191 USA	CONTACT NAME: Willis Towers Watson Certificate Center PHONE (A/C, No, Ext): 1-877-945-7378 FAX (A/C, No): 1-888-467-2378 E-MAIL ADDRESS: certificates@willis.com
INSURED ECS Opco 1, LLC d/b/a Spectrum Vascular 50 Main Street, Suite 1013 White Plains, NY 10606	INSURER(S) AFFORDING COVERAGE — NAIC # INSURER A: Atlantic Specialty Insurance Company — 27154 INSURER B: INSURER C: INSURER D: INSURER E: INSURER F:

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER			711-01-82-56-0001	07/11/2024	07/11/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG $	$ 1,000,000 $ 1,000,000 $ 15,000 $ 1,000,000 $ 2,000,000 $ $
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			711-01-82-56-0001	07/11/2024	07/11/2025	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident) $	$ 1,000,000 $ $ $ $
A	[X] UMBRELLA LIAB [X] OCCUR EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $			711-01-82-56-0001	07/11/2024	07/11/2025	EACH OCCURRENCE AGGREGATE $	$ 5,000,000 $ 5,000,000 $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [ ] N/A If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $
A	Product Liability			750-00-04-95-0001	07/11/2024	07/11/2025	EACH OCCURRENCE AGGREGATE	$5,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

ECS Holdco 1, LLC and ECS Opco 1 Sub, LLC are Additional Named Insureds on the policy.

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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SR ID: 25701867 BATCH: 3413271

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 6213041055

Application/License No. _____

ECS Opco 1, LLC dba Spectrum Vascular (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 50 Main ST Ste 1000 White Plains, NY 10606 (Address of Applicant/Principal), as PRINCIPAL, and United States Fire Insurance Company (Surety Company), a corporation organized under the laws of the state of DE (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 305 Madison Avenue, Morristown, NJ 07960 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 5, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 5th day of March, 2025.

APPLICANT/PRINCIPAL

ECS Opco 1, LLC dba Spectrum Vascular COMPANY

By: _____
Authorized Representative

SURETY

United States Fire Insurance Company

By: _____
Surety Company's Representative

Michelle Anne McMahon, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Erika Prodell

_____
Witness Ashley Alexis

Countersigned by:

_____
Nevada Resident Agent Gentry Stewart
Nevada Non-Resident License No.: 3544073

Posted February 20, 2020

POWER OF ATTORNEY
UNITED STATES FIRE INSURANCE COMPANY
PRINCIPAL OFFICE - MORRISTOWN, NEW JERSEY

79560

KNOW ALL MEN BY THESE PRESENTS: That United States Fire Insurance Company, a corporation duly organized and existing under the laws of the state of Delaware, has made, constituted and appointed, and does hereby make, constitute and appoint:

Gentry Stewart, Kathryn Pryor, Michelle Anne McMahon, Joshua Sanford, Nicholas Turecamo, Sam E. Begun, Melissa J. Stanton, Robyn Salley, Rebecca M. Josephson, Jennifer Godere, Jonathan Gleason, Doritza Mojica, Nicholas Miller, Sarah Murtha, Connor Wolpert, Richard Hackner, Kristopher Pisano

each, its true and lawful Attorney(s)-In-Fact, with full power and authority hereby conferred in its name, place and stead, to execute, acknowledge and deliver: Any and all bonds and undertakings of surety and other documents that the ordinary course of surety business may require, and to bind United States Fire Insurance Company thereby as fully and to the same extent as if such bonds or undertakings had been duly executed and acknowledged by the regularly elected officers of United States Fire Insurance Company at its principal office, in amounts or penalties: **Unlimited**

This Power of Attorney limits the act of those named therein to the bonds and undertakings specifically named therein, and they have no authority to bind United States Fire Insurance Company except in the manner and to the extent therein stated.

This Power of Attorney is granted pursuant to Article IV of the By-Laws of United States Fire Insurance Company as now in full force and effect, and consistent with Article III thereof, which Articles provide, in pertinent part:

Article IV, Execution of Instruments - Except as the Board of Directors may authorize by resolution, the Chairman of the Board, President, any Vice-President, any Assistant Vice President, the Secretary, or any Assistant Secretary shall have power on behalf of the Corporation:

(a) to execute, affix the corporate seal manually or by facsimile to, acknowledge, verify and deliver any contracts, obligations, instruments and documents whatsoever in connection with its business including, without limiting the foregoing, any bonds, guarantees, undertakings, recognizances, powers of attorney or revocations of any powers of attorney, stipulations, policies of insurance, deeds, leases, mortgages, releases, satisfactions and agency agreements;
(b) to appoint, in writing, one or more persons for any or all of the purposes mentioned in the preceding paragraph (a), including affixing the seal of the Corporation.

Article III, Officers, Section 3.11, Facsimile Signatures. The signature of any officer authorized by the Corporation to sign any bonds, guarantees, undertakings, recognizances, stipulations, powers of attorney or revocations of any powers of attorney and policies of insurance issued by the Corporation may be printed, facsimile, lithographed or otherwise produced. In addition, if and as authorized by the Board of Directors, dividend warrants or checks, or other numerous instruments similar to one another in form, may be signed by the facsimile signature or signatures, lithographed or otherwise produced, of such officer or officers of the Corporation as from time to time may be authorized to sign such instruments on behalf of the Corporation. The Corporation may continue to use for the purposes herein stated the facsimile signature of any person or persons who shall have been such officer or officers of the Corporation, notwithstanding the fact that he may have ceased to be such at the time when such instruments shall be issued.

IN WITNESS WHEREOF, United States Fire Insurance Company has caused these presents to be signed and attested by its appropriate officer and its corporate seal hereunto affixed this 28th day of September, 2021.

UNITED STATES FIRE INSURANCE COMPANY

Matthew E. Lubin, President

State of New Jersey }
County of Morris }

On this 28th day of September, 2021, before me, a Notary public of the State of New Jersey, came the above named officer of United States Fire Insurance Company, to me personally known to be the individual and officer described herein, and acknowledged that he executed the foregoing instrument and affixed the seal of United States Fire Insurance Company thereto by the authority of his office.

MELISSA H. D'ALESSIO
NOTARY PUBLIC OF NEW JERSEY
Commission # 50125833
My Commission Expires 4/7/2025

Melissa H. D'Alessio (Notary Public)

I, the undersigned officer of United States Fire Insurance Company, a Delaware corporation, do hereby certify that the original Power of Attorney of which the foregoing is a full, true and correct copy is still in force and effect and has not been revoked.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the corporate seal of United States Fire Insurance Company on the 5th day of March, 2025.

UNITED STATES FIRE INSURANCE COMPANY

Michael C. Fay, Senior Vice President

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG ECS Opco 1, LLC d/b/a Spectrum Vascular MDEG License # (if applicable) N/A

Physical Address 50 Main Street, Suite 1000

City White Plains State NY Zip 10606

Mailing Address (if different from physical address) c/o State License Servicing, Inc. 225 Dolson Avenue, 4th floor

City Middletown State NY Zip 10940

Telephone (845) 544-2482 Website www.spectrumvascular.com

Licensing Company Email ECS@SLSNY.COM

Section 2: Personal Information

First Sharon Middle W Last Klugewicz

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Rockville Ctr State NY Zip [redacted]

Telephone [redacted] Email sklugewicz@spectrumvascular.com

Are you a citizen of the United States? × Yes | No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		N/A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Adelphi University		1991 - 08/31/1994	
Address: 1 South Ave	City: Garden City	State: NY	Zip: 11530
Diploma/Degree obtained, if any: Master of Science (MS), Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
Stony Brook University		08/1987 - 12/21/1990	
Address: 100 Nicolls Road	City: Stony Brook	State: NY	Zip: 11790
Diploma/Degree obtained, if any: Bachelor of Science (BS), Neurobiology			

School Name		From - To (MM/YY – MM/YY)	
SEVERNA PARK HIGH SCHOOL*		09/1984 - 06/1986	
Address: 60 ROBINSON RD	City: Severna Park	State: MD	Zip: 21146
Diploma/Degree obtained, if any: High School Diploma	* attended Seoul American High School 1982-1984 in Seoul, Korea (Freshman / Sophomore YR)		

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2020 - Present	[redacted]	Rockville Ctr	NY	[redacted]
11/1991 - 12/2020		Rockville Centre	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
ECS Opco 1, LLC d/b/a Spectrum Vascular			08/2023 - Present	
Business Address		**City**	**State**	**Zip**
50 Main Street, 1000		White Plains	NY	10606
Phone	**Title**		**Number of Employed Hours**	
(914) 639-2410	Designated Representative		~ 3,400 hours	

Description of Duties

Lead daily operations of the company from Planning and Supply Chain, Engineering and R&D, Quality and Regulatory Affairs, to successfully execute the technology transfer of acquired vascular access products from Cook Medical and Angiodynamics, obtain regulatory approval for new products, as well as direct activities associated with quality, record keeping, and distribution of device and drugs.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Sharon W Klugewicz, **certify that as the MDEG Administrator for**

ECS Opco 1, LLC,

that I (initial that you have read and meet the following requirements):

1. SK ✓ Have a high school diploma or its equivalent;
2. SK ✓ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SK ✓ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SK ✓ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sharon W Klugewicz
Print Name (First, Last)

Sharon Klug
Original Signature (electronic, copies or stamps not accepted)

4/2/2025
Date

Board Use Only	Date Received: 4/8/25

Telephone: +1 503-930-0681
Website: wtwco.com
E-mail: Kendall.Young@wtwco.com

March 5, 2025

ECS Opco 1, LLC dba Spectrum Vascular
50 Main St.
Ste 1013
White Plains NY 10606
kbernius@spectrumvascular.com

RE: Bond Number: 6213041055
Obligee: Nevada State Board of Pharmacy
Description: NV 100k Pharmaceutical Wholesaler Surety Bond
Commission: 0%

We are pleased to enclose the above referenced bond you requested. This bond was executed based upon the information you provided. We urge you to check all of the information enclosed, including the Power of Attorney, signatures, dates, amounts, description, bond form and any other attachments.

Please be sure to affix the bond with the proper signature and seal.

If a premium is charged, our invoice for this bond is enclosed or will be sent to you under separate cover. Please note the premium payment for this bond is due upon receipt.

Willis Towers Watson negotiates commission rates with certain insurers on a corporate level. If the rate on your placement is lower than the negotiated rate, Willis Towers Watson may collect the difference directly from the insurer. These payments will not increase the cost of your bonds or otherwise impact your premium or rates. Details of these arrangements where there is compensation beyond the base compensation detailed in your commission schedule can be found at: https://www.wtwco.com/en-us/notices/p-c-national-commission-rates.

Thank you for the opportunity to service your surety needs. Should you have any questions, please do not hesitate to contact me.

Sincerely,

Kendall Young

Willis Towers Watson Northeast, Inc.
830 NE Holladay St., Floor 2, Suite 108
Portland, OR 97232

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: ECS Opco 1, LLC d/b/a Spectrum Vascular

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 50 Main Street, Suite 1000

City: White Plains State: NY Zip: 10606

Mailing Address (if different from physical address): c/o State License Servicing, 225 Dolson Avenue, 4th floor

City: Middletown State: NY Zip: 10940

Telephone: (845) 544-2482 Website: www.spectrumvascular.com

Licensing Company Email: ECS@SLSNY.COM

Section 2: Personal Information

First: Sharon Middle: W Last: Klugewicz

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Rockville Ctr State: NY Zip: [redacted]

Telephone: [redacted] Email: sklugewicz@spectrumvascular.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Adelphi University		1991 - 08/31/1994	
Address	**City**	**State**	**Zip**
1 South Ave	Garden City	NY	11530
Diploma/Degree obtained, if any			
Master of Science (MS), Biochemistry			

School Name		From - To (MM/YY – MM/YY)	
Stony Brook University		08/1987 12/21/1990	
Address	**City**	**State**	**Zip**
100 Nicolls Road	Stony Brook	NY	11790
Diploma/Degree obtained, if any			
Bachelor of Science (BS), Neurobiology			

School Name		From - To (MM/YY – MM/YY)	
SEVERNA PARK HIGH SCHOOL*		09/1984-1986 - 06/1986	
Address	**City**	**State**	**Zip**
60 ROBINHOOD RD	SEVERNA PARK	MD	21146
Diploma/Degree obtained, if any			
High School Diploma	* ATTENDED SEOUL AMERICAN HIGH SCHOOL IN SEOUL, KOREA FRESHMAN/SOPH YRS 1982-1984		

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/2020 - Present	[redacted]	Rockville Ctr	NY	[redacted]
11/1991 - 12/2020		Rockville Centre	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
ECS Opco 1, LLC d/b/a Spectrum Vascular			08/2023 - Present	
Business Address		**City**	**State**	**Zip**
50 Main Street, Suite 1000		White Plains	NY	10606
Phone	**Title**		**Number of Employed Hours**	
(914) 639-2410	Designated Representative		~ 3,400 hours	

Description of Duties

Lead daily operations of the company from Planning and Supply Chain, Engineering and R&D, Quality and Regulatory Affairs, to successfully execute the technology transfer of acquired vascular access products from Cook Medical and Angiodynamics, obtain regulatory approval for new products, as well as direct activities associated with quality, record keeping, and distribution of device and drugs.

Business Name			From - To (MM/YY – MM/YY)	
Bioventus			10/2021 - 06/2023	
Business Address		**City**	**State**	**Zip**
4721 Emperor Blvd, STE 100		Durham	NC	27703
Phone	**Title**		**Number of Employed Hours**	
800-637-4391	Senior Vice President, Quality and Regulatory Affairs		~ 3,440 hours	

Description of Duties

Led strategic and day-to-day activities to obtain product market approval in the USA (FDA 510K/PMA), EU (EU MDR), and international (e.g., China NMPA, Health Canada, Brazil ANVISA, Mexico COFEPRIS, etc.) markets, as well as assure effective global quality management systems, including directing activities associated with quality, record keeping and distribution of devices, to meet customer and regulatory requirements.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy? N/A		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

N/A

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

N/A

Date

I, Sharon W Klugewicz, **certify that as the designated representative for**

ECS Opco 1, LLC d/b/a Spectrum Vascular,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SK I am at least 21 years of age;
3. SK I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SK I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SK I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SK I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SK I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sharon W Klugewicz

Print Name (First, Last)

Sharon Klug

Original Signature (electronic, copies or stamps not accepted)

4/2/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sharon W Klugewicz

Print Name (First, Last)

Sharon Klug — 4/2/2025

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of Westchester

I, Rukhsana Solangi-Bresloff, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Sharon Klug — 4/2/25

Original Signature Sharon W Klugewicz — **Date**

Subscribed and Sworn to before me this 2 day of April 2025.

Notary Public Signature

Rukhsana Solangi-Bresloff
Notary Public, State of New York
Reg. No. 1SO6394022
Qualified in Westchester County
Commission Expires July 15 2027

(Seal)

Last name	First Name	Department	Job Title
Aguilar	Andrea	Operations (Quality)	QA Manager
Anderson	Amanda	Sales	Sr. District Manager
Bernius	Keith	Finance	CFO
Bodus	Ryan	Sales	Sr. District Manager
Burns	Linda	Clinical	Clinical Sales Specialist
Cinquemano	Candace	Sales	District Manager
Crocker	Nathan	Sales	Sr. District Manager
Daniels	Adelina	Finance	Accounting Manager
Davis	Chris	Marketing	VP of Global Marketing
Del Rio	Paulo	Corporate Accts (LatAm)	Corporate Accts (LatAm)
DiPofi	Jim	Sales	VP of NA Sales
Fay	Richard	ECS Opco 1	CEO
Gargiule	Martin	Finance	VP of Finance & Corporate Controller
Jackson	Amanda	Corporate Accts	National Contracts Manager
Jackson	Stephen	Marketing & Training	Global Director of Marketing & Sales Enablement
Klugewicz	Sharon	Operations	COO & Sr. VP of Regulatory Affairs
Kobeissi	Michael	Corporate Accts (EMEA)	Corporate Accts (EMEA)
Koskotas	Andrew	Finance	FP&A Manager
Kraus	Dr. Dennis	Chief Medical Officer	Chief Medical Officer
Lindekugel	Joshua	Sales	District Manager
Litman-Goch	Deb	Human Resources	Human Resources Director
McKinney	Kyle	Corporate Accts	Corporate Accts & Global Contracting Director
McNeely	Monica	Sales	Exec. District Manager
Mitchell	Billy	Operations	Sr. Sustaining Engineer
Potucek	Frank	Sales	Exec. District Manager
Scherba	Zachary	Sales	Sr. District Manager
Smith	Dodey	Clinical	Sr. Clinical Specialist
Smith	Jeffrey	Corporate Accts	Vice President, Corporate Accounts/Global Contracting
Solorzano	James	Regulatory Affairs	Regulatory Affairs Manager
Stotz	Shawn	Finance	Finance (Contractor)

Thunberg	Denise	Clinical	Sr. Clinical Specialist
Valentine	Petal	Operations	Supply Chain & Planning Sr. Manager
Weinstock	Ann	Clinical	Sr. Clinical Specialist
Yamamoto	Chris	ECS Opco 1 / Spectrum Vascular	President / CEO

4TT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
☑ New Wholesaler	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9)
☐ Ownership Change*		☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 6, 8, 9)
☐ Location Change* (in-state only)	WH _____	☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Urgo Medical North America LLC

Physical Address: 100 Lexington Street, Suite 400

City: Fort Worth State: TX Zip: 76102

Mailing Address (if different from physical address): 100 Lexington Street, Suite 400

City: Fort Worth State: TX Zip: 76102

Telephone: 855-888-8273 Website: www.urgomedical.us

Name of Designated Representative (DR): Allan Couch

Licensing Company Email: licensing@us.urgo.com DR Email: allan.couch@us.urgo.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	☐ Dangerous Drugs	☑ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		☑
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		☑
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		☑
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		☑
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		☑

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3-4-25

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: MATIV
Address: 8181 Eastpoint Drive City: Dallas State: TX Zip: 75227
Name: Beier Drawtex Healthcare (pty) LTD.
Address: 40 Gillitts Road, Pinetown City: Kwa-Zulu Natal State: South Africa Zip: N/A
Name: AmerisourceBergen- ICS
Address: 5025 Plano Parkway City: Carrollton State: TX Zip: 75010
Name: Strukmyer
Address: 1801 Big Town Blvd City: Mesquite State: TX Zip: 75149

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas
Parent Company (if any): Urgo US Inc
Corporation/Organization Name: Urgo Medical North America LLC
Mailing Address: 100 Lexington Street, Suite 400,
City: Fort Worth State: TX Zip: 76102
Telephone: 855-888-8273 Email: licensing@us.urgo.com
Contact Person Name: Steven Dowdley

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:	✓	
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Urgo Medical North America LLC

Facility Name

Britt Ingebritson

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3-4-25

Date

Board Use Only	Date Received: _____ Amount: _____

FDA

FDA Home[3] Medical Devices[4] Databases[5]

Establishment Registration & Device Listing

New Search Back To Search Results

Establishment:
URGO Medical North America, LLC
100 Lexington Street, Suite 400
Fort Worth, TX 76102
Registration Number: 3010060216
FEI Number*: 3010060216
Status: Active
Initial Distributor/Importer: Yes
*Note Firm May Have Additional Establishment Types. Please Review Listings For Further Information.
Date Of Registration Status: 2024

Owner/Operator:
URGO Medical North America LLC[6]
100 Lexington Street, Suite 400
Suite 400
Fort Worth, TX US 76102
Owner/Operator Number: 10042824[7]

Official Correspondent:
Steven Dowdley
100 Lexington Street
Suite 400
Fort Worth, TX 76102
Phone: 01-678-4518062

* Firm Establishment Identifier (FEI) should be used for identification of entities within the imports message set

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6. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10042824&OwnerOperatc
7. /scripts/cdrh/cfdocs/cfRL/rl.cfm?start_search=1&establishmentName=®Num=&StateName=&CountryName=&RegistrationNumber=&OwnerOperatorNumber=10042824&OwnerOperatc

Page Last Updated: 01/22/2024

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FDA

U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
Ph. 1-888-INFO-FDA (1-888-463-6332)
Contact FDA

USA.gov

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U.S. Department of **Health & Human Services**

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URGO MEDICAL
Healing people®

Owner/Officer List

Michael Steadman, President

Ownership: 15%

Work Address: 100 Lexington Street, Suite 400, Fort Worth, Texas 76102

[redacted]

Brett Ingebritson, Senior Vice President & Chief Financial Officer

Ownership: 1%

Work Address: 100 Lexington Street, Suite 400, Fort Worth, Texas 76102

[redacted]

Franchise Tax Account Status

As of : 01/15/2025 10:46:49

This summary page is designed to satisfy standard business needs. If you need to reinstate or terminate a business with the Texas Secretary of State, you must
obtain a certificate **specific to that purpose.**

URGO MEDICAL NORTH AMERICA, LLC

Texas Taxpayer Number	32042872930
Mailing Address	100 LEXINGTON ST STE 400 FORT WORTH, TX 76102-2740
Right to Transact Business in Texas	ACTIVE
State of Formation	DE
SOS Registration Status (SOS status updated each business day)	ACTIVE
Effective SOS Registration Date	10/21/2010
Texas SOS File Number	0801333702
Registered Agent Name	CAPITOL CORPORATE SERVICES, INC.
Registered Office Street Address	1501 S MOPAC EXPY STE 220 AUSTIN, TX 78746

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "URGO MEDICAL NORTH AMERICA, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF JULY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "URGO MEDICAL NORTH AMERICA, LLC" WAS FORMED ON THE EIGHTH DAY OF SEPTEMBER, A.D. 2010.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

4869239 8300

SR# 20243107721

Authentication: 203897688

Date: 07-10-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/medical-device-manufacturers-distributors**.
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

URGO MEDICAL NORTH AMERICA LLC
100 LEXINGTON ST STE 400
FORT WORTH TX 76102

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

URGO MEDICAL NORTH AMERICA LLC

100 LEXINGTON ST STE 400
FORT WORTH, TX 76102

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

DEVICE MANUFACTURER

License # 1002375
Expires: January 4, 2027

NON-TRANSFERABLE

Commissioner

514853

Client#: 817153 URGOMEDIC

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 01/07/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer any rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Brenda K. Shepherd, CISR	
Marsh & McLennan Agency LLC 1600 West Seventh St., Ste. 300 Fort Worth, TX 76102	PHONE (A/C, No, Ext): 817 336-3030	FAX (A/C, No):
	E-MAIL ADDRESS: brenda.shepherd@MarshMMA.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED Urgo Medical North America, LLC 100 Lexington Street, Suite #400 Fort Worth, TX 76102	INSURER B : Great Northern Insurance Company	20303
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY			35948163WCU	12/31/2024	12/31/2025	EACH OCCURRENCE	$1,000,000
	CLAIMS-MADE X OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$1,000,000
							MED EXP (Any one person)	$5,000
							PERSONAL & ADV INJURY	$1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$2,000,000
	X POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$0
	OTHER:							$
B	AUTOMOBILE LIABILITY			24735665349	12/31/2024	12/31/2025	COMBINED SINGLE LIMIT (Ea accident)	$1,000,000
	ANY AUTO						BODILY INJURY (Per person)	$
	OWNED AUTOS ONLY / SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	X HIRED AUTOS ONLY / X NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
A	X UMBRELLA LIAB X OCCUR			79880873	12/31/2024	12/31/2025	EACH OCCURRENCE	$5,000,000
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$5,000,000
	DED RETENTION $							$
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? Y/N: N (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below	N/A		2471744844	12/31/2024	12/31/2025	X PER STATUTE / OTH-ER	
							E.L. EACH ACCIDENT	$1,000,000
							E.L. DISEASE - EA EMPLOYEE	$1,000,000
							E.L. DISEASE - POLICY LIMIT	$1,000,000
A	Products Liability			99486363	12/31/2024	12/31/2025	$5,000,000 Aggregate $5,000,000 Each Occ. $1,000 BI/PD	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Extended General Liability Including Human Clinical Trials For Life Sciences - 80022056 11/09
Extended Products Completed Operations Liability (Including Human Clinical Trials Claims Made For Life Sciences - 80022085 11/09
Commercial Automobile Broad Form Endorsement - 16020292 11/16
Waiver Of Our Right To Recover From others - WC000313 04/84
(See Attached Descriptions)

CERTIFICATE HOLDER

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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DESCRIPTIONS (Continued from Page 1)

Blanket Additional Insured status for the General Liability, Products Liability and Automobile Liability coverage is provided to the certificate holder per written contract by the attached forms 80022056, 80022085 11/09 and 16020292 11/16.

Blanket Waiver Of Subrogation status for the General Liability, Products Liability, Automobile Liability and Workers Compensation coverage is provided to the certificate holder per written contract by the attached forms 80022056 11/09, 80022085 11/09, 16020292 11/16 and WC000313 04/84.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 100811758

Application/License No. _____

URGO MEDICAL NORTH AMERICA, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 100 LEXINGTON STREET SUITE 400 FORT WORTH, TX, 76102 (Address of Applicant/Principal), as PRINCIPAL, and AMERICAN CONTRACTORS INDEMNITY COMPANY (Surety Company), a corporation organized under the laws of the state of California (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 801 S. Figueroa Street, Suite 700, Los Angeles, CA 90017 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of TWENTY-FIVE THOUSAND DOLLARS ($25,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 10/19/2023 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statue (NRS) 639.515 and Nevada Administrative Code (NAC) 639.5937 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $25,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and NAC 639.5937 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515 and NAC 639.5937. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 26th day of October, 2023.

AMERICAN CONTRACTORS INDEMNITY CO. INCORPORATED SEPT. 25, 1990 CALIFORNIA

APPLICANT/PRINCIPAL

URGO MEDICAL NORTH AMERICA, LLC

Authorized Representative
Michael Steadman

SURETY

AMERICAN CONTRACTORS INDEMNITY COMPANY

Surety Company's Representative

ERIC FAUERBACH, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness
Angela Hostetler

Witness

SIGNED and SEALED in the presence of:

Witness
Taylor Braun

Witness
Emily Murray

EMILY MURRAY
Notary Public, State of South Carolina
My Commission Expires 2/11/2026

Countersigned by:

N/A
Nevada Resident Agent

TOKIO MARINE HCC

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS:

That American Contractors Indemnity Company of the State of California, a California corporation, does hereby appoint,

ERIC FAUERBACH

its true and lawful Attorney-in-Fact, with full authority to execute on its behalf bond number 100811758, issued in the course of its business and to bind the Company thereby, in an amount not to exceed Twenty-five thousand and 00/100 ($25,000.00).

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following resolutions adopted by the Board of Directors of AMERICAN CONTRACTORS INDEMNITY COMPANY at a meeting duly called and held on the 1st day of September, 2011.

"Be it Resolved, that the President, any Vice-President, any Assistant Vice-President, any Secretary or any Assistant Secretary shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements or indemnity and other conditional or obligatory undertakings, including any and all consents for the release of retained percentages and/or final estimates on engineering and construction contracts, and any and all notices and documents canceling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be binding upon the Company as if signed by the President and sealed and effected by the Corporate Secretary.

Be it Resolved, that the signature of any authorized officer and seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signature or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached."

The Attorney-in-Fact named above may be an agent or a broker of the Company. The granting of this Power of Attorney is specific to this bond and does not indicate whether the Attorney-in-Fact is or is not an appointed agent of the Company.

IN WITNESS WHEREOF, American Contractors Indemnity Company has caused its seal to be affixed hereto and executed by its President on this 18th day of April, 2022.

AMERICAN CONTRACTORS INDEMNITY COMPANY

By: _____
Adam S. Pessin, President

A Notary Public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Los Angeles

On this 18th day of April, 2022, before me, Sonia O. Carrejo, a notary public, personally appeared Adam S. Pessin, President of American Contractors Indemnity Company, who proved to me on the basis of satisfactory evidence to be the person whose name is subscribed to the within instrument and acknowledged to me that he executed the same in his authorized capacity, and that by his signature on the instrument the person, or the entity upon behalf of which the person acted, executed the instrument.

I certify under PENALTY OF PERJURY under the laws of the State of CALIFORNIA that the foregoing paragraph is true and correct.

WITNESS my hand and official seal.

Signature _____ (seal)

SONIA O. CARREJO
Notary Public - California
Los Angeles County
Commission # 2398710
My Comm. Expires Apr 23, 2026

I, Kio Lo, Assistant Secretary of American Contractors Indemnity Company, do hereby certify that the Power of Attorney and the resolution adopted by the Board of Directors of said Company as set forth above, are true and correct transcripts thereof and that neither the said Power of Attorney nor the resolution have been revoked and they are now in full force and effect.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the seals of said Companies at Los Angeles, California this 26th day of October, 2023.

Bond No. 100811758
Agency No. 700358

Kio Lo, Assistant Secretary

Visit tmhcc.com/surety for more information

HCCSOZZPOAACIC07/2023

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: Urgo Medical North America LLC — MDEG License # (if applicable): APPLYING

Physical Address: 100 Lexington Street, Suite 400

City: Fort Worth — State: TX — Zip: 76102

Mailing Address (if different from physical address): 100 Lexington Street, Suite 400

City: Fort Worth — State: TX — Zip: 76102

Telephone: 855-888-8273 — Website: www.urgomedical.us

Licensing Company Email: licensing@us.urgo.com

Section 2: Personal Information

First: Allan — Middle: — Last: Couch

Alias(es, nicknames, name changes, etc.): N/A

Date of Birt[redacted] — SSN or ITI[redacted] — Sex: ■ M ☐ F ☐ X

Mailing Address: 100 Lexington Street, Suite 400

City: Fort Worth — State: TX — Zip: 76102

Telephon[redacted] — Email: allan.couch@us.urgo.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		☑
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		☑
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		☑

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		☑
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Missouri - Columbia		08/04-08/08	
Address	City	State	Zip
230 Jesse Hall	Columbia	MO	65211
Diploma/Degree obtained, if any			
BS Biochemistry			
School Name		From - To (MM/YY – MM/YY)	
Fort Zumwalt South High School		09/92-05/96	
Address	City	State	Zip
8050 Mexico Road	St. Peters	MO	63376
Diploma/Degree obtained, if any			
High School			
School Name		From - To (MM/YY – MM/YY)	
Pepperdine University		08/04-08/08	
Address	City	State	Zip
24255 Pacific Coast Hwy	Malibu	CA	90263
Diploma/Degree obtained, if any			
MBA, General Business			
School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2014-Present	[redacted]	McKinney	TX	[redacted]
09/09-05/14		Dallas	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Urgo Medical North America, LLC			04/2019-Present	
Business Address		City	State	Zip
100 Lexington St., Suite 400		Fort Worth	TX	76102
Phone	Title		Number of Employed Hours	
855-888-8273	Vice President of Supply Chain, Manufacturing and Engineering		10,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)	
Enovis (formerly DJO, LLC)			01/2018-12/2019	
Business Address		City	State	Zip
5919 Sea Otter Place, Suite 200		Carlsbad	CA	92010
Phone	Title		Number of Employed Hours	
800.321.9549	SENIOR MANAGER, GLOBAL QUALITY SYSTEMS		2,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)	
Statlab Medical Products			01/2015-12/2018	
Business Address		City	State	Zip
2090 Commerce Drive		McKinney	TX	75069
Phone	Title		Number of Employed Hours	
972-436-1010	Director of Quality and Regulatory Affairs		6,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)	
Verify Inc.			01/2011-12/2015	
Business Address		City	State	Zip
2445 Gateway Dr Ste 160		Irving	TX	75063
Phone	Title		Number of Employed Hours	
(972) 916-2100	DIRECTOR, INTEGRATED PROGRAM TEAM/General Manager		8,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)	
Vehicle Acceptance Corporation			01/2009-12/2011	
Business Address		City	State	Zip
901 Main St Ste 3450		Dallas	TX	75202
Phone	Title		Number of Employed Hours	
(214) 599-9510	DIRECTOR/CHIEF COMPLIANCE OFFICER		4,000	

Description of Duties

See Attached

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Amgen Inc., Thousand Oaks, CA			01/2008-12/2009	
Business Address		City	State	Zip
1 Amgen Center Dr		Thousand Oaks	CA	91320
Phone	Title		Number of Employed Hours	
(805) 447-1000	SPECIALIST, QUALITY CONTROL		2,000	
Description of Duties				
See Attached				

Business Name			From - To (MM/YY – MM/YY)	
Amgen Inc., Thousand Oaks, CA			01/2006-12/2008	
Business Address		City	State	Zip
1 Amgen Center Dr		Thousand Oaks	CA	91320
Phone	Title		Number of Employed Hours	
(805) 447-1000	SENIOR ASSOCIATE PROJECT MANAGEMENT, MEDICAL AFFAIRS		4,000	
Description of Duties				
See Attached				

Business Name			From - To (MM/YY – MM/YY)	
Amgen Inc., Thousand Oaks, CA			01/2003-12/2006	
Business Address		City	State	Zip
1 Amgen Center Dr		Thousand Oaks	CA	91320
Phone	Title		Number of Employed Hours	
(805) 447-1000	MANUFACTURING ASSOCIATE III, PROCESS DEVELOPMENT		6,000	
Description of Duties				
See Attached				

Business Name			From - To (MM/YY – MM/YY)	
VitaGen Inc.			01/2002-12/2003	
Business Address		City	State	Zip
15222 AVENUE OF SCIENCE C		San Diego	CA	92128
Phone	Title		Number of Employed Hours	
(858) 673-6840	MANUFACTURING ASSOCIATE II, MANUFACTURING.		2,000	
Description of Duties				
See Attached				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		☑
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	YES	☐
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		☑

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/24/2006	05/08/2006	CA	Ventura	Ventura

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2006011486	Superior Court of California, County of Ventura

Reason/Charge
23152(b) - Driving when my blood-alcohol level was .08 percent or higher

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
People of the State of California	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

See attached "No Contest" Plea

Original Signature (electronic, copies or stamps not accepted)

3.4.25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/24/2006	05/08/2006	CA	Ventura	Ventura
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2006011486		Superior Court of California, County of Ventura		
Reason/Charge				
23152(b) - Driving when my blood-alcohol level was .08 percent or higher				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
People of the State of California		N/A		
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

See attached "No Contest" Plea

Original Signature (electronic, copies or stamps not accepted)

3.4.25
Date

USE FOR OFFENSES COMM[illegible]ED ON AND AFTER JANUARY 1[illegible]06

SUPERIOR COURT OF CALIFORNIA	For court use only
COUNTY OF VENTURA	
Plaintiff: PEOPLE OF THE STATE OF CALIFORNIA	
Defendant: Allan Taylor Couch	
DUI ADVISEMENT OF RIGHTS, WAIVER, AND PLEA FORM (First Offense Only – Vehicle Code §23152)	CASE NUMBER: 2006011486 / COURTROOM

INSTRUCTIONS

Fill out this form if you wish to plead guilty or no contest to the charges against you. Initial the box for each applicable item only if you understand it, and **sign and date the form on page 4**. If you have any questions about your case, the possible sentence, or the information on this form, ask your attorney or the judge.

	INITIALS
RIGHT TO AN ATTORNEY	
1. I understand that I have the right to be represented by an attorney throughout the proceedings. I understand that the Court will appoint a free attorney for me if I cannot afford to hire one, but at the end of the case, I may be asked to pay all or part of the cost of that attorney, if I can afford to. I understand that there are dangers and disadvantages to giving up my right to an attorney, and that it is almost always unwise to represent myself.	AC
2. I give up my right to an attorney, and I choose to represent myself. (Does not apply if you have an attorney.)	2.
NATURE OF THE CHARGES (Complete all items you are charged with.)	
I understand that I am charged with a violation of Vehicle Code section(s):	
3. **23152(a)** – Driving under the influence of alcohol or drugs, or both.	AC
4. **23152(b)** – Driving when my blood-alcohol level was .08 percent or higher.	AC
5. **23152(d)** – Driving a commercial vehicle when my blood-alcohol level was .04 percent or higher.	5.
6. **23103, 23103.5** – Reckless driving involving alcohol or drugs, or both.	6.
7. **If applicable** – I understand that I am also charged with the following **other offense(s)**: _____ (Type of offense(s) and section number(s))	7.
8. I understand the charge(s) against me, and the possible pleas and defenses.	AC
CONSTITUTIONAL RIGHTS/WAIVER OF RIGHTS	
9. **RIGHT TO A JURY TRIAL** – I understand that I have the right to a speedy, public jury trial. At the trial, I would be presumed innocent, and I could not be convicted unless 12 impartial jurors were convinced of my guilt beyond a reasonable doubt.	AC
10. I give up my right to a jury trial.	AC
11. **RIGHT TO CONFRONT WITNESSES** – I understand that I have the right to confront and cross-examine all witnesses testifying against me.	AC
12. I give up my right to confront and cross-examine witnesses.	AC

CONSTITUTIONAL RIGHTS/WAIVER OF RIGHTS (Continued)

INITIALS↓

13. **RIGHT AGAINST SELF-INCRIMINATION** – I understand that I have the right to remain silent and not incriminate myself, and the right to testify on my own behalf. I understand that by pleading guilty or no contest, I am incriminating myself. ..... 13. [redacted] Ac

14. I give up my right to remain silent and not to incriminate myself. ..... 14. [redacted] Ac

15. **RIGHT TO PRODUCE EVIDENCE** – I understand that I have the right to present evidence and to have the Court issue subpoenas to bring into court all witnesses and evidence favorable to me, at no cost to me. ..... 15. [redacted] Ac

16. I give up my right to produce evidence and witnesses on my own behalf. ..... 16. [redacted] Ac

SENTENCES FOR DRIVING UNDER THE INFLUENCE OF ALCOHOL AND/OR DRUGS (SECTION 23152)

Offense	Minimum and Maximum Sentences when Probation Is Granted (3 to 5 Years Probation Term)	Minimum and Maximum Sentences without Probation
First Offense Within 10 years	The Court may order me to serve between 48 hours to 6 months in jail. It will impose a fine of $390 to $1,000 and order me to complete a 3-month alcohol/drug treatment program (or a 9 month program if my blood-alcohol content was .20 percent or more, or if I refused a chemical test upon my arrest). The DMV will also impose a 6-month driver's license suspension.	96 hours to 6 months in jail, and a $390 to $1,000 fine. The DMV will also impose a 6-month driver's license suspension.
Second Offense Within 10 years	A jail term of either: (a) 10 days to 1 year, or (b) 96 hours to 1 year, a $390 to $1,000 fine, and completion of an 18-month (or 30-month) alcohol/drug treatment program. The DMV will also impose a 2-year driver's license suspension.	90 days to 1 year in jail, and a $390 to $1,000 fine. The DMV will also impose a 2-year driver's license suspension.

SENTENCES FOR RECKLESS DRIVING (Sections 23103, 23103.5)

Offense		Minimum and Maximum Sentences	Other consequences
Reckless driving Reduced from driving under the influence (DUI)	If probation is granted	A maximum of 90 days in jail, or $1,000 fine, or both, plus attendance at treatment program.	If alcohol or drugs are involved, this conviction will act as a separate DUI conviction if I commit a subsequent DUI offense within 10 years.
	If probation is **not** granted	5 days to 90 days in jail, or $145 to $1,000 fine, or both.	

CONSEQUENCES OF PLEA OF GUILTY OR NO CONTEST

INITIALS↓

17. I have read and understood the above charts which list the minimum and maximum penalties for the offense(s) I am charged with. (See item No.32 for the offenses not listed in the charts.) ..... 17. [redacted] Ac

18. I understand that in addition to the fine, **the Court will add assessments, which will significantly increase the amount I must pay.** I will also be ordered to make restitution and to pay a restitution fine of $100 to $1,000 unless the Court finds compelling and extraordinary reasons not to do so. ..... 18. [redacted] Ac

19. **If applicable** – I understand that if I was **under the age of 21** at the time of my arrest, my driver's license will also be suspended for 1 year, and I must surrender my license to the Court. If I do not have a valid driver's license, the Court will order the DMV to delay issuing a license to me for 1 year after I become eligible to drive. ..... 19. [redacted] Ac

20. I understand that being under the influence of alcohol or drugs, or both, impairs my ability to safely operate a motor vehicle. Therefore, it is extremely dangerous to human life to drive while under the influence of alcohol or drugs, or both. If I continue to drive while under the influence of alcohol or drugs, or both, and as a result of my driving, someone is killed, I can be charged with murder. ..... 20. [redacted] Ac

21. I understand that the Court may order my vehicle impounded at my expense for up to 30 days. It may also require me to install an ignition interlock device (IID) for up to three years. Installation of this device, which prevents the vehicle from starting if I have alcohol in my body, does not authorize me to drive without a valid license. ..... 21. [redacted] Ac

CONSEQUENCES OF PLEA OF GUILTY OR NO CONTEST (Continued)

INITIALS

22. I understand that if the Court determines that I would present a traffic safety or public safety risk if I am authorized to drive during the license suspension period, I will be unable to obtain a restricted driver's license from the DMV, which would allow me to drive to and from work, and to and from the alcohol/drug treatment program. ..... 22 AC

23. I understand that the DMV may suspend my driver's license under a civil procedure, which is separate from this criminal action. I understand that the DMV's action, if any, will be in addition to the Court's sentence and that I must obey it. ..... 23 AC

24. I understand that the DMV will prohibit me from operating a **commercial** vehicle for one year if I am convicted of a first DUI violation, or willfully refused to submit to or complete a chemical test to determine my blood-alcohol level, which occurred in **any** vehicle. ..... 24 AC

25. I understand that the DMV will revoke my driver's license for a period of 4 years if I have a prior **felony** conviction in the past 10 years of Vehicle Code § 23152 or 23153, or Penal Code § 191.5, 192(c)(1) or 192(c)(3). ..... 25 AC

26. I understand that proof of my successful completion of an alcohol/drug program must be received at DMV headquarters in order for me to have my driving privilege reinstated, **even if I am not ordered to attend such a program by the court**. I also understand that I must surrender my license to the court. ..... 26 AC

27. I understand that the DMV will not restore my driving privilege following a driver's license suspension unless I provide the DMV with **proof of insurance** for 3 years. ..... 27 AC

28. I understand that the DMV may consider any of my other convictions for DUI or reckless driving, **even those that are not charged in the proceeding**, and may impose a more severe driver's license suspension, or revocation as a result. ..... 28 AC

29. I understand that if I am not a citizen, a plea of guilty or no contest could result in my deportation, exclusion from admission to this country, or denial of naturalization. ..... 29 AC

30. I understand that a plea of no contest (*nolo contendere*) will have exactly the same effect in this case as a plea of guilty, but it cannot be used against me in a civil lawsuit. ..... 30 AC

31. I understand that any pleas entered in this case may be grounds for revoking probation or parole, which has previously been granted to me in any other case. ..... 31 AC

PENALTIES FOR OTHER CHARGES

32. **If applicable** - I understand that the possible consequences for the offense(s) charged, which are not listed on the penalty charts on page 2, include the following:

SECTION NUMBER	JAIL – MIN.	MAX.	FINE – MIN.	MAX.
OTHER CONSEQUENCES:				
SECTION NUMBER	JAIL – MIN.	MAX.	FINE – MIN.	MAX.
OTHER CONSEQUENCES:				
SECTION NUMBER	JAIL – MIN.	MAX.	FINE – MIN.	MAX.
OTHER CONSEQUENCES:				

32

Continued on reverse

PLEA(S)

INITIALS

33. I hereby freely and voluntarily plead No Contest to: (GUILTY OR NO CONTEST)
VC § 23152(b) - Count 2 (LIST CHARGE(S)) 33 AC

34. I understand that I have the right to a delay of from 6 hours to 5 days prior to being sentenced. I give up this right and agree to be sentenced at this time. 34 AC

35. **If applicable-** I understand that I have the right to enter my plea before, and to be sentenced by, a judge. I give up this right and agree to enter my pleas before, and to be sentenced by: 35 AC

TEMPORARY JUDGE'S NAME

X DEFENDANT'S SIGNATURE [signature] X DATE 5/5/06

ATTORNEY'S STATEMENT

I am the attorney of record for the defendant. I have reviewed the form and any addenda with my client. I have explained each of the defendant's rights to the defendant and answered all of the defendant's questions with regard to this plea. I have also discussed the facts of the defendant's case with the defendant, and explained the consequences of this plea, the elements of the offense(s), and the possible defenses. I concur in this plea and in the defendant's decision to waive his or her constitutional rights.

[signature] 5/5/06

SIGNATURE OF DEFENDANT'S ATTORNEY DATE

INTERPRETER'S STATEMENT (if applicable)

I having been sworn or having a written oath on file, certify that I truly translated this form to the defendant in the language indicated below. The defendant stated that (s)he understood the contents of the form, and then (s)he initialed and signed the form. Language: ☐ Spanish ☐ Other (specify):

COURT INTERPRETER'S SIGNATURE TYPE OR PRINT NAME DATE

COURT'S FINDINGS AND ORDER

The Court, having reviewed this form and any addenda, and having questioned the defendant concerning the defendant's constitutional rights, finds that the defendant has expressly, knowingly, understandingly, and intelligently waived his or her constitutional rights. The Court finds that the defendant's pleas is freely and voluntarily made with an understanding of the nature and consequences thereof, and that there is a factual basis for the plea. The Court accepts the defendant's plea and orders this form filed and incorporated in the docket by reference as though fully set forth therein.

☐ Judge of the Superior Court
☐ Temporary Judge of the Superior Court

Date

I, Allan Couch, **certify that as the MDEG Administrator for**

Urgo Medical North America, LLC,

that I (initial that you have read and meet the following requirements):

1. AC Have a high school diploma or its equivalent;
2. AC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. AC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. AC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Allan Couch
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3.4.25
Date

Board Use Only	Date Received:

ALLAN TAYLOR COUCH

Vice President, Senior Executive / Manufacturing / Quality / Regulatory Affairs / R and D

[redacted]

SUMMARY

- **Implemented ISO 13485, 21 CFR 820 compliant Quality Management Systems at multiple companies achieving certification to ISO 13485 + MDSAP**
- **Directed certification body registering clients to ISO 9001, AS9100 and ISO 14001 - included oversight of both internal and certification audits as an Exemplar Global certified ISO 9001 Lead Auditor**
- **Directed account management team delivering supplier performance management services - QMS audits, source inspection and supplier development**
- **As General Manager and head of Business Development responsible for top line growth and profit/loss for $13.5M portfolio - achieved 52% growth in 2 1/2 years**
- **FDA/EMEA audit representation**
- **Directed Research and Development and Engineering execution activities for novel equipment base process**
- **Initiated process improvement and optimized execution to facilitate increased unit demand because of significant product growth**
- **Led comprehensive upgrade of clinical manufacturing facility including clean room characterization and validation design ensuring compliance (GMP, CFR)**
- **Validated equipment and sterilization processes as part of facility upgrades and ongoing new equipment/process introductions**
- **Defended multiple program development initiatives providing cost/benefit analysis for asset acquisition and resource commitments**

PROFESSIONAL EXPERIENCE

Urgo Medical North America **2019-Present**

VICE PRESIDENT, QUALITY AND REGULATORY AFFAIRS. Lead the organizations Quality and Regulatory Affairs functions as well as expanded oversight of Manufacturing, Engineering, Training and Research and Development functions.

- Lead the organization in successfully achieving certification to ISO 13485:2016 + MDSAP and ensured compliance with 21 CFR Part 820 and 21 CFR Part 211 regulatory requirements for combination products
- Guided contract manufacturer execution for organization providing engineering and manufacturing oversight of organization proprietary production processes
- Acted as Manufacturing Operations officer in leading advancement efforts across multiple product lines
- Launched and lead R and D activities for the organization
- Ensured access to Health Canada market and guided the organization through multiple manufacturing challenges ensuring continued patient access for key products
- Mentored staff in Customer Service, Supply Chain and Human Resources functions to ensure compliance with regulations

Prior: Director of Quality and Regulatory Affairs, Senior Director of Quality and Regulatory Affairs

DJO Global **2018-2019**

SENIOR MANAGER, GLOBAL QUALITY SYSTEMS. Ensures successful integration, maintenance, and continuous improvement of the Quality System's global Complaint, CAPA, and Data Analytics processes in a customer-centric manner. Interact directly with both external and internal auditors as the Subject Matter expert and ensure that the company's global complaint, CAPA, and data analytics process maintains compliance with internal and external standards and regulations. Lead and develop staff that perform complaint investigation, CAPA

maintenance, and data analytics as well as takes an active role in non-product software validations and assessing IT changes impacting business systems/software.

- Contribute to the development and optimization of operational policies and procedures that affect personnel within the assigned organizational unit and cross functional affected areas.
- Monitor daily work operations and provide direction and guidance to staff to achieve unit or project goals. Interact with internal and external customers, by meeting regularly, responding to requests and explaining procedures.
- Use data driven business cases for project and resource justifications. Optimize workflow processes for quality system CAPAs and Complaints.
- Ensure compliance with company policies and procedures (e.g., compliance with FDA and applicable international regulations etc.).
- Act as Subject Matter Expert in CAPA, complaints, data analytics, and support internal and external audits within the area.
- Provide input to Quality Management Review and supporting processes.
- This position supports the integration and harmonization of sites processes and serves as the Agile PC system business owner.
- This position has expanded global responsibilities working with multiple locations to develop, implement, continually improve, and maintain a comprehensive CAPA, Complaint, and Data Analytics system

StatLab Medical Products **2015-2018**

DIRECTOR OF QUALITY AND REGULATORY AFFAIRS. Directs the execution of the StatLab Quality Management System and ensures regulatory compliance for StatLab Medical Products.

- Lead the development, implementation, and monitoring of the quality system to meet ISO 13485 and 21 CFR Part 820 regulatory requirements and organizational goals achieving registrar certification to ISO 13485.
- Analyze operations data to identify areas of non-conformance or opportunities for improvement, develop inspection programs to ensure materials meet customer and organizational specifications
- Manage root cause analysis, and facilitate corrective and preventive action program to resolve product and process defects efficiently and effectively.
- Manage Quality Control laboratory operations including implementation of automated Epicor administered quality control release testing.
- Designed and implemented incoming inspection practices, internal audit program, calibration program and management review activities.
- Responsible for all environmental quality regulatory obligations for firm.

Verify Inc., Irving, TX **2011-2015**

DIRECTOR, INTEGRATED PROGRAM TEAM. Oversee operations and business development activities for portfolio of aerospace and defense accounts in execution of quality management services.

- Managed operations and sales for inspection, audit, and supplier performance.
- Increased revenue in three years from $9 Million to $13.5 Million.
- Improved operating profit by $1.5 Million.

The Registrar Company, Richardson, TX (Verify, Inc.)

GENERAL MANAGER. Planned and directed the organization's operations, objectives, and initiatives. Managed organization's certification program and performed oversight of the Quality Management System. Developed new business development initiatives including corporate image revitalization, sales material development and new website launch.

- Redesigned marketing platform which increased sales 10% to $400,000.
- Developed financial plan and led corporate divestiture through due diligence to sale.
- Managed post sale transition including benefits package and insurance selection for acquirer.

Vehicle Acceptance Corporation, Dallas, TX **2009 – 2011**

DIRECTOR/CHIEF COMPLIANCE OFFICER. Generated new sales leads, managed account inception, and advanced strategic partnership development initiatives. In the role of Chief Compliance Officer, established operating policies and procedures, to ensure branch compliance with multiple regulations.

- Designed the business compliance program, training of employees to meet FCRA, OFAC, GLB, and identity theft regulations to protect customers.
- Revamped marketing platform and implemented contractor sales force that grew YOY sales by 300%.
- Improved positioning and market share via revitalized sales/marketing strategy.

Amgen Inc., Thousand Oaks, CA **2003 – 2009**

SPECIALIST, QUALITY CONTROL (2008-2009). Led execution of regulatory inspections and audits by presenting quality program data, defending facility programs, conducting investigations, and collaborating on formal audit responses. System owner and subject matter expert for clinical manufacturing's Environmental and Utility Monitoring Program ensuring full compliance with multiple regulatory agencies and with standard regulations across more than five operational buildings.

- Initiated and led five plant program to reduce clean room contamination incidents saving $300,000 per year.
- Managed company response to regulatory audits of manufacturing quality. Gained approval of practices, despite vague rules and regulators contentions.
- Reengineered receiving and dispensing activates to meet ISO-compliant clean room requirements aligning operations with EMEA requirements.

SENIOR ASSOCIATE PROJECT MANAGEMENT, MEDICAL AFFAIRS (2006-2008). Planned and administered budget aligning technology tool generation/deployment, resource planning, and strategic operational decision-making across the functional area. Managed all phases of various project lifecycles including development and maintenance of capacity models, maintenance of project timelines, and development, tracking, analysis and reporting of functional metrics.

- Planned and administered annual $12 Million budget.
- Led project management of a web-based e-Learning tool and cross-functional business practice.
- Improved compliance and budget monitoring by developing tracking tools on an Access platform.

MANUFACTURING ASSOCIATE III, PROCESS DEVELOPMENT (2003-2006). Led NC/CAPA investigations and change control for cell bank operations. Directed all work order facilitation, compliance assessments, and IQ/OQ/PQ validation for cell bank equipment. Directed the project lifecycle for the cell bank storage stability monitoring program and acted as section writer for IND and BLA submissions for multiple molecules.

- Designed the department's NC/CAPA program including formal report writing and quality data trending.
- Designed and implemented cell bank stability monitoring during storage including assay design, technical report generation, and data trending.
- Directed all maintenance, compliance assessments, and IQ/OQ/PQ validation execution.
- Led submission of division's manufacturing process in FDA approval filings.

VitaGen Inc., San Diego, CA **2002 – 2003**

MANUFACTURING ASSOCIATE II, MANUFACTURING. Maximized the operational effectiveness of the production process supporting the development of the Extracorporeal Liver Assist Device (ELAD®), a state-of-the-art artificial liver device. Enhanced process performance by conducting cell culture assays to analyze cell growth as well as used automated bioreactor units to monitor/operate dynamic cell expansion activities. Composed a variety of critical documents including standard operating procedures, change control documents, research/engineering protocols, final research reports, and validation documents.

- Conducted cell culture assays to analyze cell growth to process only best lots improving yield by 10%.
- Designed new sterilization cycles including validation, saving $500,000.

EDUCATION

MBA, General Business, Pepperdine University, Graziadio School of Business and Management

BS, Biochemistry, University of Missouri-Columbia

CERTIFICATION AND COMPETENCIES

Root cause analysis, corrective and preventive action design, change management
Exemplar Global Certified ISO 9001 Lead Auditor –Certificate #114578
Advanced Excel, Project, Word, PowerPoint, Access, Visio and Outlook
Drug manufacturing regulations - FDA, EMEA, USP, EU, ISO, MDR, cGMP and CFR
Certification standards - ISO 9001, 14001, AS9100 and AS9003

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Urgo Medical North America LLC

Pharmacy/Wholesaler License # (if applicable): APPLYING

Physical Address: 100 Lexington Street, Suite 400

City: Fort Worth State: TX Zip: 76102

Mailing Address (if different from physical address): 100 Lexington Street, Suite 400

City: Fort Worth State: TX Zip: 76102

Telephone: 855-888-8273 Website: www.urgomedical.us

Licensing Company Email: licensing@us.urgo.com

Section 2: Personal Information

First: Allan Middle: Last: Couch

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: 100 Lexington Street, Suite 400

City: Fort Worth State: TX Zip: 76102

Telephone: [redacted] Email: licensing@us.urgo.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		☑
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		☑
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		☑

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		☑
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Missouri - Columbia			09/96-05/01	
Address		City	State	Zip
230 Jesse Hall		Columbia	MO	65211
Diploma/Degree obtained, if any				
BS, Biochemistry				
School Name			From - To (MM/YY – MM/YY)	
Fort Zumwalt South High School			9/92-05-96	
Address		City	State	Zip
8050 Mexico Road		St. Peters	MO	63376
Diploma/Degree obtained, if any				
High School				
School Name			From - To (MM/YY – MM/YY)	
Pepperdine University			08/04-08/08	
Address		City	State	Zip
24255 Pacific Coast Hwy		Malibu	CA	90263
Diploma/Degree obtained, if any				
MBA, General Business				
School Name			From - To (MM/YY – MM/YY)	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
N/A				
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2014-Present	[redacted]	McKinney	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
09/09/-05/14		Dallas	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Urgo Medical North America, LLC			04/2019- Present
Business Address	**City**	**State**	**Zip**
100 Lexington St., Suite 400	Fort Worth	TX	76102
Phone	**Title**	**Number of Employed Hours**	
855-888-8273	Vice President of Supply, Manufacturing and Engineering	10,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
Enovis (formerly DJO, LLC)			01/2018-12/2019
Business Address	**City**	**State**	**Zip**
5919 Sea Otter Place, Suite 200	Carlsbad	CA	92010
Phone	**Title**	**Number of Employed Hours**	
800.321.9549	SENIOR MANAGER, GLOBAL QUALITY SYSTEMS	2,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
Statlab Medical Products			01/2015-12/2018
Business Address	**City**	**State**	**Zip**
2090 Commerce Drive	McKinney	TX	75069
Phone	**Title**	**Number of Employed Hours**	
972-436-1010	Director of Quality and Regulatory Affairs	6,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
Verify Inc.			01/2011-12/2015
Business Address	**City**	**State**	**Zip**
2445 Gateway Dr Ste 160	Irving	TX	75063
Phone	**Title**	**Number of Employed Hours**	
(972) 916-2100	DIRECTOR, INTEGRATED PROGRAM TEAM/General Manager	8,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
Vehicle Acceptance Corporation			01/2009-12/2011
Business Address	**City**	**State**	**Zip**
901 Main St Ste 3450	Dallas	TX	75202
Phone	**Title**	**Number of Employed Hours**	
(214) 599-9510	DIRECTOR/CHIEF COMPLIANCE OFFICER	4,000	

Description of Duties

See Attached

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Amgen Inc., Thousand Oaks, CA			01/2008-12/2009
Business Address	**City**	**State**	**Zip**
1 Amgen Center Dr	Thousand Oaks	CA	91320
Phone	**Title**	**Number of Employed Hours**	
(805) 447-1000	SPECIALIST, QUALITY CONTROL	2,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
Amgen, Inc			01/2006-12/2008
Business Address	**City**	**State**	**Zip**
1 Amgen Center Dr	Thousand Oaks	CA	91320
Phone	**Title**	**Number of Employed Hours**	
(805) 447-1000	SENIOR ASSOCIATE PROJECT MANAGEMENT. MEDICAL AFFAIRS	4,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
Amgen, Inc.			01/2003-12/2006
Business Address	**City**	**State**	**Zip**
1 Amgen Center Dr	Thousand Oaks	CA	91320
Phone	**Title**	**Number of Employed Hours**	
(805) 447-1000	MANUFACTURING ASSOCIATE III, PROCESS DEVELOPMENT	6,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
VitaGen Inc.			01/2002-12/2003
Business Address	**City**	**State**	**Zip**
15222 AVENUE OF SCIENCE C	San Diego	CA	92128
Phone	**Title**	**Number of Employed Hours**	
(858) 673-6840	MANUFACTURING ASSOCIATE II, MANUFACTURING.	2,000	

Description of Duties

See Attached

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	YES	☐
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		NO
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		☑
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		☑
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		☑
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		☑
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		☑
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		☑
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		☑
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		☑

I, Allan Couch, **certify that as the designated representative for**

Urgo Medical North America LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AC I am at least 21 years of age;
3. AC I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AC I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AC I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AC I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AC I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Allan Couch

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3.4.25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Allan Couch

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3.4.25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Tarrant

I, Allan Couch, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3.4.25

Date

Subscribed and Sworn to before me this 4th day of March 2025

Elizabeth Gray

Notary Public Signature

ELIZABETH GRAY
Notary Public, State of Texas
Comm. Expires 02-21-2026
Notary ID 125131418

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Urgo Medical North America

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 100 Lexington Street, Suite 400

City: Fort Worth State: TX Zip: 76102

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 855-888-8273 N/A Website: www.urgomedical.us.

Licensing Company Email: licensing@us.urgo.com

Section 2: Personal Information

First: Michael Middle: _____ Last: Steadman

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: 100 Lexington Street, Suite 400

City: Fort Worth State: TX Zip: 76102

Telephone: [redacted] Email: licensing@us.urgo.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Eastern Illinois University		1983-1987	
Address	**City**	**State**	**Zip**
600 Lincoln Av	Charleston	IL	61920
Diploma/Degree obtained, if any			
BA, Marketing			

School Name		From - To (MM/YY – MM/YY)	
Hindsdale South High School		~~1979-1983~~ 1976- 1980 ok	
Address	**City**	**State**	**Zip**
7401 Clarendon Hills Rd.	Darien	IL	60561
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/18 - Current	[redacted]	Fort Worth	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/12-12/18		Fort Worth	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Urgo Medical North America			12/23 - Current	
Business Address		**City**	**State**	**Zip**
100 Lexington Street, Suite 400		Fort Worth	TX	76102
Phone	**Title**			
817.885.8273	CEO			

Description of Duties

- Created and built SteadMed Medical from concept to business in 2010/2011.
- Report to the Board of Directors of SteadMed Medical, a $15 million medical device company.

Business Name			From - To (MM/YY – MM/YY)	
Urgo Medical North America			07/18-01/23	
Business Address		**City**	**State**	**Zip**
3909 Hulen Street, Suite 251		Fort Worth	TX	76107
Phone	**Title**			
817.885.8273	CEO			

Description of Duties

- Created and built SteadMed Medical from concept to business in 2010/2011.
- Report to the Board of Directors of SteadMed Medical, a $15 million medical device company.

Business Name			From - To (MM/YY – MM/YY)	
SteadMed Medical			01/13-07/18	
Business Address		**City**	**State**	**Zip**
3909 Hulen Street, Suite 251		Fort Worth	TX	76107
Phone	**Title**			
817.885.8273	CEO			

Description of Duties

- Created and built SteadMed Medical from concept to business in 2010/2011.
- Report to the Board of Directors of SteadMed Medical, a $15 million medical device company.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Steadman

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Tarrant

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/2/2025

Date

Subscribed and Sworn to before me this 2nd day of April 2025.

Notary Public Signature

YVONNE Y. RODRIGUEZ
Notary Public, State of Texas
Comm. Expires 09-20-2025
Notary ID 129470080

(Seal)

Urgo Medical North America, LLC – Employee List

FirstName	LastName
Felipe	Acencio
Carla	Allison
Dario	Aluisi
Connor	Anderson
James	Atkins
Alana	Ausiejus
Alexander	Baker
Richard	Baldwin III
Bret	Barrie
Marisol	Barrientos
David	Bates
Andrew	Blood
Ryder	Bohlander
Mark	Bosquez
Erika	Breau
Patrick	Breen
Jon	Brlas
Daniel	Bronsweig
Leigh	Brown
Donna	Bruno
Kerry	Byrd
Gary	Cali
Abigail	Cantwell
Charity	Carrington
Jennette	Cascio
Kaylee	Cassidy
Melissa	Cavadas
Luis	Cavazos
Deschamps	Celine
Debashish	Chakravarthy
Robert	Chaplin
David	Chris
Cobi	Clark
Traci	Clift
Lexi	Colasanto
Stephanie	Corliss
Allan	Couch
Graham	Cowieson
Lauren	Craven

FirstName	LastName
Blane	Crowder
Patrick	Culberson
Gerald	Curtis
Cody	Daniels
Nicholas	Davisson
Norma	Delgado
Dieretou	Dia
Steven	Dowdley
Jim	Dubinski
Jacob	Duncan
William	Dyjak
Ed	Eckert III
Jason	Evans
Mark	Fancher
Noah	Fancher
Ted	Ford
Vickie	Freitas
Masaki	Fujishima
Donna	Ganey
Benoit	Giraud
Bryan	Glennie
Melea	Goolsby
Molly	Gordon
Audrey	Gordon
Elizabeth	Gray
Misty	Greenwood
Ieva	Griciute
Jordi	Guillen Gutierrez
Suzanne	Guilteaux
Elizabeth	Halicki
Josh	Haymaker
Jay	Heitz
Donna	Hekkenberg
Trey	Hendricks
Kassi	Hinds
Joseph	Hodges
Rachel	Hodges
Rylee	Holley
Mike	Holm
Renee	Hunkle

FirstName	LastName
Hannah	Hunter
Britt	Ingebritson
Greg	Jackson
Lauren	Johnson
James	Johnson
Amy	Johnson
Katie	Jordan
Stefany	Juarez
Gerry	Keith
Rio	Kesslar
Kim	Knotts
Courtney	Lacey
Megan	Lambert
Pierre	Langlois
Corey	Laskey
Sarah	Lattie
Maria	Lecuna
Anna	Letsche
Laurie	Lilly
Sara	Lowis
Tammy	Lutzke
Spencer	Majerik
Jean	Mande
Samantha	Martin
Jodi	Martindale
Aaron	Mattice
Karissa	McDonald
Angela	McIntyre
Sean	McKigney
Phil	McKinney
Jessica	Montgomery
Jenna	Moore
Courtney	Morse
Chad	Mouledous
Derek	Murphy
Mark	Nakamura
Hilary	Nash
Taylor	Naughton
Nathan	Navigato
Jill	Neaves

FirstName	LastName
Ashley	Neiderer
Tyler	Nichols
Griselda	Nunez
Caitlin	Ohlemacher
Brian	Ondreyka
Anthony	Palagi
Svetlana	Panicheva
Jill	Payne
Caroline	Pearce
Eric	Pearce
Gregory	Peck
Gabriela	Perez
Patricia	Pescatore
Anna	Phifer
Joel	Pickering
Brooke	Polk
Audrey	Prewitt-Campbell
Krystal	Price
Larry	Rabalais
Crystal	Rader
Kathleen	Raiche
Allyson	Ramer
Scott	Randolph
Mira	Rao
Michael	Rapagnani
Samantha	Rivera
Britny	Robinson
Yvonne	Rodriguez
Chris	Romanyszyn
Keith	Romero
Kate	Rostad
Jaclyn	Schultzel
Svenja	Schulze
Kyle	Schwetz
Collin	Sharp
Spencer	Shore
Matt	Siddall
Rona	Smith
Kenzie	Smith
Michelle	Spiewak

FirstName	LastName
Annie	St. Hilaire
Michael	Steadman
Mark	Stehman
Morgan	Sullivan
Ryan	Sullivan
Chris	Summons
Emma	Taigounov
Joe	Tatta
Brendan	Thomas
Chad	Thornton
Kevin	Tran
Nicholas	Troiani
Justin	Tubbs
Kylie	Vaughan
Eli	Walker
Hannah	Wall
Danielle	Wallace
Kara	Weier
Lauren	Weingartner
Matthew	Weiss
Sarah	Welsh
Andy	Wheeler
David	Whitmore
Thomas	Wigniolle
Travis	Williams
Eric	Winters
Makensie	Wood
Anna	Yeager
Jordan	Zacharia
Michael	Zajac

State of Delaware
Secretary of State
Division of Corporations
Delivered 12:15 PM 09/08/2010
FILED 12:13 PM 09/08/2010
SRV 100890835 - 4869239 FILE

CERTIFICATE OF FORMATION

OF

STEADMED MEDICAL, LLC

This Certificate of Formation ("Certificate") of SteadMed Medical, LLC (the "Company") is being duly executed and filed by the undersigned, as an authorized person, to form a limited liability company under the Delaware Limited Liability Company Act (6 Del.C. § 18-101, et seq.).

1. The name of the Company hereby formed is "SteadMed Medical, LLC".

2. The address of the registered office of the Company in the State of Delaware is Capitol Services, Inc., 615 South Dupont Hwy, Dover, Delaware 19901.

3. The name and address of the registered agent for service of process on the Company in the State of Delaware are Capitol Services, Inc., 615 South Dupont Hwy, Dover, Delaware 19901.

IN WITNESS WHEREOF, the undersigned has executed this Certificate of Formation as of September 8, 2010.

Calvin M. Jackson, Authorized Person

1165581_1.DOC

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:36 AM 05/29/2019
FILED 11:36 AM 05/29/2019
SR 20194742916 - File Number 4869239

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT

1. Name of Limited Liability Company: SteadMed Medical, LLC

2. The Certificate of Formation of the limited liability company is hereby amended as follows:

1. The name of the Company hereby formed is "Urgo Medical North America, LLC."

IN WITNESS WHEREOF, the undersigned have executed this Certificate on the 29th day of May, A.D. 2019.

By: _____
Authorized Person(s)

Name: Michael E. Steadman
Print or Type

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY THE ATTACHED IS A TRUE AND CORRECT COPY OF THE CERTIFICATE OF AMENDMENT OF "STEADMED MEDICAL, LLC", CHANGING ITS NAME FROM "STEADMED MEDICAL, LLC" TO "URGO MEDICAL NORTH AMERICA, LLC", FILED IN THIS OFFICE ON THE TWENTY-NINTH DAY OF MAY, A.D. 2019, AT 11:36 O`CLOCK A.M.

Jeffrey W. Bullock, Secretary of State

4869239 8100
SR# 20194742916

Authentication: 202945482
Date: 06-03-19

You may verify this certificate online at corp.delaware.gov/authver.shtml

State of Delaware
Secretary of State
Division of Corporations
Delivered 11:36 AM 05/29/2019
FILED 11:36 AM 05/29/2019
SR 20194742916 - File Number 4869239

STATE OF DELAWARE
CERTIFICATE OF AMENDMENT

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IN WITNESS WHEREOF, the undersigned have executed this Certificate on the 29th day of May, A.D. 2019.

By: _____
Authorized Person(s)

Name: Michael E. Steadman
Print or Type

4UU

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☒ Nevada ☐ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☒ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH WH02670	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☒ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Secura Bio

Physical Address: 1995 Village Center Cir. Suite 128

City: Las Vegas State: NV Zip: 89134

Mailing Address (if different from physical address): 1995 Village Center Cir. Suite 128

City: Las Vegas, State: NV Zip: 89134-6360

Telephone: 858-251-1414 Website: www.securabio.com

Name of Designated Representative (DR): William Brown

Licensing Company Email: Skurzeja@securabio.com DR Email: wbrown@securabio.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☒ Pharmacies	☒ Dangerous Drugs	☒ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☒ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		x
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		x
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		x
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		x
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		x

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See attached description of operations

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Secura Bio Holdings

Corporation/Organization Name: Secura Bio, Inc.

Mailing Address: 1995 Village Center Cir. Suite 128

City: Las Vegas, State: NV Zip: 89134-6360

Telephone: 858-251-1414 Email: wbrown@securabio.com

Contact Person Name: William Brown

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Secura Bio

Facility Name

William Brown

Print Name of Authorized Person Submitting Application

William Brown

Original signature of Authorized Person (copies or stamps not accepted)

April 17, 2025

Date

Board Use Only	Date Received: _____ Amount: _____

An official website of the United States government Here's how you know

FDA

Home ▶ Drug Databases ▶ NDC ▶ Search Result

Share Tweet LinkedIn Email Print

Current through December 17, 2024

You have searched Finished drug products

Search Results: *'secura bio'*

Back to Search Page

Showing 1 to 4 of 4 entries Show 50 entries

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Pr Ty
COPIKTRA	73116-215-28	15mg/1	CAPSULE	ORAL	NDA211155	Secura Bio, Inc	73116-215	duvelisib	DUVELISIB	HU PF DF
COPIKTRA	73116-215-56	15mg/1	CAPSULE	ORAL	NDA211155	Secura Bio, Inc	73116-215	duvelisib	DUVELISIB	HU PF DF
COPIKTRA	73116-225-28	25mg/1	CAPSULE	ORAL	NDA211155	Secura Bio, Inc	73116-225	duvelisib	DUVELISIB	HU PF DF

Proprietary Name	NDC Package Code	Strength	Dosage Form	Route	Application Number / Monograph ID	Labeler Name	Product NDC	Non Proprietary Name	Substance Name	Pr Ty
COPIKTRA	73116-225-56	25mg/1	CAPSULE	ORAL	NDA211155	Secura Bio, Inc	73116-225	duvelisib	DUVELISIB	HU PF DF

Previous 1 Next

Background Information

Drug questions email: DRUGINFO@FDA.HHS.GOV

See also: Drug Registration and Listing Instructions
National Drug Code Directory Data Files

U.S Department of Health and Human Services
Public Health Service
Food and Drug Administration

SECURA BIO™

DESCRIPTION OF OPERATIONS

Secura Bio, Inc. ("Secura") is a privately-held, Nevada-based, commercial-stage pharmaceutical company that develops and commercializes oncology therapies across the United States. Secura provides FARYDAK (panobinostat) capsules, a multiple myeloma treatment that works at the DNA level and slows the progression of multiple myeloma.

THIRD-PARTY LOGISTICS

Secura's products are manufactured by a contract manufacturer and distributed to customers by their third-party logistics provider, Integrated Commercialization Solutions, LLC ("ICS"). Secura utilizes the following ICS facility for distribution of product:

Integrated Commercialization Solutions, LLC
167 International Blvd., Suite A
Brooks, KY 40109

CONTRACT MANUFACTURERS

Secura uses the following contract manufacturer to produce product:

AndersonBrecon Inc
PCI of Illinois
4545 Assembly Drive
Rockford, IL 61109
FEI Number:1421377
FEIN# Expiration: 12/31/2021

PRODUCTS

As a virtual manufacturer, Secura does not manufacture, distribute or store product at their Nevada facility. At no time do contact manufacturers own Secura's products, contract with Secura's customers, invoice or sell Secura products. Secura's products are not controlled substances. Accordingly, Secura is not required to maintain DEA registration.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Secura Bio

Facility Name

Brett Lund

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11/12/2024

Date

Board Use Only	Date Received: 12/23/24	Amount: $1000 ck 2987

SECURA BIO™

OWNERSHIP

Secura Bio, Inc. ("Secura") is a privately-held, San Diego-based, clinical-stage pharmaceutical company that plans to develop and commercialize oncology therapies across the United States. Secura is a 100% wholly owned subsidiary of Secura Bio Holdings, Inc.

Secura provides FARYDAK (panobinostat) capsules, a multiple myeloma treatment that works at the DNA level and slows the progression of multiple myeloma.

COMPANY INFORMATION

Secura Bio, Inc.
1995 Village Center Cir, Suite 128
Las Vegas, NV 89134
Phone: (858) 251-1414
Tax ID: 36-4922937

CORPORATE OFFICERS

Joseph M. Limber, Chief Executive Officer
William Michael Brown, Chief Financial Officer

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SECURA BIO HOLDINGS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TENTH DAY OF JUNE, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SECURA BIO HOLDINGS, INC." WAS INCORPORATED ON THE THIRTIETH DAY OF OCTOBER, A.D. 2018.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.





7124551 8300

SR# 20242817311

Authentication: 203664918

Date: 06-10-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

SECURA BIO, INC.

Nevada Business Identification # NV20191360745
Expiration Date: 05/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/19/2025.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502195449988
You may verify this certificate online at https://www.nvsilverflume.gov/home


Secura Bio Holdings, Inc.
EIN# 99-5106223
Secura Bio, Inc.
EIN# 36-4922937


Secura Bio Holdings, Inc.
EIN# 83-2452762
Secura Bio, Inc.
EIN# 36-4922937

GENERAL SURETY RIDER

To be attached and form a part of

Bond No.	810001466
For	Pharmaceutical Wholesaler Surety Bond 1 Year, State of NV
Dated effective	05/24/2019 (MONTH, DAY, YEAR)
Executed by	Secura Bio, Inc., as Principal, (PRINCIPAL)
And by	Atlantic Specialty Insurance Company, as Surety, (SURETY)
And in favor of	State of Nevada- Nevada State Board of Pharmacy (OBLIGEE)

In consideration of the mutual agreements herein contained the Principal and the Surety hereby consent to changing

INFORMATION	FROM	TO
Principal Address	1887 Whitney Mesa Drive #1050	1995 Village Center Circle, Suite 128
Principal City	Henderson	Las Vegas
Principal Zip	89014	89134

Nothing herein contained shall vary, alter or extend any provision or condition of this bond except as herein expressly stated.

This rider is effective **03/24/2025**

(MONTH, DAY, YEAR)

Signed and Sealed **03/24/2025**

(MONTH, DAY, YEAR)

Secura Bio, Inc.
PRINCIPAL

BY Will Brown

Will Brown, CFO **TITLE**

Atlantic Specialty Insurance Company
SURETY

BY Sandra Corona

Sandra Corona, ATTORNEY-IN-FACT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Secura Bio

Pharmacy/Wholesaler License # (if applicable) WH02670

Physical Address 1995 Village Center Cir. Suite 128

City Las Vegas State NV Zip 89134

Mailing Address (if different from physical address) 1995 Village Center Cir. Suite 128

City Las Vegas, State NV Zip 89134-6360

Telephone 858-251-1414 Website www.securabio.com

Licensing Company Email Skurzeja@securabio.com

Section 2: Personal Information

First William Middle Michael Last Brown

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 1995 Village Center Cir. Suite 128

City Las Vegas State NV Zip 89134

Telephone [redacted] Email wbrown@securabio.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		x

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		x
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	Not Applicable	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Auburn University at Montgomery		2005	
Address	**City**	**State**	**Zip**
7400 East Dr.	Montgomery	Alabama	36117
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Auburn University at Montgomery		08/01 - 05/04	
Address	**City**	**State**	**Zip**
7400 East Dr	Montgomery	AL	36117
Diploma/Degree obtained, if any			
Accounting			

School Name		From - To (MM/YY – MM/YY)	
Hooper Academy		08/88 - 05/00	
Address	**City**	**State**	**Zip**
380 Fischer Rd	Hope Hull	AL	36043
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/15 - Present	[redacted]	Highlands Ranch	CO	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

SECURA BIO™

March 4, 2025

Via Email

Nevada State Board of Pharmacy
ATTN: Maria Herrara

RE: Secura Bio Wholesale Distributor WH02670- Notice of Changes

Dear Maria,

In response to your email of Thursday, February 27, 2025, attached please find the Designated Representative Application page 8 of 9 which I erroneously failed to complete in my earlier submission.

Also attached is my updated resume where I have added my current responsibilities of overseeing the supply chain team. Please note that I have been continuously employed in the pharma and biotech industry since 2018, and I have served as the lead executive overseeing operations and supply chain during that time.

Finally, I reside at [redacted] Nevada while I am at the Nevada facility.

I apologize for the oversight in not including this information is my original application. I belive this additional information will clarify my qualificaitons for the Designated Representative role.

Thank you,

William Brown
Chief Financial Officer

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Secura Bio, Inc.			2024 - Present
Business Address	**City**	**State**	**Zip**
1995 Village Center Cir. Suite 128	Las Vegas	NV	89134
Phone	**Title**	**Number of Employed Hours**	
858-251-1414	Chief Financial Officer	9,600	
Description of Duties			
See attached			

Business Name			From - To (MM/YY – MM/YY)
ObsEva SA			01/22 - 05/23
Business Address	**City**	**State**	**Zip**
One Financial Center, 24th Floor	Boston	MA	02111
Phone	**Title**	**Number of Employed Hours**	
857-972-9366	Interim CEO, Chief Financial Officer	2080+	
Description of Duties			
See attached			

Business Name			From - To (MM/YY – MM/YY)
Altimmune, Inc			05/18 to 12/21
Business Address	**City**	**State**	**Zip**
910 Clopper Road	Gaithersburg	MD	20878
Phone	**Title**	**Number of Employed Hours**	
240-654-1450	Chief Financial Officer	6240+	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Redmont CPAs			2016 - 2018
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			
See attached resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Will Brown
[redacted]

Overview

Record of success as chief financial officer of publicly traded biotechs in accessing capital markets, managing board member relationships, closing acquisitions & disposals, navigating shareholder issues, government relations, public relations, investor relations, managing legal function, SEC reporting, navigating complex accounting issues, treasury management, & more.

Professional Certifications

Certified Public Accountant — *July 2006 – September 2023*

Education

M.B.A. Accounting, Auburn University at Montgomery — *December 2005*

B.S. Accounting, Auburn University at Montgomery — *May 2004*

Relevant Experience

Secura Bio, Inc. (Private), *Las Vegas, Nevada* — *March 2024 – Present*
Chief Financial Officer

- Privately held oncology company
- Oversee supply chain team including distribution, dispensing and record keeping of our drug product, Copiktra
- Company Officer overseeing operations, finance, accounting, strategy, IT, legal, and other responsibilities

ObsEva SA (Nasdaq: OBSV), *Geneva, Switzerland* — *Jan 2022 – May 2023*
Interim Chief Executive Officer
Chief Financial Officer

- Led Company's restructuring efforts following loss of lead asset.
- During restructuring, assigned ~$15M worth of contracts; restructured & subsequently paid off $42M in debt; sold out-licensed rights for >$112M; preserved Nasdaq listing through bankruptcy; ensured all vendors and debtors were paid.
- As interim CEO led Company's efforts to delist from Nasdaq and deregister from the SEC to create a Swiss domestic company.
- Company Officer overseeing supply chain, operations, finance, accounting, strategy, IT, legal, and other responsibilities

Altimmune, Inc. (Nasdaq: ALT), *Gaithersburg, MD* — *May 2018 - Dec 2021*
Chief Financial Officer

- Raised >$300 million through registered direct offerings, public offerings and ATMs
- Negotiated $93 million acquisition of Spitfire Pharmaceuticals, Inc.
- Company Officer overseeing operations, finance, accounting, strategy, IT, legal, and other responsibilities

Redmont CPAs/ Sole Practitioner, *Denver, CO* — *2016 - 2018*
Managing Partner

- Co-founder of full service CPA firm offering tax, assurance, and advisory services
- Technical review partner on all engagements

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		x
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		x
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		x
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		x
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		x
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		x
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		x
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		x
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		x

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, William Brown, **certify that as the designated representative for**

Secura Bio,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. WB I am at least 21 years of age;
3. WB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. WB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. WB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. WB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. WB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

William Brown

Print Name (First, Last)

William Brown

Original Signature (electronic, copies or stamps not accepted)

3-4-25

Date

I, William Brown, **certify that as the designated representative for**

Secura Bio,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

William Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

William Brown

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1-31-25

Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Douglas

I, William Brown, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1-31-25

Date

Subscribed and Sworn to before me this 31st day of January, 2025.

Notary Public Signature

KYU TAE KIM
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID 20224039121
MY COMMISSION EXPIRES 10/10/2026

(Seal)

Secura Bio Employee List

Last	First
Allen Bard	Sandra
Andria	Michael
Barthe	Cari
Brown	William
Caradonna	Julie
Chang	Milan
Dowd	Kevin
Earl	Cody
Eng	Christopher
Esposito	Daren
Estruch	Juan
Fajardo	Rowena
Fitzgerald	Shannon
Glover	Samantha
Kiyomiya	Dennis
Kurzeja	Steve
Langdon	John
Lemoine	Colleen
Limber	Michael
Marsico	David
Michael	Ryan
Misius	Kevin
Nguyen	Le
Niro	Natacha
Oladipo	Anthony
Padegs	Gynt
Panyavong	Katrina
Reddick	Catherine
Rizzo	Kate
Romp	Charles
Rubbe	Ann
Sakkos	John
Salituro	Vincent
Santini	Lia
Scheimann	Laura
Shindler	Linda
Smith	Ryan A
Starling	Makaela
Sulley	Jamie
Tagliaferro	Matthew

Tamunodiepri	George
Tapiador	Benjamin
Terry	Julisa
Thomason	John
Thompson	Jordan
Waters	Sheila
Wessels	Gregory
Wright	Kenneth
Zeron	Rolando
Zhao	Zheng
Zhong	Xander

4VV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	See Attachment A * If making a change, provide current license number: WH 00558	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: J. Knipper and Company, Inc.

Physical Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Mailing Address (if different from physical address): N/A - Same as above address.

City: State: Zip:

Telephone: Website: https://www.knipper.com/

Name of Designated Representative (DR): James Garcia

Licensing Company Email: Licensing@knipper.com DR Email: Licensing@knipper.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☑ Controlled Substances	☑ Repacker
☑ Hospitals	☑ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☑ Warehouse
☑ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

3/3/2025

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	February 18, 2020	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2019-3775	Colorado Board of Pharmacy

Reason/Charge
J. Knipper and Company was subject to disciplinary action and a penalty in Colorado for delayed notification of change of designated representative for its 1550 Oak Street, Lakewood, NJ facility.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Colorado Board of Pharmacy claimant	N/A

Name of Business/Industry/Entity
J. Knipper and Company, Inc.

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/3/2025
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	2/18/2020	CO	Denver	Denver
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2019-3775		Colorado Board of Pharmacy		
Reason/Charge				
J. Knipper & Co. was subject to disciplinary action & a penalty in Colorado for delayed notification of change of designated rep for its 1550 Oak St facility				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Colorado Board of Pharmacy claimant		N/A		
Name of Business/Industry/Entity				
J. Knipper and Company, Inc.				

Provide explanation below:

Please see attached Stipulation & Final agency order as well as closure letter from Colorado Board of Pharmacy.

Original Signature (electronic, copies or stamps not accepted)

3/4/25
Date

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

February 19, 2020

J. Knipper and Company, Inc.
1550 Oak Street
Lakewood, NJ 08701-5937

Sent via email: compliance@knipper.com, teresita.weiss@knipper.com

RE: Case No. 2019-3775 Stipulation and Final Agency Order

Dear Pharmacy Manager:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the terms and conditions of the above listed Stipulation and Final Agency Order effective February 18, 2020.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released you from the terms and conditions of the February 18, 2020, Stipulation and Final Agency Order and restored your Registration No. WHO.0007269 to unencumbered status.

Although this disciplinary action will remain a public document, our records show that the requirements of your Order are complete. Please retain this letter for your records.

Your cooperation during the pendency of this matter is sincerely appreciated.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Dmitry Kunin
Program Director

cc: Jeremy Alexander, Esq., sent via email: jalexander@reedsmith.com
John Kendzior, Esq., sent via email: jkendzior@reedsmith.com
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2019-3775

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF J. KNIPPER AND COMPANY, INC., REGISTRATION NO. WHO-7269,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and J. Knipper and Company, Inc., ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2019-3775, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as a non-resident wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2018).

2. Respondent Outlet was originally registered in the State of Colorado on or about June 20, 2007, being issued registration #WHO-7269, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 1550 Oak St, Lakewood, NJ 08701.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, 189 days transpired between November 13, 2018, the date the previous designated representative ceased the position, and May 21, 2019, the date the application and fee were received.

6. On or about June 3, 2019, the Board initiated a complaint against Respondent Outlet because of the delay of 189 days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline. (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board.

Pharmacy Board Rules and Regulations

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

8. The Board finds and concludes, and Respondent Outlet agrees, that based upon Respondent Outlet's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

9. Fine with Surcharge. Pursuant to section 12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

10. Compliance. Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in its designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

11. Other Requirements. Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

12. Advisements and Waivers. Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

13. Acknowledgments. The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

14. Violations. Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under sections 12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

15. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Outlet

Dated: 2/12/2020

Teresita Weiss, Ph.D., J.D.
SVP, Regulatory Affairs and Compliance

APPROVED AS TO FORM
FOR RESPONDENT OUTLET

Reed Smith LLP
Jeremy M. Alexander
John D. Kendzior

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18 day of February, 2020.

State Board of Pharmacy

BY:

Dmitry Kunin
Program Director

Ree

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of FEBRUARY 2020, addressed as follows:

J. Knipper and Company, Inc.
Attn: Amer Bazoqa, Designated Representative
1550 Oak St
Lakewood, NY 08701

By Email: compliance@knipper.com; teresita.weiss@knipper.com

Jeremy M. Alexander
John D. Kendzior
Reed Smith LLP
1301 K Street, N.W.
Ste 1000 - East Tower
Washington, D.C. 20005

By email: jalexander@reedsmith.com; jkendzior@reedsmith.com

Agent of the Board

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment J

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): Knipper Holding, Inc.

Corporation/Organization Name: J. Knipper and Company, Inc.

Mailing Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: (732) 905-7878 Email: Licensing@knipper.com

Contact Person Name: Teresita Weiss

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
N/A 1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
N/A • **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachments A and D		✓		
N/A • **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** See Attachment G	✓	✓	✓	✓
N/A • **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment H	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment I	✓	✓	✓	✓
N/A • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
N/A • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

J. Knipper and Company, Inc.

Facility Name

Teresita Weiss, General Manager for Regulatory Affairs and Compliance

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/3/2025

Date

Board Use Only	Date Received: 3/12/25	Amount: $1000 EC

December 3, 2024

Re: Notice of Upcoming Transaction
Distributor Licensee: J. Knipper and Company, Inc.

To Whom It May Concern:

On behalf of J. Knipper and Company, Inc. (the "**Licensee**"), this notice is to advise you of an upcoming transaction that involves the transfer of the indirect equity interest in the Licensee (the "**Proposed Transaction**").

Specifically, as part of the Proposed Transaction, JKC Parent, Inc., a Delaware corporation and the indirect parent of the Licensee (the "**Parent**"), has entered into an Agreement and Plan of Merger, dated as of November 24, 2024, by and among the Parent, [FH KH Intermediate, Inc.], a Delaware corporation ("**Buyer**"), [FH KH Merger Sub, Inc.], a Delaware corporation and wholly owned subsidiary of Buyer ("**Merger Sub**"), and the other parties thereto, pursuant to which, and subject to the terms and conditions set forth therein, Merger Sub will merge with and into the Parent, with the Parent continuing as the surviving corporation of such merger. As a result, Buyer shall be the owner of Parent and the indirect owner of the Licensee. Pre- and post-closing organizational charts depicting the Proposed Transaction are attached hereto.

Importantly, the Proposed Transaction will not result in any changes in the Licensee, its tax identification number, its operational management team, or its day-to-day operations (other than changes in the ordinary course).

The closing of the Proposed Transaction is currently expected to take place on or about January 31, 2025. Unless we hear from you otherwise, we understand that this letter satisfies any notice requirements applicable to the Licensee regarding the Proposed Transaction.

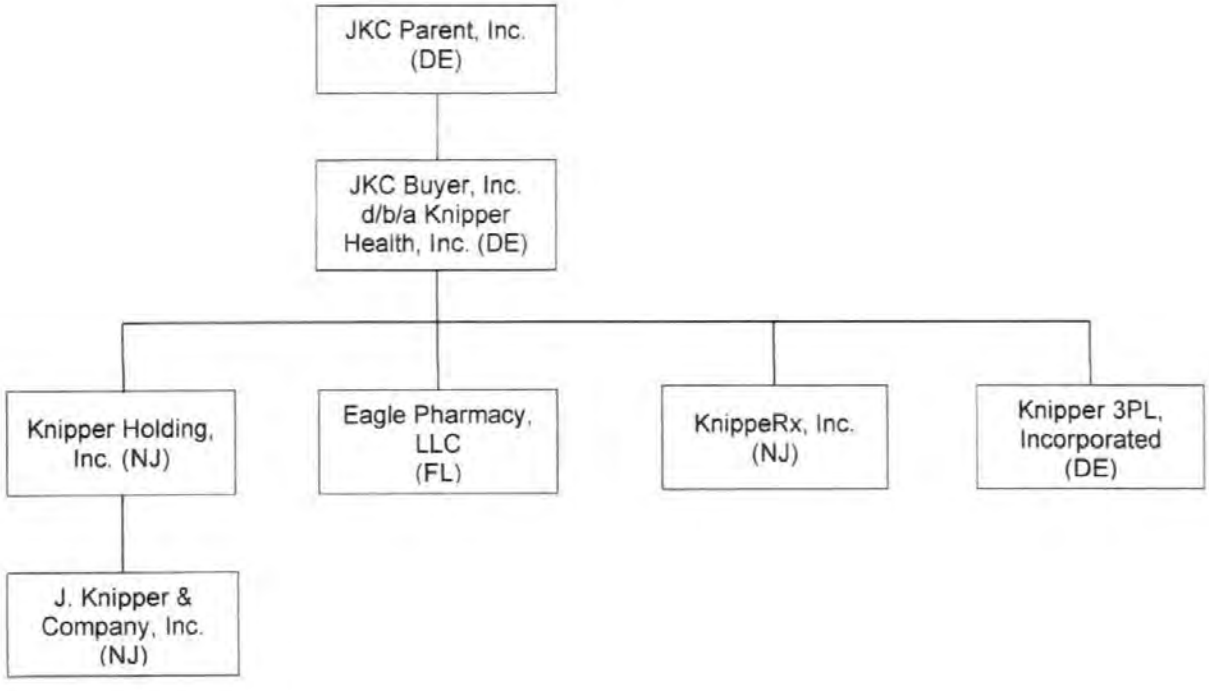
We kindly request that you keep all information disclosed in this letter confidential.

Sincerely,

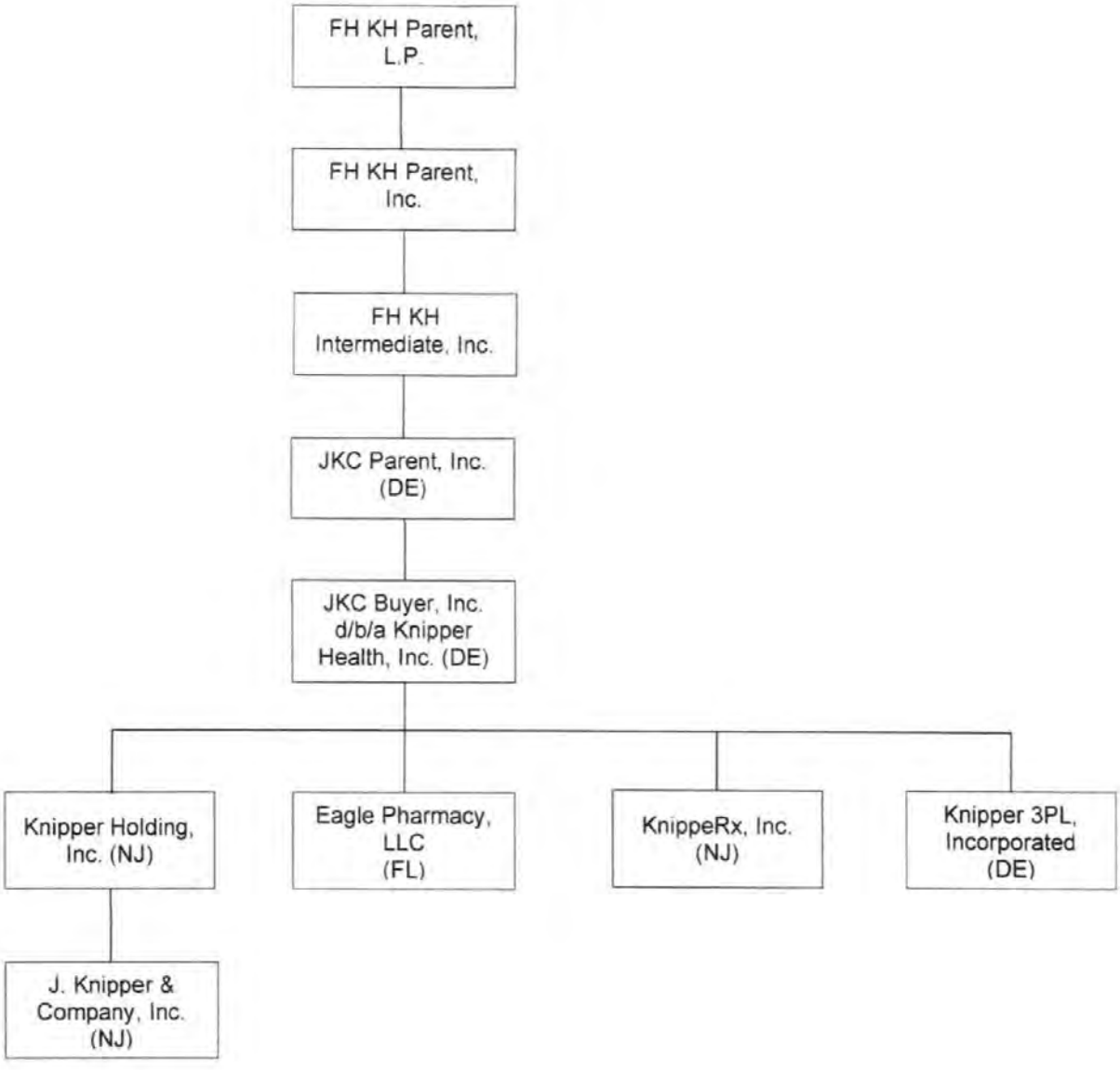
Teresita Weiss, Ph.D., J.D.
General Manager, Regulatory Affairs & Compliance

Attachments Exhibit A - Pre-closing organization chart
Exhibit B - Post-closing organizational chart

Knipper – Pre-Closing Legal Structure



Knipper – Post-Closing Legal Structure



Accredited Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State [All]

Search Reset

Current list of 38 NABP-Accredited Drug Distributors

Accreditation is valid for three years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

<<Previous 1 2 3 4 Next >>

Name	Address	Accreditation Date
Direct Success, Inc	1710 Highway 34 Farmingdale, NJ 07727	11/18/22
Glenmark Pharmaceuticals Inc, USA	750 Corporate Dr Mahwah, NJ 07430	Reaccreditation in process
Glenmark Pharmaceuticals Inc., USA	301 Island Rd Mahwah, NJ 07430	12/18/23
Hikma Injectables USA Inc dba Hikma 503B	36 Stults Road Dayton, NJ 08810	03/19/24
Hikma Pharmaceuticals USA Inc	2 Esterbrook Ln Cherry Hill, NJ 08003	02/15/24
Imprimis NJOF, LLC	1705 Route 48 Ledgewood, NJ 07852	09/08/22
IND Therapeutics, LLC	22 World's Fair Dr, Ste J Somerset, NJ 08873	09/18/23
J Knipper and Company, Inc	One Healthcare Way Lakewood, NJ 08701	12/05/24
J Knipper and Company, Inc	1550 Oak St Lakewood, NJ 08701	07/17/24
JOM Pharmaceutical Services, LLC	1 Cottontail Ln Somerset, NJ 08873	05/08/22

<<Previous 1 2 3 4 Next >>

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- FCRA Dispute Process

NABP ACCREDITED
DRUG DISTRIBUTOR

J Knipper and Company, Inc

located at

One Healthcare Way, Lakewood, NJ 08701

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

12/05/2021 - 12/04/2024
Period of Accreditation

2170

Corporate Officers for J. Knipper and Company, Inc.

- Michael J. Laferrera - President and Chief Executive Officer



- Todd Phillips – Chief Financial Officer



Corporate names:	J. Knipper and Company, Inc.
State of Incorporation:	New Jersey
FEIN:	22-2755742
Parent Company:	100% wholly owned by Knipper Holding, Inc.
Grandparent Company:	100% wholly owned by JKC Buyer, Inc. d/b/a Knipper Health, Inc.
Great-Grandparent Co:	100% wholly owned by JKC Parent, Inc.
Private Equity Ownership:	Frazier Healthcare Partners

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

J. KNIPPER AND COMPANY, INC.
0100313707

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on October 09, 1986.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 14th day of November, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6158972614

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

0753060

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

ONE HEALTHCARE WAY LAKEWOOD, NJ 08701-
1550 OAK ST LAKEWOOD,NJ 08701-
1250 PATROL RD CHARLESTOWN, IN 47111-

Reg. No.
5001714

J. KNIPPER AND COMPANY, INC.
ATTN: TERESITA WEISS
ONE HEALTHCARE WAY
LAKEWOOD, NJ 08701-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0292487	12-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-26-2024

J KNIPPER & COMPANY INC
ONE HEALTHCARE WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0292487	12-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-26-2024

J KNIPPER & COMPANY INC
ONE HEALTHCARE WAY
LAKEWOOD, NJ 08701

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0292487	12-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-26-2024

J KNIPPER & COMPANY INC
ONE HEALTHCARE WAY
LAKEWOOD, NJ 08701

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

RIDER NO.

This Rider to be attached to and form part of Bond No. 021143V ,effective March 1, 2024 , covering

Pharmaceutical Wholesaler Surety Bond ,

on behalf of J. Knipper & Company, Inc. ,

and in favor of Nevada State Board of Pharmacy .

The following additional location is being added to the above captionend bond.

5100 Hickory Hill Road, Memphis, TN 38141

The attached bond shall be subject to all its agreements, limitations, and conditions except as herein expressly modified.

This Rider is effective from the 14th day of January , 2025 .

Signed and dated this 14th day of January , 2025 .

☒ WESTFIELD INSURANCE COMPANY
☐ WESTFIELD NATIONAL INSURANCE COMPANY
☐ OHIO FARMERS INSURANCE COMPANY

By _____
Robyn Rost Attorney-in-Fact

Accepted N/A

By _____

BD 5596 OFWWN (03-01)

POWER NO. 3120081 01
General Power of Attorney

Westfield Insurance Co.
Westfield National Insurance Co.
Ohio Farmers Insurance Co.
Westfield Center, Ohio

CERTIFIED COPY

Know All Men by These Presents, That WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, corporations, hereinafter referred to individually as a "Company" and collectively as "Companies," duly organized and existing under the laws of the State of Ohio, and having their principal offices in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint **ROBYN ROST, JOINTLY OR SEVERALLY**
of **RED BANK** and State of NJ its true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in their names, place and stead, to execute, acknowledge and deliver **any and all bonds, undertakings, and recognizances; provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed TWENTY MILLION DOLLARS AND NO CENTS ($20,000,000)---**

LIMITATION: THIS POWER OF ATTORNEY CANNOT BE USED TO EXECUTE NOTE GUARANTEE, MORTGAGE DEFICIENCY, MORTGAGE GUARANTEE, OR BANK DEPOSITORY BONDS.

and to bind any of the Companies thereby as fully and to the same extent as if such bonds were signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of each of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY:

"**BE IT RESOLVED**, that the President, any Senior Executive, any Secretary or any Fidelity & Surety Operations Executive or other Executive shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings and any and all notices and documents cancelling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be as binding upon The Company as if signed by the President and sealed and attested by the Corporate Secretary."

"**BE IT FURTHER RESOLVED**, that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." (Each adopted at a meeting held on February 8, 2000.)

In Witness Whereof, WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY have caused these presents to be signed by their Senior Executive and their corporate seals to be hereto affixed this **15TH** day of **NOVEMBER**, A.D., **2013**.

Corporate Seals Affixed

WESTFIELD INSURANCE COMPANY
WESTFIELD NATIONAL INSURANCE COMPANY
OHIO FARMERS INSURANCE COMPANY

By: _____
Dennis P. Baus
National Surety Leader and Senior Executive

State of Ohio
County of Medina ss.:

On this **15TH** day of **NOVEMBER**, A.D., **2013**, before me personally came **Dennis P. Baus**, to me known, who, being by me duly sworn, did depose and say, that he resides in **Wooster, Ohio**, that he is **National Surety Leader and Senior Executive** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, the companies described in and which executed the above instrument, that he knows the seals of said Companies; that the seals affixed to said instrument are such corporate seals; that they were so affixed by order of the Board of Directors of said Companies, and that he signed his name thereto by like order.

Notarial Seal Affixed

By: _____
William J. Kahelin, Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss.:

CERTIFICATE

I, **Frank Carrino**, Secretary of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Companies, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Westfield Center, Ohio, this 14th day of January A.D. 2025.

By: _____
Frank Carrino, *Secretary*

BPOAC4A

Financial Statement

December 31, 2023

Westfield Insurance Co.
Westfield Center, Ohio 44251-5001

WESTFIELD INSURANCE COMPANY
BALANCE SHEET

12/31/23
(in thousands)

Assets	
Cash, cash equivalents, and short term investments	34,614
Bonds	1,387,543
Stocks	370,629
Agents' balances and uncollected premiums, net	458,142
Other admitted assets	1,080,285
Total admitted assets	3,331,213
Liabilities	
Reserve for unearned premiums	713,530
Reserve for unpaid losses and loss expenses	1,106,583
Reserve for taxes and other liabilities	304,081
Total liabilities	2,124,194
Capital stock	8,220
Surplus to policyholders	1,198,799
Total surplus	1,207,019
Total liabilities and surplus	3,331,213

State of Ohio
ss:
County of Medina

The undersigned, being duly sworn, says: That he is National Surety Leader - Surety Operations of Westfield Insurance Company, Westfield Center, Ohio; that said Company is a corporation duly organized, existing and engaged in business as a Surety Company by virtue of the Laws of the State of Ohio and authorized to do business in the State of ..... and has duly complied with all the requirements of the laws of said State applicable to said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved July 1947, 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true, and correct statement of the financial condition of the said Company on the 31st day of December, 2023.

Attest:

Frank A. Carrino
Group Legal Leader, Secretary

Gary W. Stumper
National Surety Leader
Senior Executive

WESTFIELD INSURANCE CO. SEAL

Sworn to before me this 14th day of February A.D. 2024.

David A. Kotnik
Attorney at Law
Notary Public – State of Ohio

NOTARY PUBLIC STATE OF OHIO

My Commission Does Not Expire
Sec. 147.03 Ohio Revised Code

Client#: 1541191 JKNI

ACORD™ CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 1/15/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer any rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Heather Sherwin	
USI Insurance Services, LLC 180 Park Avenue Suite 103 Florham Park, NJ 07932	PHONE (A/C, No, Ext): 973-315-0440	FAX (A/C, No):
	E-MAIL ADDRESS: heather.sherwin@usi.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Federal Insurance Company	20281
INSURED J. Knipper & Company, Inc. One Healthcare Way Lakewood, NJ 08701	INSURER B :	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY			35809008	12/10/2024	12/10/2025	EACH OCCURRENCE	$5,000,000
	[X] CLAIMS-MADE [ ] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
	[X] Products Liability						MED EXP (Any one person)	$
	[X] Retro: 10/20/2023			Deductible(s):			PERSONAL & ADV INJURY	$5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:			$50,000 occ. /			GENERAL AGGREGATE	$
	[X] POLICY [ ] PRO-JECT [ ] LOC			$250,000 agg.			PRODUCTS - COMP/OP AGG	$
	[ ] OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	[ ] ANY AUTO						BODILY INJURY (Per person)	$
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$
	[ ] EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$
	[ ] DED [ ] RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						[ ] PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ]	N / A					E.L. EACH ACCIDENT	$
	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Professional Liability/E&O Retro: 09/30/2002			35809008	12/10/2024	12/10/2025	$5,000,000 occ/agg Ded: $50,000 each claim	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: NCPDP: 1568560

Evidence of Coverage for:

One Healthcare Way, Lakewood Township, NJ 08701
(See Attached Descriptions)

CERTIFICATE HOLDER

National Council for
Prescription Drug Programs, Inc.
9240 East Raintree Drive
Scottsdale, AZ 85260-7519

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Ulle Scott

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DESCRIPTIONS (Continued from Page 1)

1550 Oak Street, Lakewood, NJ 08701
270 Davidson Avenue, Somerset, NJ 08873
1009 Lenox Drive, Lawrenceville, NJ 08648
1250 Patrol Road, Charlestown, IN 47111
160 Chubb Avenue, Suite 305, Lyndhurst, NJ 07071
200 Patrol Road, Suite 300, Jeffersonville, IN 47130
310 Eagles Landing Drive, 330 Eagles Landing Drive, 350 Eagles Landing Drive, Lakeland, FL 33810
2700 Blankenbaker Pkwy, Louisville, KY 40299
5100 Hickory Road, Memphis, TN 38141

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 021143V

Application/License No. _____

J. Knipper and Company, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is One Healthcare Way, Lakewood, NJ 08701 (Address of Applicant/Principal), as PRINCIPAL, and Westfield Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Park Circle, P.O. Box 5001, Westfield Center, Ohio 44251 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 1, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of March, 2024.

APPLICANT/PRINCIPAL

COMPANY
J. Knipper and Company, Inc.

Authorized Representative

SURETY

Westfield Insurance Company

Surety Company's Representative

Robyn Rost, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Bridget Serean

Witness Kristina Lutz

SIGNED and SEALED in the presence of:

Witness Karla Luongo

Witness Nicole Kaetzel

Countersigned by:

Nevada Resident Agent

ACKNOWLEDGEMENT OF SURETY

State of New Jersey

County of Morris

City of Florham Park

On this 1st day of March in the year 2024 before me personally

Came Robyn Rost to me known, who, being by me duly sworn, did

depose and say that he resides in Florham Park, NJ that he is the Attorney-

In-Fact for Westfield Insurance Company the corporation described

In and which executed the attached instrument; that he knows the seal of the said

corporation; that the seal affixed to the said instrument is such corporate seal;

and that it was so affixed by Order of the Board of Directors of the said corporation,

and that he signed his name thereto by like order.

Notary Public

THOMAS F DORNER SR.
Notary Public, State of New Jersey
My Commission Expires Apr 23, 2028

Corporate Acknowledgement

STATE OF New Jersey

COUNTY OF Ocean

7 day March the year 2024, before me Teresita Weiss, NOTARY PUBLIC personally appeared on behalf of J. Knipper and Company, Inc.

personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who executed the within instrument as president (or secretary)or on behalf of the corporation therein named and acknowledged to me that the corporation executed it.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal, the day and year first above written.

My Commission expires September 29, 2024

Bridget Serzan

Notary Public, residing at Lakewood, New Jersey

(SEAL)

BRIDGET H. SERZAN
Commission # 50003532
Notary Public, State of New Jersey
My Commission Expires
September 29, 2024

POWER NO. 3120081 01
General Power of Attorney

CERTIFIED COPY

Westfield Insurance Co.
Westfield National Insurance Co.
Ohio Farmers Insurance Co.
Westfield Center, Ohio

Know All Men by These Presents, That WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, corporations, hereinafter referred to individually as a "Company" and collectively as "Companies," duly organized and existing under the laws of the State of Ohio, and having their principal offices in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint **ROBYN ROST, JOINTLY OR SEVERALLY**
of **RED BANK** and State of NJ its true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in their names, place and stead, to execute, acknowledge and deliver any and all bonds, undertakings, and recognizances; provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed **TWENTY MILLION DOLLARS AND NO CENTS ($20,000,000)**—

LIMITATION: THIS POWER OF ATTORNEY CANNOT BE USED TO EXECUTE NOTE GUARANTEE, MORTGAGE DEFICIENCY, MORTGAGE GUARANTEE, OR BANK DEPOSITORY BONDS.

and to bind any of the Companies thereby as fully and to the same extent as if such bonds were signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of each of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY:

"**BE IT RESOLVED**, that the President, any Senior Executive, any Secretary or any Fidelity & Surety Operations Executive or other Executive shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings and any and all notices and documents cancelling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be as binding upon The Company as if signed by the President and sealed and attested by the Corporate Secretary."

"**BE IT FURTHER RESOLVED**, that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." (Each adopted at a meeting held on February 8, 2000.)

In Witness Whereof, WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY have caused these presents to be signed by their Senior Executive and their corporate seals to be hereto affixed this **15TH** day of **NOVEMBER, A.D., 2013**.

Corporate Seals Affixed

WESTFIELD INSURANCE COMPANY
WESTFIELD NATIONAL INSURANCE COMPANY
OHIO FARMERS INSURANCE COMPANY

By: _____
Dennis P. Baus
National Surety Leader and Senior Executive

State of Ohio
County of Medina ss.:

On this **15TH** day of **NOVEMBER**, A.D., **2013**, before me personally came **Dennis P. Baus**, to me known, who, being by me duly sworn, did depose and say, that he resides in Wooster, Ohio, that he is **National Surety Leader and Senior Executive** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, the companies described in and which executed the above instrument, that he knows the seals of said Companies; that the seals affixed to said instrument are such corporate seals; that they were so affixed by order of the Board of Directors of said Companies, and that he signed his name thereto by like order.

Notarial Seal Affixed

By: _____
William J. Kahelin, Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss.:

CERTIFICATE

I, **Frank Carrino**, Secretary of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Companies, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Westfield Center, Ohio, this 1st day of March, A.D., 2024.

By: _____
Frank Carrino, *Secretary*

BPOAC4A

Financial Statement

Reset Form

December 31, 2022

Westfield Insurance Co.
Westfield Center, Ohio 44251-5001

WESTFIELD INSURANCE COMPANY
BALANCE SHEET
12/31/22
(in thousands)

Assets	
Cash, cash equivalents, and short term investments	14,523
Bonds	1,431,438
Stocks	409,103
Agents' balances and uncollected premiums, net	407,991
Other admitted assets	999,270
Total admitted assets	3,262,325
Liabilities	
Reserve for unearned premiums	612,303
Reserve for unpaid losses and loss expenses	1,046,687
Reserve for taxes and other liabilities	351,958
Total liabilities	2,010,948
Capital stock	8,220
Surplus to policyholders	1,243,157
Total surplus	1,251,377
Total liabilities and surplus	3,262,325

State of Ohio
ss:
County of Medina

The undersigned, being duly sworn, says: That he is National Surety Leader - Surety Operations of Westfield Insurance Company, Westfield Center, Ohio; that said Company is a corporation duly organized, existing and engaged in business as a Surety Company by virtue of the Laws of the State of Ohio and authorized to do business in the State of .....NV..... and has duly complied with all the requirements of the laws of said State applicable to said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved July 1947, 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true, and correct statement of the financial condition of the said Company on the 31st day of December, 2022.

Attest:

Frank Carrino
.....
Frank A. Carrino
Group Legal Leader, Secretary

.....
Gary W. Stumper
National Surety Leader
Senior Executive

WESTFIELD INSURANCE CO. SEAL

Sworn to before me this 8th day of February A.D. 2023.

David A. Kotnik
.....
David A. Kotnik
Attorney at Law
Notary Public – State of Ohio

NOTARY PUBLIC STATE OF OHIO

My Commission Does Not Expire
Sec. 147.03 Ohio Revised Code

BD5402 D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: J. Knipper and Company, Inc. MDEG License # (if applicable): N/A

Physical Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Mailing Address (if different from physical address): One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: 732-905-7878 Website: www.knipper.com

Licensing Company Email: Licensing@knipper.com

Section 2: Personal Information

First: James Middle: Michael Last: Garcia

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITI: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: 732-905-7878 Email: Licensing@knipper.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. Peters University		09/81-05/87	
Address	City	State	Zip
2641 JFK Blvd.	Jersey City	NJ	07306
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Bayoone High School		09/80-06/81	
Address	City	State	Zip
669 Ave. A	Bayoone	NJ	07002
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Marist High School		09/77-06-80	
Address	City	State	Zip
1241 JFK Blvd.	Bayoone	NJ	07002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07-2008-Present	[redacted]	Brick	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
J. Knipper and Company, Inc.			12/18 - present	
Business Address		**City**	**State**	**Zip**
One Healthcare Way		Lakewood	NJ	08701
Phone	**Title**		**Number of Employed Hours**	
(732) 905-7878	Director of Distribution		9,600	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	2/18/2020	CO	Denver	Denver
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
2019-3775		Colorado Board of Pharmacy		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Colorado Board of Pharmacy Claimant		N/A		
Name of Business/Industry/Entity				
J. Knipper and Company, Inc.				

Provide explanation below:

J. Knipper and Company, Inc. was subject to disciplinary action and a penalty in Colorado for delayed notification of a change of designated representative for its 1500 Oak Street, Lakewood, NJ facility. The company has since implemented corrective actions to ensure changes are submitted timely going forward. Provided is a copy of the stipulation and final order issued by the Colorado Board of Pharmacy.

Original Signature (electronic, copies or stamps not accepted)

4/21/25
Date

I, James Michael Garcia, **certify that as the MDEG Administrator for**

J. Knipper and Company, Inc.,

that I (initial that you have read and meet the following requirements):

1. _____ Have a high school diploma or its equivalent;
2. _____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. _____ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. _____ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Garcia
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/21/25
Date

Board Use Only	Date Received: 4/22/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler J. Knipper and Company, Inc.

Pharmacy/Wholesaler License # (if applicable) WH00558

Physical Address One Healthcare Way

City Lakewood State NJ Zip 08701

Mailing Address (if different from physical address) One Healthcare Way

City Lakewood State NJ Zip 08701

Telephone (732) 905-7878 Website https://www.knipper.com/

Licensing Company Email Licensing@knipper.com

Section 2: Personal Information

First James Middle Michael Last Garcia

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address One Healthcare Way

City Lakewood State NJ Zip 08701

Telephone (732) 905-7878 Email Licensing@knipper.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
St. Peters University		09/81 - 05/87	
Address: 2641 JFK Blvd.	City: Jersey City	State: NJ	Zip: 07306
Diploma/Degree obtained, if any: Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Bayonne High School		09/80 - 06/81	
Address: 669 Ave A	City: Bayonne	State: NJ	Zip: 07002
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Marist High School		09/77 - 06/80	
Address: 1241 JFK Blvd	City: Bayonne	State: NJ	Zip: 07002
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2008 - Present	[redacted]	Brick	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
J. Knipper and Company, Inc.			12/18 - present	
Business Address		**City**	**State**	**Zip**
One Healthcare Way		Lakewood	NJ	08701
Phone	**Title**		**Number of Employed Hours**	
(732) 905-7878	Director of Distribution		~11,800	
Description of Duties				
Director of Distribution: Oversight of all processing and shipping of sample drug and literature. This includes all aspects of the distribution operation such as; receiving, put-away, storage, movement and relocation, picking, and packing.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
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Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, James Michael Garcia, **certify that as the designated representative for**

J. Knipper and Company, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JG I am at least 21 years of age;
3. JG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James Garcia
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/4/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James Garcia

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/4/25

Date

Please have this section completed in the presence of a Notary Public.

State of NEW JERSEY, ss. County of OCEAN

I, James Garcia, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/4/25

Date

Subscribed and Sworn to before me this 4 day of March 2025.

Notary Public Signature Bridget H. Serzan

BRIDGET H. SERZAN
Notary Public, State of New Jersey
Comm. # 50003532
My Commission Expires 9/29/2029

(Seal)

J Knipper and Company, Inc.
One Healthcare Way
Lakewood, NJ 08701

Source Name	Country	City	State
Aerie Pharmaceuticals, Inc.	United States	Bedminster	NJ
ANI Pharmaceuticals	United States	Baudette	MN
Arbor Pharmaceuticals,LLC	United States	Atlanta	GA
Ascendis	United States	Princeton	NJ
Bausch Health	United States	Bridgewater	NJ
Biocyrst Pharmaceuticals, Inc.	United States	Durham	NC
Boehringer Ingleheim	United States	Ridgefield	CT
Bracco Diagnostics	Italy	Milan	Italy
Cumberland Pharmaceuticals	United States	La Vergne	TN
Fresenius Medical Care-North America	United States	Waltham	MA
Genentech	United States	Louisville	KY
Gilead Sciences, Inc	United States	Foster City	CA
Inceptua, Inc	United States	New York	NY
Incyte Corporation	United States	Wilmington	DE
Indivior, Inc.	United States	Richmond	VA
Intra-Cellular Therapies	United States	Towson	MD
Mallinckrodt Pharmaceuticals	United States	Hobart	NY
Mannkind Corp	United States	Westlake Villiage	CA
Merck	United States	Kenilworth	NJ
Noven Pharmaceuticals	United States	Miami	FL
Novo Nordisk Inc	United States	Plainsboro	NJ
OptiNose	United States	Yardley	PA
Paratek Pharmaceuticals	United States	Boston	MA
RVL Pharmaceuticals, Inc	United States	Bridgewater	NJ
Scilex Pharmaceuticals, Inc.	United States	Malvern	PA
SST Corporation	United States	Clifton	NJ
TEVA	United States	North Whales	PA
Thea Pharma, Inc.	United States	Waltham	MA
Vanda Pharmaceuticals	United States	Washington DC	DC
West-Ward Pharmaceuticals Corp	United States	Eatontown	NJ



J. KNIPPER & COMPANY

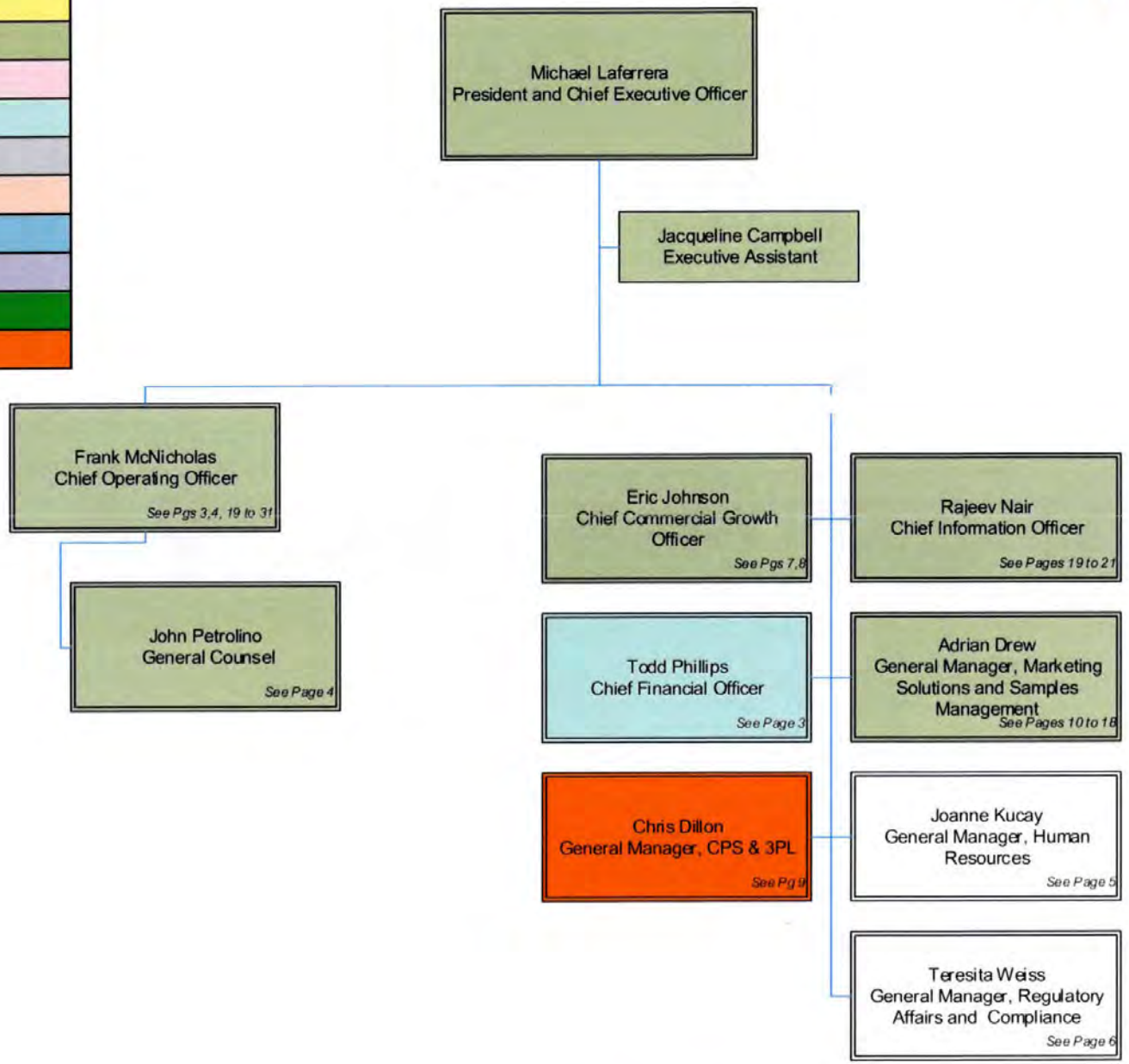
ORGANIZATIONAL CHART

December 31, 2024

CONFIDENTIAL

Executive Staff

Legend	
OHW	
KDC	
SOM	
LAW	
LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



CONFIDENTIAL

Finance



Michael Laferrera
President and Chief Executive Officer

Todd Phillips
Chief Financial Officer

Ralph Colon
Sr VP, Finance

Brian Costello
Corporate Controller

Aissa Subida
Assistant Treasurer

Robert Cassella
Controller, SMM

Steven Schlotter
Controller, KRX

Adam Landsberg
Assistant Corporate Controller

Darlene Faone
Manager, Accounts Payable

Michele Akdogen
Procurement Administrator

Jake Hovey
Director, Financial Planning and Analysis

Cara Crawford
Administrative Assistant

Michelle Frazier
Supervisor, Billing

Aida Pomponio
Supervisor, Billing

Faye Salari
Sr. Financial Analyst, Pharmacy

Matthew Klein
Staff Accountant

Brian Crane
Accounts Payable Clerk

Anthony Pellicciotta
Accounts Payable Clerk

Diane Coiro
Financial Analyst

Diane Dougherty
Billing Analyst

Mauro Duarte Lopez
Billing Analyst

Chetna Kharawala
Billing Analyst

Ximena Guilca
Billing Analyst

Deirdre Nichols
Billing Analyst

Luz Lopez
Billing Analyst

Kelly O'Brien
Billing Analyst

Sharon Walls
Billing Analyst

Milena Narine
Billing Analyst

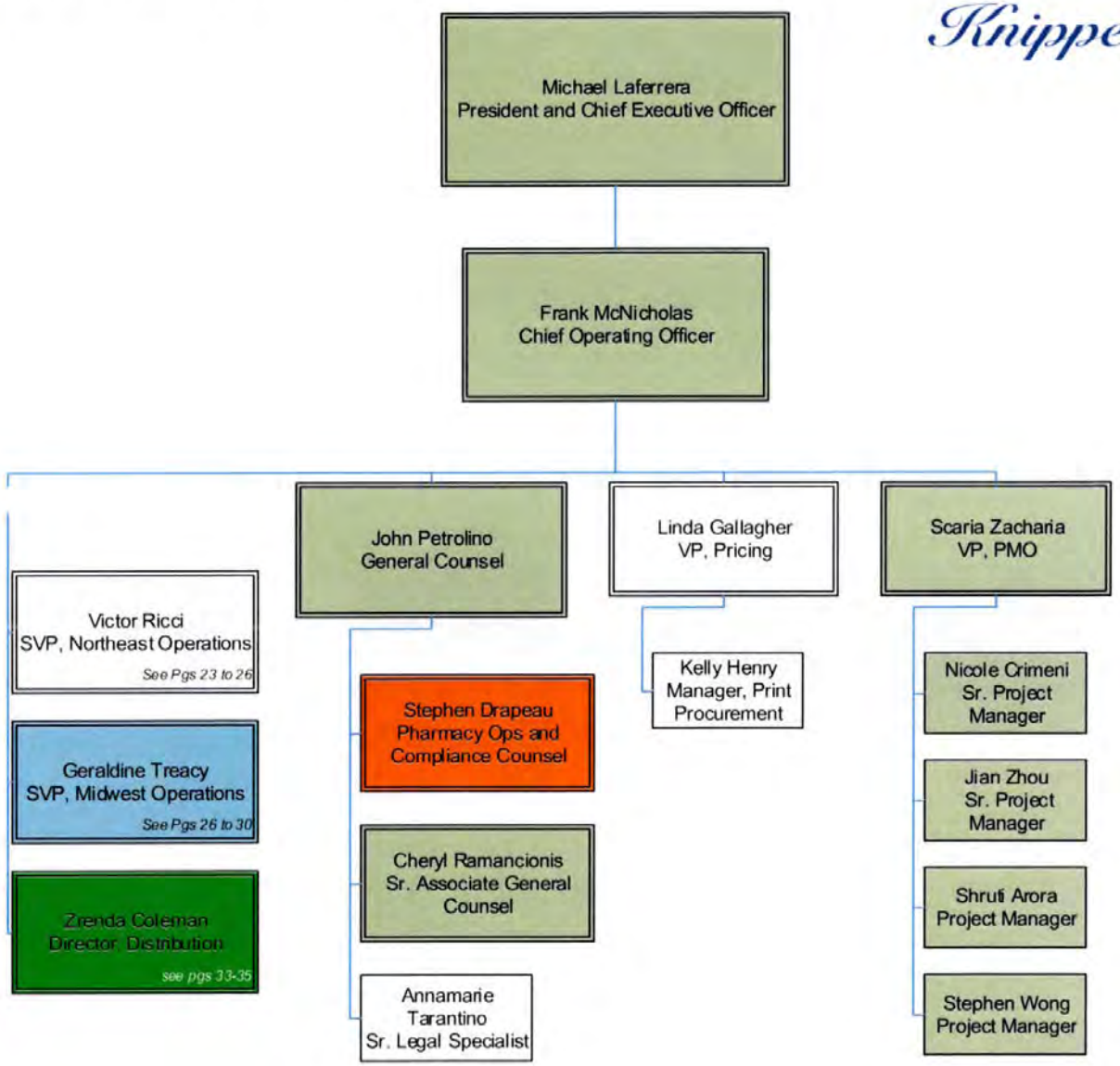
Lynda Triminsky
Billing Analyst

Org Chart JKC 12-31-2024 V2.vsdm

CONFIDENTIAL

Operations, PMO, & Legal

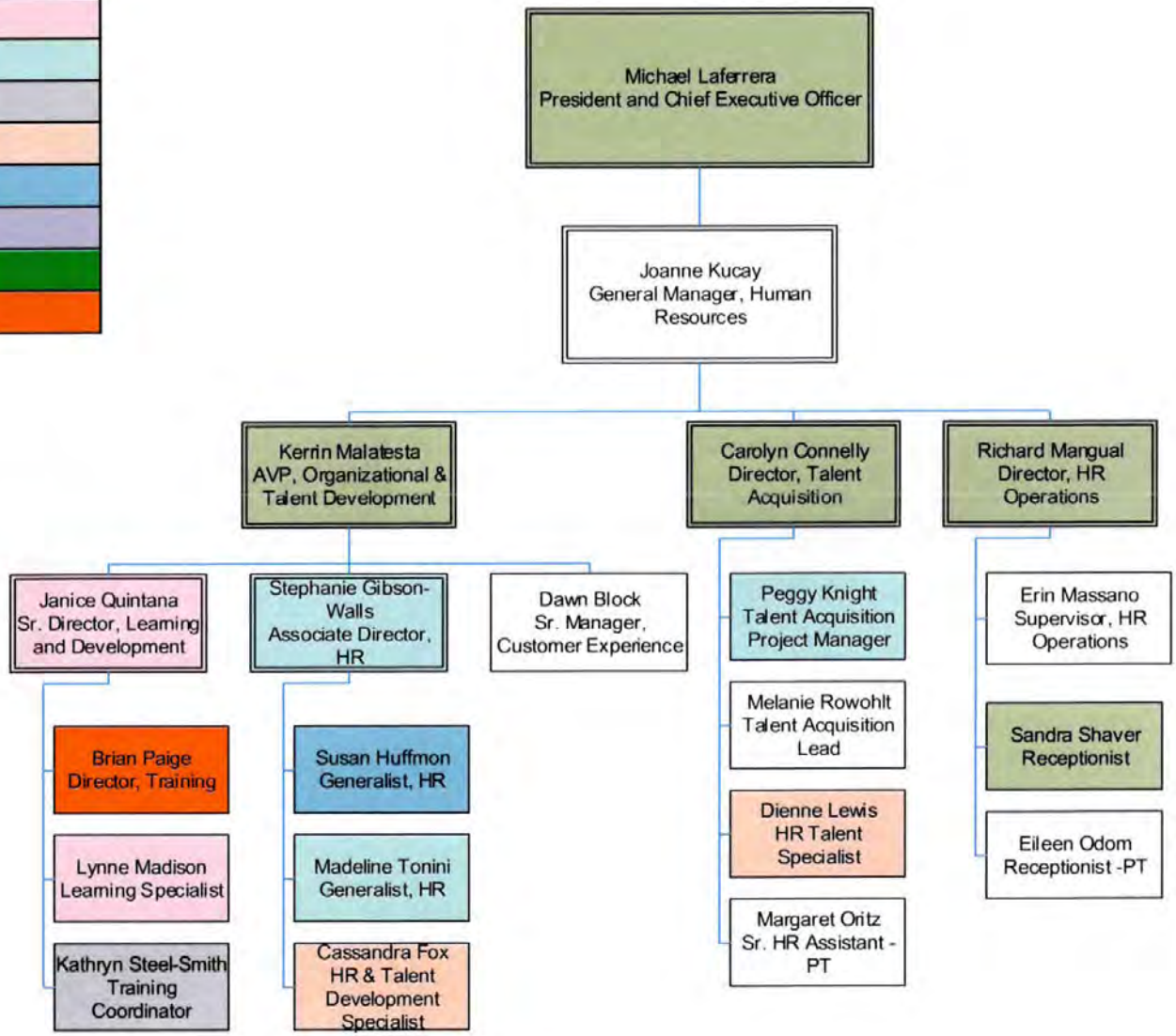
Legend	
OHW	
KDC	
SOM	
LAW	
LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



CONFIDENTIAL

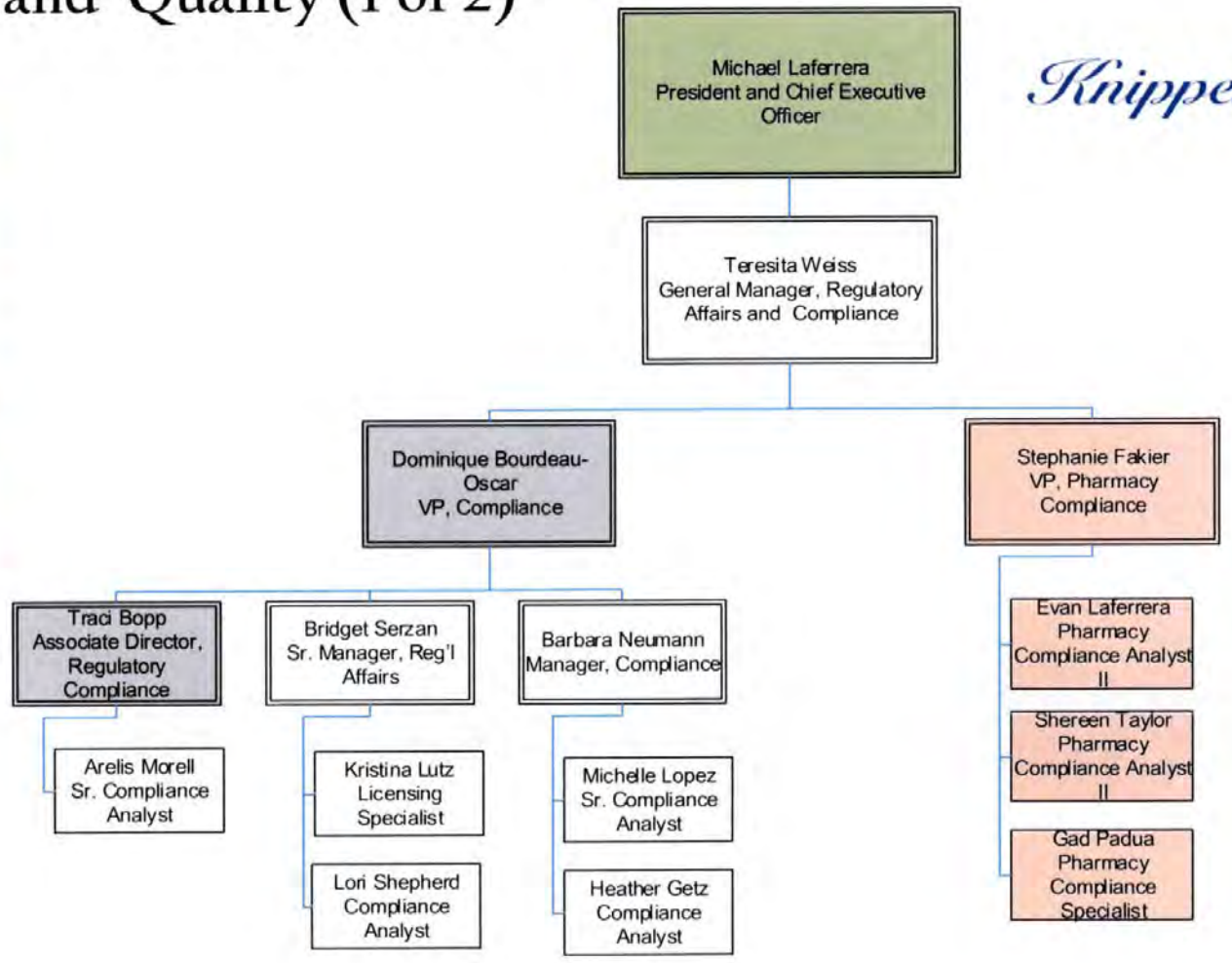
Human Resources

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LYN	
KEP	
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MDC	
Remote	



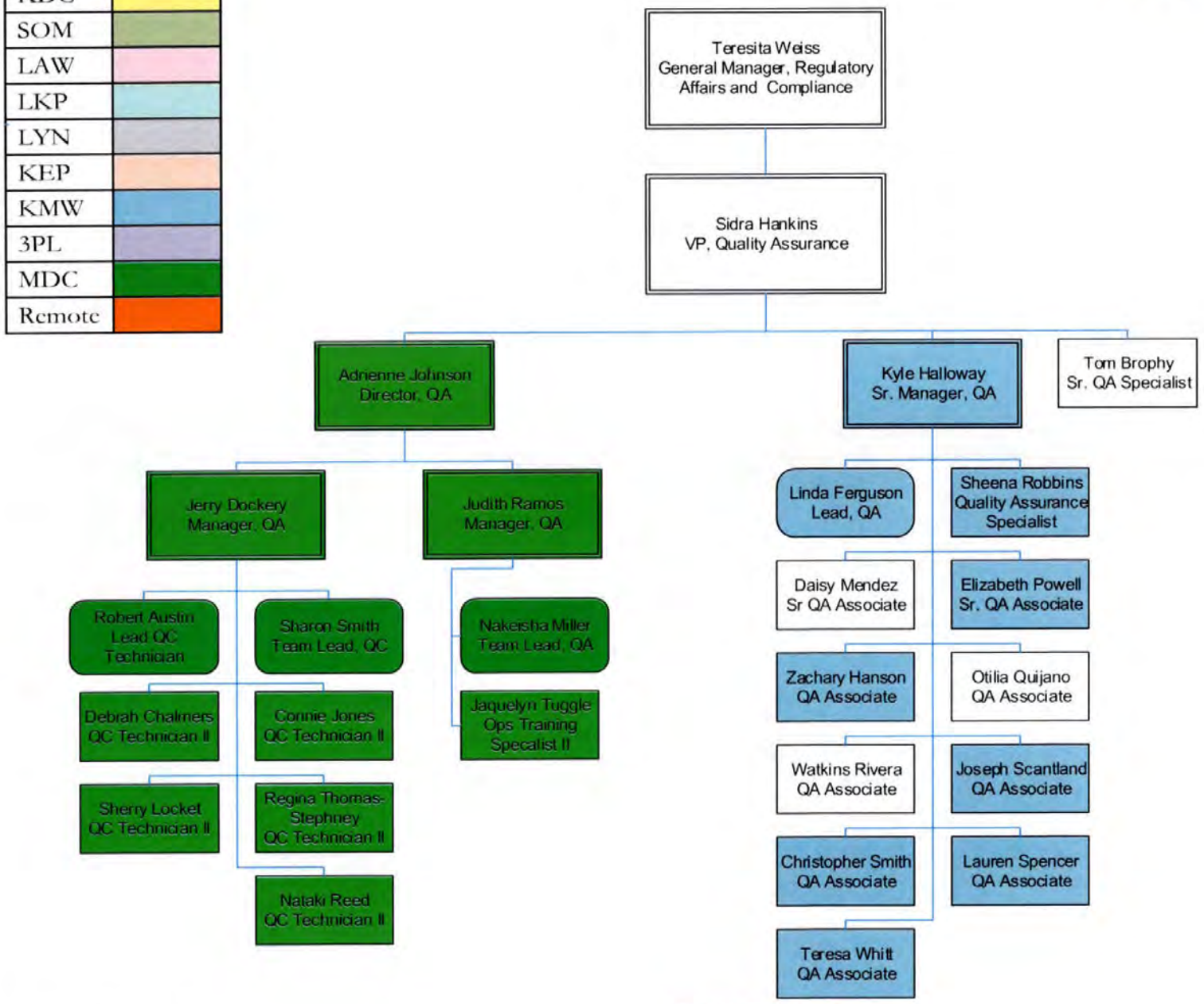
Regulatory and Quality (1 of 2)

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LKP	
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KEP	
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3PL	
MDC	
Remote	

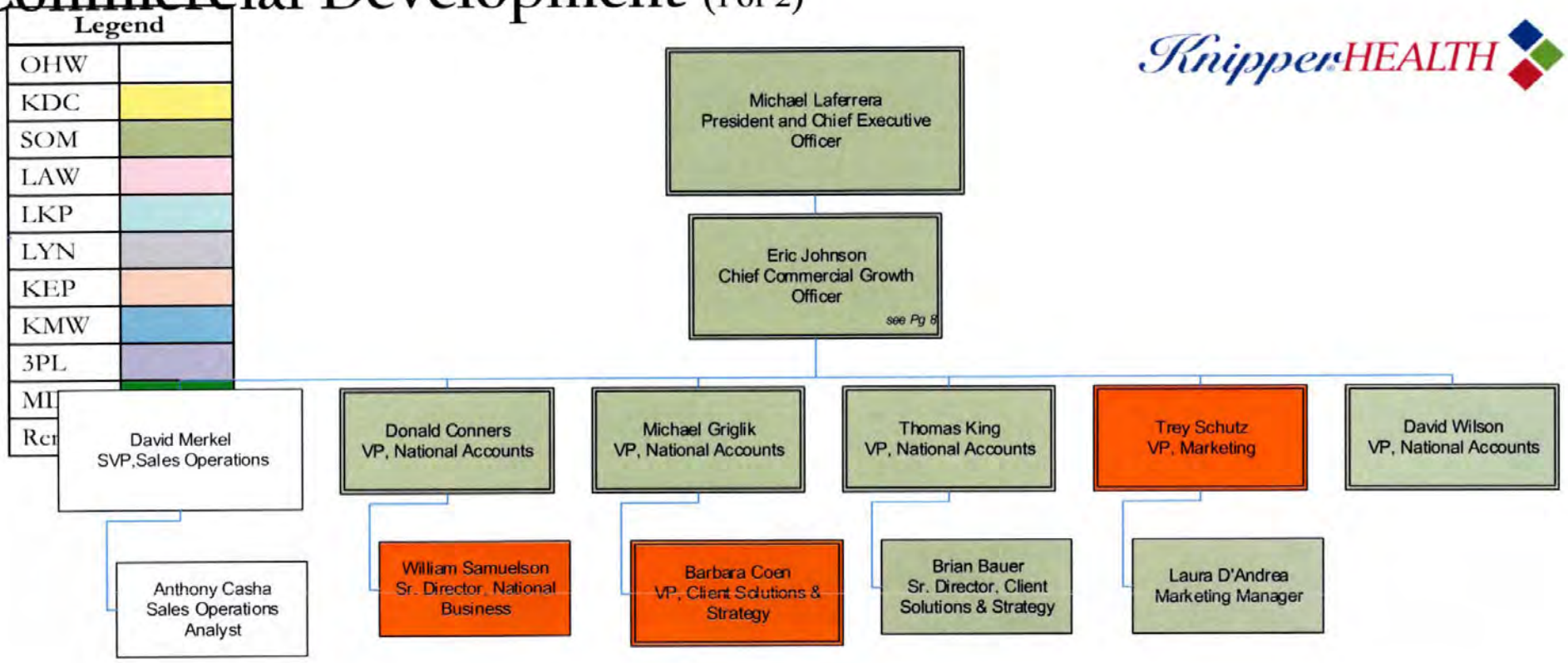


Regulatory and Quality (2 of 2)

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MDC	
Remote	

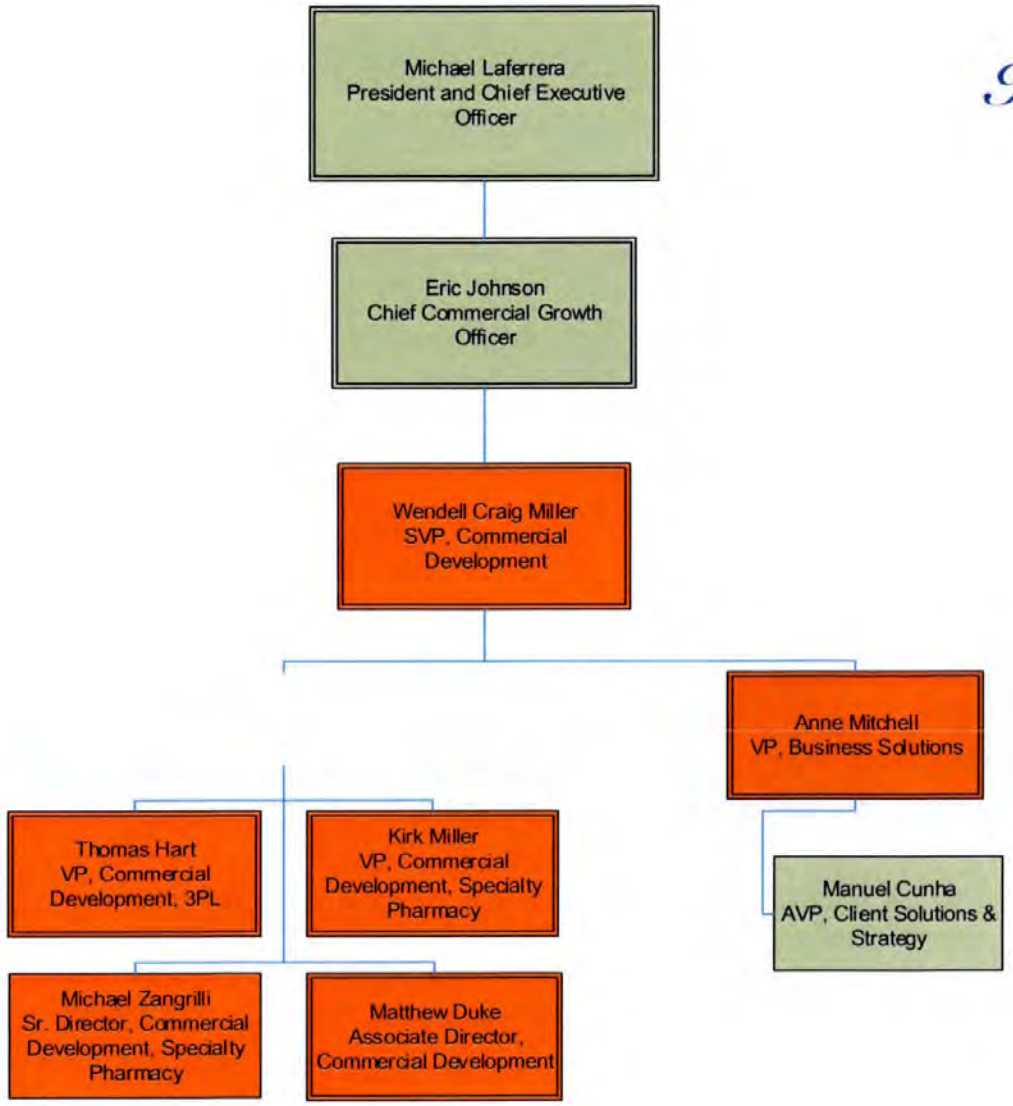


Commercial Development (1 of 2)



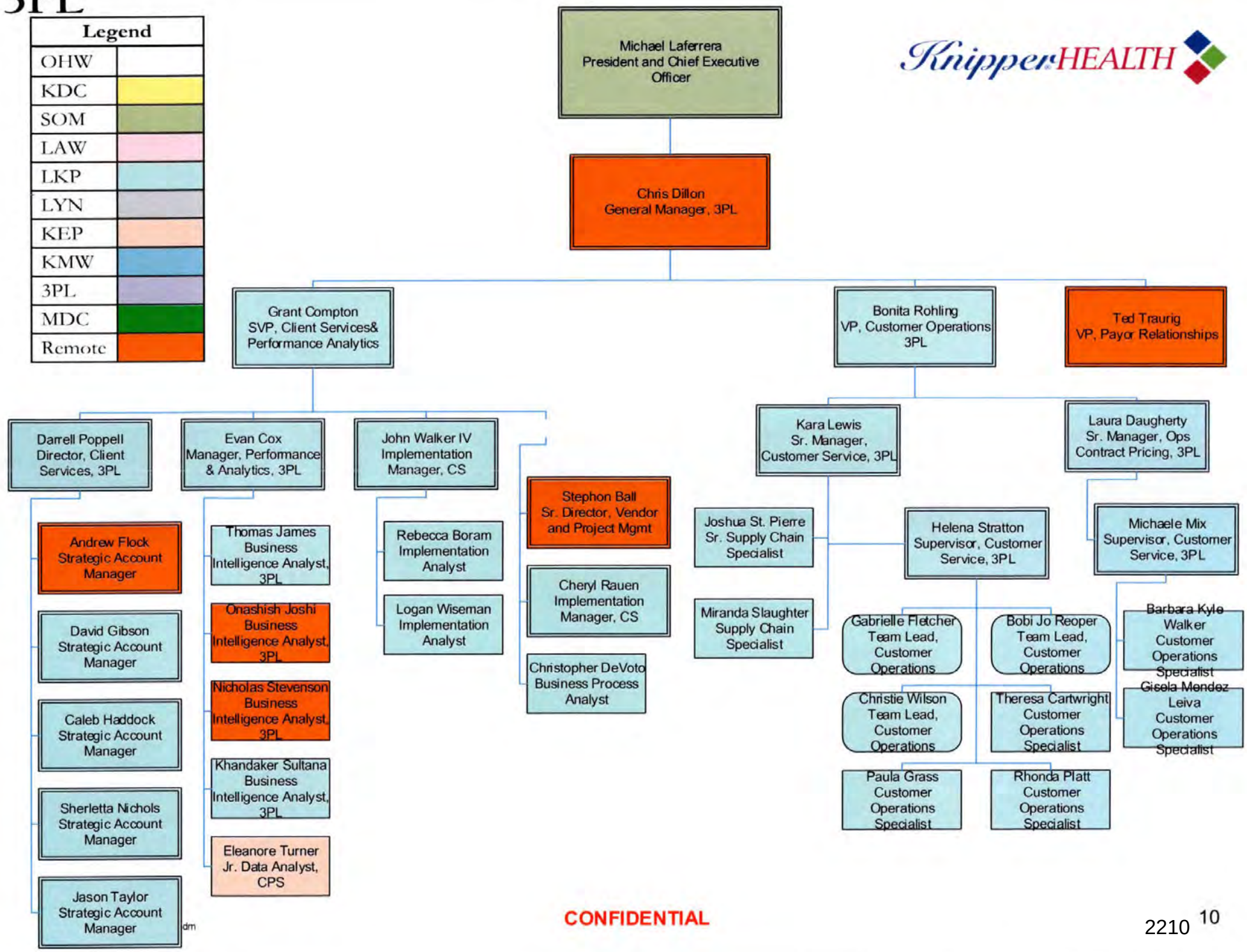
CONFIDENTIAL

Legend	
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LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



3PL

Legend	
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MDC	
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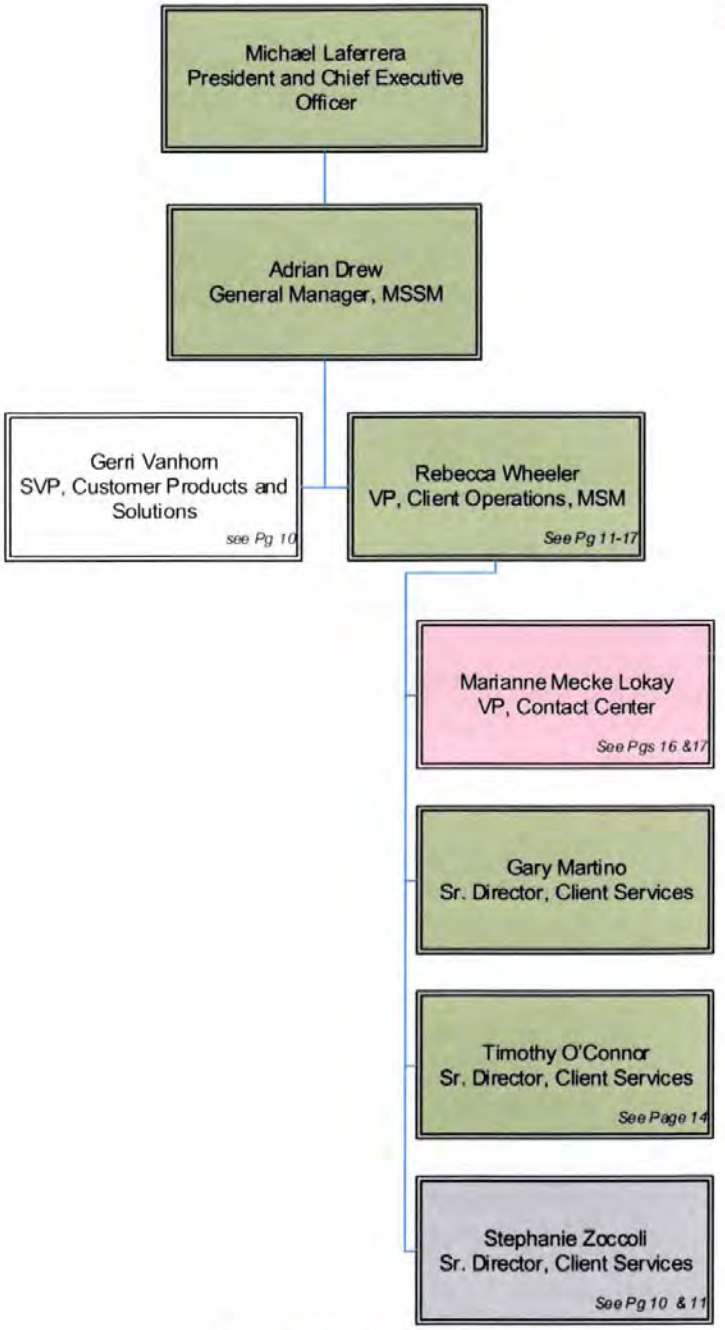


dm

CONFIDENTIAL

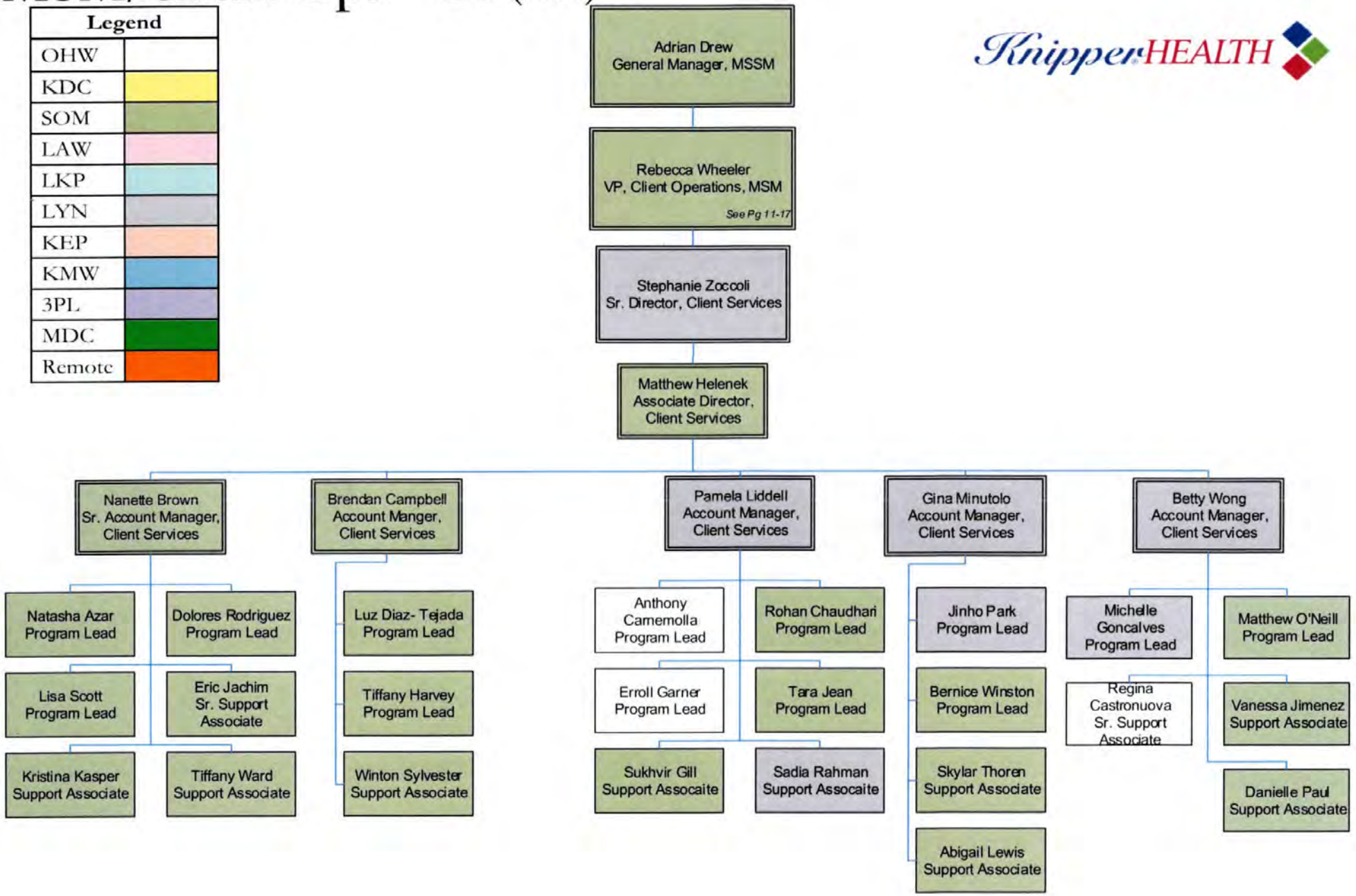
MSM/Client Operations

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KEP	
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3PL	
MDC	
Remote	



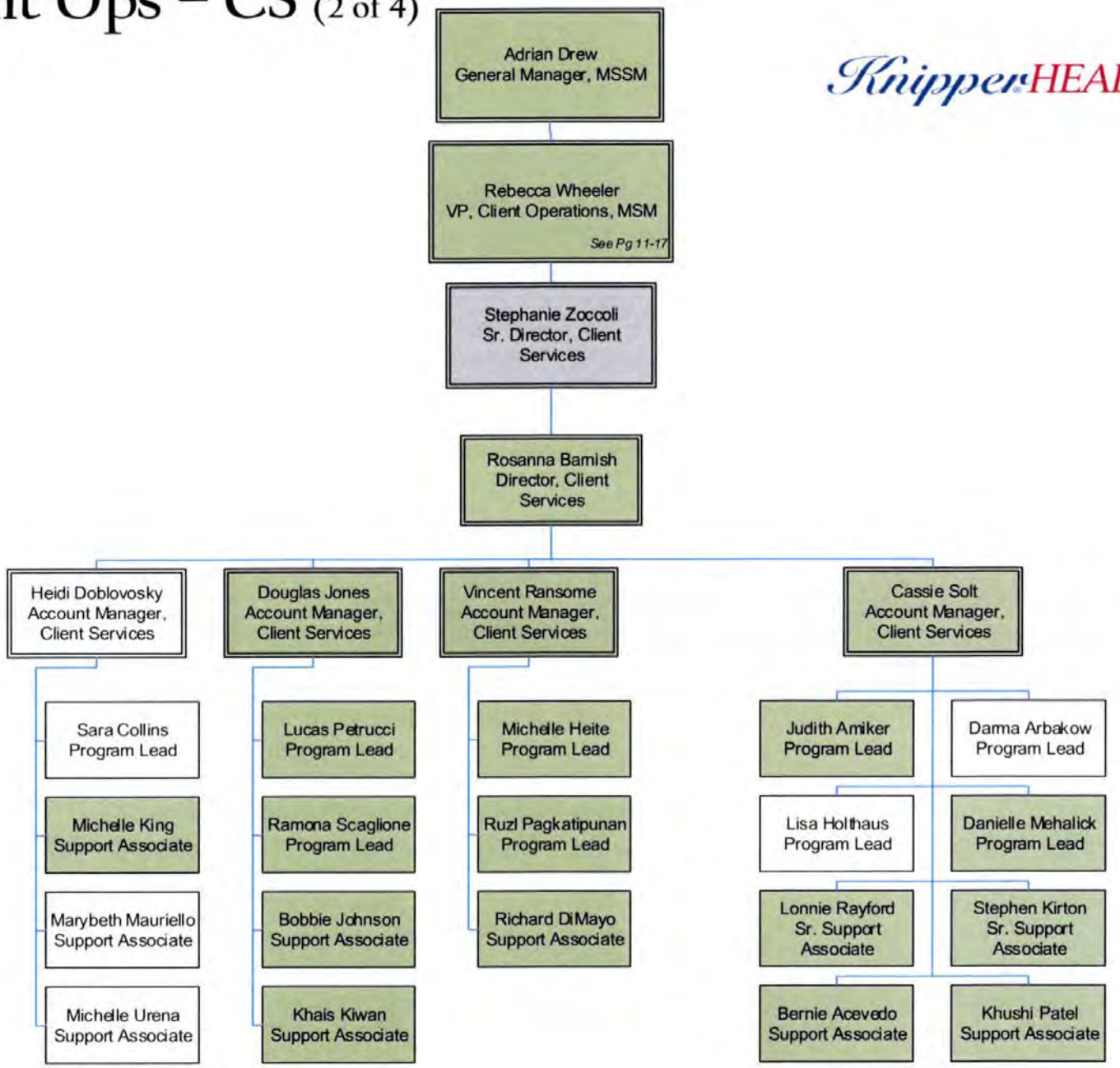
MSM/Client Ops – CS (1 of 5)

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MDC	
Remote	



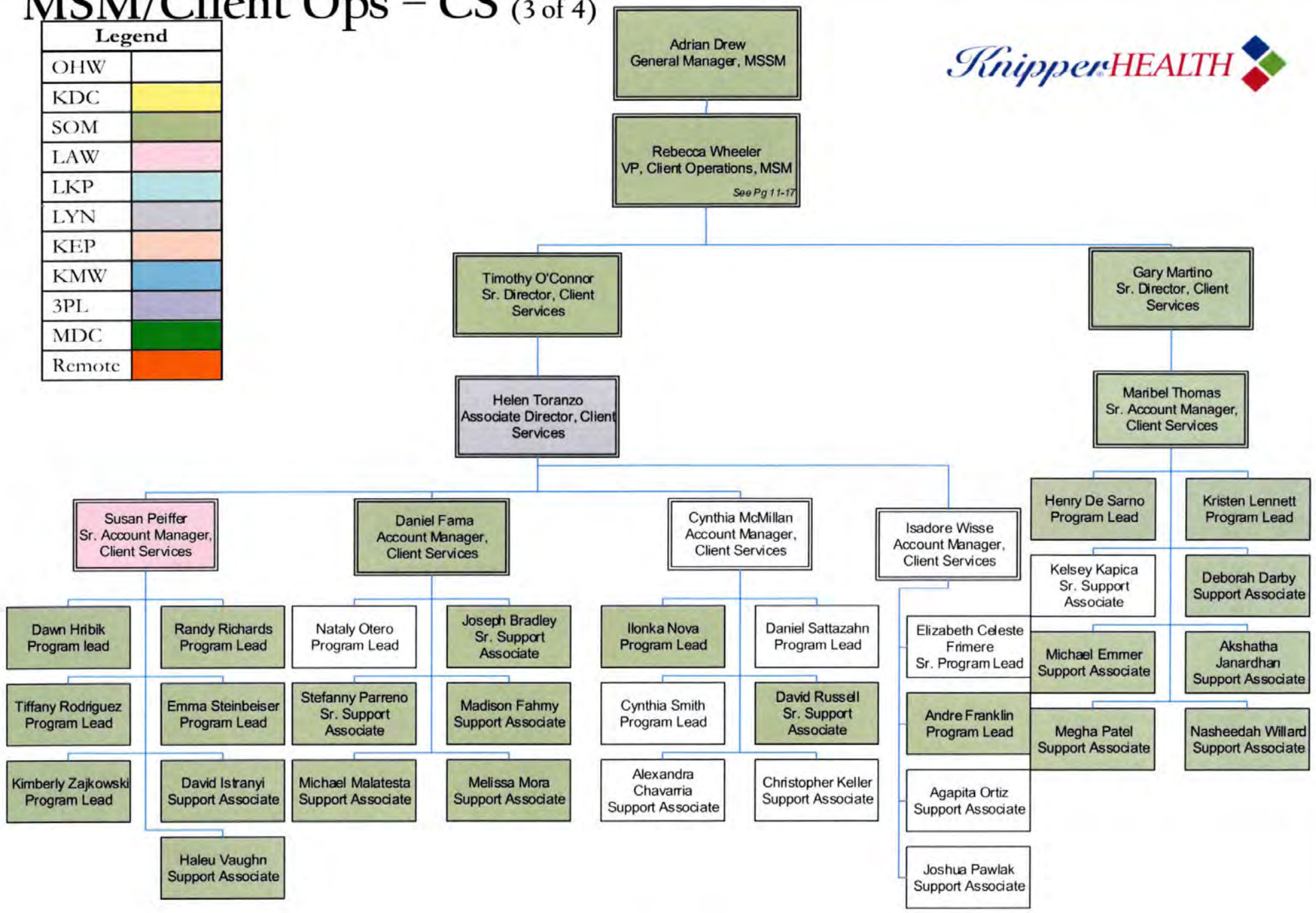
MSM/Client Ops – CS (2 of 4)

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3PL	
MDC	
Remote	



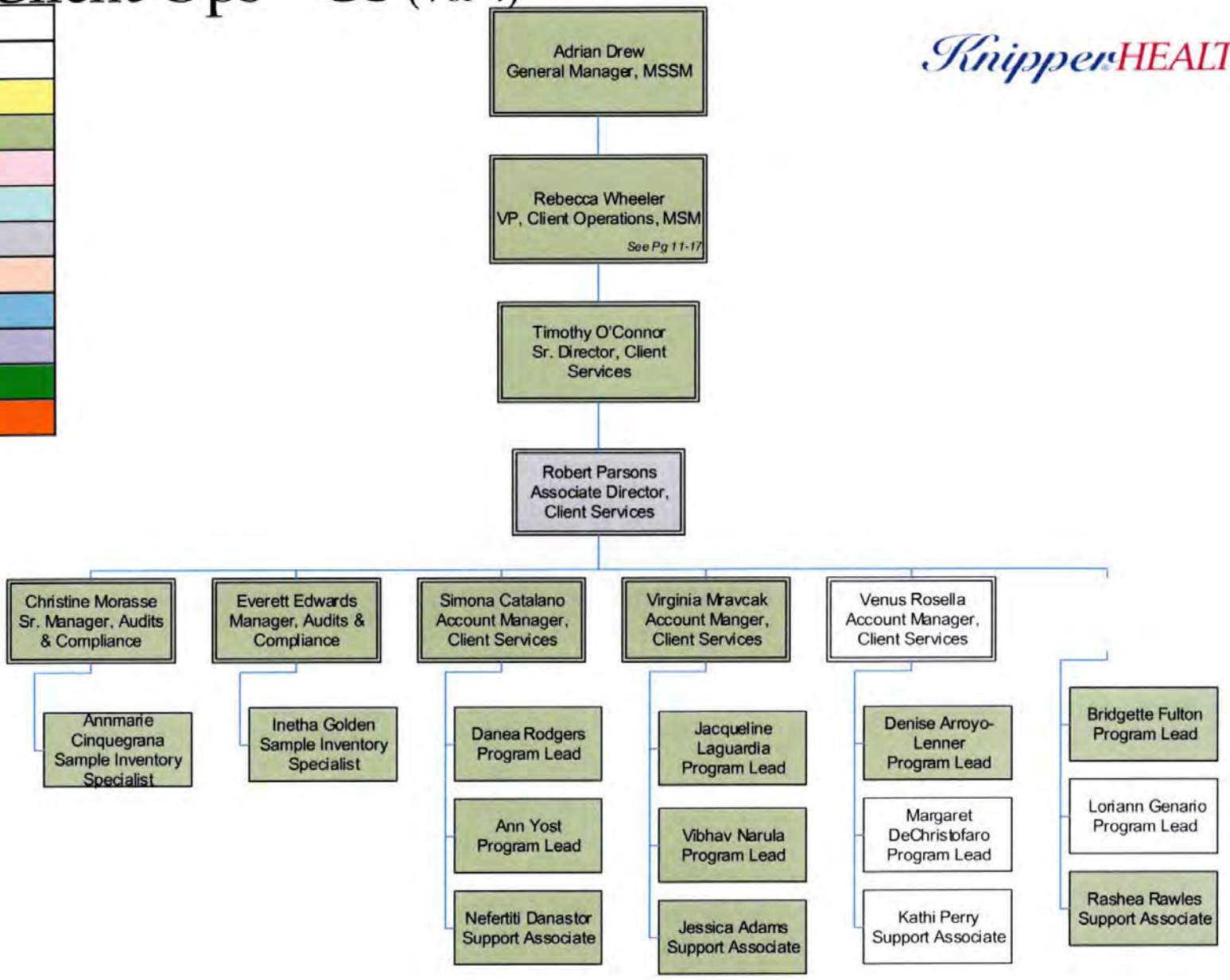
MSM/Client Ops – CS (3 of 4)

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3PL	
MDC	
Remote	



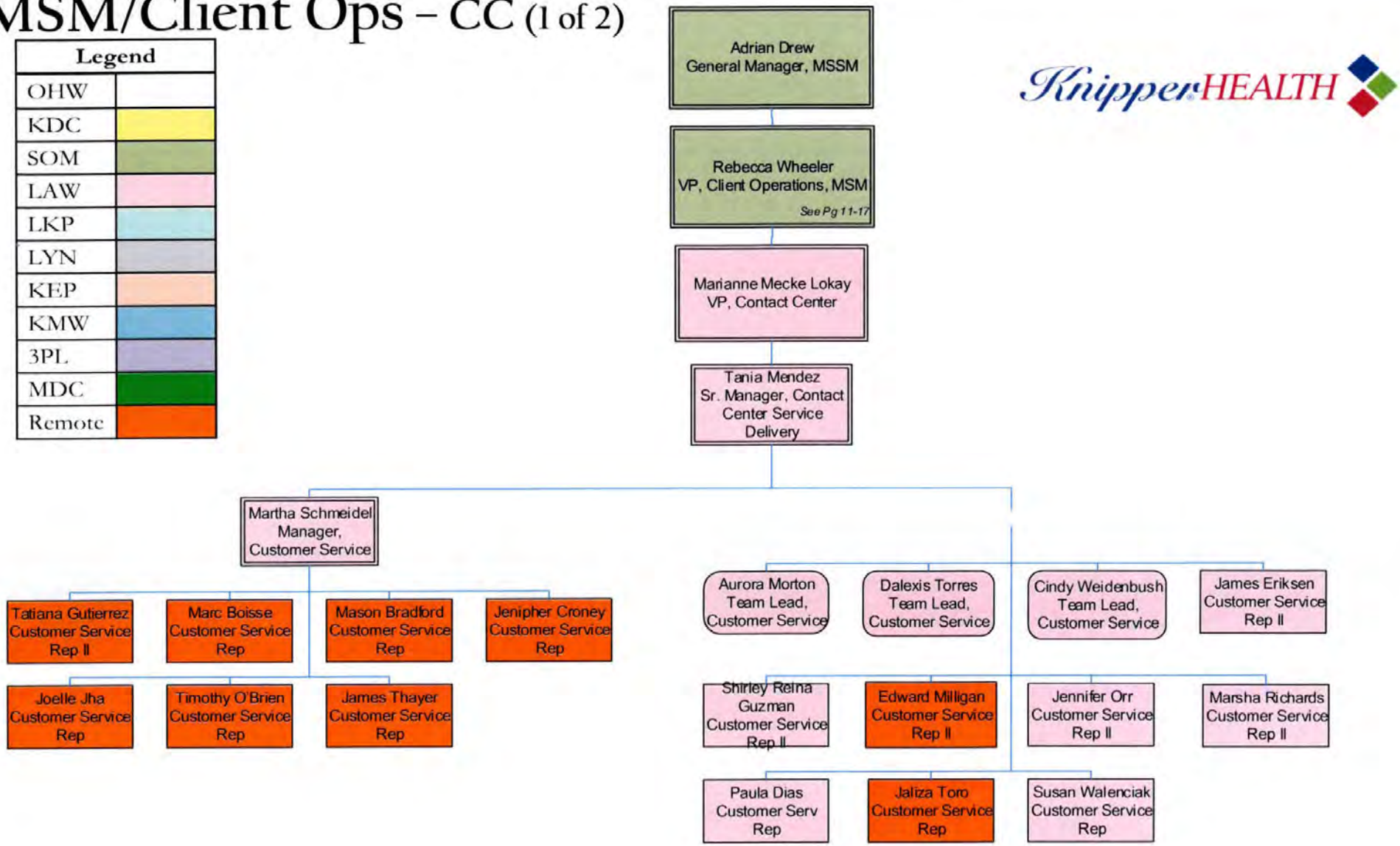
MSM/Client Ops – CS (4 of 4)

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3PL	
MDC	
Remote	



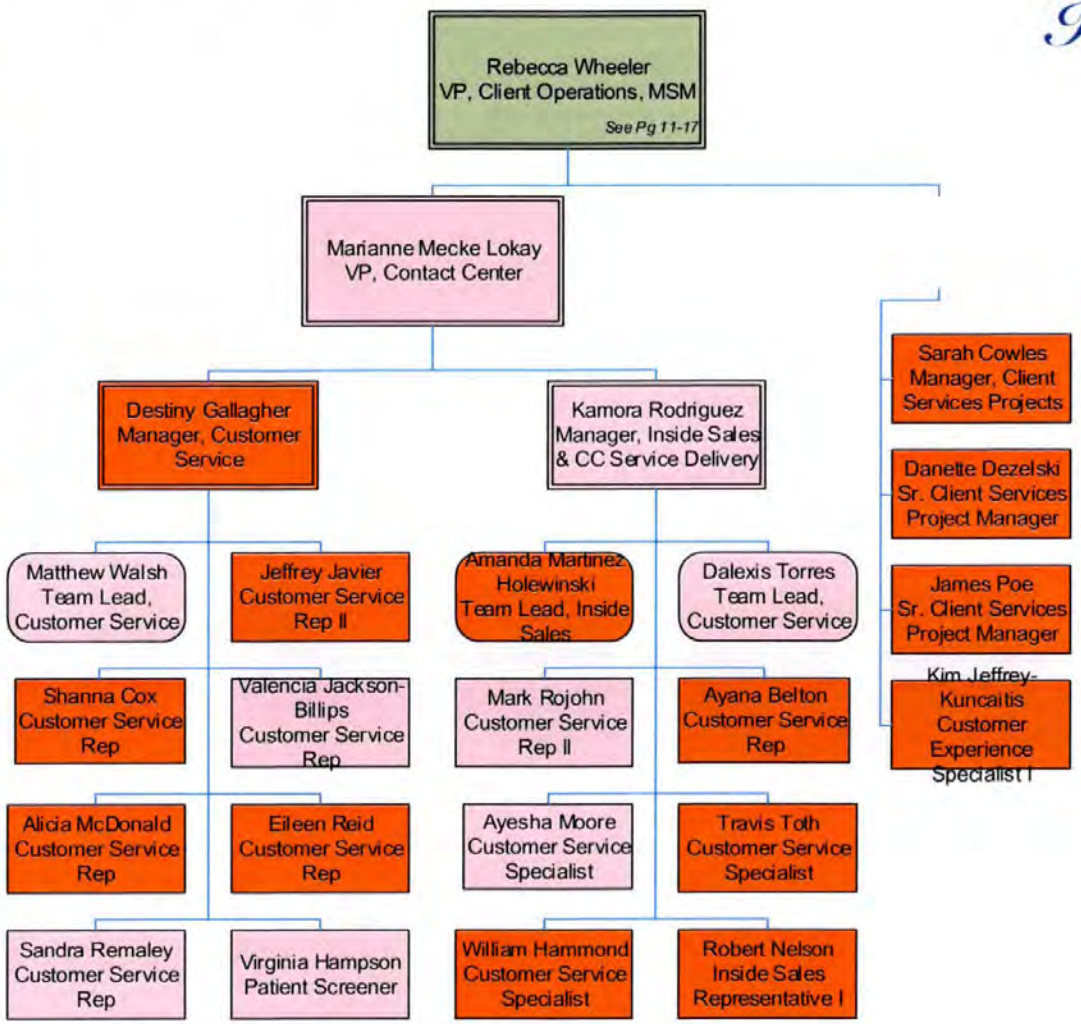
MSM/Client Ops – CC (1 of 2)

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3PL	
MDC	
Remote	



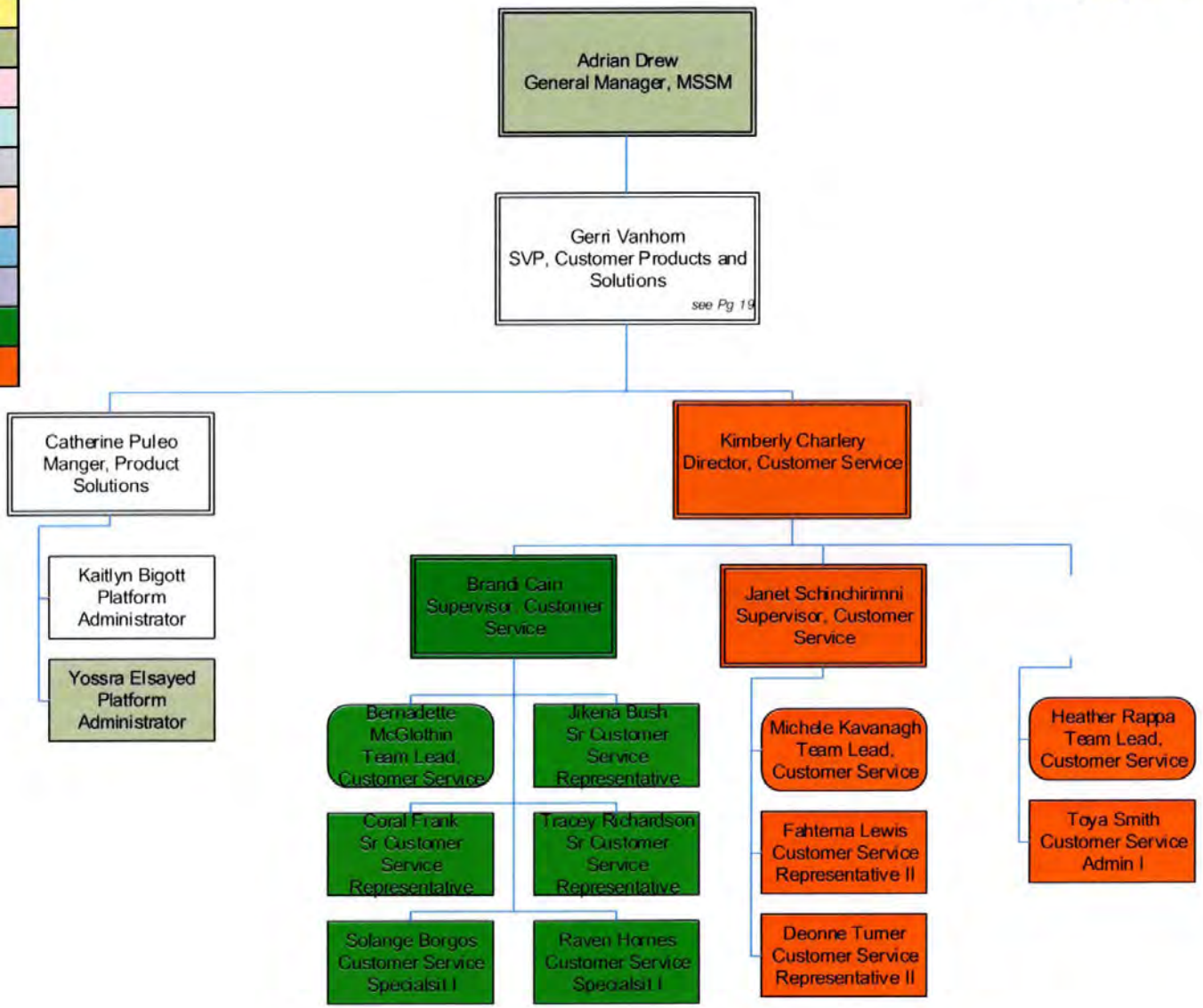
MSM/Client Ops – CC (2 of 2)

Legend	
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MDC	
Remote	



MSM/Client Ops - CST (1 of 2)

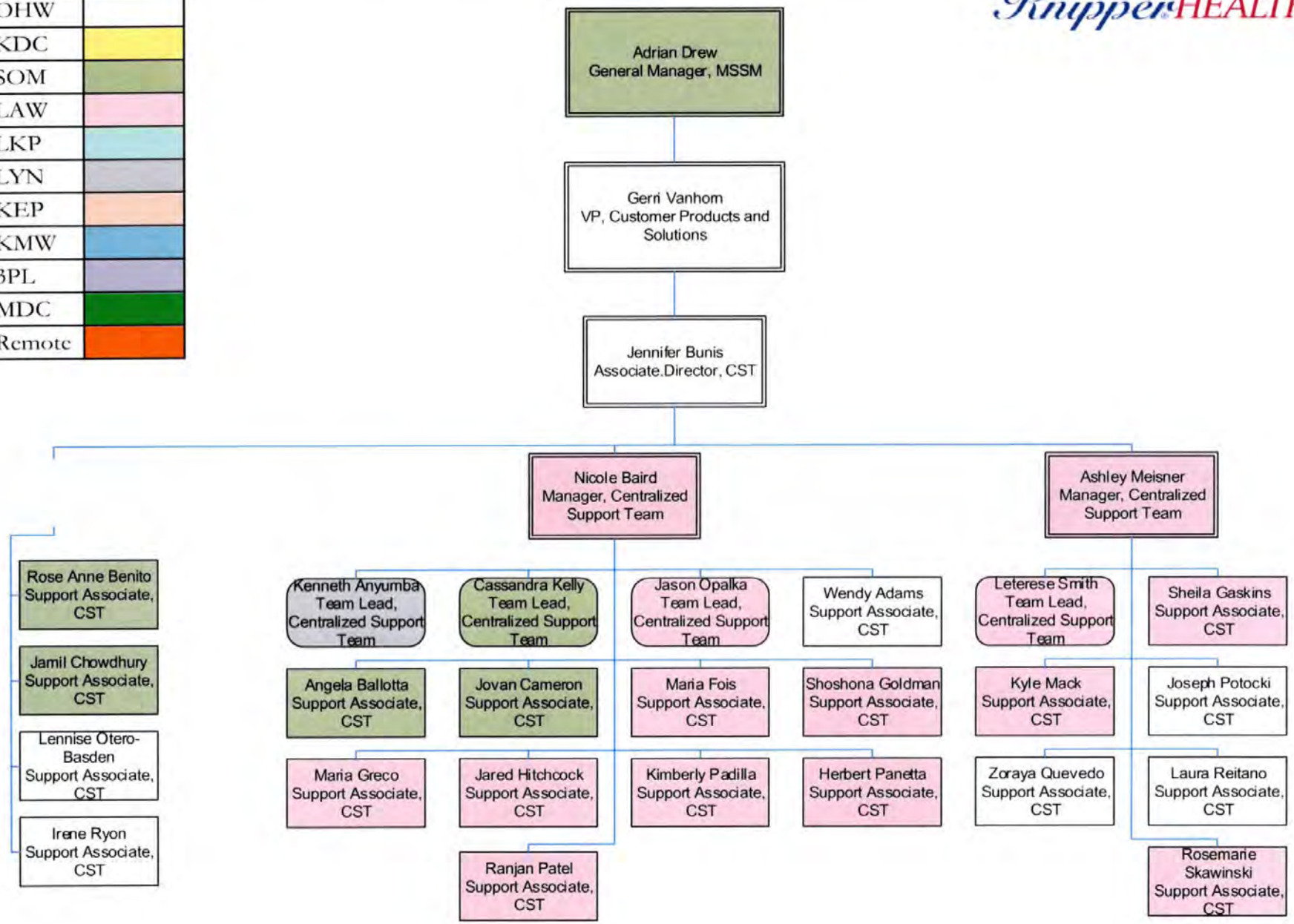
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CONFIDENTIAL

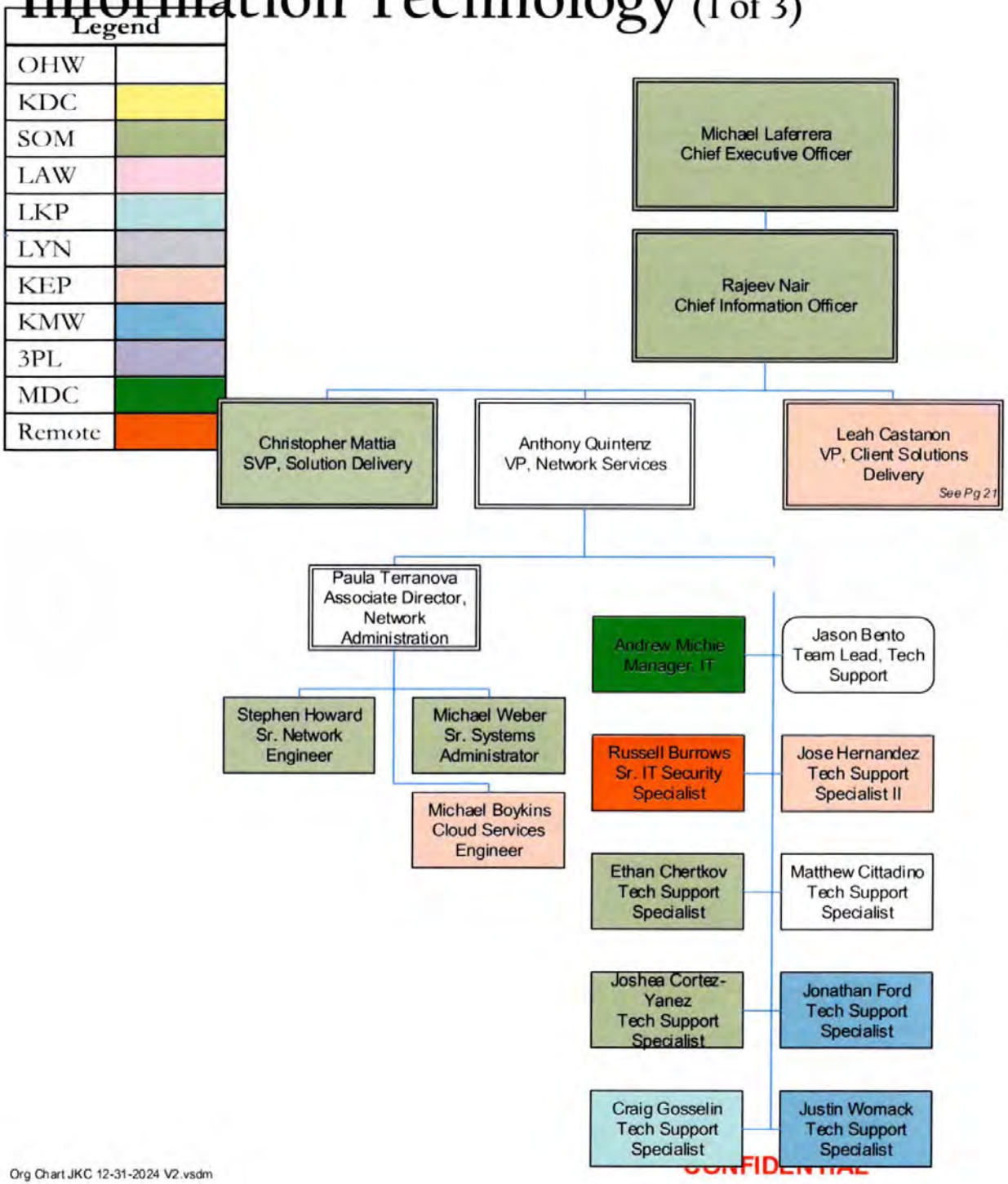
MSM/Client Ops - CST (2 of 2)

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Remote	



CONFIDENTIAL

Information Technology (1 of 3)

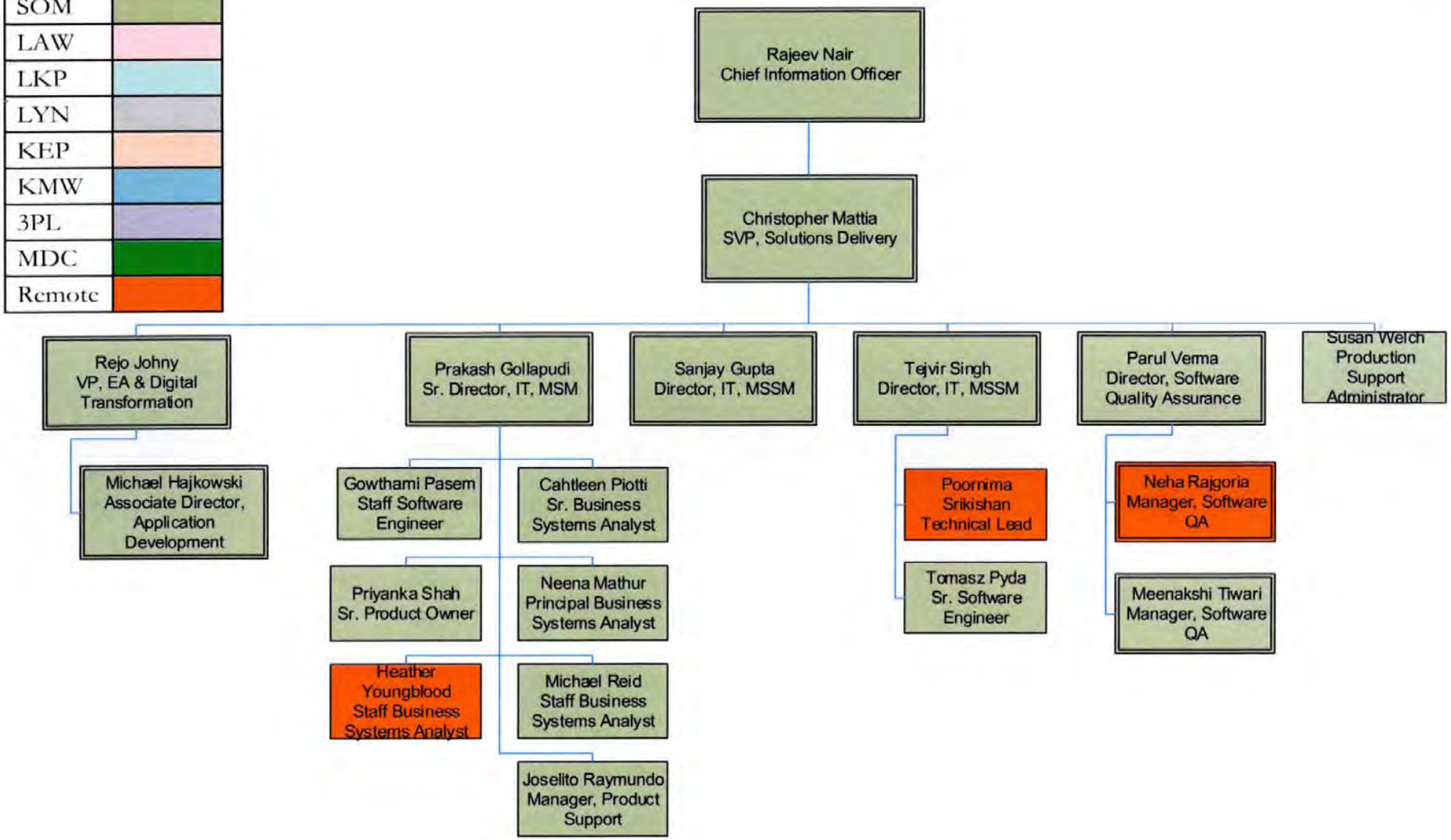


Org Chart JKC 12-31-2024 V2.vsdm

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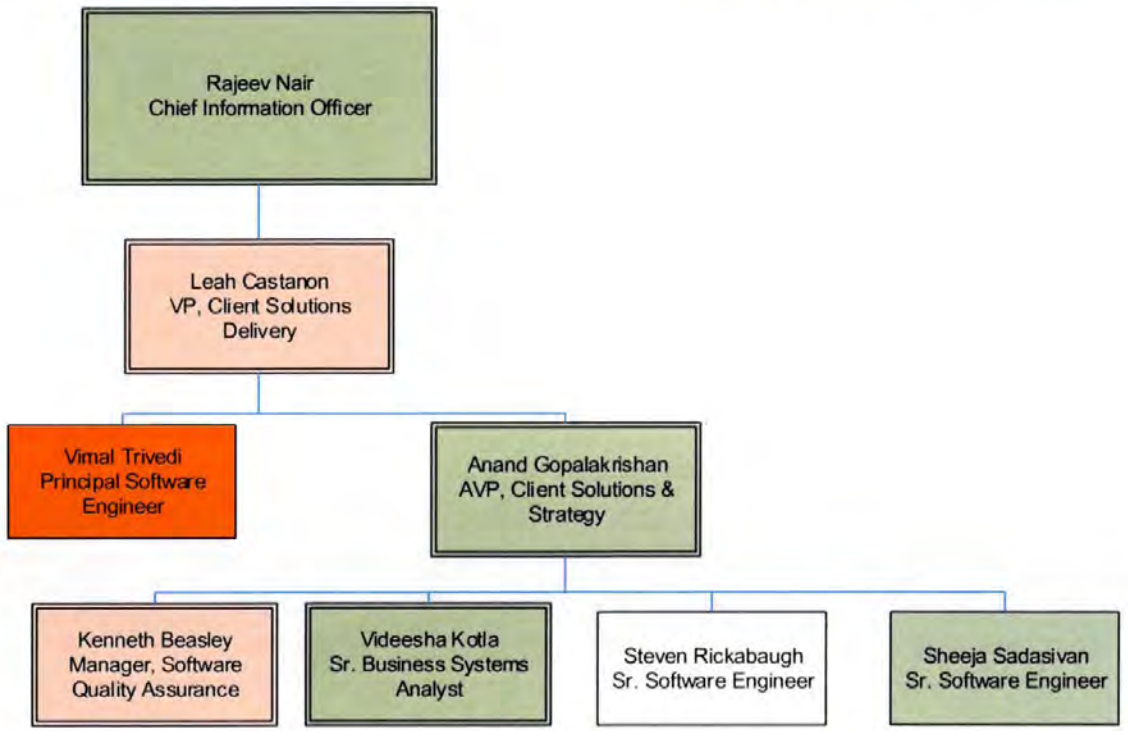
Information Technology (2 of 3)

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Information Technology (3 of 3)

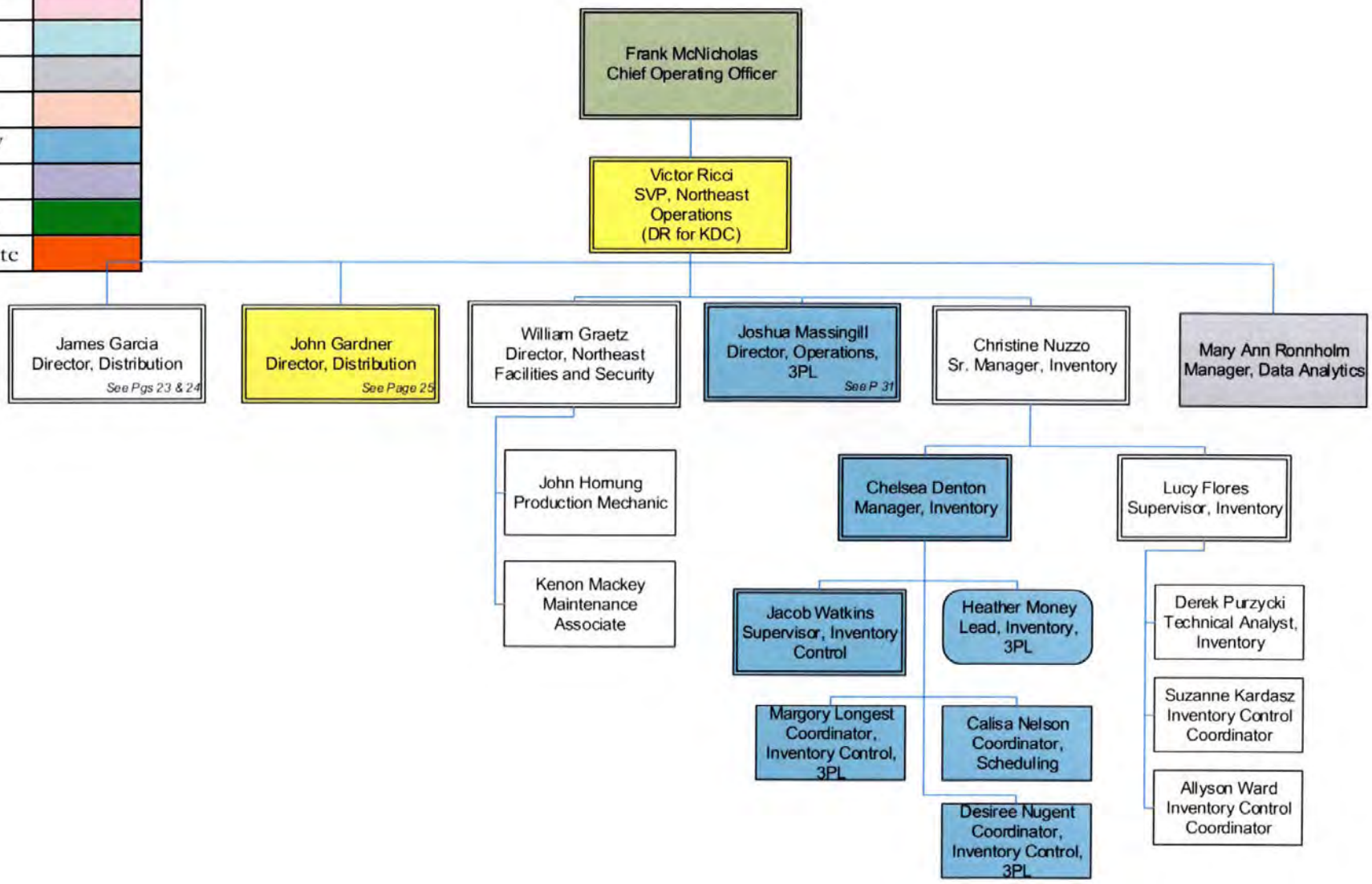
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KEP	
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MDC	
Remote	



CONFIDENTIAL

Operations (1 of 13)

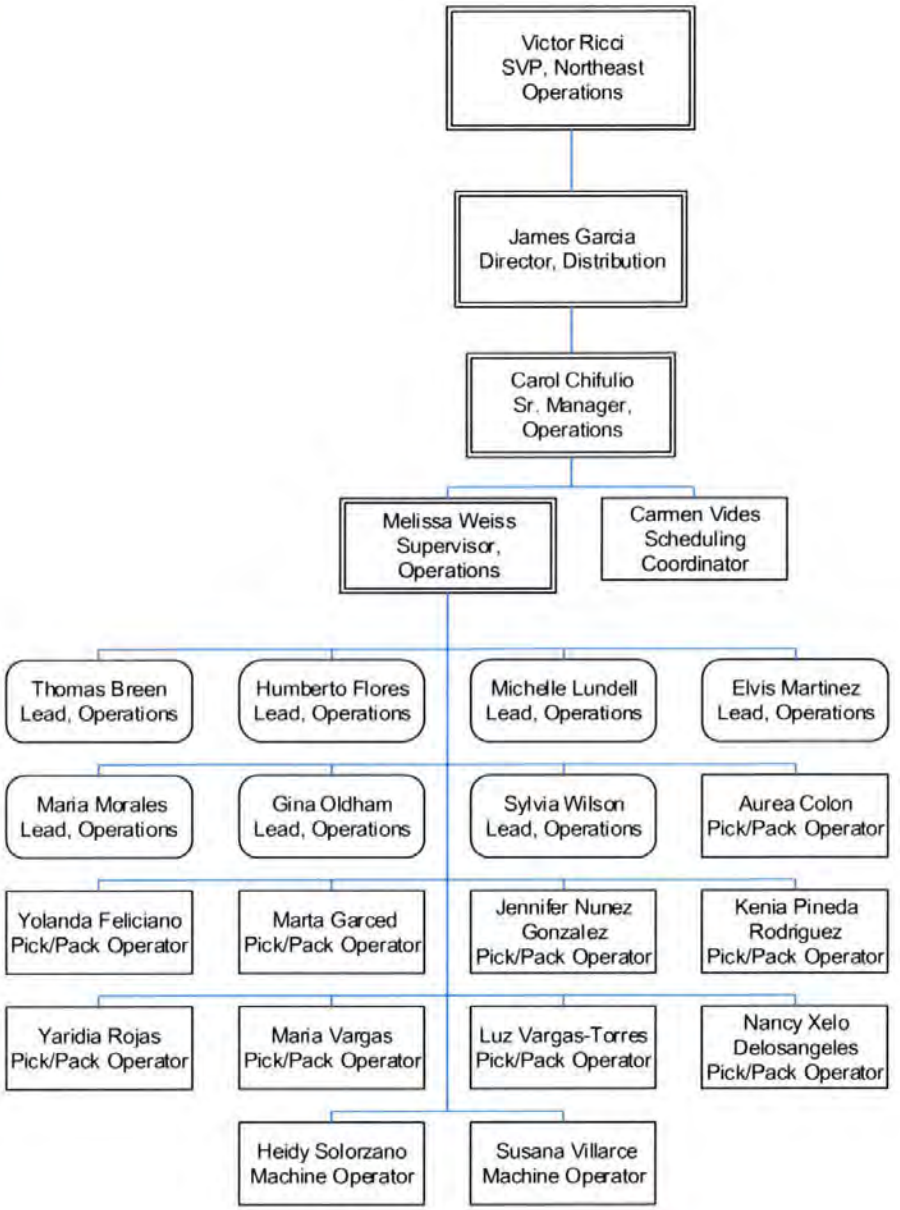
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KEP	
KMW	
3PL	
MDC	
Remote	



Operations (2 of 13)

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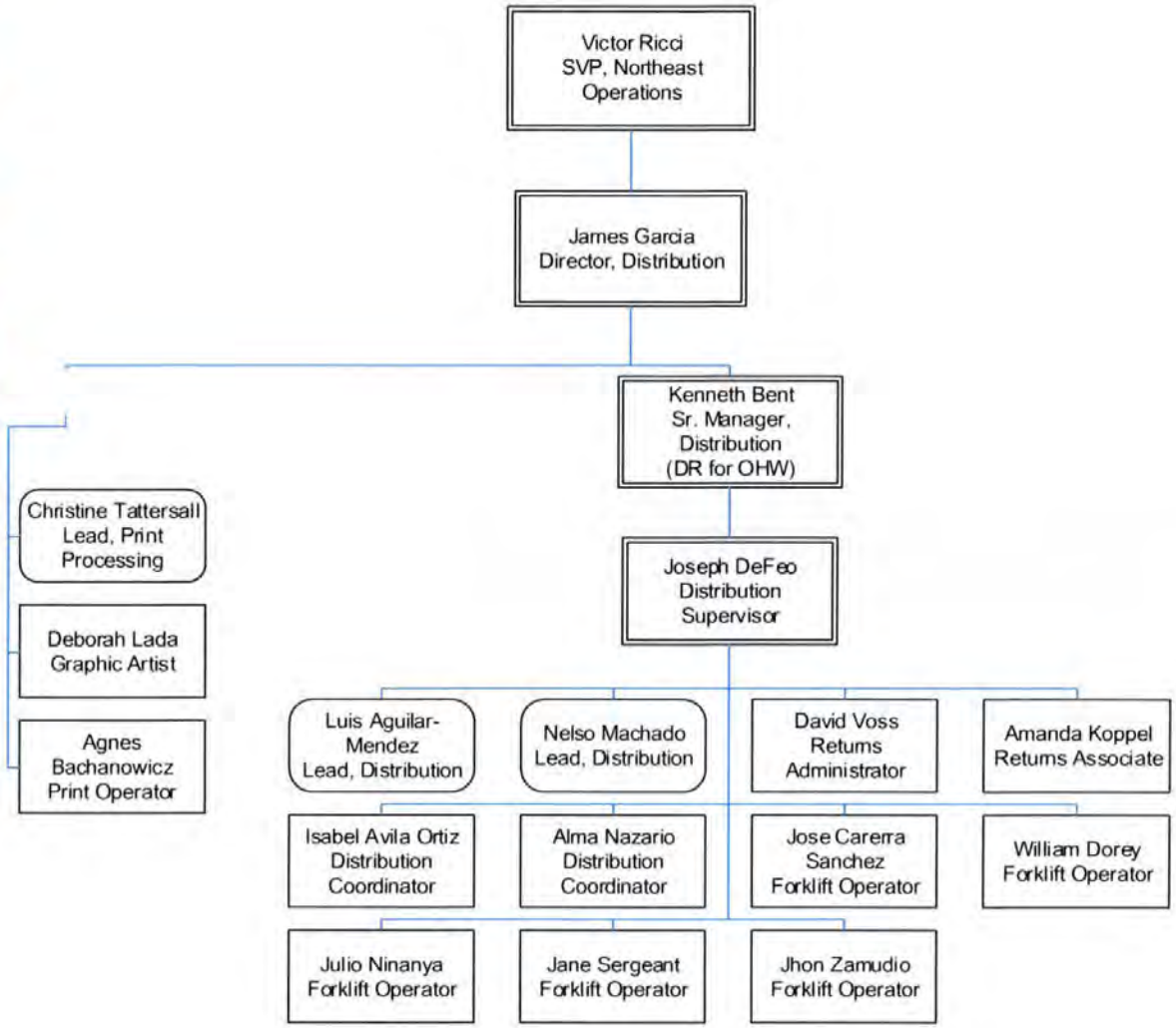
KnipperHEALTH



CONFIDENTIAL

Operations (3 of 13)

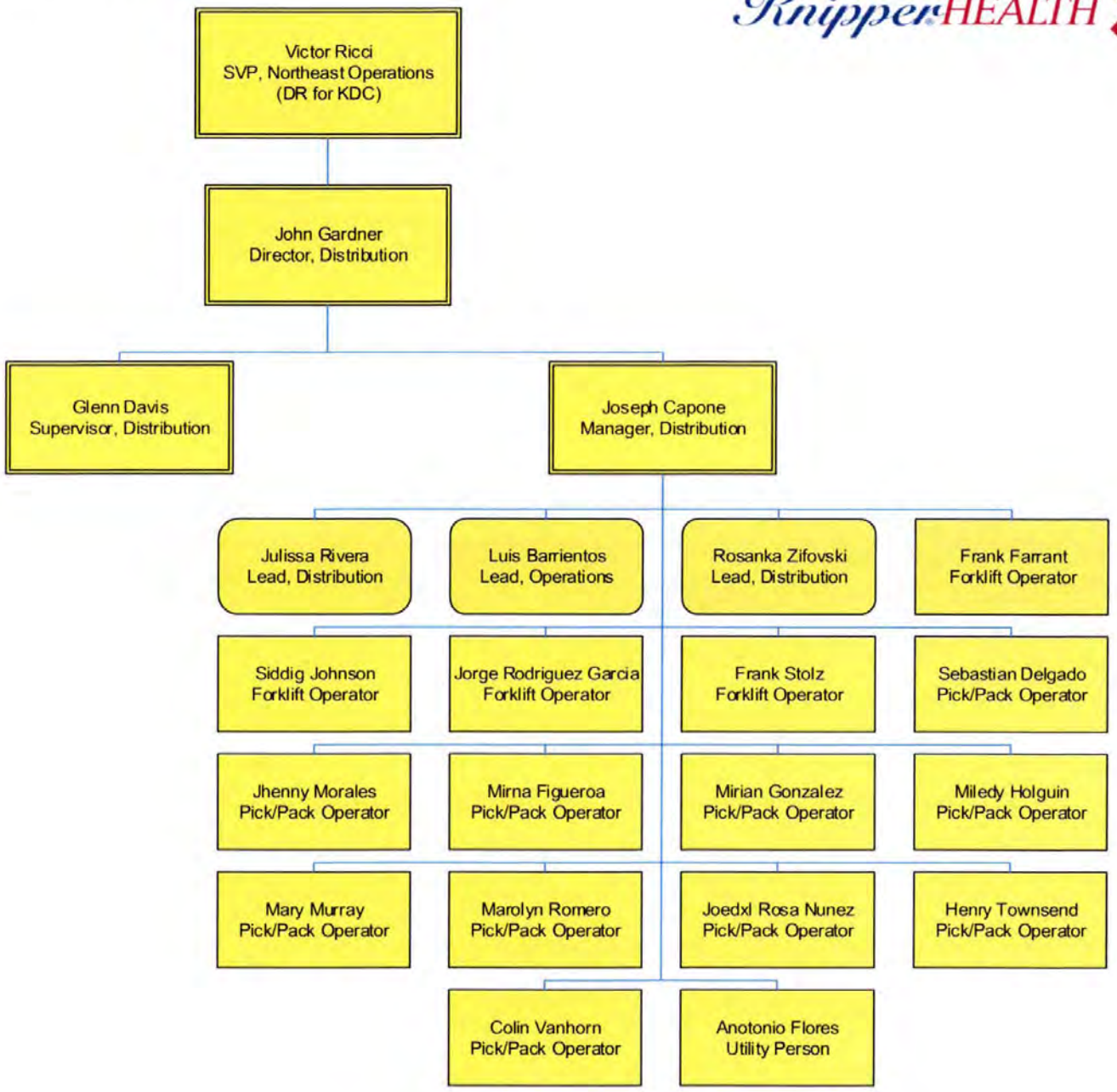
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CONFIDENTIAL

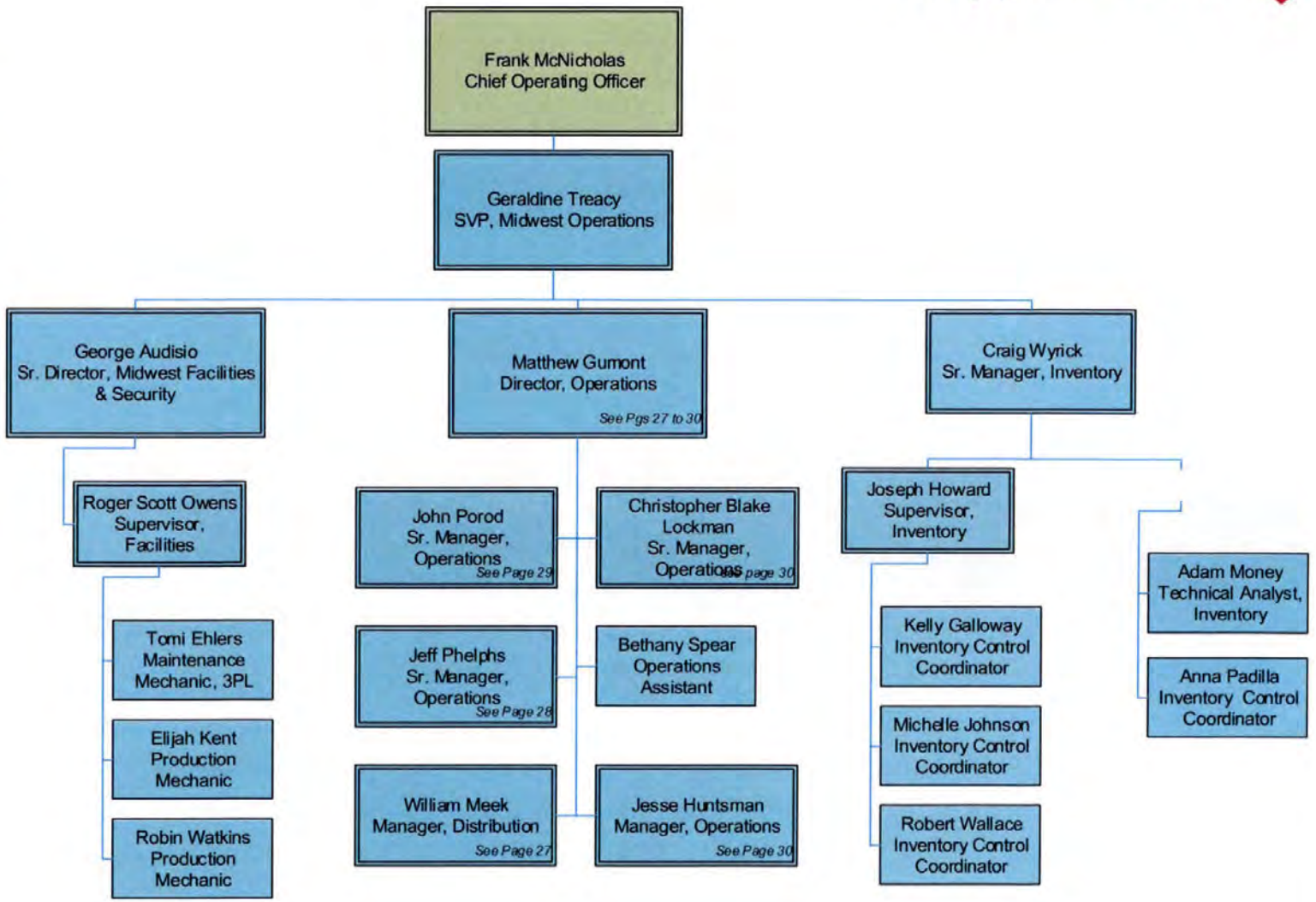
Operations (4 of 13)

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MDC	
Remote	



Operations (5 of 13)

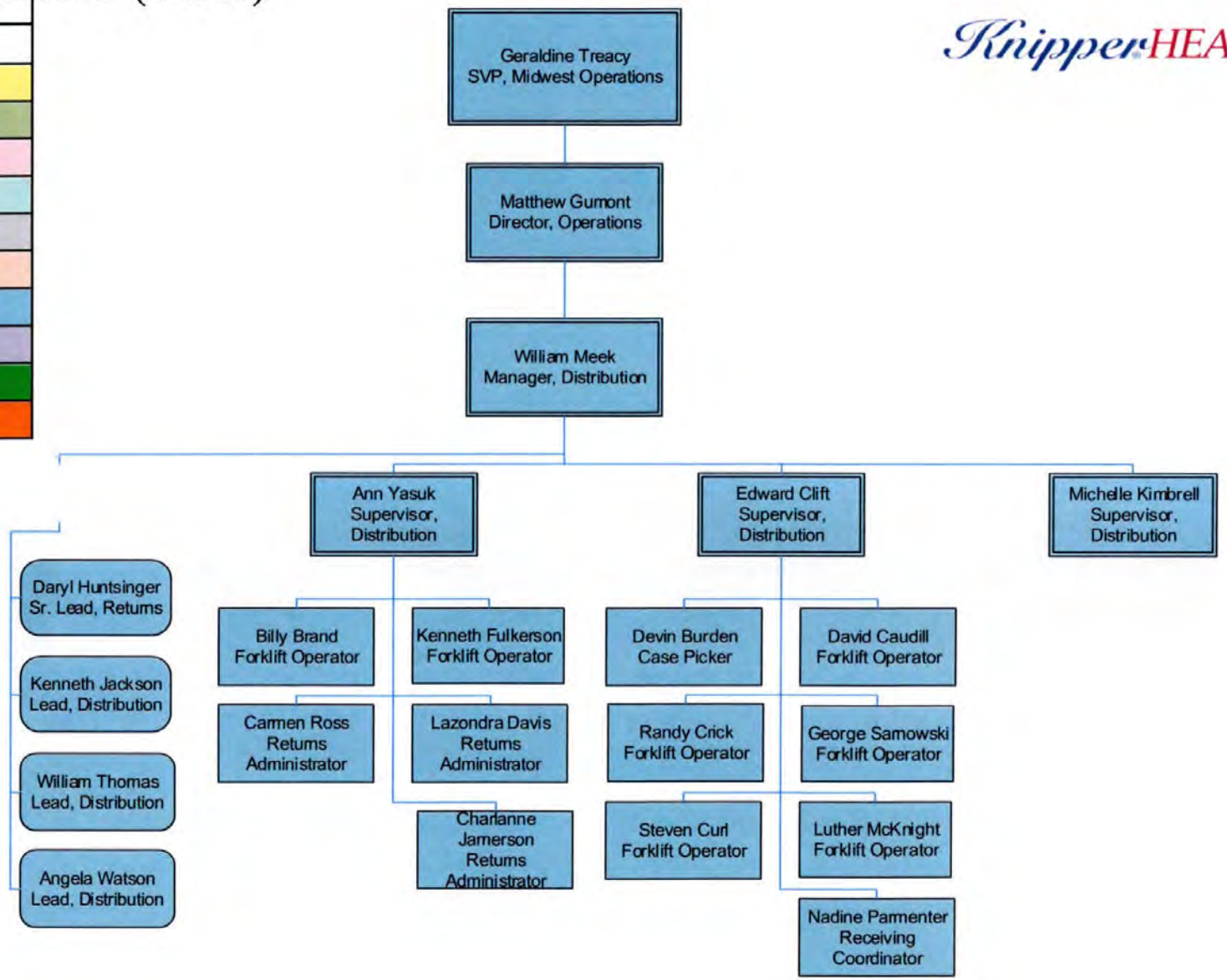
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Remote	



CONFIDENTIAL

Operations (6 of 13)

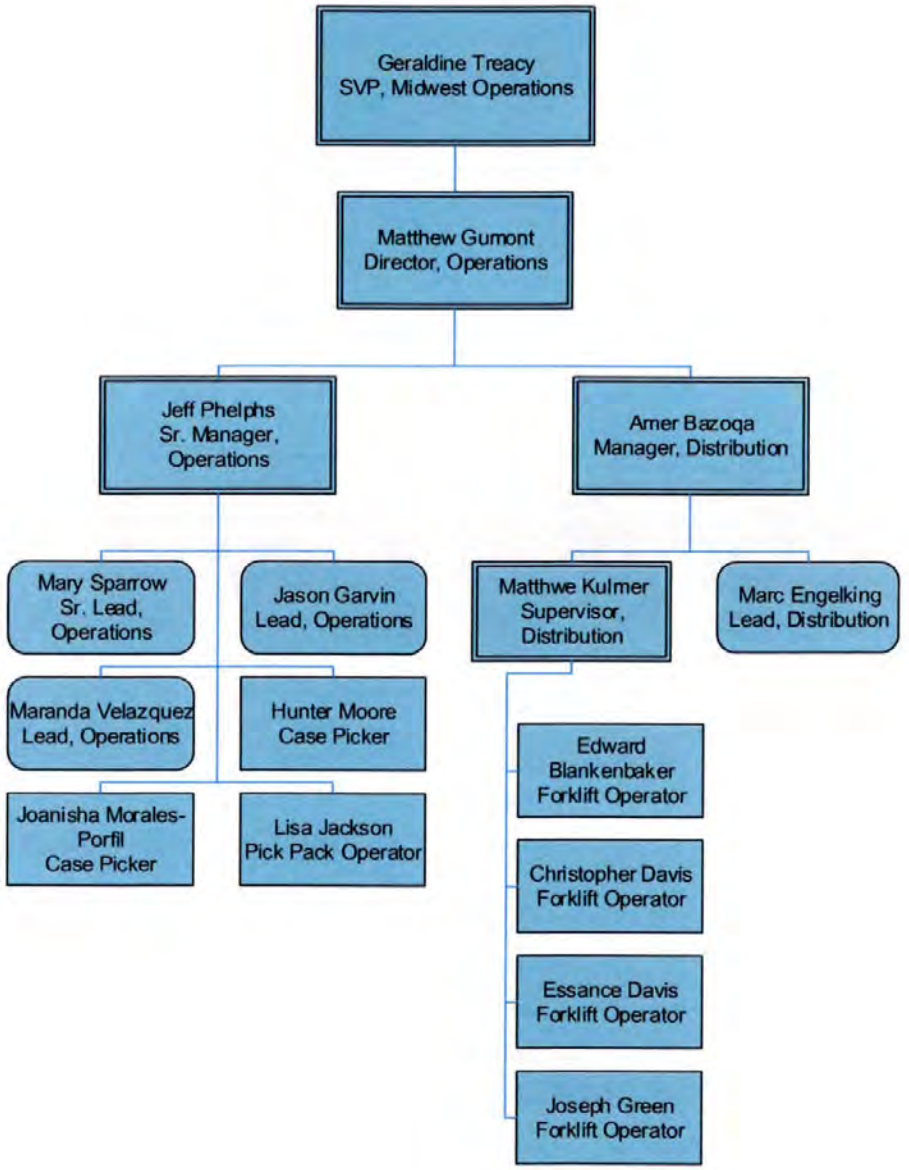
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MDC	
Remote	



CONFIDENTIAL

Operations (7 of 13)

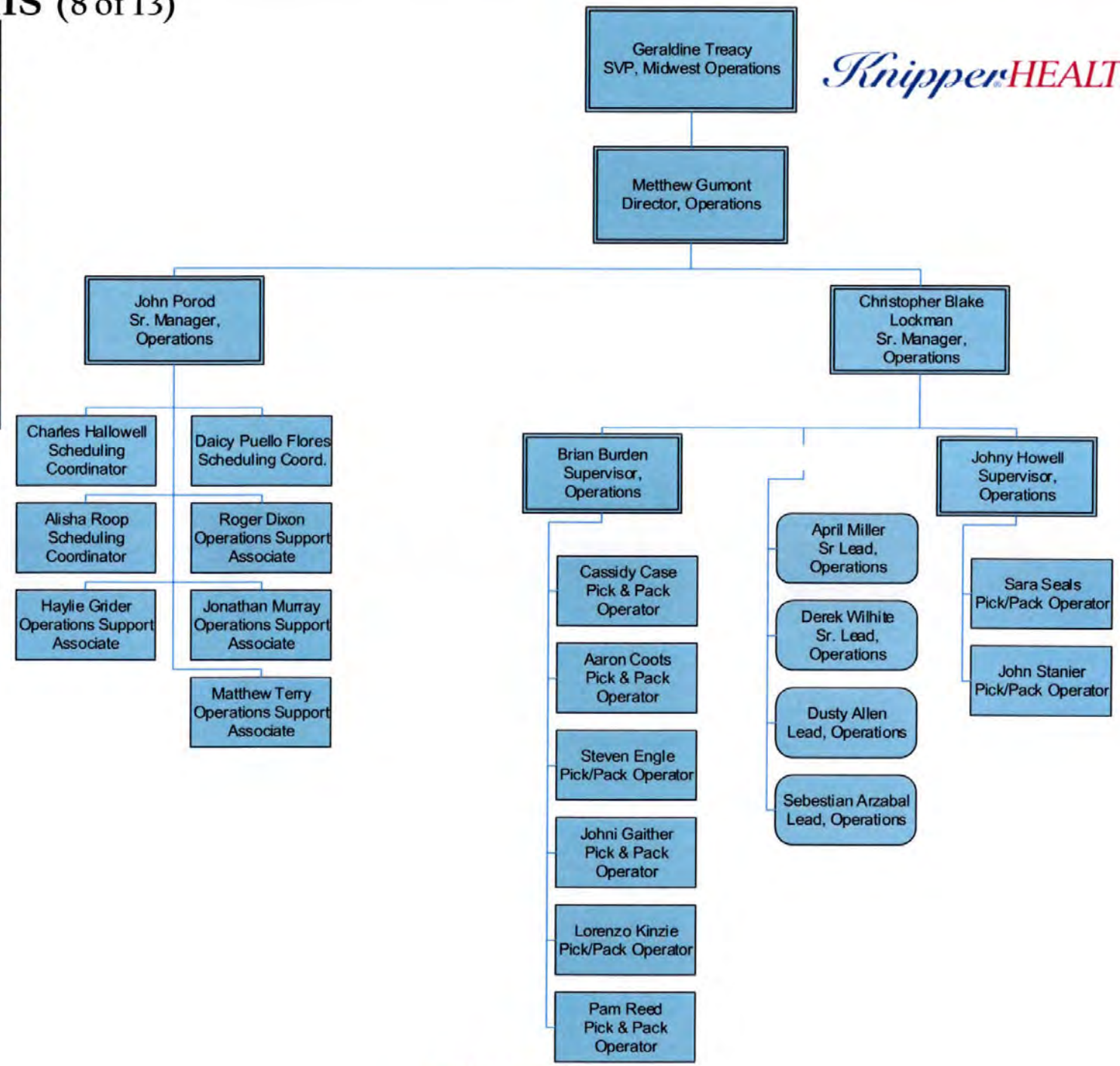
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Remote	



CONFIDENTIAL

Operations (8 of 13)

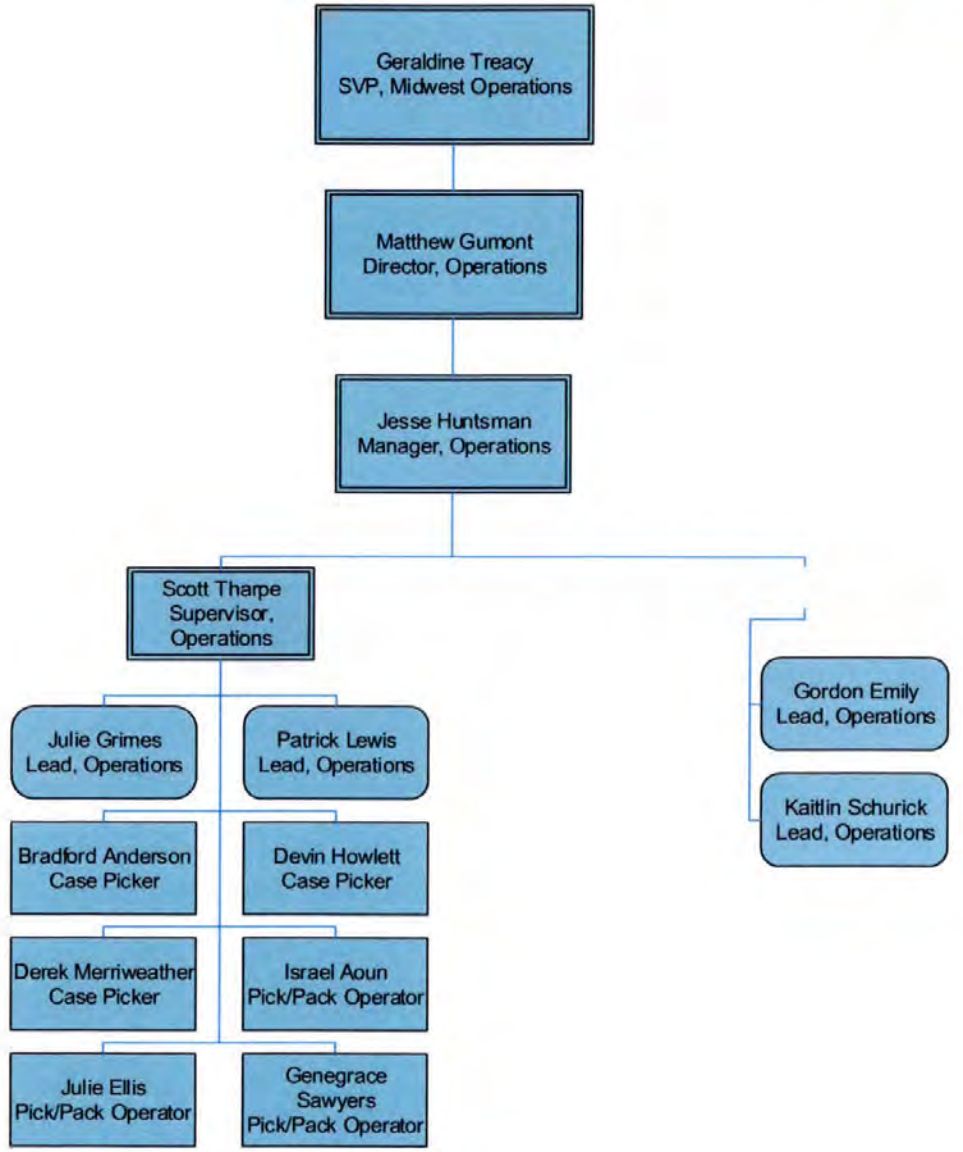
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MDC	
Remote	



CONFIDENTIAL

Operations (9 of 13)

Legend	
OHW	
KDC	
SOM	
LAW	
LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



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Operations (10 of 13)



Victor Ricci
SVP, Northeast Operations

Joshua Massingill
Director, Operations, 3PL
See P 23

Alexandira Anderson
Manager, Operations, 3PL

James Bray
Manager, Operations, 3PL

Caleb Clifton
Manager, Operations, 3PL

Keith Goldsmith
Manager, Operations, 3PL

Kyle Richmer
Manager, Operations, 3PL

AJ Stivers
Supervisor, Operations, 3PL

Traci Van De Bossche
Lead, Operations, 3PL

Frederick Kerstiens
Supervisor, Operations, 3PL

Jason Hearn
Supervisor, Operations, 3PL

Robert McGinnis
Supervisor, Operations, 3PL

Brooklin Crain
Lead, Transportation, 3PL

Tabitha Feltner
Operations Lead, 3PL

Demetrius Hall
Operations Lead, 3PL

Charles Florence
Forklift Operator

Shonna Lenz
Forklift Operator

Sidney Netherton
Forklift Operator

Earrick Yates
Forklift Operator

Brad Hersman
Case Picker

Christopher King
Lead, Operations, 3PL

Anthony Walker
Lead, Operations, 3PL

Daniel Smith
Forklift Operator

Sean Ross
Lead, Operations, 3PL

Jonathan Anderson
Case Picker

Sandra Vickers
Case Picker

Jennifer Jewell
Lead, Operations, 3PL

Terry Lewis
Lead, Operations, 3PL

Tonya Nally
Lead, Operations, 3PL

William Tichenor
Lead, Operations, 3PL

Johnna Barr
Case Picker

Sheila Brianvil
Case Picker

Roger Decola
Case Picker

Carl King
Case Picker

Catherine Knight
Case Picker

Marvin Rodgers
Case Picker

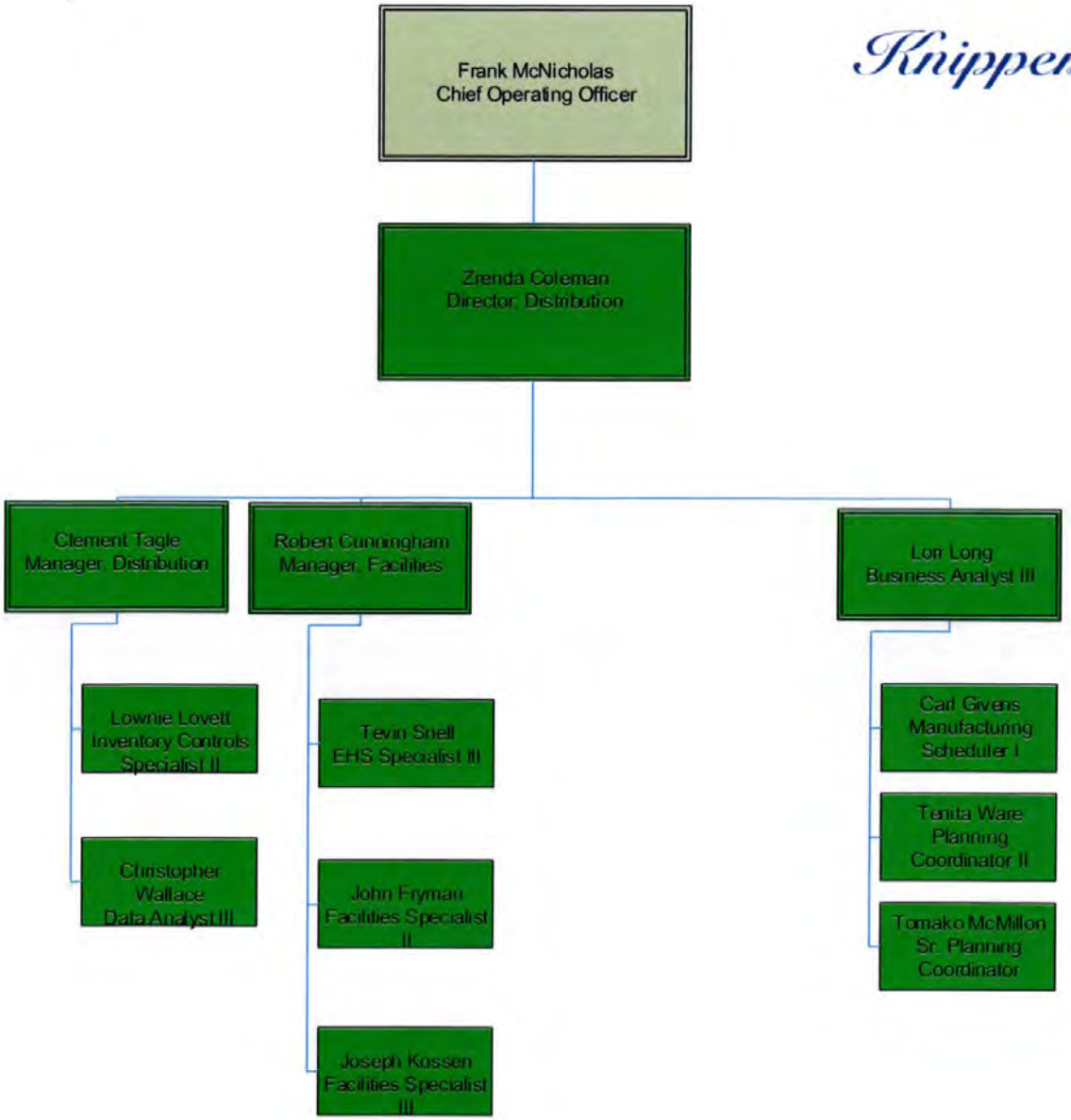
Kaurshawna Phegley
Case Picker

Nolan Lewis
Case Picker

CONFIDENTIAL

Operations (11 of 13)

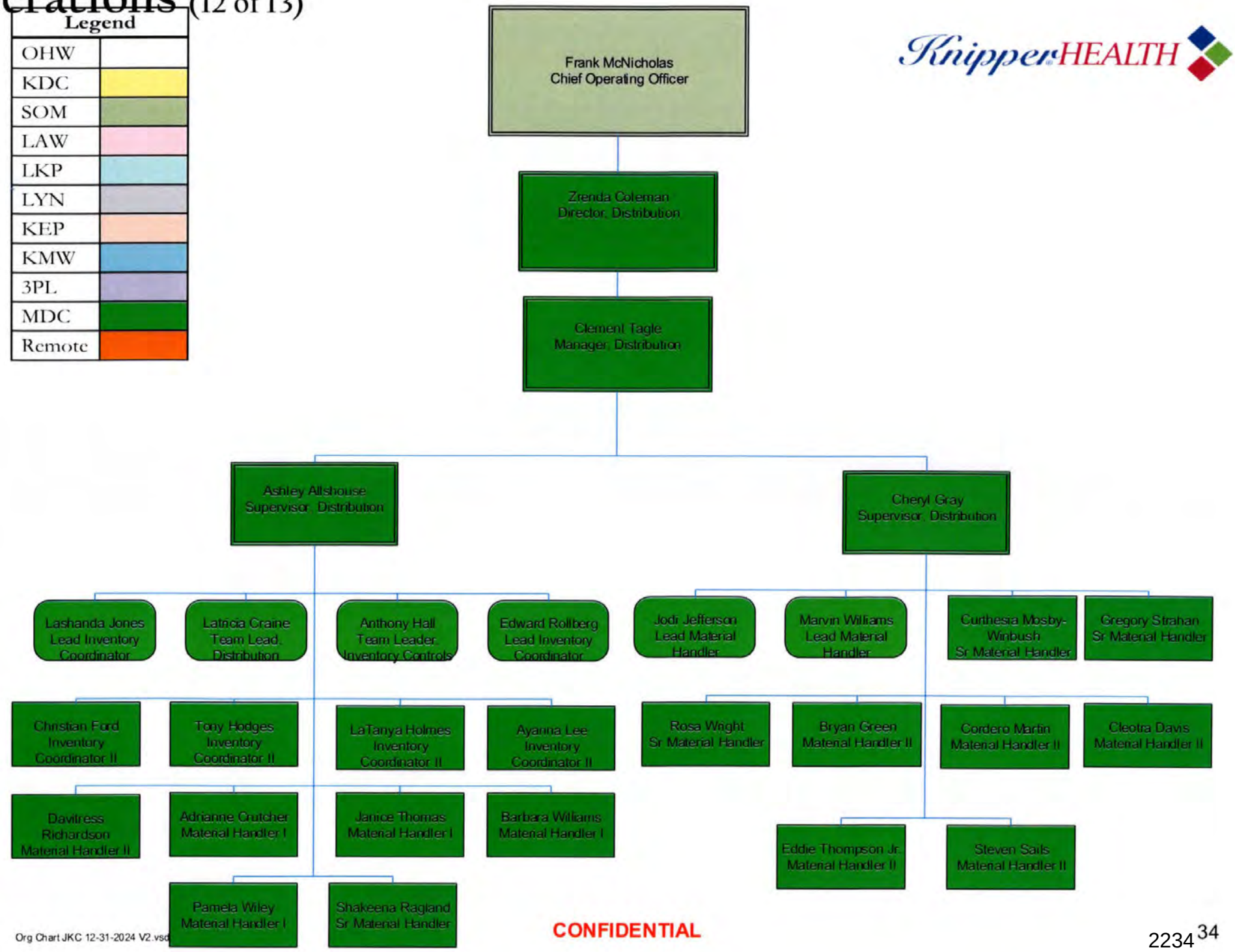
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3PL	
MDC	
Remote	



CONFIDENTIAL

Operations (12 of 13)

Legend	
OHW	
KDC	
SOM	
LAW	
LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



Org Chart JKC 12-31-2024 V2.vsd

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Operations (13 of 13)

Legend	
OHW	
KDC	
SOM	
LAW	
LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



Org Chart JKC 12-31-2024 V2.vsdm

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4WW

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ☑ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	See Attachment A * If making a change, provide current license number: WH 01435	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: J. Knipper and Company, Inc.

Physical Address: 1550 Oak Street

City: Lakewood State: NJ Zip: 08701

Mailing Address (if different from physical address): One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: (732) 905-7878 Website: https://www.knipper.com/

Name of Designated Representative (DR): John Gardner

Licensing Company Email: Licensing@knipper.com DR Email: Licensing@knipper.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☐ Controlled Substances	☐ Repacker
☑ Hospitals	☑ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☑ Warehouse
☑ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	February 18, 2020	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2019-3775	Colorado Board of Pharmacy

Reason/Charge
J. Knipper and Company was subject to disciplinary action and a penalty in Colorado for delayed notification of change of designated representative for its 1550 Oak Street, Lakewood, NJ facility.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Colorado Board of Pharmacy claimant	N/A

Name of Business/Industry/Entity
J. Knipper and Company, Inc.

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/3/2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	2/18/2020	CO	Denver	Denver
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2019-3775		Colorado Board of Pharmacy		
Reason/Charge				
J. Knipper & company was subject to disciplinary action & a penalty in Colorado for delayed notification of change of designated rep for its 1550 Oak St facility.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Colorado Board of Pharmacy Claimant		N/A		
Name of Business/Industry/Entity				
J. Knipper and Company, Inc.				

Provide explanation below:

Please see attached Stipulation & Final Agency order as well as closure letter from Colorado Board of Pharmacy.

Original Signature (electronic, copies or stamps not accepted)

03/6/2025
Date

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

February 19, 2020

J. Knipper and Company, Inc.
1550 Oak Street
Lakewood, NJ 08701-5937

Sent via email: compliance@knipper.com, teresita.weiss@knipper.com

RE: Case No. 2019 3775 Stipulation and Final Agency Order

Dear Pharmacy Manager:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the terms and conditions of the above listed Stipulation and Final Agency Order effective February 18, 2020.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released you from the terms and conditions of the February 18, 2020, Stipulation and Final Agency Order and restored your Registration No. WHO.0007269 to unencumbered status.

Although this disciplinary action will remain a public document, our records show that the requirements of your Order are complete. Please retain this letter for your records.

Your cooperation during the pendency of this matter is sincerely appreciated.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Dmitry Kunin
Program Director

cc: Jeremy Alexander, Esq., sent via email: jalexander@reedsmith.com
John Kendzior, Esq., sent via email: jkendzior@reedsmith.com
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2019-3775

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF J. KNIPPER AND COMPANY, INC., REGISTRATION NO. WHO-7269,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and J. Knipper and Company, Inc., ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2019-3775, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as a non-resident wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2018).

2. Respondent Outlet was originally registered in the State of Colorado on or about June 20, 2007, being issued registration #WHO-7269, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 1550 Oak St, Lakewood, NJ 08701.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, 189 days transpired between November 13, 2018, the date the previous designated representative ceased the position, and May 21, 2019, the date the application and fee were received.

6. On or about June 3, 2019, the Board initiated a complaint against Respondent Outlet because of the delay of 189 days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline. (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board.

Pharmacy Board Rules and Regulations

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

8. The Board finds and concludes, and Respondent Outlet agrees, that based upon Respondent Outlet's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

9. Fine with Surcharge. Pursuant to section 12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

10. **Compliance**. Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in its designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

11. **Other Requirements**. Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

12. **Advisements and Waivers**. Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

13. **Acknowledgments**. The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

14. Violations. Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under sections 12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

15. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Outlet

Dated: 2/12/2020

Teresita Weiss, Ph.D., J.D.
SVP, Regulatory Affairs and Compliance

APPROVED AS TO FORM
FOR RESPONDENT OUTLET

Reed Smith LLP
Jeremy M. Alexander
John D. Kendzior

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18 day of February, 2020.

State Board of Pharmacy

BY:

Dmitry Kunin
Program Director

Ree

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of FEBRUARY 2020, addressed as follows:

J. Knipper and Company, Inc.
Attn: Amer Bazoqa, Designated Representative
1550 Oak St
Lakewood, NY 08701

By Email: compliance@knipper.com; teresita.weiss@knipper.com

Jeremy M. Alexander
John D. Kendzior
Reed Smith LLP
1301 K Street, N.W.
Ste 1000 - East Tower
Washington, D.C. 20005

By email: jalexander@reedsmith.com; jkendzior@reedsmith.com

Agent of the Board

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment I

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): Knipper Holding, Inc.

Corporation/Organization Name: J. Knipper and Company, Inc.

Mailing Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: (732) 905-7878 Email: Licensing@knipper.com

Contact Person Name: Teresita Weiss

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

	Section 8: NABP Accreditation/FDA Registration	Yes	No
	Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
	1. Copy of Certification See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		
	Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
N/A	1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

	Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
	• **List of all Officers and Directors.** See Attachment D	✓	✓		
N/A	• **List the top four corporation shareholders and their percent ownership.**	✓			
	• **List of all corporation shareholders and their percent ownership.** See Attachments A and D		✓		
N/A	• **List of all partners and their percent ownership.**			✓	
	• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**. See Attachment E	✓	✓	✓	✓
	• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
	• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company.		✓	✓	✓
N/A	• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
N/A	• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
	• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment G	✓	✓	✓	✓
	• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment H	✓	✓	✓	✓
N/A	• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
N/A	• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
N/A	**ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
	• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
	• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

J. Knipper and Company, Inc.

Facility Name

Teresita Weiss, General Manager for Regulatory Affairs and Compliance

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/3/2025

Date

Board Use Only	Date Received: 3/13/25	Amount: $1500-cc

Accredited Drug Distributors

Find an Accredited Drug Distributor

Facility Name

State (All)

Search Reset

Current list of 38 NABP-Accredited Drug Distributors

Accreditation is valid for three years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

<<Previous 1 2 3 4 Next >>

Name	Address	Accreditation Date
Direct Success, Inc	1710 Highway 34 Farmingdale, NJ 07727	11/18/22
Glenmark Pharmaceuticals Inc, USA	750 Corporate Dr Mahwah, NJ 07430	Reaccreditation in process
Glenmark Pharmaceuticals Inc., USA	301 Island Rd Mahwah, NJ 07430	12/18/23
Hikma Injectables USA Inc dba Hikma 5038	36 Stults Road Dayton, NJ 08810	03/19/24
Hikma Pharmaceuticals USA Inc	2 Esterbrook Ln Cherry Hill, NJ 08003	02/15/24
Imprimis NJOF, LLC	1705 Route 46 Ledgewood, NJ 07852	09/08/22
INO Therapeutics, LLC	22 World's Fair Dr, Ste J Somerset, NJ 08873	09/18/23
J Knipper and Company, Inc	One Healthcare Way Lakewood, NJ 08701	12/05/24
J Knipper and Company, Inc	1550 Oak St Lakewood, NJ 08701	07/17/24
JOM Pharmaceutical Services, LLC	1 Cottontail Ln Somerset, NJ 08873	05/08/23

<<Previous 1 2 3 4 Next >>

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- Terms & Policies
- Privacy Policies
- FCRA Dispute Process

December 3, 2024

Re: Notice of Upcoming Transaction
Distributor Licensee: J. Knipper and Company, Inc.

To Whom It May Concern:

On behalf of J. Knipper and Company, Inc. (the "**Licensee**"), this notice is to advise you of an upcoming transaction that involves the transfer of the indirect equity interest in the Licensee (the "**Proposed Transaction**").

Specifically, as part of the Proposed Transaction, JKC Parent, Inc., a Delaware corporation and the indirect parent of the Licensee (the "**Parent**"), has entered into an Agreement and Plan of Merger, dated as of November 24, 2024, by and among the Parent, [FH KH Intermediate, Inc.], a Delaware corporation ("**Buyer**"), [FH KH Merger Sub, Inc.], a Delaware corporation and wholly owned subsidiary of Buyer ("**Merger Sub**"), and the other parties thereto, pursuant to which, and subject to the terms and conditions set forth therein, Merger Sub will merge with and into the Parent, with the Parent continuing as the surviving corporation of such merger. As a result, Buyer shall be the owner of Parent and the indirect owner of the Licensee. Pre- and post-closing organizational charts depicting the Proposed Transaction are attached hereto.

Importantly, the Proposed Transaction will not result in any changes in the Licensee, its tax identification number, its operational management team, or its day-to-day operations (other than changes in the ordinary course).

The closing of the Proposed Transaction is currently expected to take place on or about January 31, 2025. Unless we hear from you otherwise, we understand that this letter satisfies any notice requirements applicable to the Licensee regarding the Proposed Transaction.

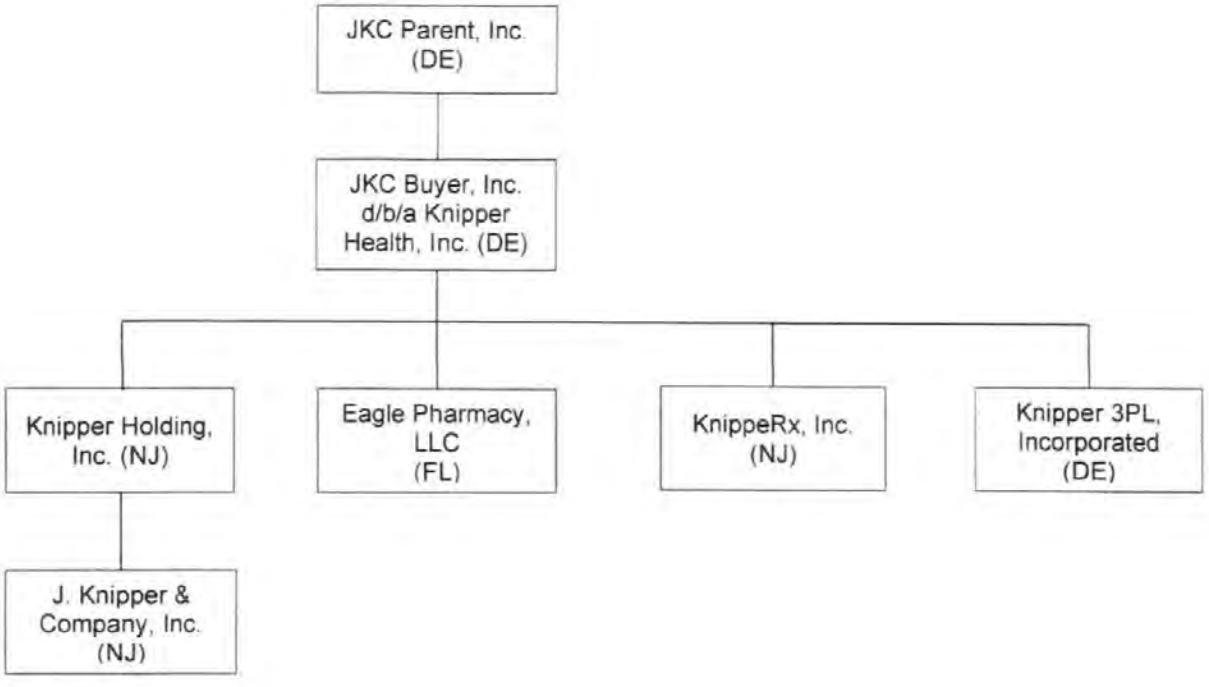
We kindly request that you keep all information disclosed in this letter confidential.

Sincerely,

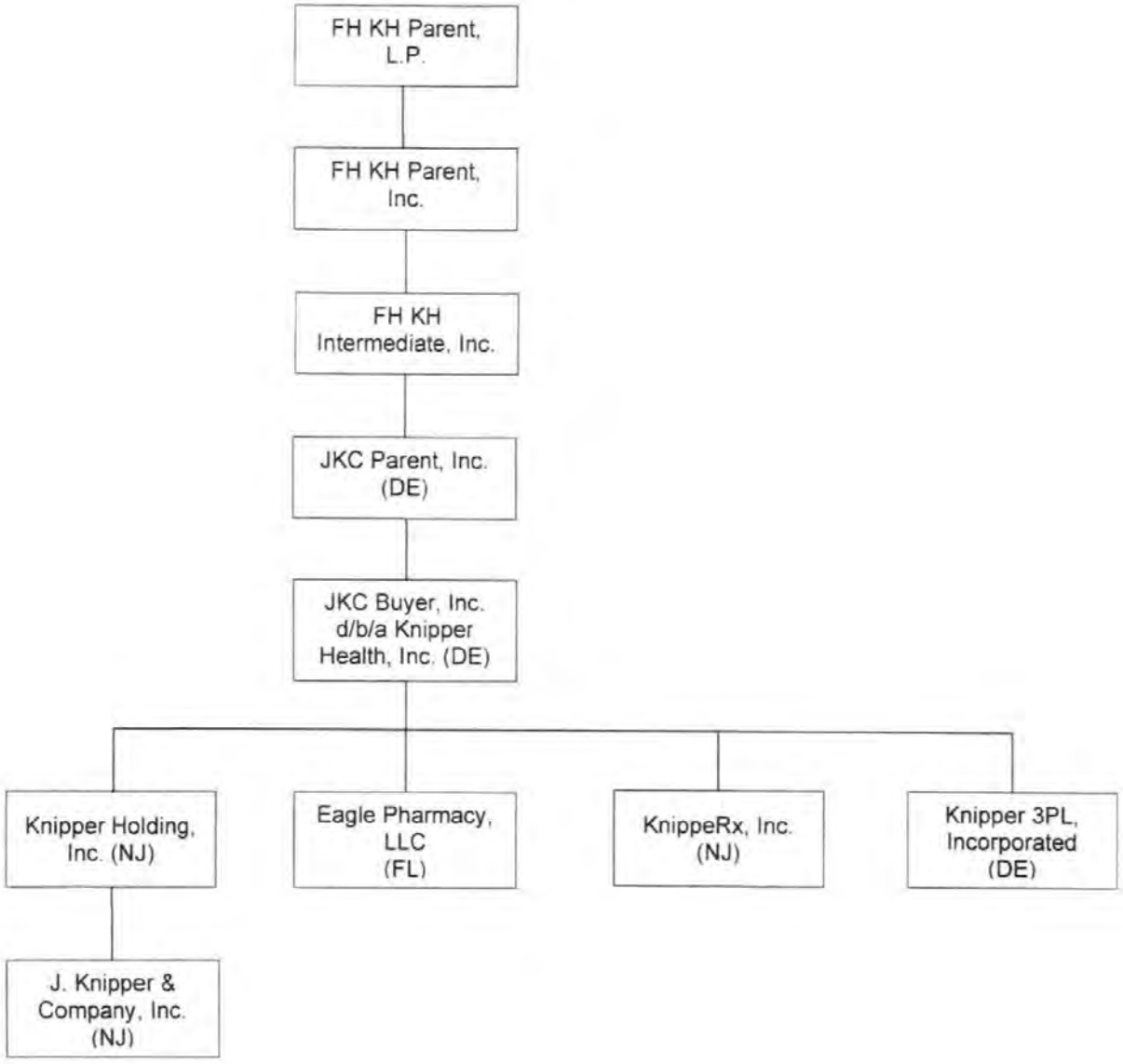
Teresita Weiss, Ph.D., J.D.
General Manager, Regulatory Affairs & Compliance

Attachments Exhibit A - Pre-closing organization chart
Exhibit B - Post-closing organizational chart

Knipper – Pre-Closing Legal Structure



Knipper – Post-Closing Legal Structure



Corporate Officers for J. Knipper and Company, Inc.

- Michael J. Laferrera - President and Chief Executive Officer
  - [redacted] Flemington, NJ [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- Todd Phillips – Chief Financial Officer
  - [redacted] Pewee Valley, KY [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

Corporate names:	J. Knipper and Company, Inc.
State of Incorporation:	New Jersey
FEIN:	22-2755742
Parent Company:	100% wholly owned by Knipper Holding, Inc.
Grandparent Company:	100% wholly owned by JKC Buyer, Inc. d/b/a Knipper Health, Inc.
Great-Grandparent Co:	100% wholly owned by JKC Parent, Inc.
Private Equity Ownership:	Frazier Healthcare Partners

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

J. KNIPPER AND COMPANY, INC.
0100313707

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on October 09, 1986.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 14th day of November, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6158972614

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEW JERSEY DEPARTMENT OF HEALTH
CONSUMER AND ENVIRONMENTAL HEALTH SERVICE
P.O. Box 369, Trenton, New Jersey 08625-0369

0753060

DRUG AND MEDICAL DEVICE CERTIFICATE OF REGISTRATION

N.J.S.A. 24:6B-5 -- "If any location of a registered business is to be changed, the registrant shall give the department written notice prior to the change of the address of such new location and the name and address of the individual to be in charge thereof. A fee of $20.00 shall accompanying such notification."

Registered as: ☐ manufacturer ☒ wholesaler which conducts business at the following locations in this State:

ONE HEALTHCARE WAY LAKEWOOD, NJ 08701-
1550 OAK ST LAKEWOOD,NJ 08701-
1250 PATROL RD CHARLESTOWN, IN 47111-

Reg. No.
5001714

J. KNIPPER AND COMPANY, INC.
ATTN: TERESITA WEISS
ONE HEALTHCARE WAY
LAKEWOOD, NJ 08701-

ISSUED PURSUANT TO
N.J.S.A. 24:6B

EXPIRES: January 31, 2026

Establishment Copy

2256

Client#: 1541191 JKNI

ACORD CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 1/15/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer any rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Heather Sherwin
USI Insurance Services, LLC 180 Park Avenue Suite 103 Florham Park, NJ 07932	PHONE (A/C, No, Ext): 973-315-0440 FAX (A/C, No): E-MAIL ADDRESS: heather.sherwin@usi.com
INSURED J. Knipper & Company, Inc. One Healthcare Way Lakewood, NJ 08701	INSURER(S) AFFORDING COVERAGE / NAIC # INSURER A : Federal Insurance Company 20281 INSURER B : INSURER C : INSURER D : INSURER E : INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY			35809008	12/10/2024	12/10/2025	EACH OCCURRENCE	$5,000,000
	[ ] [X] CLAIMS-MADE [ ] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
	[X] Products Liability						MED EXP (Any one person)	$
	[X] Retro: 10/20/2023			Deductible(s):			PERSONAL & ADV INJURY	$5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:			$50,000 occ. /			GENERAL AGGREGATE	$
	[X] POLICY [ ] PRO-JECT [ ] LOC			$250,000 agg.			PRODUCTS - COMP/OP AGG	$
	[ ] OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	[ ] ANY AUTO						BODILY INJURY (Per person)	$
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$
	[ ] EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$
	[ ] DED [ ] RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						[ ] PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ]	N / A					E.L. EACH ACCIDENT	$
	(Mandatory in NH)						E.L. DISEASE - EA EMPLOYEE	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$
A	Professional Liability/E&O			35809008	12/10/2024	12/10/2025	$5,000,000 occ/agg	
	Retro: 09/30/2002						Ded: $50,000 each claim	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: NCPDP: 1568560

Evidence of Coverage for:

One Healthcare Way, Lakewood Township, NJ 08701
(See Attached Descriptions)

CERTIFICATE HOLDER

National Council for
Prescription Drug Programs, Inc.
9240 East Raintree Drive
Scottsdale, AZ 85260-7519

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Ulle Scott

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DESCRIPTIONS (Continued from Page 1)

1550 Oak Street, Lakewood, NJ 08701
270 Davidson Avenue, Somerset, NJ 08873
1009 Lenox Drive, Lawrenceville, NJ 08648
1250 Patrol Road, Charlestown, IN 47111
160 Chubb Avenue, Suite 305, Lyndhurst, NJ 07071
200 Patrol Road, Suite 300, Jeffersonville, IN 47130
310 Eagles Landing Drive, 330 Eagles Landing Drive, 350 Eagles Landing Drive, Lakeland, FL 33810
2700 Blankenbaker Pkwy, Louisville, KY 40299
5100 Hickory Road, Memphis, TN 38141

License No. _____

RIDER

To be attached to and form part of Bond No. 021143V.

Issued on behalf of J. Knipper and Company, Inc. as Principal, and in favor of Nevada State Board of Pharmacy as Obligee.

It is agreed that:

☐ 1. The Surety hereby gives its consent to change the Name:

from: _____

to: _____

☐ 2. The Surety hereby gives its consent to change the Address:

from: _____

to: _____

☒ 3. The Surety hereby gives its consent to add the following locations to the above-captioned bond:

1550 Oak Street, Lakewood, NJ 08701

1250 Patrol Road, Charlestown, IN 47111

5100 Hickory Hill Road, Memphis, TN 38141

This rider shall become effective as of April 3, 2025

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated April 3, 2025.

Westfield Insurance Company

By: Robyn Rost

Robyn Rost Attorney-in-Fact

Accepted: _____ or _____

Obligee Principal

By: _____ By: _____

S-4111 (8/66)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 021143V

Application/License No. _____

J. Knipper and Company, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is One Healthcare Way, Lakewood, NJ 08701 (Address of Applicant/Principal), as PRINCIPAL, and Westfield Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Park Circle, P.O. Box 5001, Westfield Center, Ohio 44251 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 1, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of March, 2024.

APPLICANT/PRINCIPAL

COMPANY
J. Knipper and Company, Inc.

Authorized Representative

SURETY

Westfield Insurance Company

Surety Company's Representative

Robyn Rost, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Bridget Serzan

Witness Kristina Luiz

SIGNED and SEALED in the presence of:

Witness Karla Luongo

Witness Nicole Kaetzel

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

ACKNOWLEDGEMENT OF SURETY

State of New Jersey

County of Morris

City of Florham Park

On this 1st day of March in the year 2024 before me personally

Came Robyn Rost to me known, who, being by me duly sworn, did

depose and say that he resides in Florham Park, NJ that he is the Attorney-

In-Fact for Westfield Insurance Company the corporation described

In and which executed the attached instrument; that he knows the seal of the said

corporation; that the seal affixed to the said instrument is such corporate seal;

and that it was so affixed by Order of the Board of Directors of the said corporation,

and that he signed his name thereto by like order.

Notary Public

THOMAS F DORNER SR.
Notary Public, State of New Jersey
My Commission Expires Apr 23, 2028

Corporate Acknowledgement

STATE OF New Jersey

COUNTY OF Ocean

7 day March the year 2024, before me Teresita Weiss, NOTARY PUBLIC personally appeared on behalf of J. Knipper and Company, Inc.

personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who executed the within instrument as president (or secretary)or on behalf of the corporation therein named and acknowledged to me that the corporation executed it.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal, the day and year first above written.

My Commission expires September 29, 2024

Notary Public, residing at Lakewood, New Jersey

(SEAL)

BRIDGET H. SERZAN
Commission # 50003532
Notary Public, State of New Jersey
My Commission Expires
September 29, 2024

POWER NO. 3120081 01
General Power of Attorney

CERTIFIED COPY

Westfield Insurance Co.
Westfield National Insurance Co.
Ohio Farmers Insurance Co.
Westfield Center, Ohio

Know All Men by These Presents, That WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, corporations, hereinafter referred to individually as a "Company" and collectively as "Companies," duly organized and existing under the laws of the State of Ohio, and having their principal offices in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint **ROBYN ROST, JOINTLY OR SEVERALLY**
of **RED BANK** and State of NJ its true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in their names, place and stead, to execute, acknowledge and deliver **any and all bonds, undertakings, and recognizances; provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed TWENTY MILLION DOLLARS AND NO CENTS ($20,000,000)---**

LIMITATION: **THIS POWER OF ATTORNEY CANNOT BE USED TO EXECUTE NOTE GUARANTEE, MORTGAGE DEFICIENCY, MORTGAGE GUARANTEE, OR BANK DEPOSITORY BONDS.**

and to bind any of the Companies thereby as fully and to the same extent as if such bonds were signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of each of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY:

"**BE IT RESOLVED**, that the President, any Senior Executive, any Secretary or any Fidelity & Surety Operations Executive or other Executive shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings and any and all notices and documents cancelling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be as binding upon The Company as if signed by the President and sealed and attested by the Corporate Secretary."

"**BE IT FURTHER RESOLVED**, that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." (Each adopted at a meeting held on February 8, 2000.)

In Witness Whereof, WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY have caused these presents to be signed by their **Senior Executive** and their corporate seals to be hereto affixed this **15TH** day of **NOVEMBER**, A.D. **2013**.

Corporate Seals Affixed

WESTFIELD INSURANCE COMPANY
WESTFIELD NATIONAL INSURANCE COMPANY
OHIO FARMERS INSURANCE COMPANY

By: _____
Dennis P. Baus
National Surety Leader and Senior Executive

State of Ohio
County of Medina ss.:

On this **15TH** day of **NOVEMBER**, A.D., **2013**, before me personally came **Dennis P. Baus**, to me known, who, being by me duly sworn, did depose and say, that he resides in **Wooster, Ohio**, that he is **National Surety Leader and Senior Executive** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, the companies described in and which executed the above instrument, that he knows the seals of said Companies; that the seals affixed to said instrument are such corporate seals; that they were so affixed by order of the Board of Directors of said Companies, and that he signed his name thereto by like order.

Notarial Seal Affixed

By _____
William J. Kahelin, Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss.:

CERTIFICATE

I, **Frank Carrino**, Secretary of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Companies, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Westfield Center, Ohio, this 3rd day of April, A.D. 2025.

By _____
Frank Carrino, *Secretary*

BPOAC4A

Financial Statement

December 31, 2023

Westfield Insurance Co.
Westfield Center, Ohio 44251-5001

WESTFIELD INSURANCE COMPANY
BALANCE SHEET

12/31/23
(in thousands)

Assets	
Cash, cash equivalents, and short term investments	34,614
Bonds	1,387,543
Stocks	370,629
Agents' balances and uncollected premiums, net	458,142
Other admitted assets	1,080,285
Total admitted assets	3,331,213
Liabilities	
Reserve for unearned premiums	713,530
Reserve for unpaid losses and loss expenses	1,106,583
Reserve for taxes and other liabilities	304,081
Total liabilities	2,124,194
Capital stock	8,220
Surplus to policyholders	1,198,799
Total surplus	1,207,019
Total liabilities and surplus	3,331,213

State of Ohio
ss:
County of Medina

The undersigned, being duly sworn, says: That he is National Surety Leader - Surety Operations of Westfield Insurance Company, Westfield Center, Ohio; that said Company is a corporation duly organized, existing and engaged in business as a Surety Company by virtue of the Laws of the State of Ohio and authorized to do business in the State of ..... and has duly complied with all the requirements of the laws of said State applicable to said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved July 1947, 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true, and correct statement of the financial condition of the said Company on the 31st day of December, 2023.

Attest:

Frank Carrino

Frank A. Carrino
Group Legal Leader, Secretary

Gary W. Stumper
National Surety Leader
Senior Executive

WESTFIELD INSURANCE CO
SEAL

Sworn to before me this 14th day of February A.D. 2024.

David A. Kotnik
Attorney at Law
Notary Public – State of Ohio

NOTARY PUBLIC STATE OF OHIO

My Commission Does Not Expire
Sec. 147.03 Ohio Revised Code

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: J. Knipper and Company, Inc.
Pharmacy/Wholesaler License # (if applicable): WH01435
Physical Address: 1550 Oak Street
City: Lakewood State: NJ Zip: 08701
Mailing Address (if different from physical address): One Healthcare Way
City: Lakewood State: NJ Zip: 08701
Telephone: (732) 905-7878 Website: https://www.knipper.com/
Licensing Company Email: Licensing@knipper.com

Section 2: Personal Information

First: John Middle: Henry Last: Gardner
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Address: One Healthcare Way
City: Lakewood State: NJ Zip: 08701
Telephone: 732-905-7878 Email: Licensing@knipper.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Salem State University		09/85-07/87	
Address	City	State	Zip
352 Lafayette St.	Salem	Ma	01970
Diploma/Degree obtained, if any			
Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Union County College		09/84-06/85	
Address	City	State	Zip
1033 Springfield Ave	Cranford	NJ	07016
Diploma/Degree obtained, if any			
General Studies			

School Name		From - To (MM/YY – MM/YY)	
Susquehanna University		09/83-06/84	
Address	City	State	Zip
514 University Ave	Selinsgrove	Pa	17870
Diploma/Degree obtained, if any			
General Studies			

School Name		From - To (MM/YY – MM/YY)	
Union Catholic Regional H.S.			
Address	City	State	Zip
1600 Martine Ave	Scotch Plains	NJ	070706
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/21 - Current	[redacted]	Lavallette	NJ	[redacted]
09/10-10/21		Jackson	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
J. Knipper and Company, Inc.			03/19 - present	
Business Address		**City**	**State**	**Zip**
1550 Oak Street		Lakewood	NJ	08701
Phone	**Title**		**Number of Employed Hours**	
(732) 905-7878	Director of Distribution		~9,600	
Description of Duties				
Pharmacist				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, John Henry Gardner, **certify that as the designated representative for**

J. Knipper and Company, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JG — I am at least 21 years of age;
3. JG — I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JG — I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JG — I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JG — I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JG — I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

John Gardner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/06/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Gardner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/04/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Ocean

I, John Gardner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/04/2025

Date

Subscribed and Sworn to before me this 6 day of March 2025.

Notary Public Signature Bridget H. Serzan

BRIDGET H. SERZAN
Notary Public, State of New Jersey
Comm. # 50003532
My Commission Expires 9/29/2029

(Seal)

JOHN GARDNER

[redacted]

QUALIFICATIONS SUMMARY

Over 28 years of experience within the warehousing and perishable distribution industry with extensive management experience in labor measured standards, off loading programs, radio frequency programs, and inventory control. Skills include a proven track record of decreasing cost, improving quality, and enhancing revenue for the company. Success achieved through setting a strong example of high values, persistency, and integrity by being data driven.

AREAS OF EXPERTISE

• Kanban/ Lean Management	• ERP Implementation
• Team Building /Training	• Labor Management Systems
• Microsoft Software	• Mediation and Conciliation Training
• Relationship Management	• Emergency Responder Training for Liquid Ammonia

PROFESSIONAL EXPERIENCE

J. Knipper Corporation **3/19 to present**

Director of Distribution

- Responsible for the effective management and leadership of the distribution, warehouse operation, satellite facilities, and the personnel assigned to support such functions to meet all financial and client goals.
- VAWD accredited wholesale distributor recognized by the National Association of Board of Pharmacy.
- Oversee all aspects of the distribution operation; receiving, put-away, storage, movement and relocation, picking, pick to light, packing, shipping, and product returns.
- Manage all freight responsibilities including ground, LTL, FTL, and transfers. Along with maintaining or negotiating new freight contracts to drive cost and help to meet company goals while identifying market trends.
- Support of all internal and external clients. Ensured compliance with applicable regulations, procedures, and set industry best practices.
- Created and managed all Standard Operating Procedures. Managed the training and documentation of personnel to meet all FDA and DEA requirements.
- Established and managed all client service level agreements for all applications.
- Drove continuous improvement process for inventory record accuracy and quality of work throughout all operations.
- Ensured all direct reports have a clearly defined role and responsibilities, monitored employee performance to ensure maximum utilization of resources. Developed, published, and refined performance metrics to evaluate the effectiveness of daily operations.

- Promoted clear communication between departments to drive company vision and objectives in order to drive desired change.

Component Hardware Group (Lakewood, NJ) **2013 to 2019**
Operations Manager

- Oversee and manage all aspects of day to day operations of a business with multiple warehouse facilities with inventory of Eighteen million and sales in excess of One Hundred million dollars per year.
- Responsible for all budgetary operational costs including import, export, LTL, ground, and property leases.
- Developed KPI incentive program.
- System integration of new ERP and RF program.
- Strong knowledge of FCL, LCL, LTL, and FTL. Reduced shipping charges by 15%.
- Developed cycle count program along with quarterly inventories to reduce operational cost.
- Lead and manage several autonomous teams and all logistics areas including material handling, components, and finished goods flows, storage and four external warehouses.
- Ensure that quality, cost, delivery, involvement and safety standards are implemented.
- Ensure inventory accuracy.
- Manage workload of all areas to optimize all allocated resources.
- Co-ordinate corrective action plans.
- Define and follow up indicators and targets for the warehouse teams.
- Communicate with Sales and Customer Service to meet customer needs.

Nippon Express U.S.A. Inc. (Carlstadt, NJ) **07/12 – 08/13**
Warehouse Manager

- Coordinated and set up a startup operation from the ground floor for a third-party Ecommerce Apparel Company
- Managed and supervised personnel and business activities of the Warehouse
- Responsible for overseeing all Warehouse functions including receiving, storage, inventory control, pick pack, customer service, purchasing, P & L, budgeting, safety and security
- Corresponded with customer call center in Japan
- Managed operational planning, information systems and administration to ensure proper staffing and the ability to handle daily customer demand on a daily basis.
- Prepared and implemented the functional target and plan based on branch target.
- Directed the efficient and cost effective lay-out, organization and operation of the warehouse.
- Managed inbound activities related to the receipt and storage of goods, inventory management and claims.
- Managed outbound activities related to order filling, pick pack, stock replenishment and shipping.
- Responsible for budgeting, customer service, facility and equipment operation.
- Administered overall inventory management, productivity, accuracy and loss prevention to ensure that customer requirements are met.
- Coordinate cross country LTL freight from EC to DC.

Triumph Learning (Littleton, MA) **2009 to 2012**
Warehouse Manager

- Oversaw all aspects of an 80,000 sq. ft. warehouse operation including budgeting, staffing,

inventory control, distribution of product, quality control and safety compliance. Developed performance metrics along with implementation of process procedure improvements. Restored vender and corporate confidence in operations that reached 30 Billion in sales.

- Designed and implemented process and initiatives to improve production and employee morale based on performance metrics.
- Performed audit warehouse inventories.
- Developed web-based WMS monitor and track production and performance of warehouse operation. Used a Kaizen format to help reduce operational costs of $600,000 first year.
- Helped develop company policies and procedures and monitor them on an ongoing basis.
- Responsible for ensuring compliance of all Sarbanes-Oxley policies and procedures as related to the daily operation of the warehouse.
- Responsible for ensuring compliance with all local, state, federal and company payroll policies.
- Developed and maintained performance incentive program.
- Cross trained and developed staff for a more efficient operation.

Supervalu/Shaw's Supermarkets Inc. (Methuen, MA) **1996 to 2009**

Operations Manager

- Oversaw all warehouse activities for a 350,000 sq. ft. perishable operation with 500 Union employees to ensure all functions are performed following Company and Distribution guidelines.
- Managed warehousing activities to ensure that both incoming and outgoing products are handled properly using proper training, accuracy systems, and programs. Increased daily production from 120 FCL and LCL to 180 inbound and outbound loads
- Planned and assigned work for most efficient use of personnel and equipment, ensuring that production standards are being maintained.
- Coordinated with Inventory Control personnel to guarantee proper product rotation, slotting, and space allocation.
- Ensured all personnel adhere to all safety, security, sanitation, and pest control codes, and policies.
- Developed weekly, quarterly, and annual goals.
- Interfaced with warehouse management, transportation, human resources, and buyers to maintain efficiencies and service levels. Recommended and implemented improvements in warehouse practices to promote efficiency, faster service, and lower cost.
- Worked on several Six Sigma and Black Belt projections to provide continuous improvements. Black Belt project helped reduce shrink of grapes providing a cost savings of Two Million Dollars. Six Sigma project was to help reduce absenteeism and FMLA abuse by targeting the largest contributing factor to the problem.
- Developed an off-loading program to compete with independent Union lumpers. The program regulated off-loading prices for venders, passing the savings onto Shaw's Supermarkets and also generated One Million Dollars in revenue for the perishable warehouse.
- Worked with Safety Committee, in accordance with the Safety Matrix; recommend additions or changes in safety procedures and policies.
- Oversaw step two union grievances with union representatives to resolve grievances.

Chadwick's of Boston/TJX Corporation (West Bridgewater, MA) **1995 to 1996**

Shift Processing Manager

- Directed the daily activities of a mail order catalog company for a 1million sq. Ft. Fulfillment Center, including labor scheduling, supervision
- SKU assignments and proper utilization of space, equipment, and manpower
- Key responsibilities include staffing, associate development, warehouse operations, maintenance of that facility and equipment, implementation of safety, security, and budgeting

- Responsible for interfacing and coordinating between warehouse operations, customer service, traffic, and MIS. Accountable for the safe, efficient and economical operation of the facility and equipment.

Excel Logistics (Methuen, MA) **1993 to 1995**
Shift Manager

Wetterua Foods (Andover, MA) **1991 to 1993**
Warehouse Supervisor

Twin County Grociers (Edison, NJ) **1989 to 1991**
Warehouse Supervisor

EDUCATION

Bachelor of Science - Business (Marketing concentration) **1987**
Salem State University (Salem MA)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: J. Knipper and Company, Inc. MDEG License # (if applicable): N/A

Physical Address: 1550 Oak Street

City: Lakewood State: NJ Zip: 08701

Mailing Address (if different from physical address): One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: 732-905-7878 Website: www.knipper.com

Licensing Company Email: Licensing@knipper.com

Section 2: Personal Information

First: John Middle: Henry Last: Gardner

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: 732-905-7878 Email: Licensing@knipper.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Salem State University		09/85-07/87	
Address	City	State	Zip
352 Lafayette St.	Salem	MA	01970
Diploma/Degree obtained, if any			
Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Union County College		09/84-06/85	
Address	City	State	Zip
1033 Springfield Ave	Cranford	NJ	07016
Diploma/Degree obtained, if any			
General Studies			

School Name		From - To (MM/YY – MM/YY)	
Susquehanna University		09/83-06/84	
Address	City	State	Zip
514 University Ave	Selinsgrove	PA	17870
Diploma/Degree obtained, if any			
General Studies			

School Name		From - To (MM/YY – MM/YY)	
Union Catholic Regional H.S.			
Address	City	State	Zip
1600 Martine Ave	Scotch Plains	NJ	
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/23 - Current	[redacted]	Lavallette	NJ	[redacted]
09/10-10/21		Jackson	NJ	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
J. Knipper and Company, Inc.			03/19 - present
Business Address	**City**	**State**	**Zip**
1550 Oak Street	Lakewood	NJ	08701
Phone	**Title**	**Number of Employed Hours**	
(732) 905-7878	Director of Distribution	9,600	
Description of Duties			
Resume			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	2/18/2020	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2019-3775	Colorado Board of Pharmacy

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Colorado Board of Pharmacy Claimant	N/A

Name of Business/Industry/Entity
J. Knipper and Company, Inc.

Provide explanation below:

J. Knipper and Company, Inc. was subject to disciplinary action and a penalty in Colorado for delayed notification of a change of designated representative for its 1500 Oak Street, Lakewood, NJ facility. The company has since implemented corrective actions to ensure changes are submitted timely going forward. Provided is a copy of the stipulation and final order issued by the Colorado Board of Pharmacy.

Original Signature (electronic, copies or stamps not accepted)

4/17/25
Date

I, John Henry Gardner, **certify that as the MDEG Administrator for**

J. Knipper and Company, Inc.,

that I (initial that you have read and meet the following requirements):

1. JHG Have a high school diploma or its equivalent;
2. JHG Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. JHG Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. JHG Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

John Gardner
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/17/25
Date

Board Use Only	Date Received: 4/22/25

Attachment G

Emplyees

KnipperHEALTH

J. KNIPPER & COMPANY

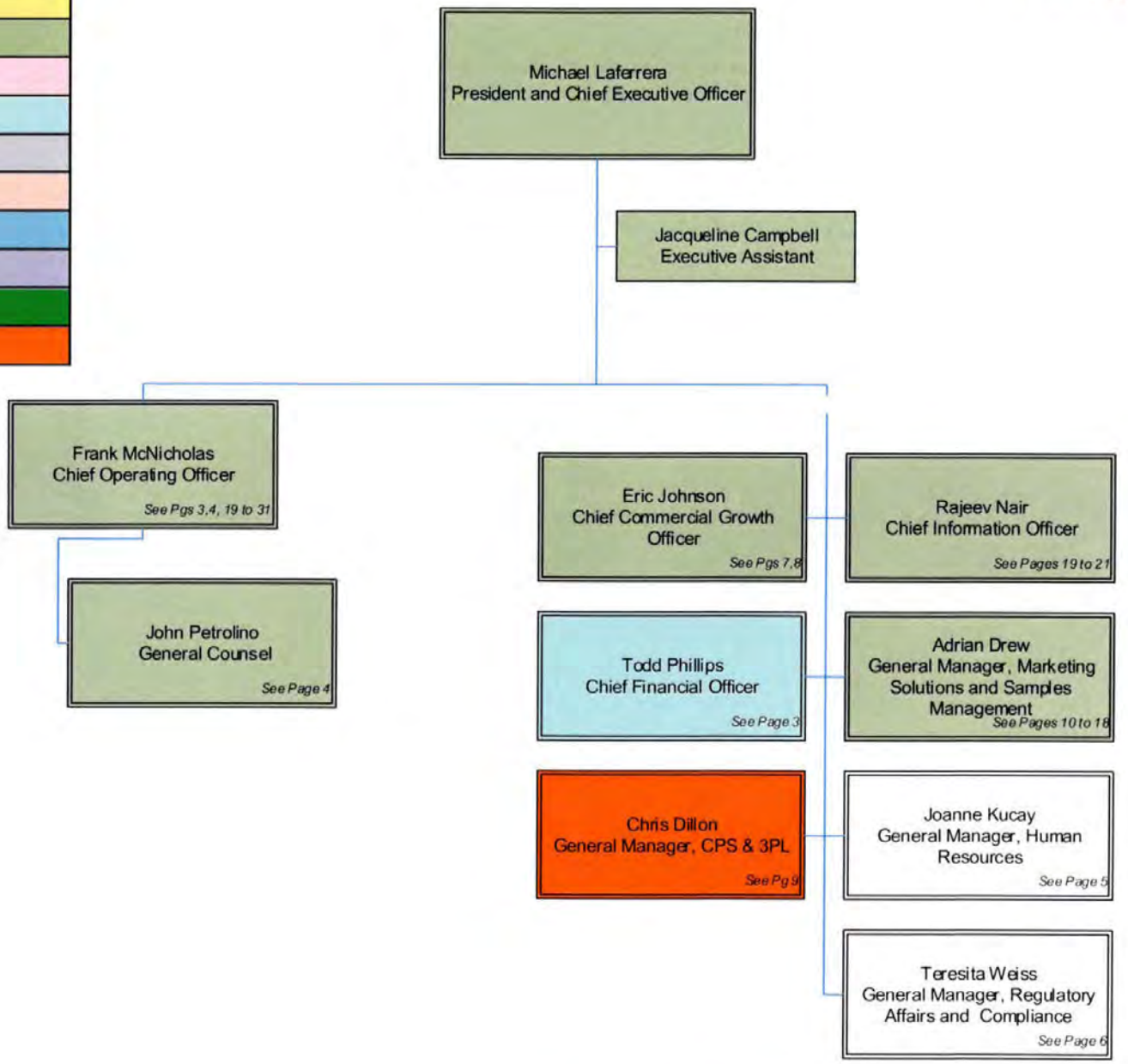
ORGANIZATIONAL CHART

December 31, 2024

CONFIDENTIAL

Executive Staff

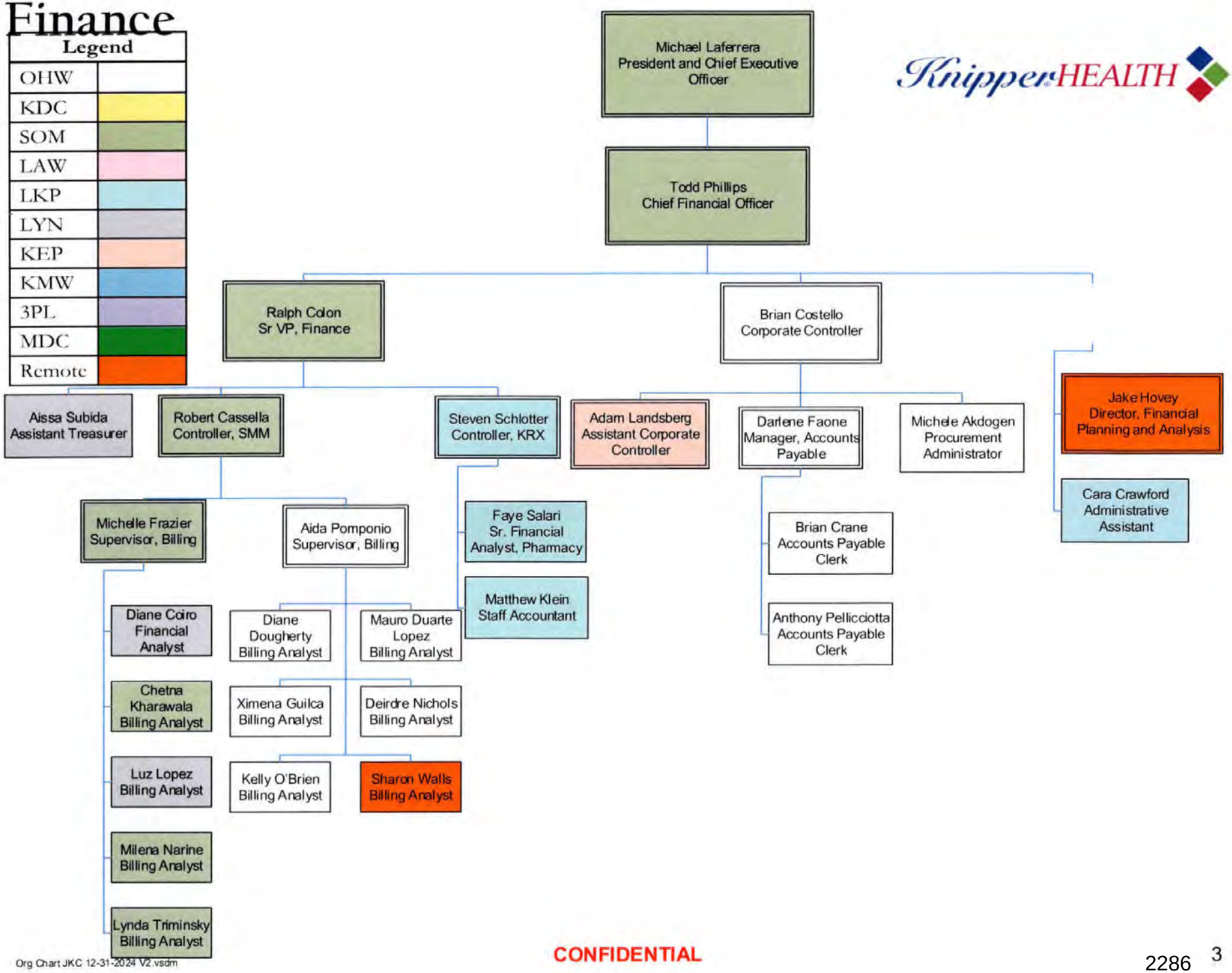
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Finance

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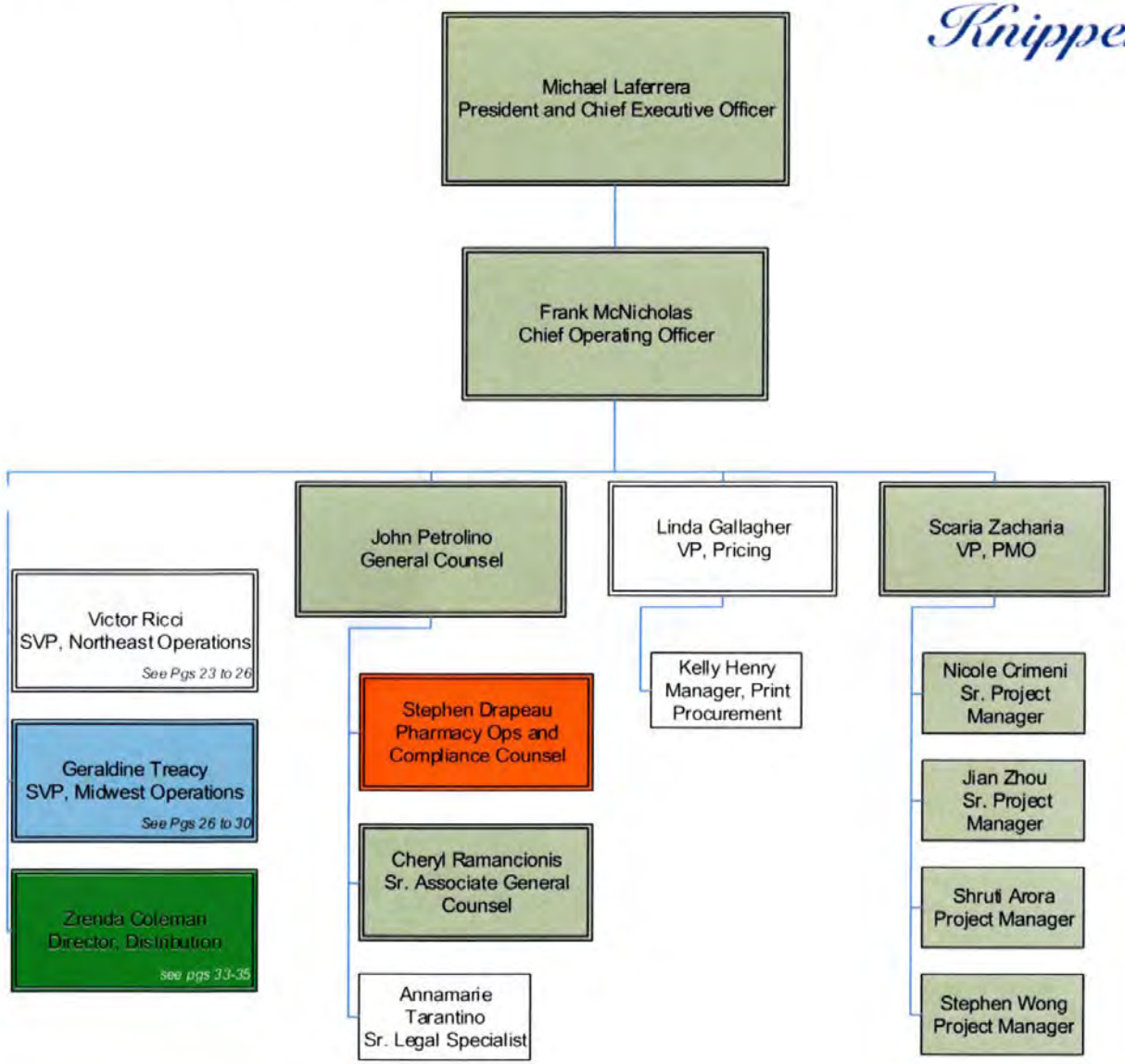


Org Chart JKC 12-31-2024 V2.vsdm

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Operations, PMO, & Legal

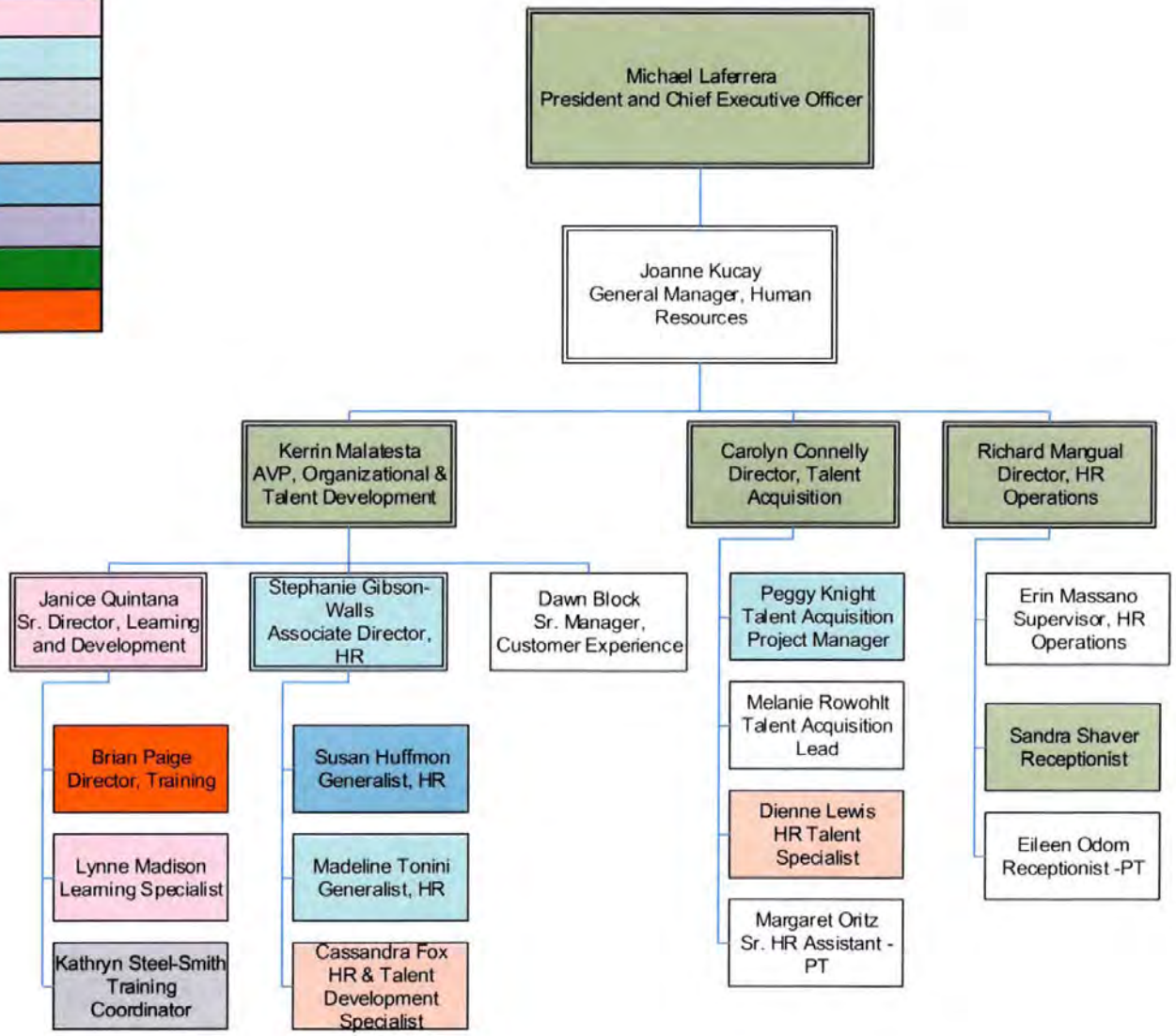
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Human Resources

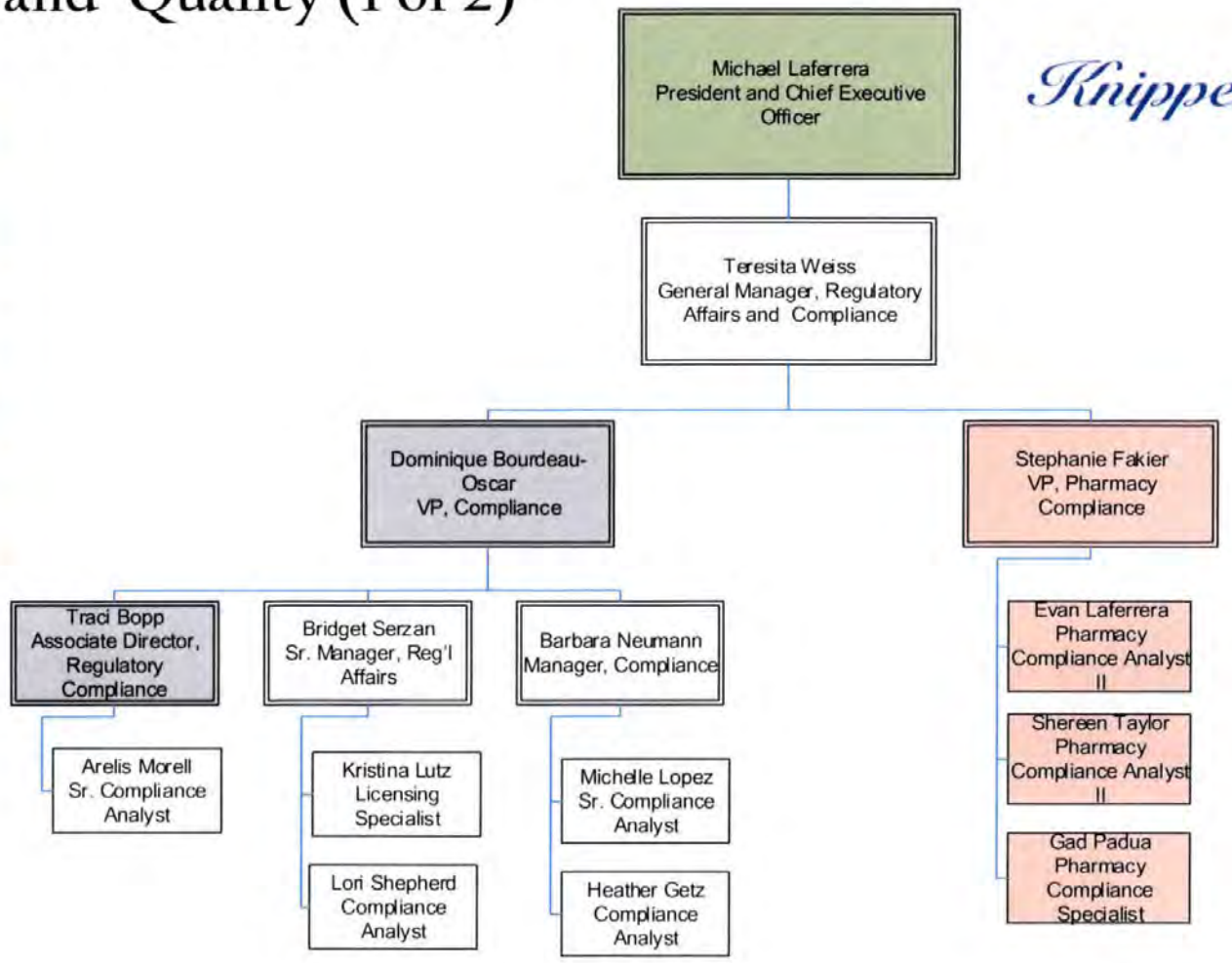
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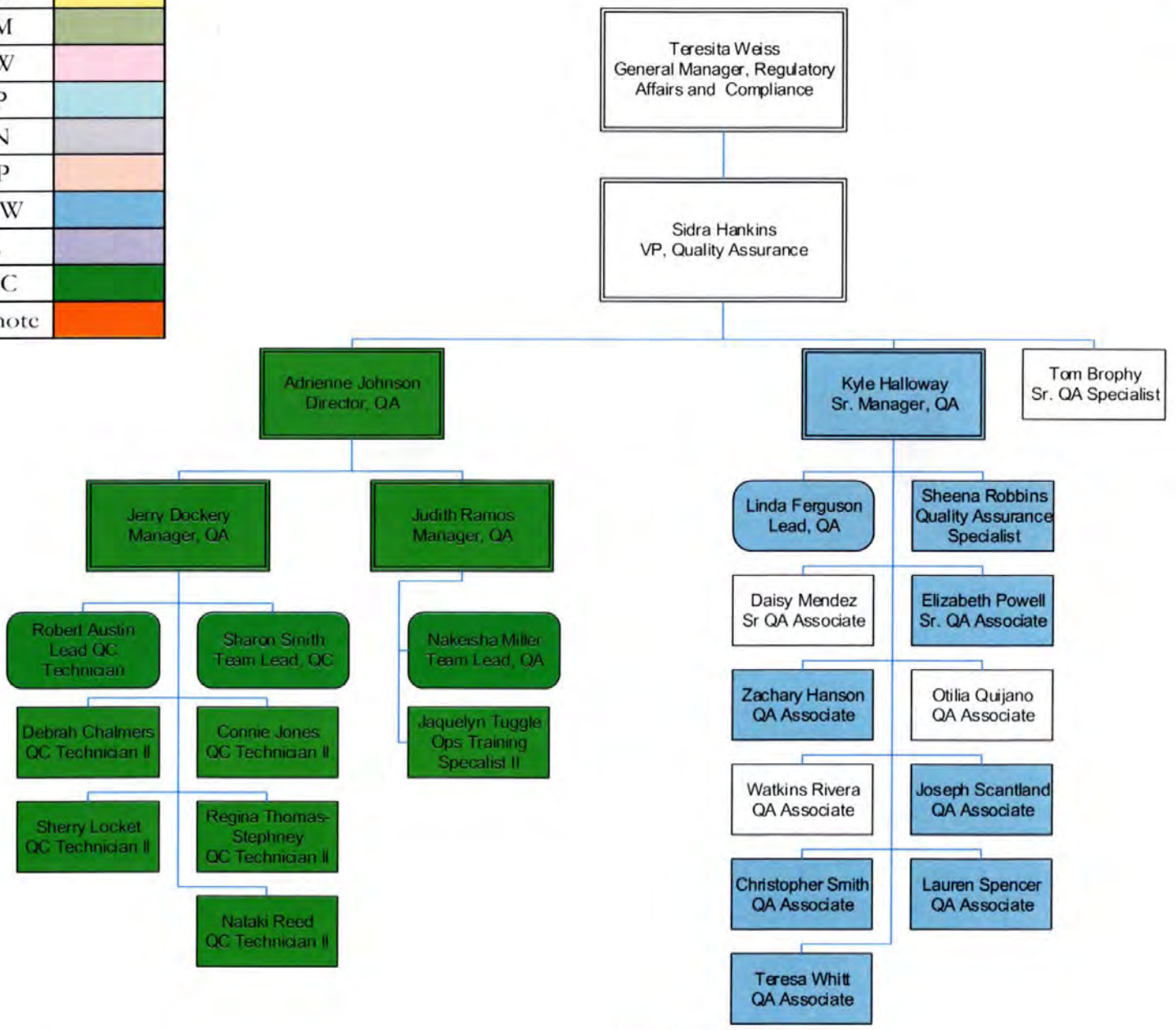
Regulatory and Quality (1 of 2)

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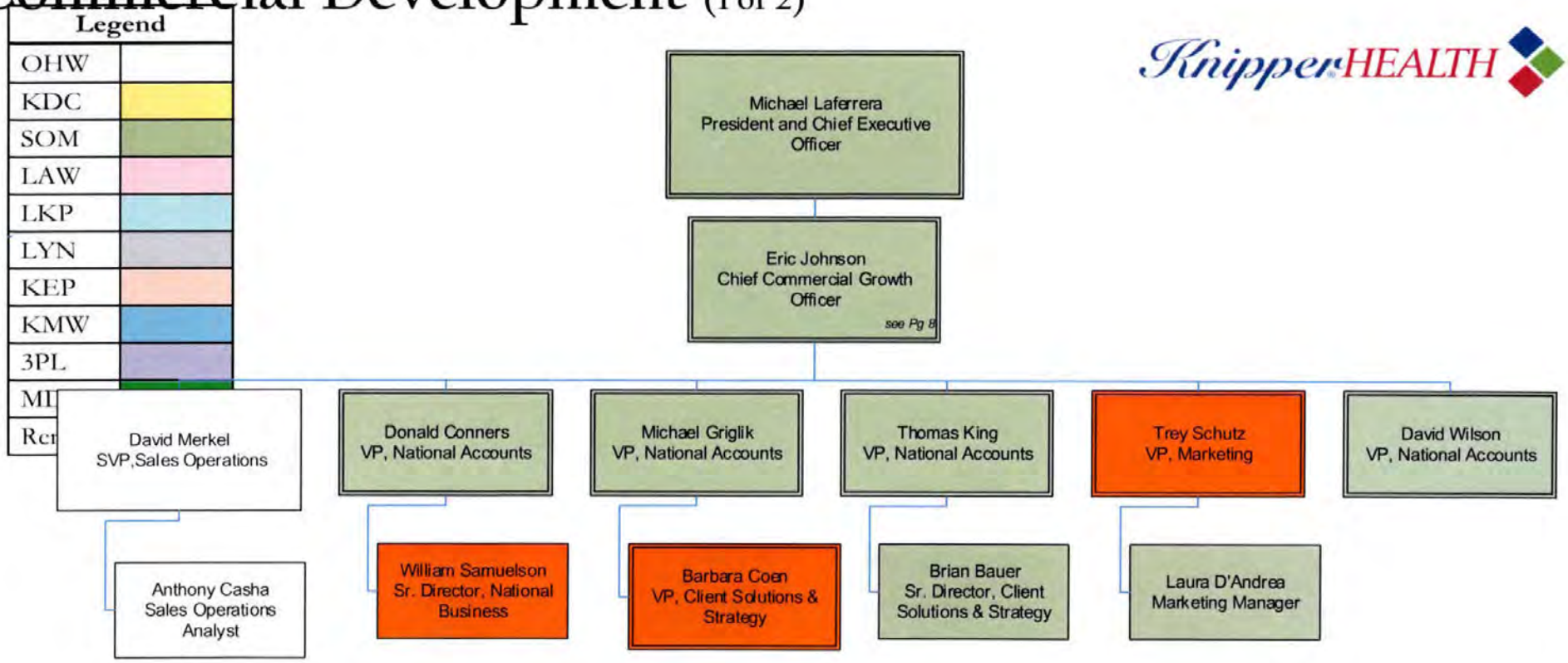
Regulatory and Quality (2 of 2)

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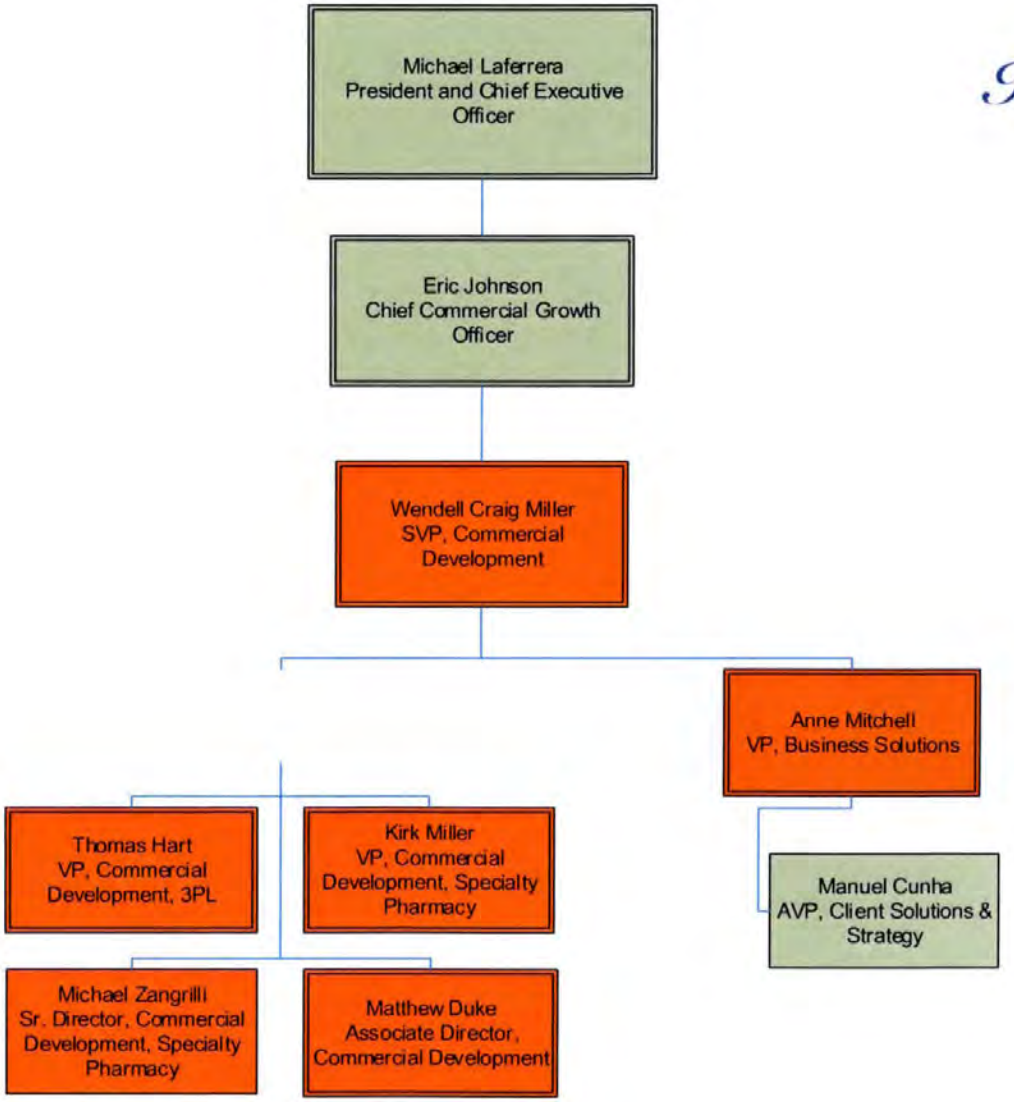


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Commercial Development (1 of 2)

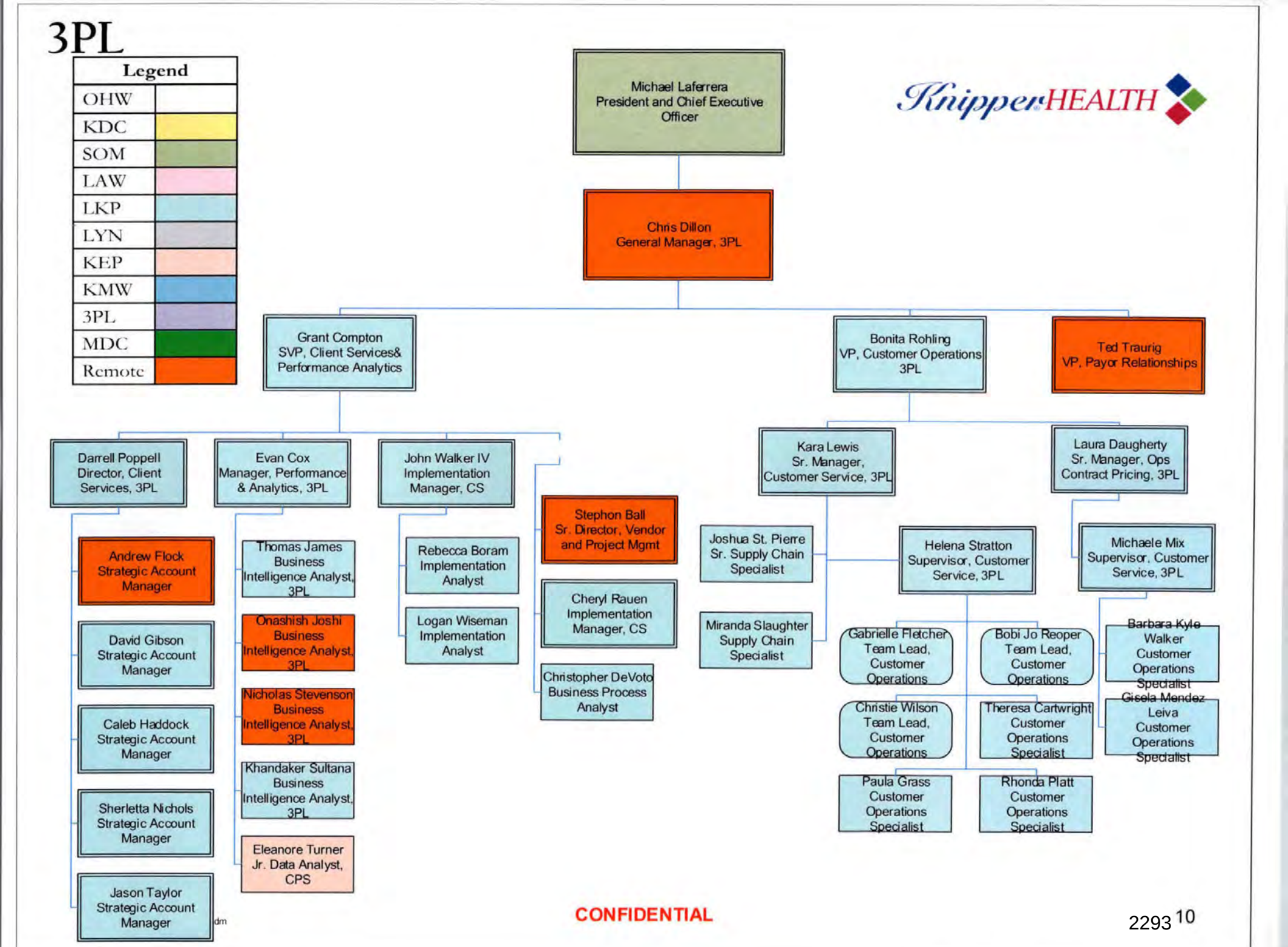


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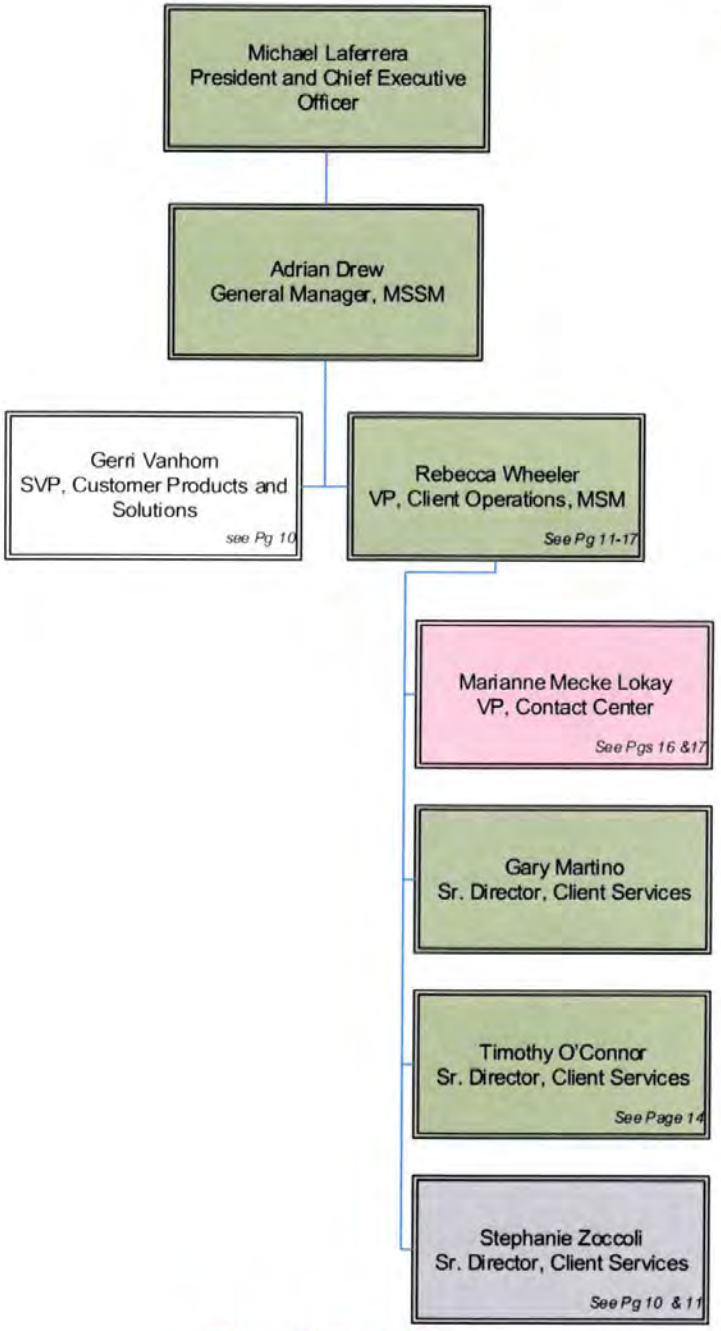
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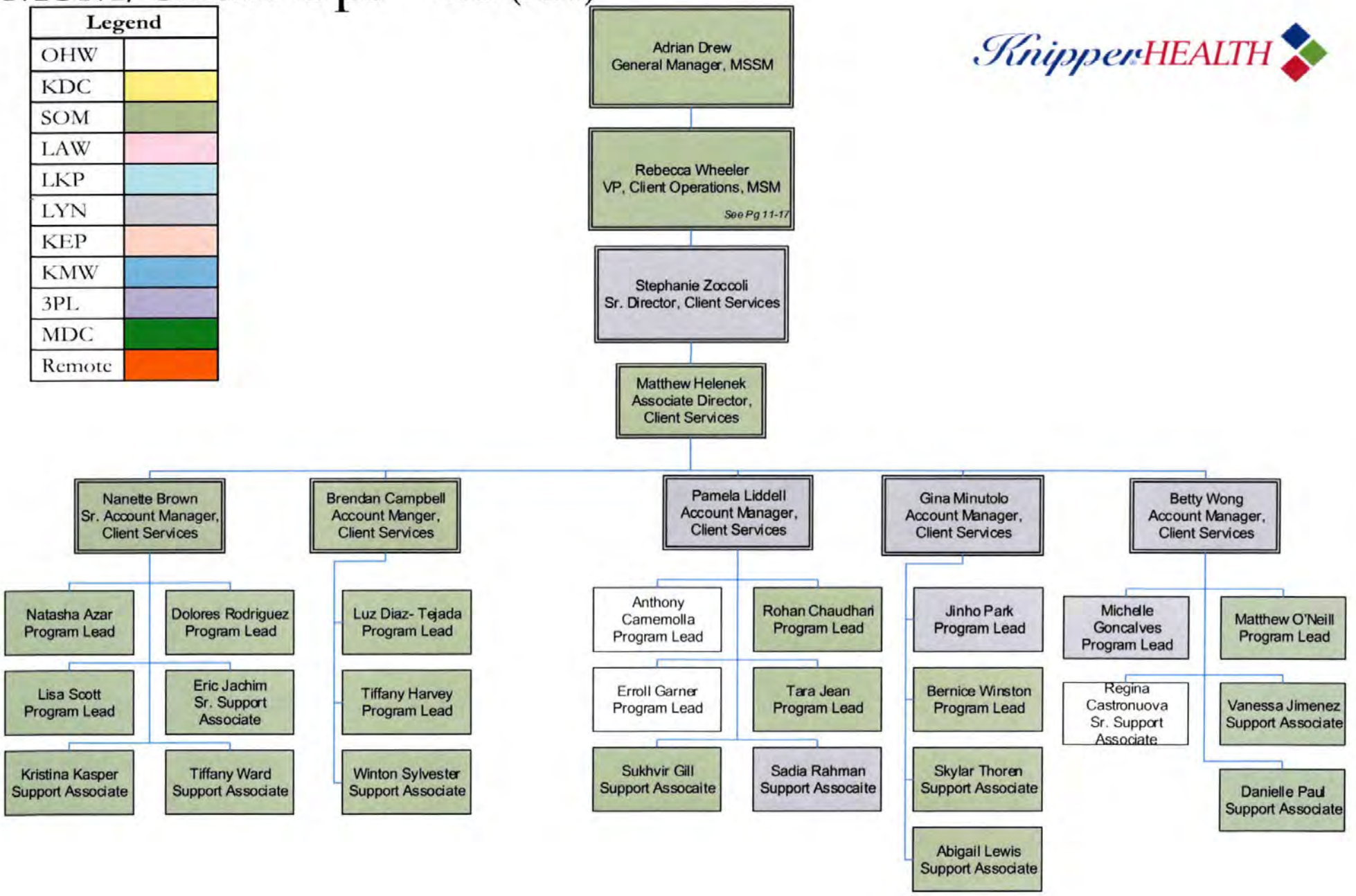
MSM/Client Operations

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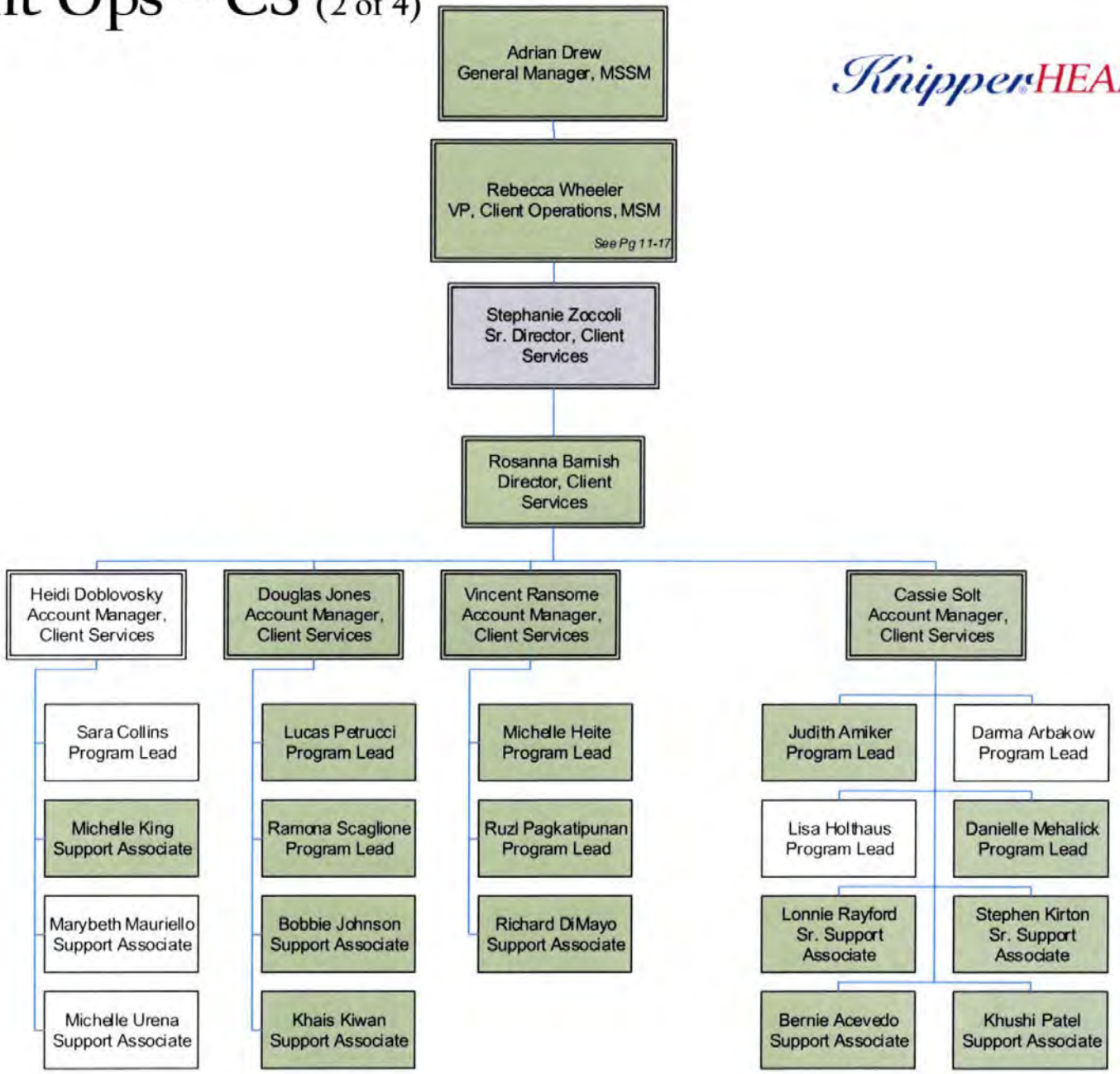
MSM/Client Ops – CS (1 of 5)

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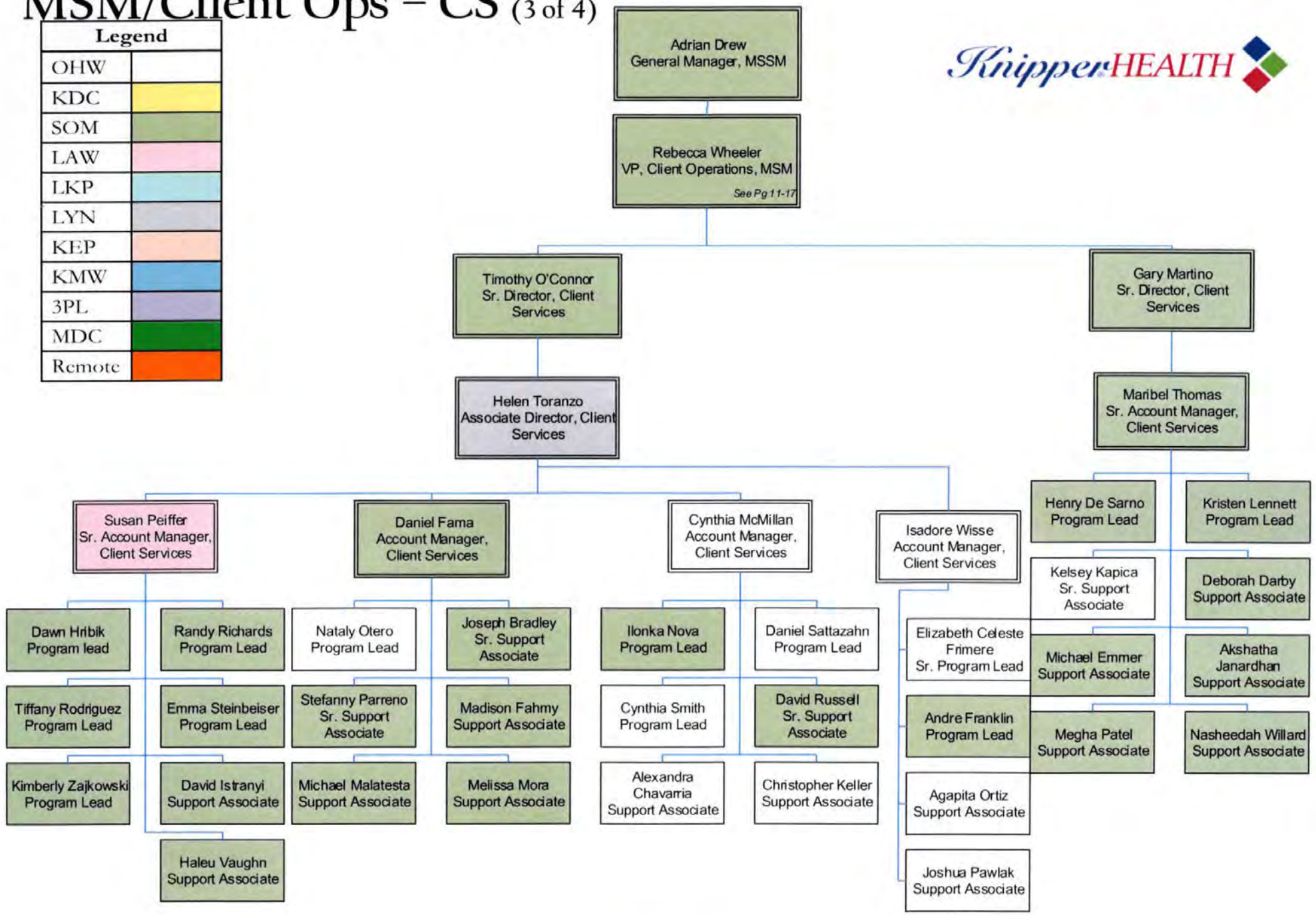
MSM/Client Ops – CS (2 of 4)

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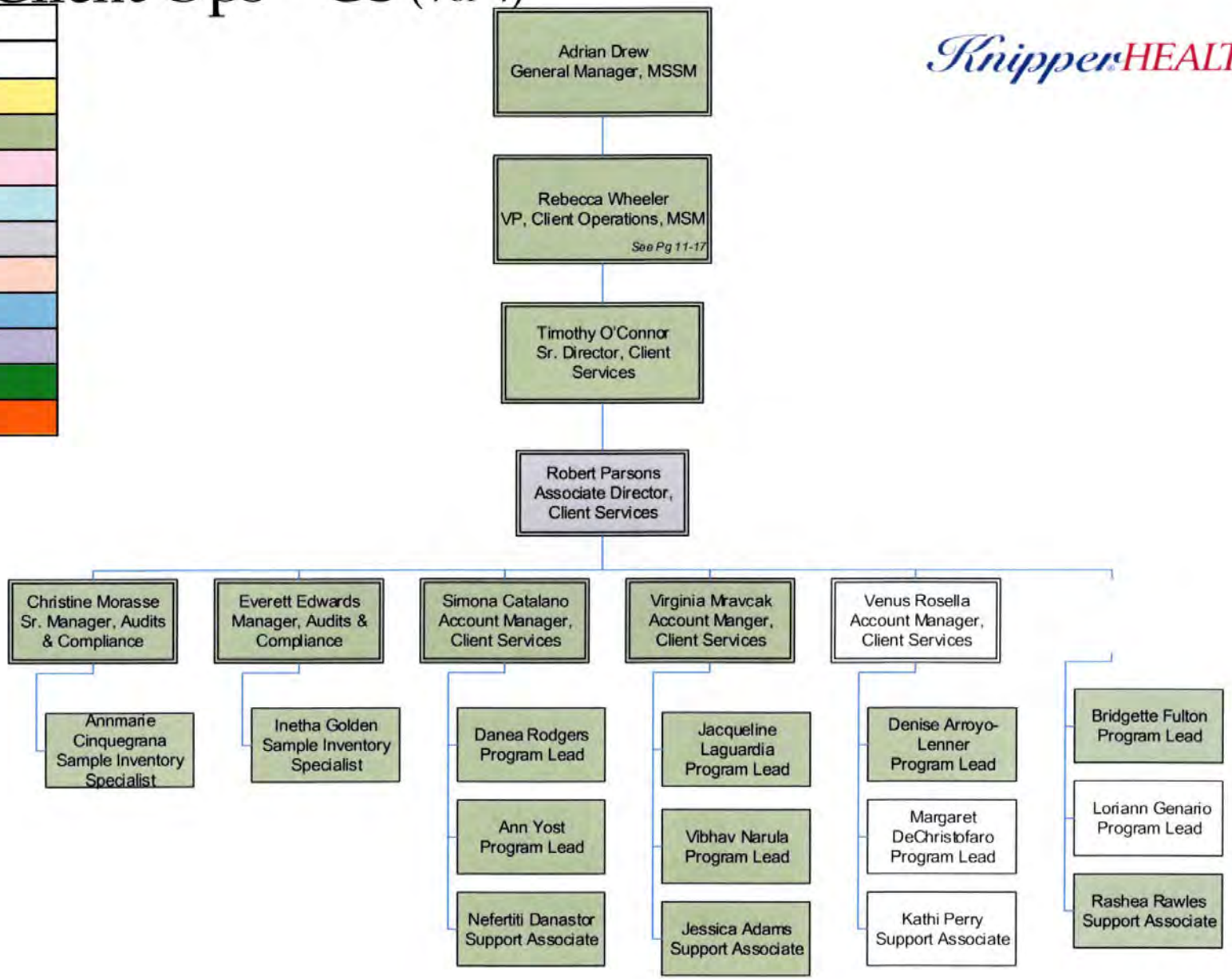
MSM/Client Ops – CS (3 of 4)

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MSM/Client Ops – CS (4 of 4)

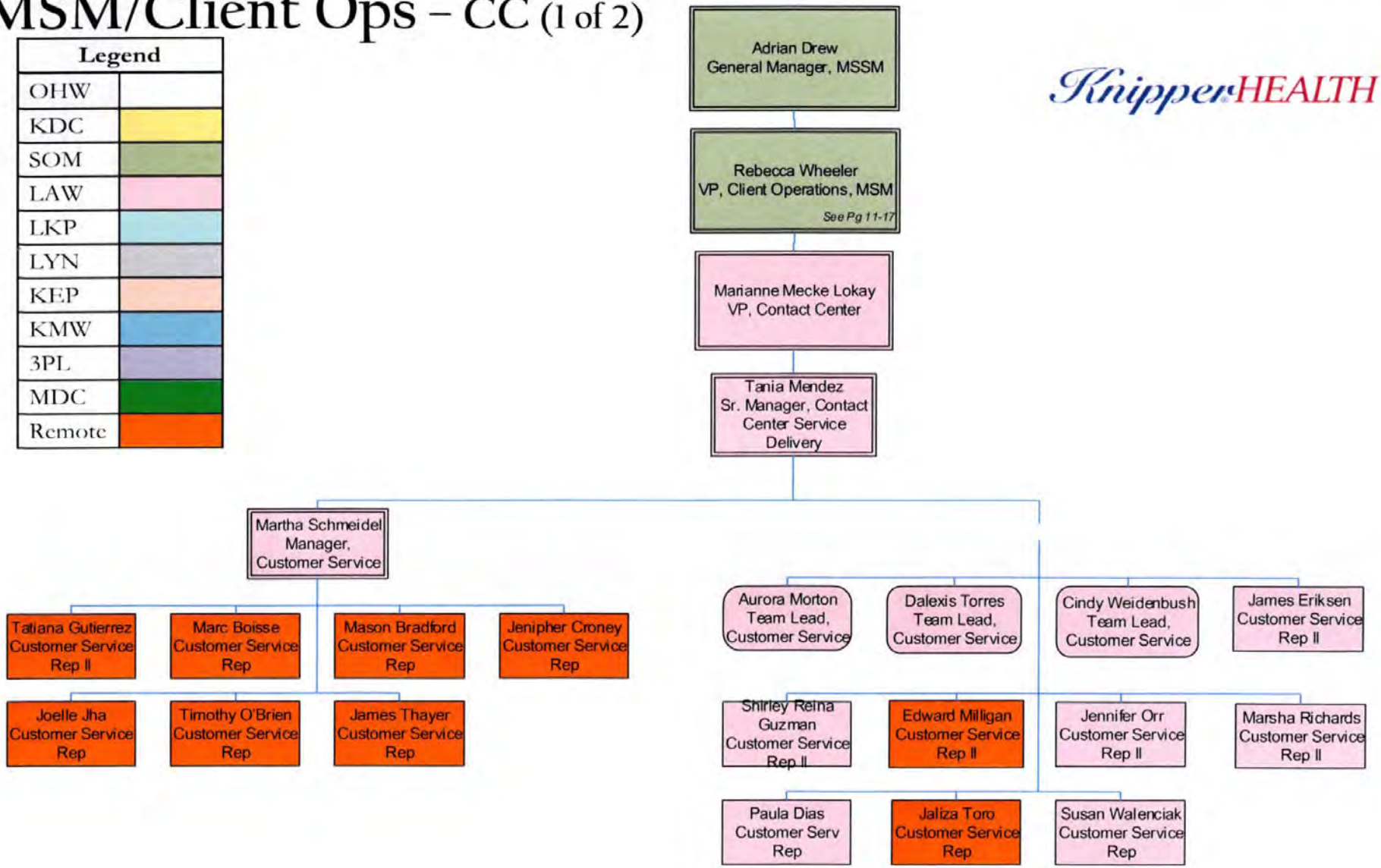
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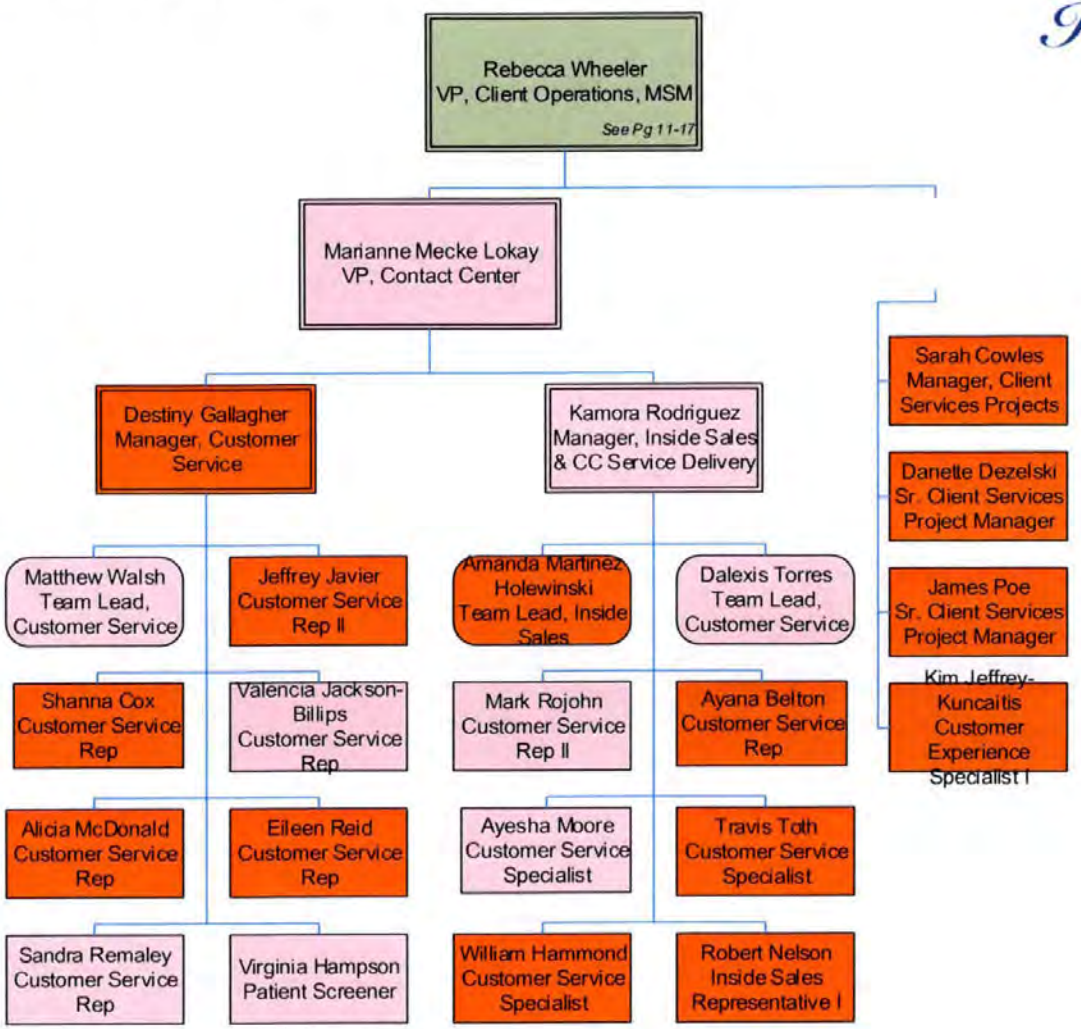
MSM/Client Ops – CC (1 of 2)

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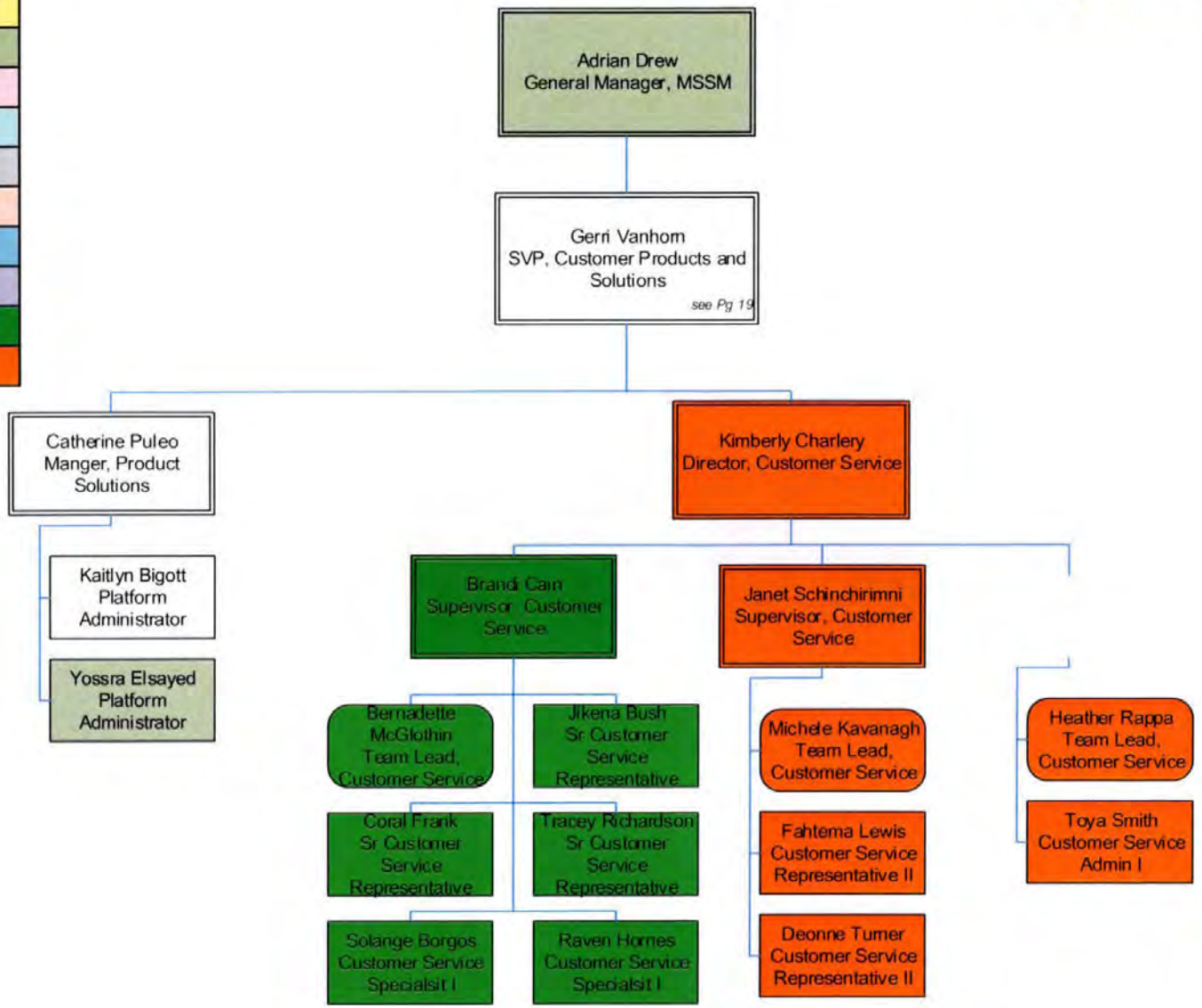
MSM/Client Ops – CC (2 of 2)

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MSM/Client Ops - CST (1 of 2)

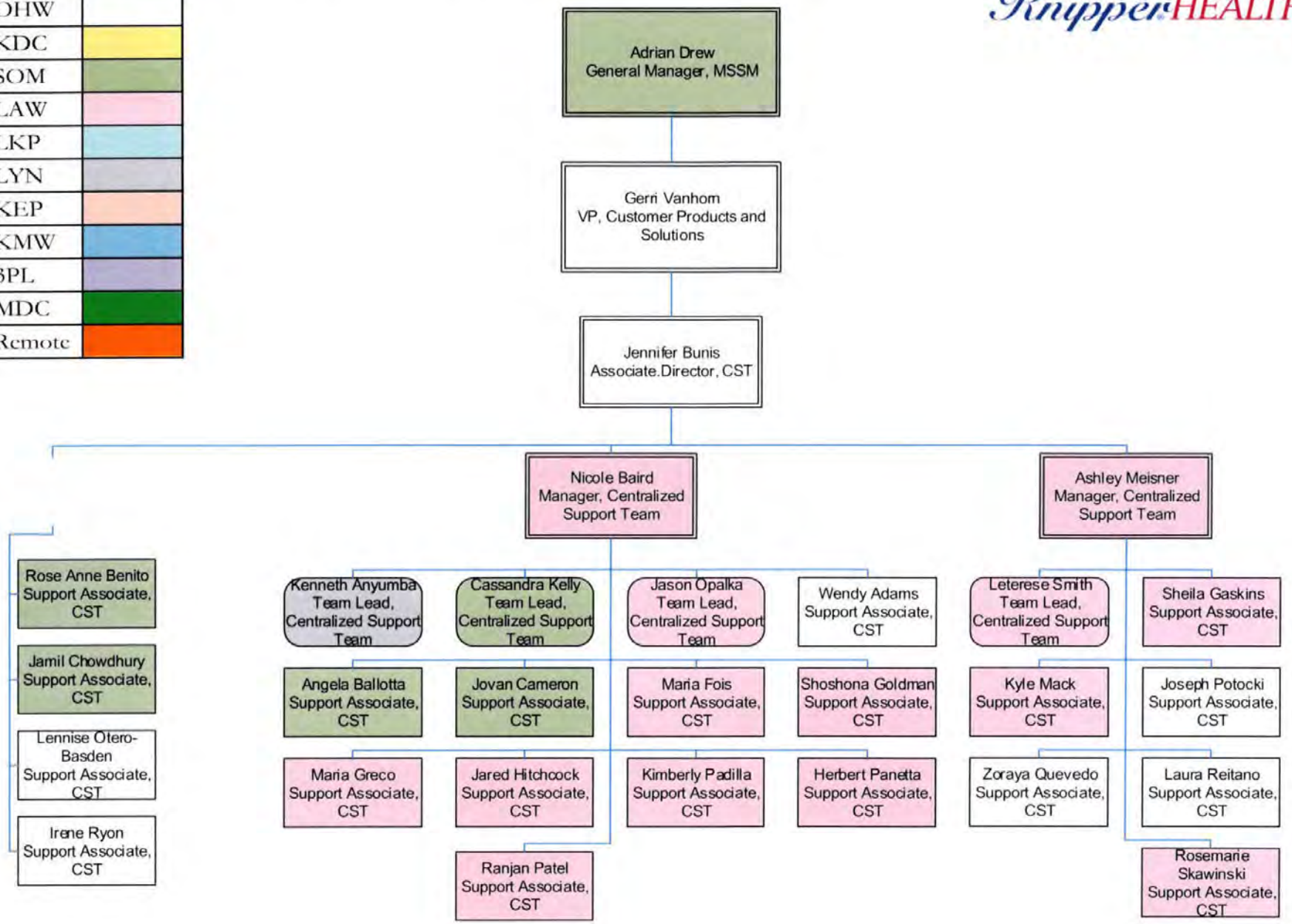
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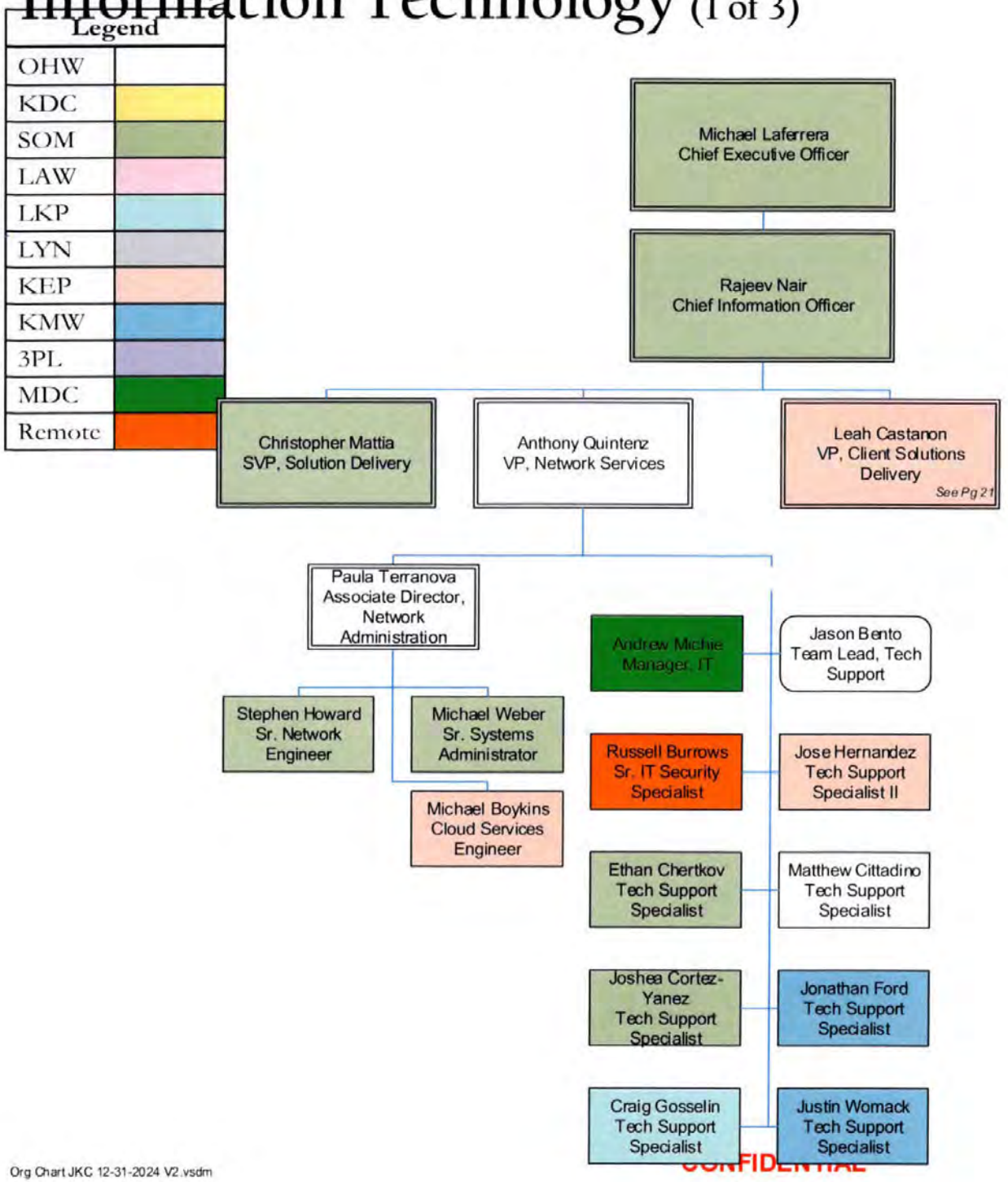
MSM/Client Ops - CST (2 of 2)

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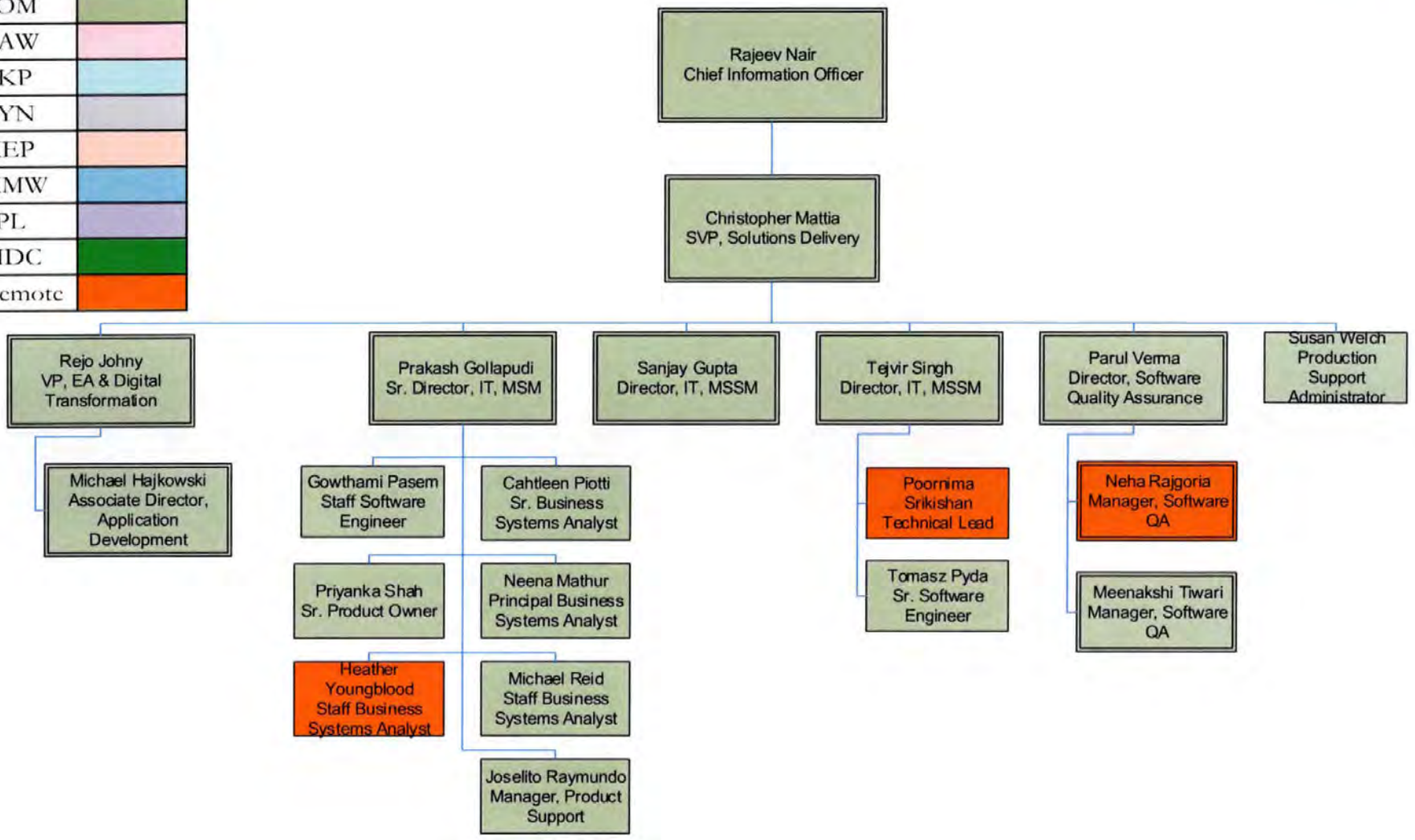
Information Technology (1 of 3)



CONFIDENTIAL

Information Technology (2 of 3)

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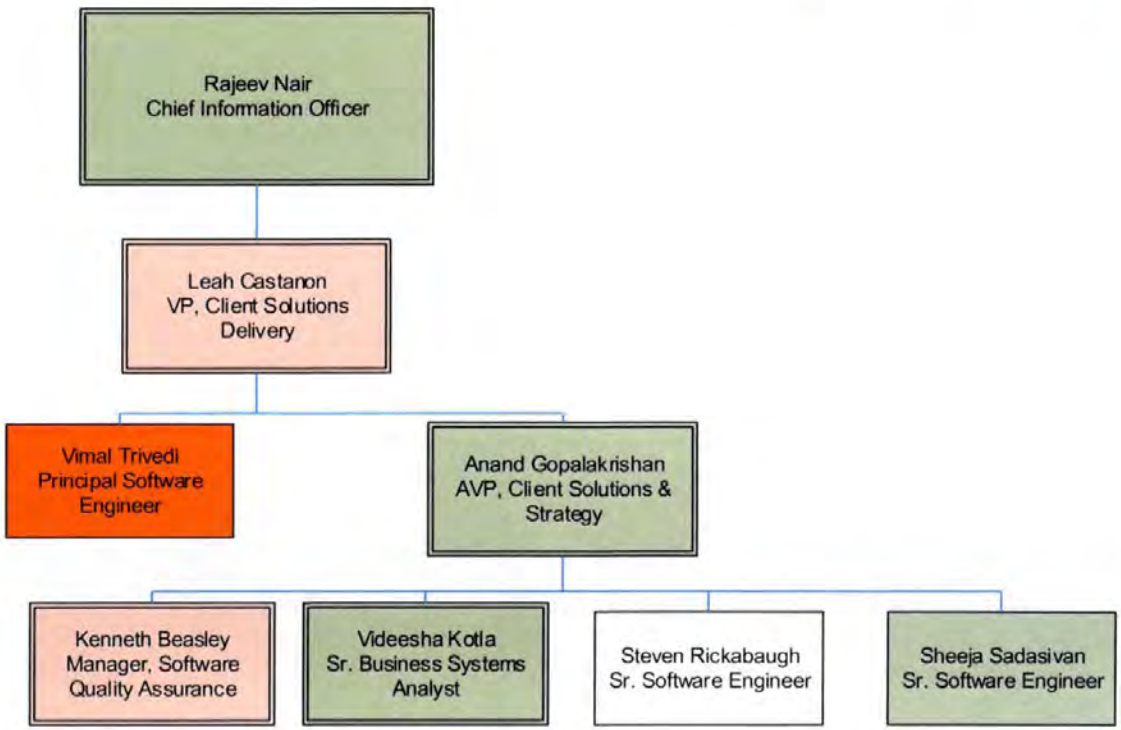


CONFIDENTIAL

Information Technology (3 of 3)

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KnipperHEALTH

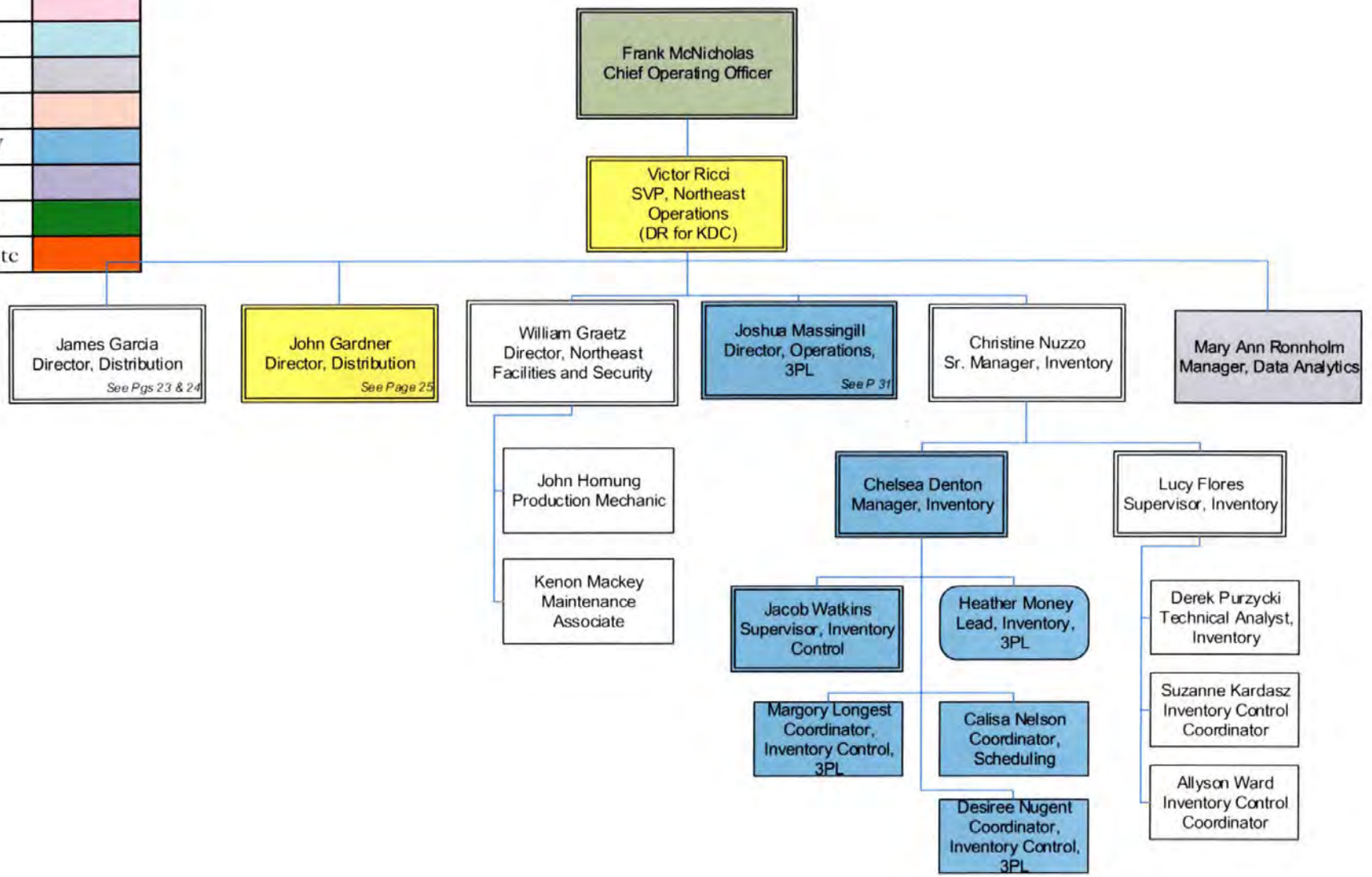


CONFIDENTIAL

Operations (1 of 13)

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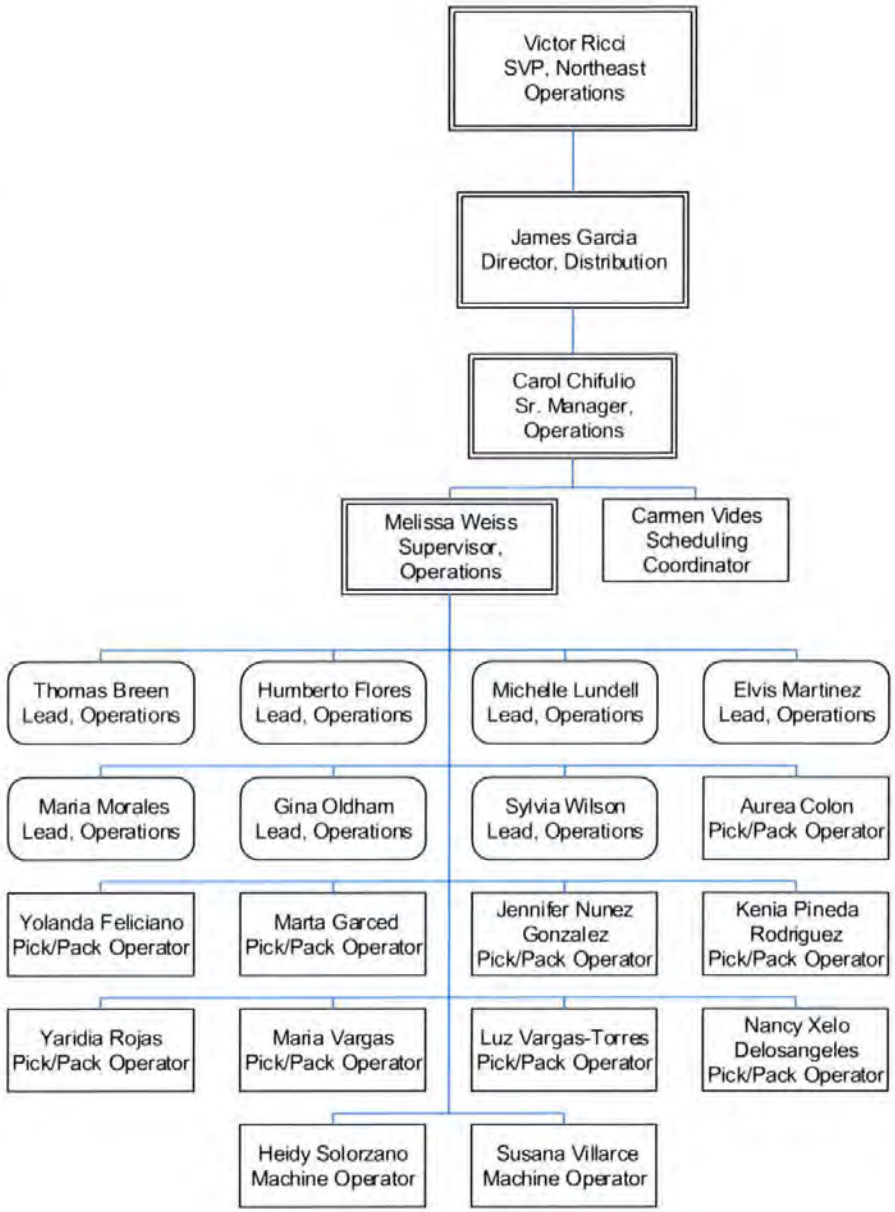
KnipperHEALTH



CONFIDENTIAL

Operations (2 of 13)

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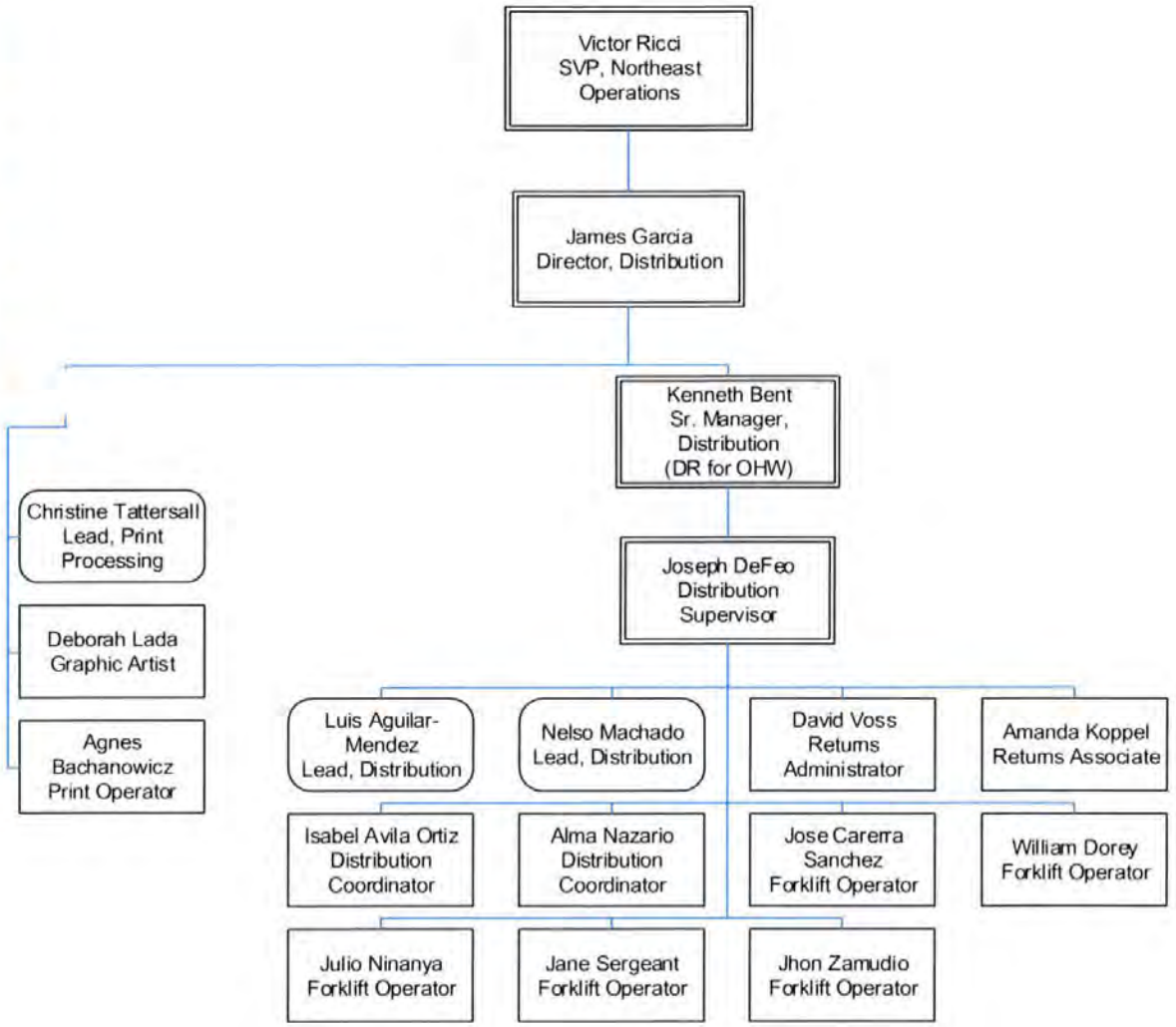


CONFIDENTIAL

Operations (3 of 13)

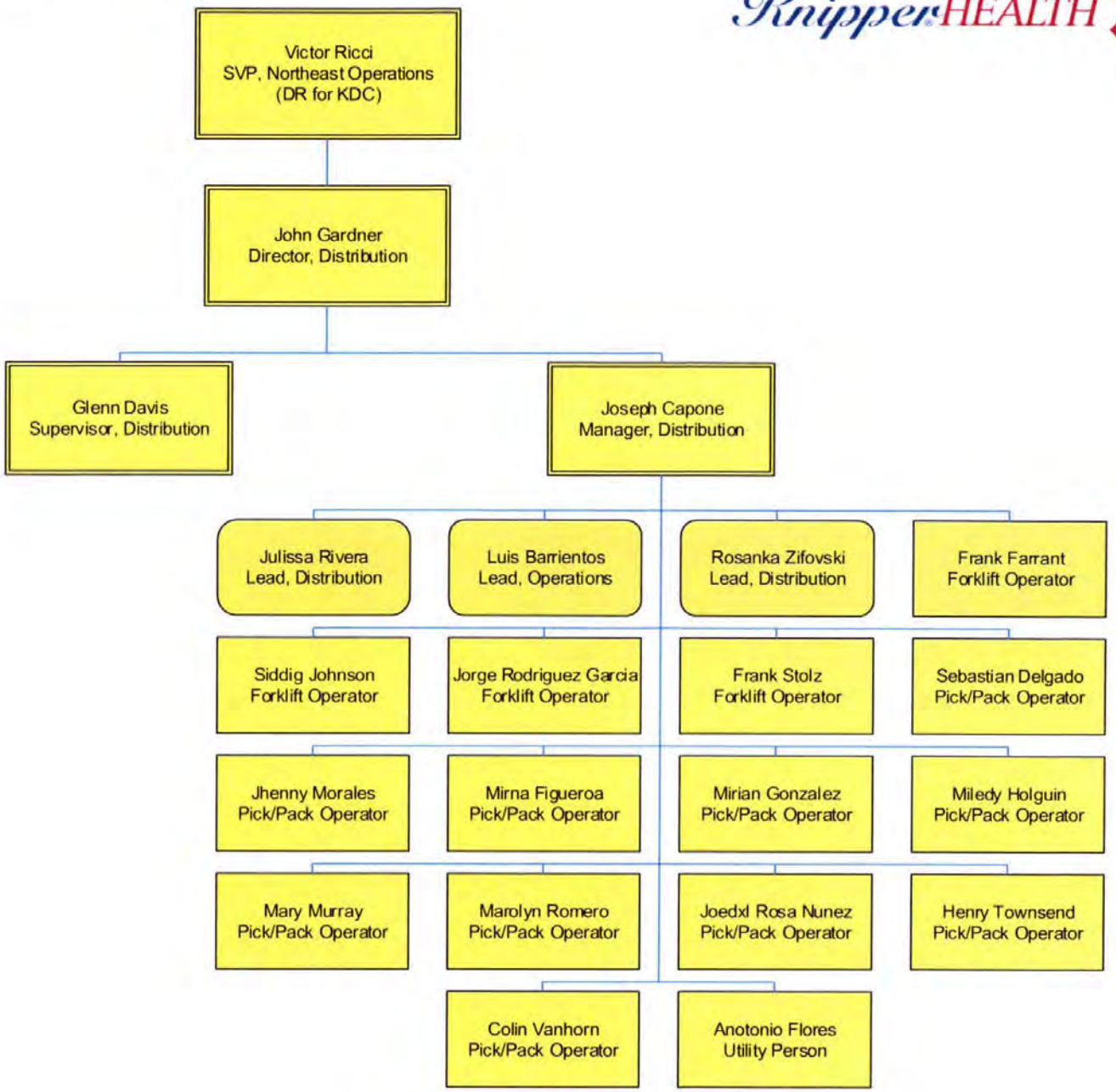
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KnipperHEALTH



Operations (4 of 13)

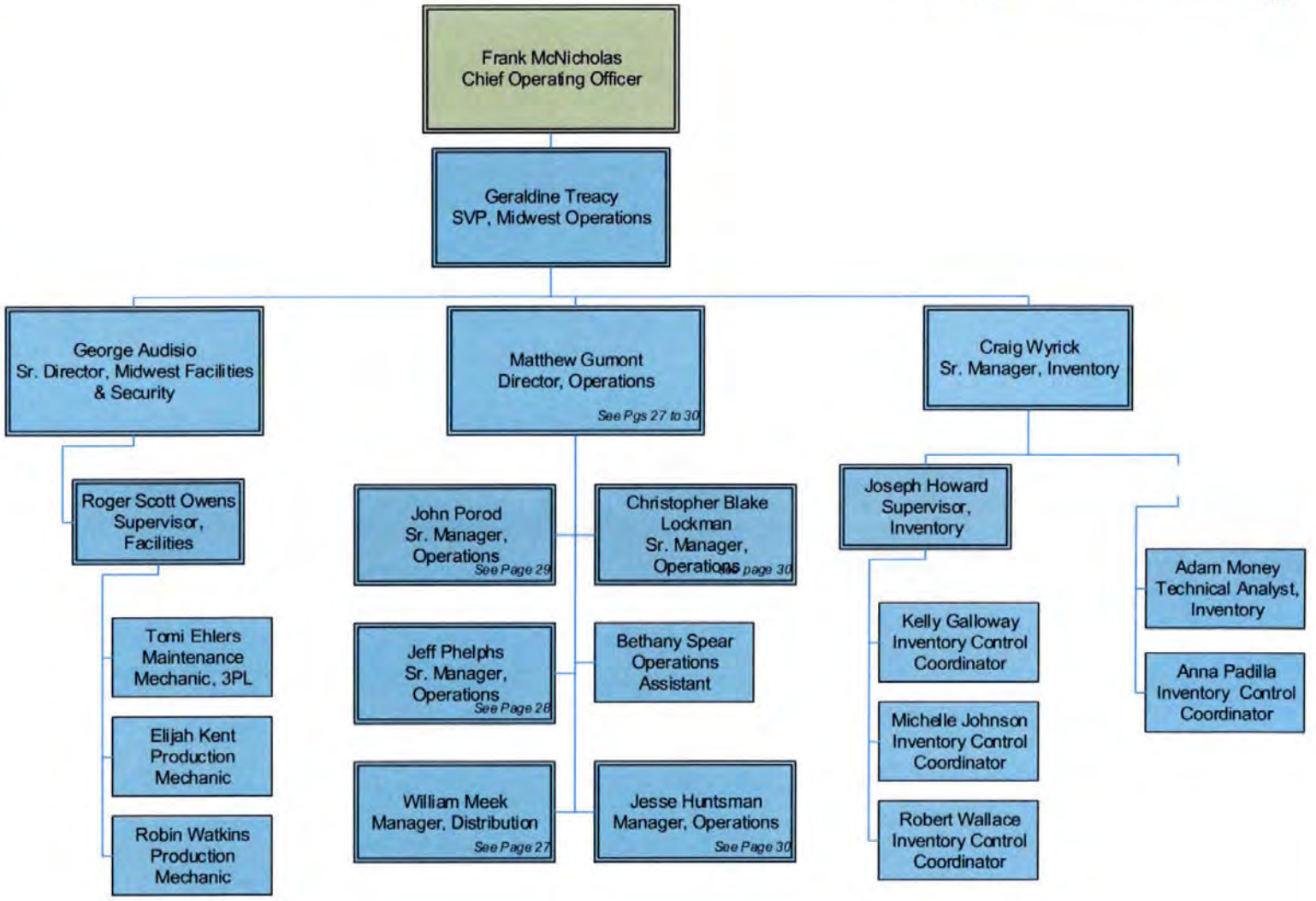
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Operations (5 of 13)

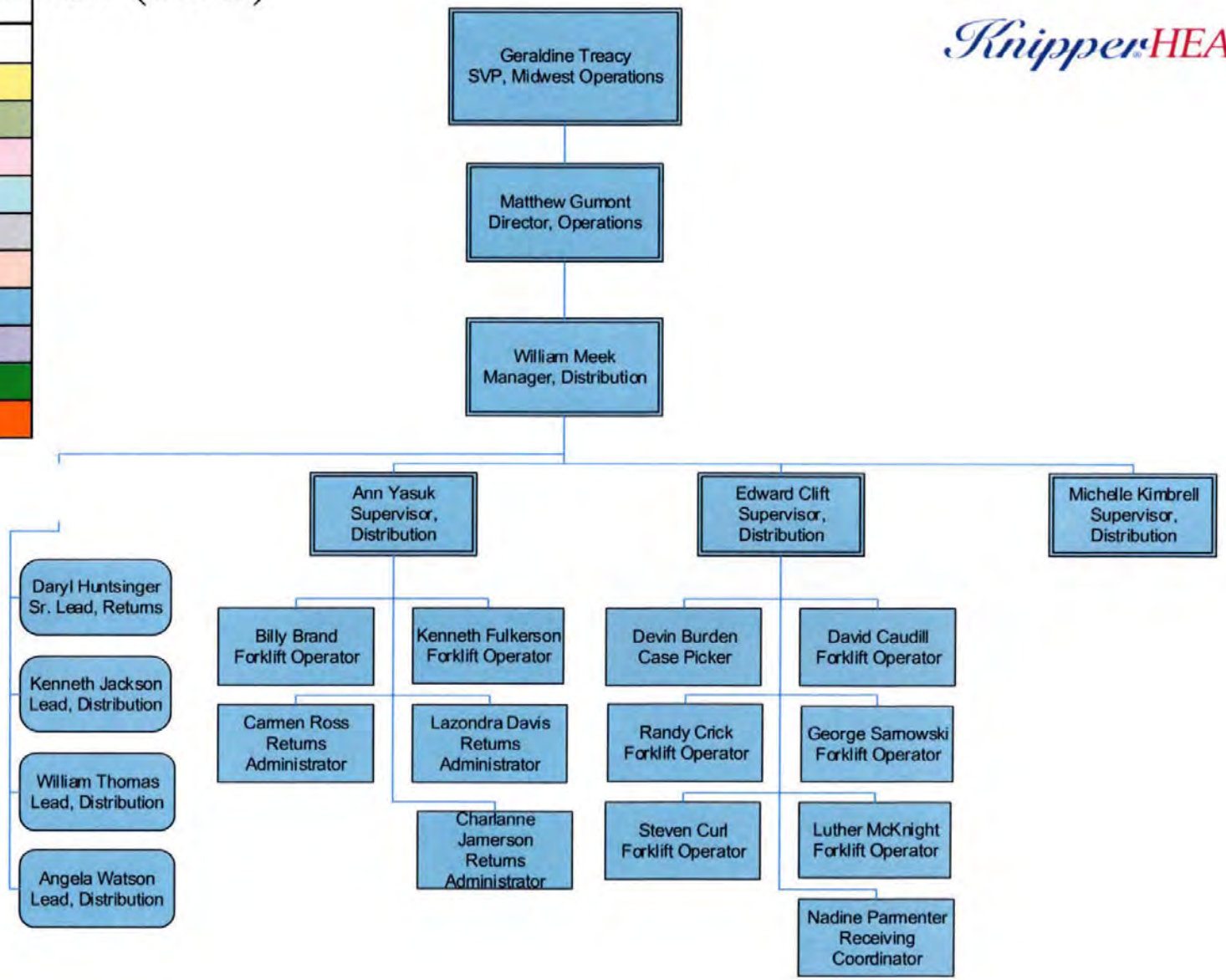
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KnipperHEALTH



Operations (6 of 13)

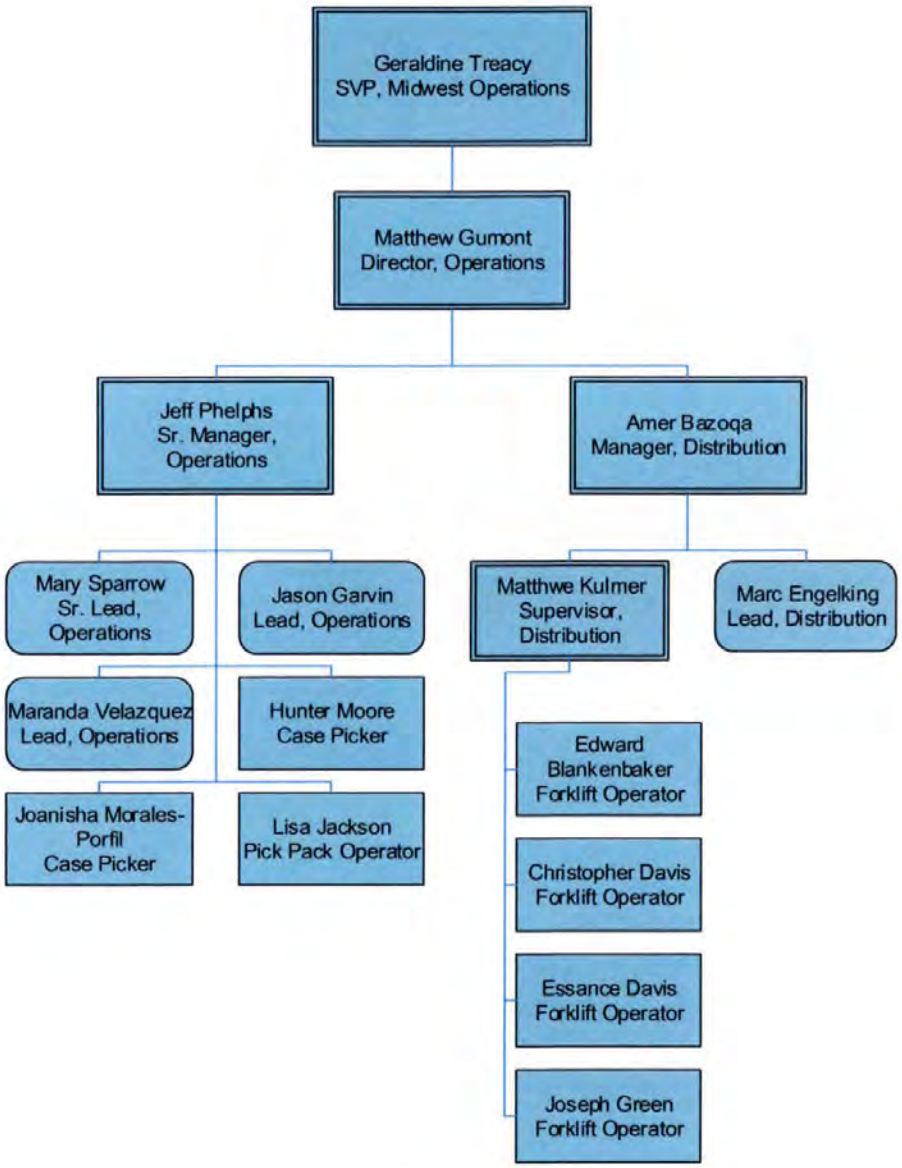
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CONFIDENTIAL

Operations (7 of 13)

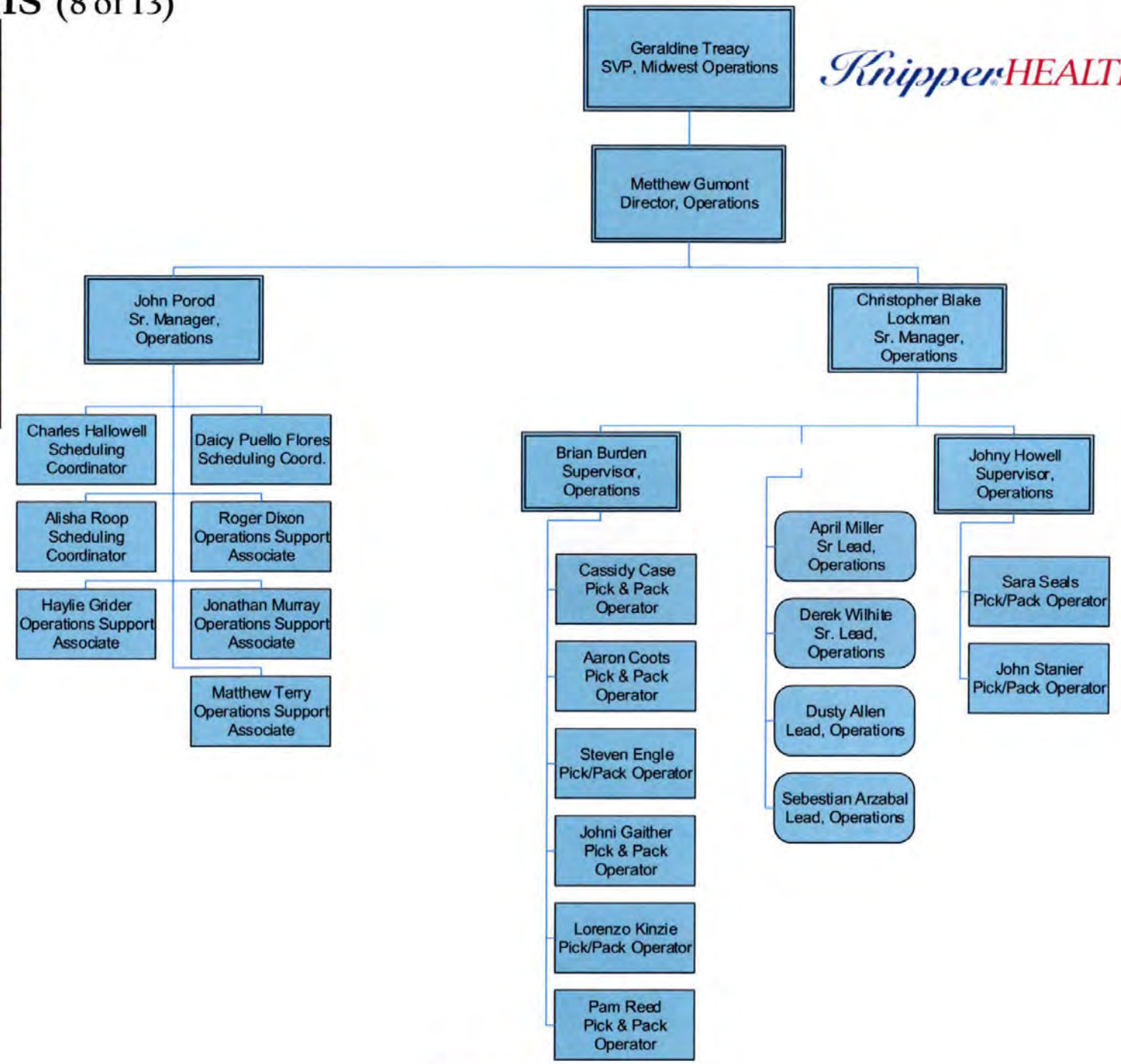
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CONFIDENTIAL

Operations (8 of 13)

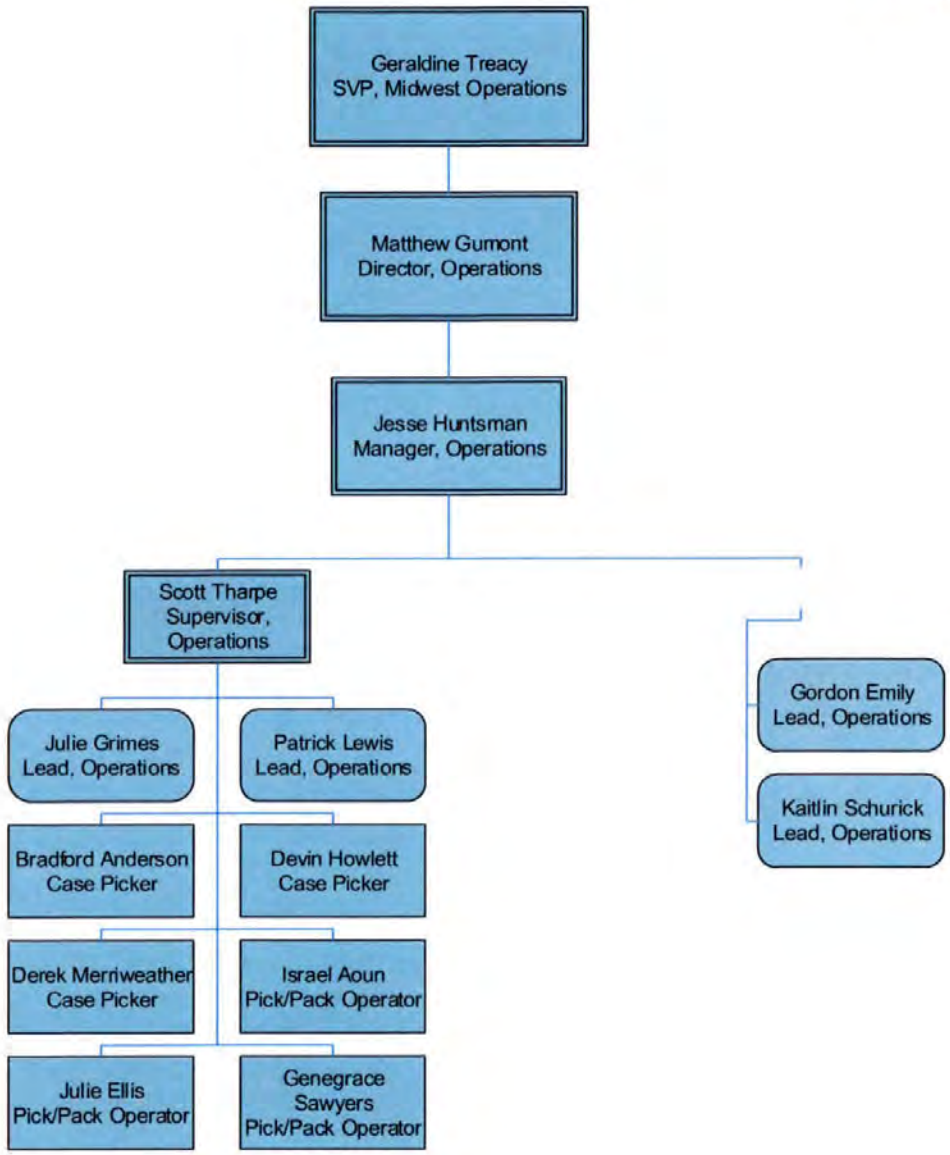
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CONFIDENTIAL

Operations (9 of 13)

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OHW	
KDC	
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KEP	
KMW	
3PL	
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Remote	



Operations (10 of 13)



Victor Ricci
SVP, Northeast Operations

Joshua Massingill
Director, Operations, 3PL
See P 23

- Alexandira Anderson, Manager, Operations, 3PL
  - AJ Stivers, Supervisor, Operations, 3PL
    - Brooklin Crain, Lead, Transportation, 3PL
    - Tabitha Feltner, Operations Lead, 3PL
    - Demetrius Hall, Operations Lead, 3PL
    - Charles Florence, Forklift Operator
    - Shonna Lenz, Forklift Operator
    - Sidney Netherton, Forklift Operator
    - Earrick Yates, Forklift Operator
    - Brad Hersman, Case Picker
- James Bray, Manager, Operations, 3PL
  - Traci Van De Bossche, Lead, Operations, 3PL
- Caleb Clifton, Manager, Operations, 3PL
  - Frederick Kerstiens, Supervisor, Operations, 3PL
    - Christopher King, Lead, Operations, 3PL
    - Anthony Walker, Lead, Operations, 3PL
    - Daniel Smith, Forklift Operator
- Keith Goldsmith, Manager, Operations, 3PL
  - Jason Hearn, Supervisor, Operations, 3PL
    - Sean Ross, Lead, Operations, 3PL
    - Jonathan Anderson, Case Picker
    - Sandra Vickers, Case Picker
- Kyle Richmer, Manager, Operations, 3PL
  - Robert McGinnis, Supervisor, Operations, 3PL
    - Jennifer Jewell, Lead, Operations, 3PL
      - Johnna Barr, Case Picker
      - Roger Decola, Case Picker
      - Catherine Knight, Case Picker
      - Kaurshawna Phegley, Case Picker
    - Terry Lewis, Lead, Operations, 3PL
      - Sheila Brianvil, Case Picker
      - Carl King, Case Picker
      - Marvin Rodgers, Case Picker
      - Nolan Lewis, Case Picker
    - Tonya Nally, Lead, Operations, 3PL
    - William Tichenor, Lead, Operations, 3PL

CONFIDENTIAL

Operations (11 of 13)

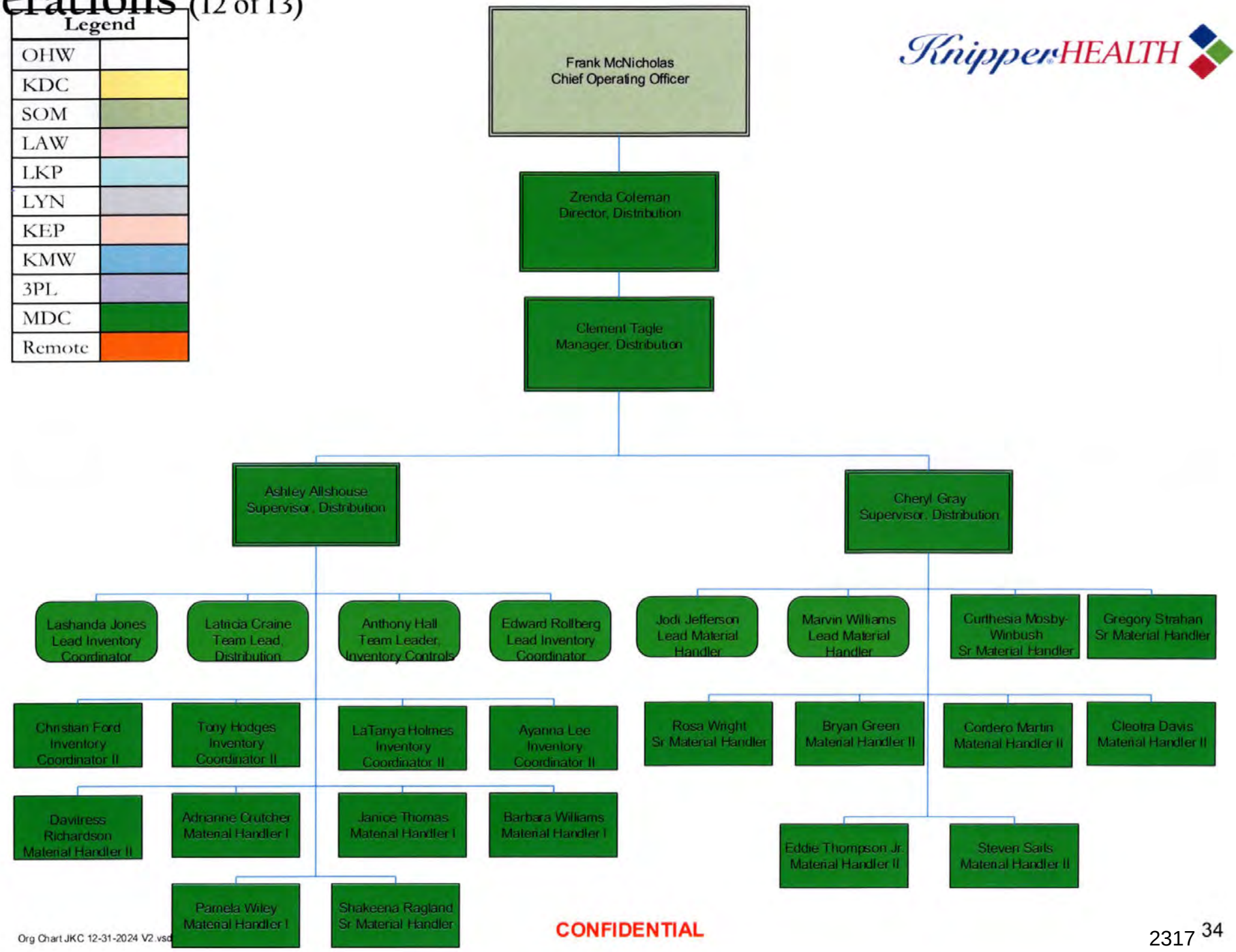
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CONFIDENTIAL

Operations (12 of 13)

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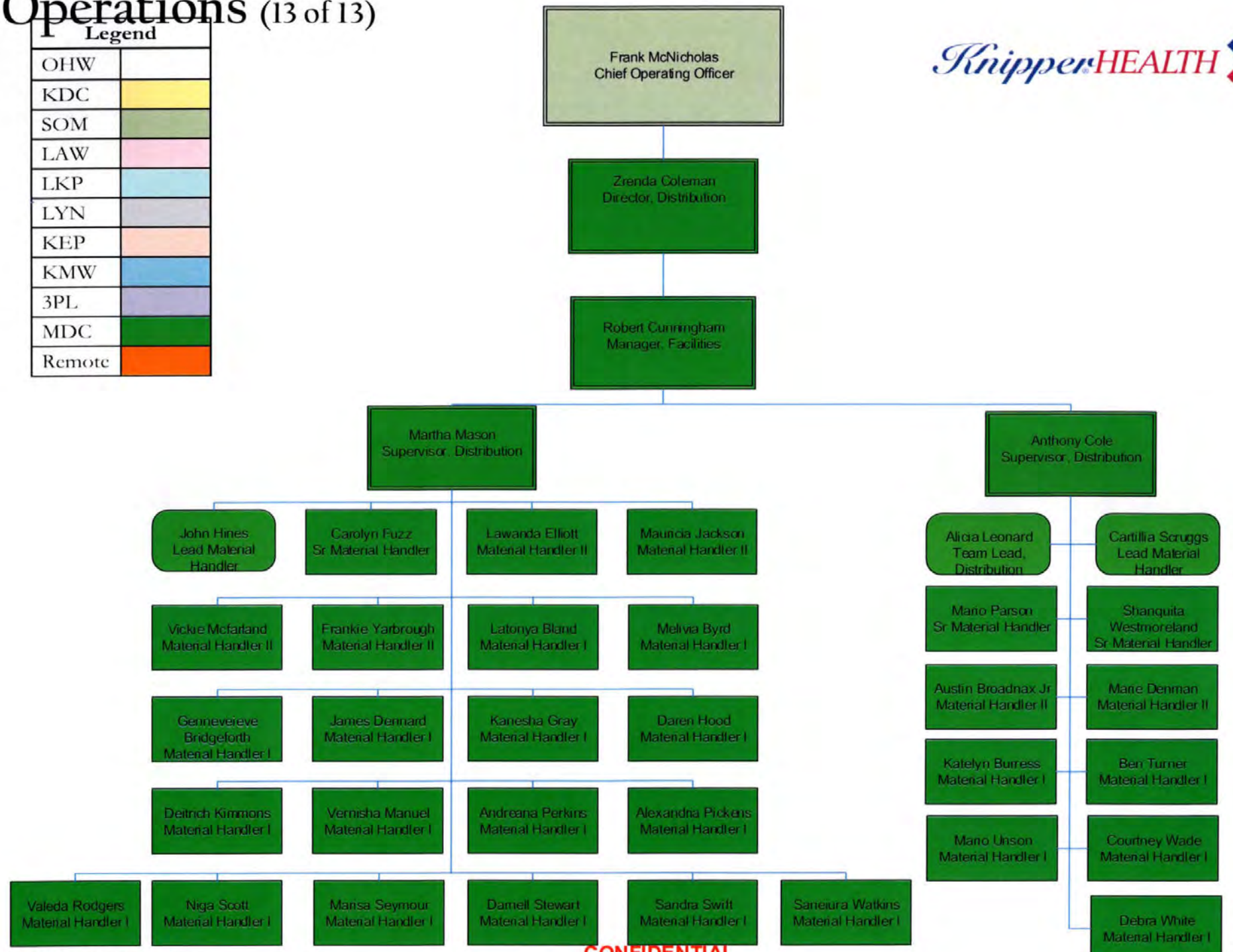


Org Chart JKC 12-31-2024 V2.vsd

CONFIDENTIAL

Operations (13 of 13)

Legend	
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LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



Org Chart JKC 12-31-2024 V2.vsdm

CONFIDENTIAL

J. Kniper and Company, Inc.
1550 Oak St.
Lakewood, NJ 08701

Source Name	Country	City	State
Aerie Pharmaceuticals, Inc.	United States	Bedminster	NJ
ANI Pharmaceuticals	United States	Baudette	MN
Arbor Pharmaceuticals,LLC	United States	Atlanta	GA
Ascendis	United States	Princeton	NJ
Bausch Health	United States	Bridgewater	NJ
Biocyrst Pharmaceuticals, Inc.	United States	Durham	NC
Boehringer Ingleheim	United States	Ridgefield	CT
Bracco Diagnostics	Italy	Milan	Italy
Cumberland Pharmaceuticals	United States	La Vergne	TN
Fresenius Medical Care-North America	United States	Waltham	MA
Genentech	United States	Louisville	KY
Gilead Sciences, Inc	United States	Foster City	CA
Inceptua, Inc	United States	New York	NY
Incyte Corporation	United States	Wilmington	DE
Indivior, Inc.	United States	Richmond	VA
Intra-Cellular Therapies	United States	Towson	MD
Mallinckrodt Pharmaceuticals	United States	Hobart	NY
Mannkind Corp	United States	Westlake Villiage	CA
Merck	United States	Kenilworth	NJ
Noven Pharmaceuticals	United States	Miami	FL
Novo Nordisk Inc	United States	Plainsboro	NJ
OptiNose	United States	Yardley	PA
Paratek Pharmaceuticals	United States	Boston	MA
RVL Pharmaceuticals, Inc	United States	Bridgewater	NJ
Scilex Pharmaceuticals, Inc.	United States	Malvern	PA
SST Corporation	United States	Clifton	NJ
TEVA	United States	North Whales	PA
Thea Pharma, Inc.	United States	Waltham	MA
Vanda Pharmaceuticals	United States	Washington DC	DC
West-Ward Pharmaceuticals Corp	United States	Eatontown	NJ

4XX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ☑ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ☑ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	See Attachment A * If making a change, provide current license number: WH 02192	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: J. Knipper and Company, Inc.

Physical Address: 1250 Patrol Road

City: Charlestown State: IN Zip: 47111

Mailing Address (if different from physical address): One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: (732) 905-7878 Website: https://www.knipper.com/

Name of Designated Representative (DR): Geraldine Treacy

Licensing Company Email: Licensing@knipper.com DR Email: Licensing@knipper.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
☑ Pharmacies	☑ Dangerous Drugs	☐ Manufacturer
☑ Practitioners	☑ Controlled Substances	☑ Repacker
☑ Hospitals	☑ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☑ Wholesalers	☐ Others:	☑ Warehouse
☑ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	February 18, 2020	CO	Denver	Denver

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2019-3775	Colorado Board of Pharmacy

Reason/Charge	
J. Knipper and Company was subject to disciplinary action and a penalty in Colorado for delayed notification of change of designated representative for its 1550 Oak Street, Lakewood, NJ facility.	
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**
Colorado Board of Pharmacy claimant	N/A
Name of Business/Industry/Entity	
J. Knipper and Company, Inc.	

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/3/2025
Date

COLORADO
Department of
Regulatory Agencies
Division of Professions and Occupations

February 19, 2020

J. Knipper and Company, Inc.
1550 Oak Street
Lakewood, NJ 08701-5937

Sent via email: compliance@knipper.com, teresita.weiss@knipper.com

RE: Case No. 2019-3775 Stipulation and Final Agency Order

Dear Pharmacy Manager:

Staff for the Colorado State Board of Pharmacy ("Board") has reviewed the terms and conditions of the above listed Stipulation and Final Agency Order effective February 18, 2020.

After due consideration, and pursuant to Board Policy 10-6, staff for the Board released you from the terms and conditions of the February 18, 2020, Stipulation and Final Agency Order and restored your Registration No. WHO.0007269 to unencumbered status.

Although this disciplinary action will remain a public document, our records show that the requirements of your Order are complete. Please retain this letter for your records.

Your cooperation during the pendency of this matter is sincerely appreciated.

Respectfully,

FOR THE COLORADO STATE BOARD OF PHARMACY

Dmitry Kunin
Program Director

cc: Jeremy Alexander, Esq., sent via email: jalexander@reedsmith.com
John Kendzior, Esq., sent via email: jkendzior@reedsmith.com
File

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2019-3775

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDINGS REGARDING THE NON-RESIDENT WHOLESALER REGISTRATION IN THE STATE OF COLORADO OF J. KNIPPER AND COMPANY, INC., REGISTRATION NO. WHO-7269,

Respondent Outlet.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and J. Knipper and Company, Inc., ("Respondent Outlet") to resolve all matters pertaining to Board Case Number 2019-3775, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent Outlet, its registration as a non-resident wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the Pharmacists, Pharmacy Businesses, and Pharmaceuticals Act at Title 12, Article 42.5, C.R.S. (2018).

2. Respondent Outlet was originally registered in the State of Colorado on or about June 20, 2007, being issued registration #WHO-7269, and has been so registered at all times relevant to this disciplinary action.

3. Respondent Outlet's address of record with the Board and current location is 1550 Oak St, Lakewood, NJ 08701.

4. Respondent Outlet admits these findings and hereby waives any further proof in this proceeding before the Board regarding the following facts.

5. Respondent Outlet failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, 189 days transpired between November 13, 2018, the date the previous designated representative ceased the position, and May 21, 2019, the date the application and fee were received.

6. On or about June 3, 2019, the Board initiated a complaint against Respondent Outlet because of the delay of 189 days in submitting an application detailing a change in designated representative and fee.

7. Respondent Outlet's conduct, as set forth above, constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

Colorado Revised Statutes

12-42.5-123. Unprofessional conduct - grounds for discipline. (1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(II) The lawful rules of the board.

Pharmacy Board Rules and Regulations

15.01.14 Change of name, location, or ownership, or designated representative.

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

8. The Board finds and concludes, and Respondent Outlet agrees, that based upon Respondent Outlet's above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

9. Fine with Surcharge. Pursuant to section 12-42.5-124(5)(a)(I), C.R.S., Respondent Outlet shall pay a fine of One Thousand Dollars and No Cents ($1,000.00). Respondent Outlet understands and acknowledges that, pursuant to section 24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies may impose an additional surcharge of 15% of this fine. Respondent Outlet shall therefore pay a total amount of One Thousand One Hundred Fifty Dollars and No Cents ($1,150.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent Outlet submits this signed Final Agency Order to the Board.

10. Compliance. Respondent Outlet shall submit all future applications and appropriate fees to the Board detailing changes in its designated representative within the required time frame specified by Board rule or statute in effect at the time of such designated representative change.

11. Other Requirements. Respondent Outlet acknowledges and agrees that, as a condition of this Final Agency Order, Respondent Outlet shall:

    a. promptly pay all Respondent Outlet's own fees and costs associated with this Final Agency Order;

    b. comply fully with this Final Agency Order; and

    c. comply fully with the Pharmacists, Pharmacy Businesses and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

12. Advisements and Waivers. Through its undersigned Authorized Representative, Respondent Outlet enters into this Final Agency Order freely and voluntarily, after having the opportunity to consult with legal counsel and/or choosing not to do so. Respondent Outlet acknowledges its understanding that it has the following rights:

    a. to have formal notice of hearing and charges served upon it;

    b. to respond to said formal notice of charges;

    c. to have a formal disciplinary hearing pursuant to sections 12-42.5-123 and 12-42.5-124, C.R.S.; and

    d. to appeal this Final Agency Order.

    Respondent Outlet freely waives these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent Outlet to the sanctions imposed herein.

13. Acknowledgments. The undersigned Authorized Representative of Respondent Outlet has read this Final Agency Order in its entirety and acknowledges, after having the opportunity to consult with legal counsel and/or choosing not to do so, that Respondent Outlet understands the legal consequences and agrees that none of the terms or conditions herein is unconscionable. Respondent Outlet is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent Outlet further acknowledges that it is not entering into this Final Agency Order under any duress.

14. Violations. Time is of the essence in this Final Agency Order. It is the responsibility of Respondent Outlet to take all appropriate steps to comply fully with this Final Agency Order. Respondent Outlet acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under sections 12-42.5-124(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent Outlet's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent Outlet to comply with all terms and conditions of this Final Agency Order.

15. Integration and Severability. Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

16. Public Record. Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

17. Effective Date. This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent Outlet

Dated: 2/12/2020

Teresita Weiss, Ph.D., J.D.
SVP, Regulatory Affairs and Compliance

APPROVED AS TO FORM
FOR RESPONDENT OUTLET

Reed Smith LLP
Jeremy M. Alexander
John D. Kendzior

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18 day of February, 2020.

State Board of Pharmacy

BY:

Dmitry Kunin
Program Director

Ree

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by electronic means or by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of FEBRUARY 2020, addressed as follows:

J. Knipper and Company, Inc.
Attn: Amer Bazoqa, Designated Representative
1550 Oak St
Lakewood, NY 08701

By Email: compliance@knipper.com; teresita.weiss@knipper.com

Jeremy M. Alexander
John D. Kendzior
Reed Smith LLP
1301 K Street, N.W.
Ste 1000 - East Tower
Washington, D.C. 20005

By email: jalexander@reedsmith.com; jkendzior@reedsmith.com

Agent of the Board

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: See Attachment J

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

Name: _____

Address: _____ City: _____ State: _____ Zip: _____

N/A

Section 4: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): Knipper Holding, Inc.

Corporation/Organization Name: J. Knipper and Company, Inc.

Mailing Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: (732) 905-7878 Email: Licensing@knipper.com

Contact Person Name: Teresita Weiss

N/A

Section 6: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

N/A

Section 7: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification See Attachment B 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. See Attachment C		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
N/A 1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** See Attachment D	✓	✓		
N/A • **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.** See Attachments A and D		✓		
N/A • **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** See Attachment E	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ See Attachment F		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A - Wholly-owned by parent company.		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** See Attachment G	✓	✓	✓	✓
N/A • **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** See Attachment H	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** See Attachment I	✓	✓	✓	✓
N/A • [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
N/A • **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
N/A **ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)**				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

J. Knipper and Company, Inc.

Facility Name

Teresita Weiss General Manager, Regulatory Affairs and Compliance

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

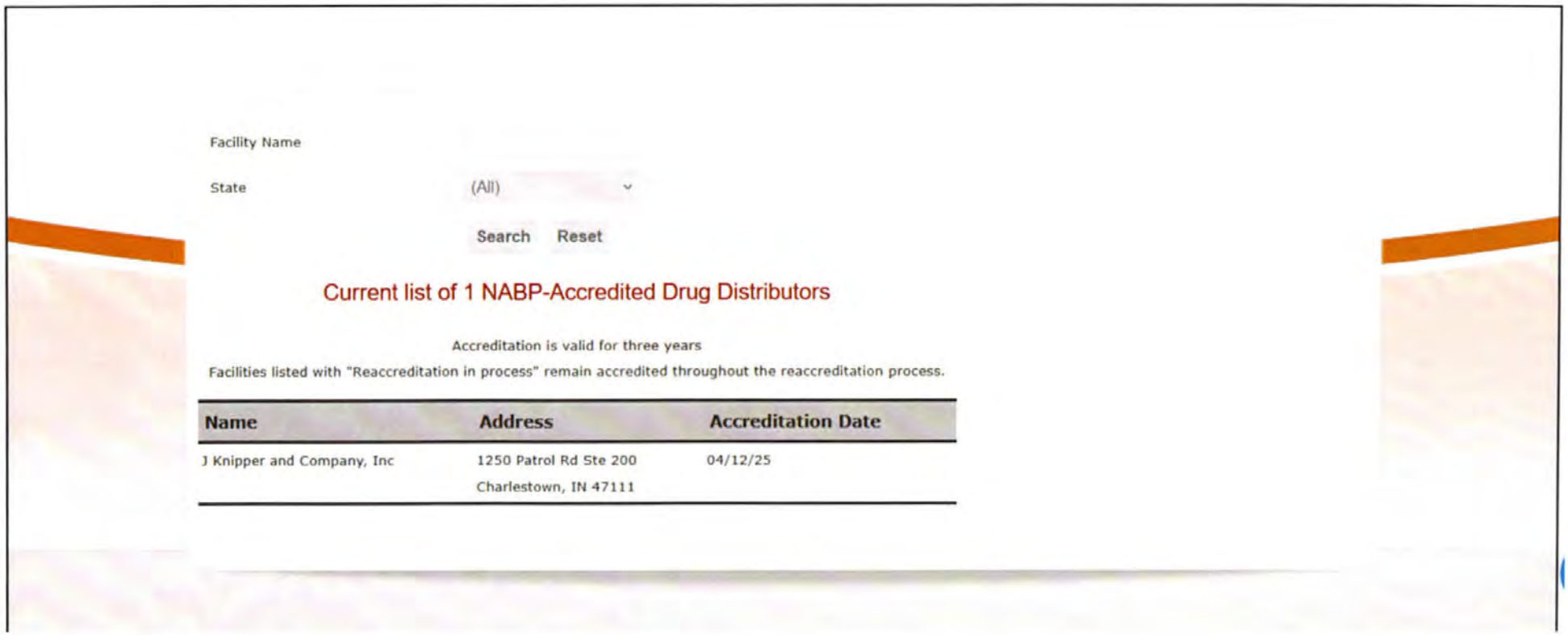
3/3/2025

Date

Board Use Only	Date Received: 3/12/25	Amount: $1000.00

Accredited Drug Distributors

Find an Accredited Drug Distributor



Facility Name

State (All)

Search Reset

Current list of 1 NABP-Accredited Drug Distributors

Accreditation is valid for three years

Facilities listed with "Reaccreditation in process" remain accredited throughout the reaccreditation process.

Name	Address	Accreditation Date
J Knipper and Company, Inc	1250 Patrol Rd Ste 200 Charlestown, IN 47111	04/12/25

NABP ACCREDITED

DRUG DISTRIBUTOR

J Knipper and Company, Inc

located at

1250 Patrol Rd, Charlestown, IN 47111

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/12/2022 - 04/11/2025
Period of Accreditation

Corporate Officers for J. Knipper and Company, Inc.

- Michael J. Laferrera - President and Chief Executive Officer
  - [redacted] Flemington, NJ [redacted]
  - [redacted]
  - [redacted]
  - [redacted]
- Todd Phillips – Chief Financial Officer
  - [redacted] Pewee Valley, KY [redacted]
  - [redacted]
  - [redacted]
  - [redacted]

Corporate names:	J. Knipper and Company, Inc.
State of Incorporation:	New Jersey
FEIN:	22-2755742
Parent Company:	100% wholly owned by Knipper Holding, Inc.
Grandparent Company:	100% wholly owned by JKC Buyer, Inc. d/b/a Knipper Health, Inc.
Great-Grandparent Co:	100% wholly owned by JKC Parent, Inc.
Private Equity Ownership:	Frazier Healthcare Partners

December 3, 2024

Re: Notice of Upcoming Transaction
Distributor Licensee: J. Knipper and Company, Inc.

To Whom It May Concern:

On behalf of J. Knipper and Company, Inc. (the "**Licensee**"), this notice is to advise you of an upcoming transaction that involves the transfer of the indirect equity interest in the Licensee (the "**Proposed Transaction**").

Specifically, as part of the Proposed Transaction, JKC Parent, Inc., a Delaware corporation and the indirect parent of the Licensee (the "**Parent**"), has entered into an Agreement and Plan of Merger, dated as of November 24, 2024, by and among the Parent, [FH KH Intermediate, Inc.], a Delaware corporation ("**Buyer**"), [FH KH Merger Sub, Inc.], a Delaware corporation and wholly owned subsidiary of Buyer ("**Merger Sub**"), and the other parties thereto, pursuant to which, and subject to the terms and conditions set forth therein, Merger Sub will merge with and into the Parent, with the Parent continuing as the surviving corporation of such merger. As a result, Buyer shall be the owner of Parent and the indirect owner of the Licensee. Pre- and post-closing organizational charts depicting the Proposed Transaction are attached hereto.

Importantly, the Proposed Transaction will not result in any changes in the Licensee, its tax identification number, its operational management team, or its day-to-day operations (other than changes in the ordinary course).

The closing of the Proposed Transaction is currently expected to take place on or about January 31, 2025. Unless we hear from you otherwise, we understand that this letter satisfies any notice requirements applicable to the Licensee regarding the Proposed Transaction.

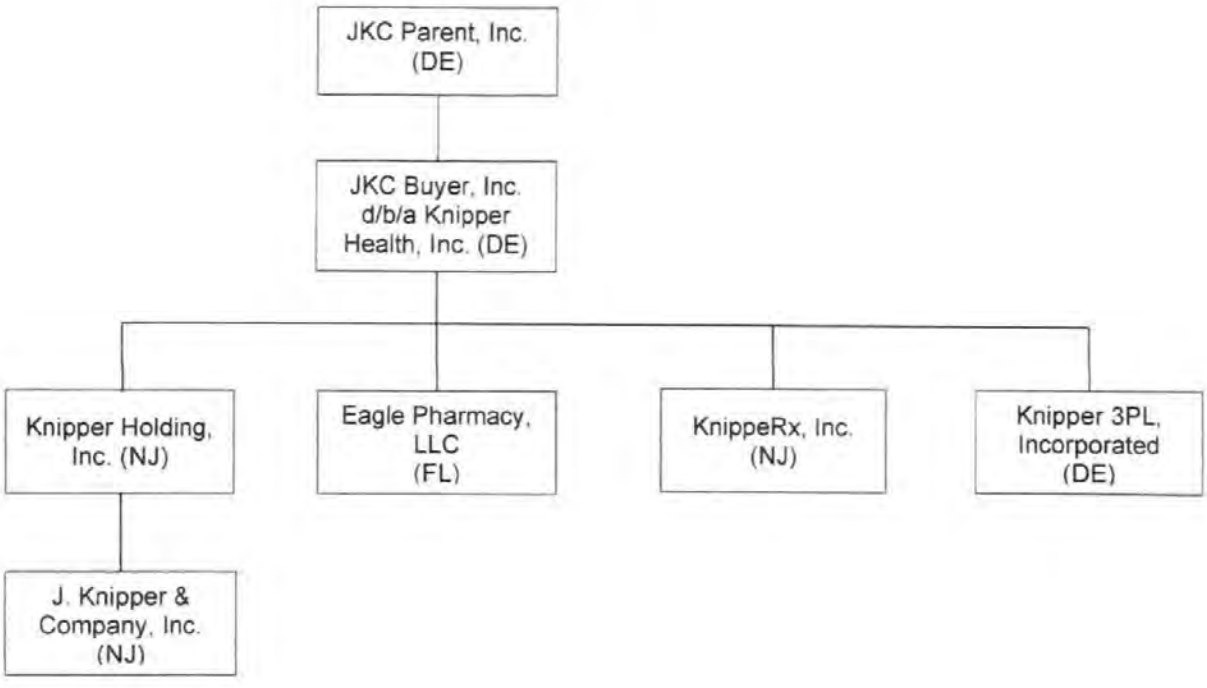
We kindly request that you keep all information disclosed in this letter confidential.

Sincerely,

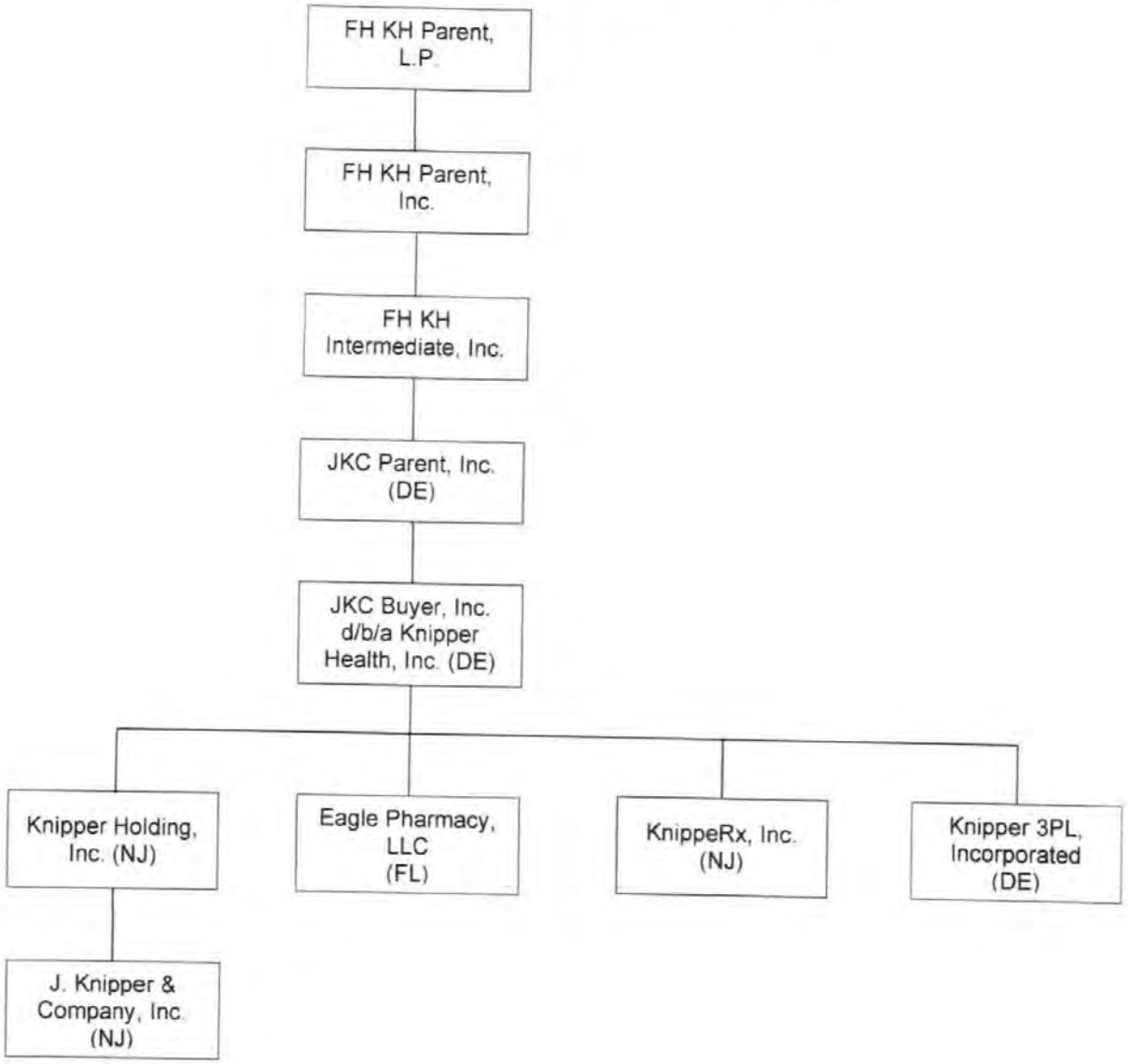
Teresita Weiss, Ph.D., J.D.
General Manager, Regulatory Affairs & Compliance

Attachments Exhibit A - Pre-closing organization chart
Exhibit B - Post-closing organizational chart

Knipper – Pre-Closing Legal Structure



Knipper – Post-Closing Legal Structure



STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

J. KNIPPER AND COMPANY, INC.
0100313707

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic For-Profit Corporation was registered by this office on October 09, 1986.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 14th day of November, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number 6158972614

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

Indiana Professional Licensing Agency
Indiana Board of Pharmacy
402 W. Washington Street, W072
Indianapolis, IN 46204

Wholesale Drug Distributor

Registration Number	Expire Date
48002393A	09/30/2026

J. Knipper and Company, Inc.
1250 Patrol Road
Charlestown IN 47111

Eric J. Holcomb
Governor
State of Indiana

Lindsay M. Hyer
Executive Director
Indiana Professional Licensing Agency

Indiana Professional Licensing Agency
402 W. Washington Street, W072
Indianapolis, IN 46204

Wholesale Drug Distributor

Registration Number	Expire Date
48002393A	**09/30/2026**

J. Knipper and Company, Inc.

Signature

J. Knipper and Company, Inc.
1250 Patrol Road, Charlestown, IN 47111

Source Name	Country	City	State
3-D Matrix	United States	Newton	MA
Abbvie US LLC	United States	N. Chicago	IL
Agile	United States	Detroit	MI
Akebia Therapeutics	United States	Cambridge	MA
Alembic Pharmaceuticals, Inc.	United States	Bedminster	NJ
Allergan	United States	Weston	FL
Amgen	United States	Thousand Oaks	CA
Antares	United States	Trenton	NJ
Arcutis Biotherapeutics, Inc.	United States	Westlake Village	CA
Ardelyx	United States	Fremont	CA
Arkray USA	United States	Minneapolis	MN
Astellas Pharma US, Inc.	United States	Northbrook	IL
Aucta Pharmaceuticals	United States	Piscataway	NJ
Bausch and Lomb	United States	Tampa	FL
Bausch Health	United States	Bridgewater	NJ
Bayer Healthcare Pharmaceuticals	United States	Whippany	NJ
Biohaven Pharmaceuticals, Inc	United States	New Haven	CT
Bioxcel	United States	New Haven	CT
Boehringer Ingleheim	United States	Ridgefield	CT
Collegium	United States	Stoughton	MA
Dermavant Sciences	United States	Long Beach	CA
EMD Serono, Inc.	United States	Rockland	MA
Esperion Therapeutics, Inc	United States	Ann Arbor	MI
Exelixis	United States	So. San Francisco	CA
Exelixis DTP	United States	So. San Francisco	CA
Galderma	United States	Fort Worth	TX
Genentech	United States	Louisville	KY
Gilead Sciences, Inc	United States	Foster City	CA
Idorsia	United States	Wayne	PA
Indivior, Inc	United States	Richmond	VA
Insulet Corporation, Inc.	United States	Acton	MA
Ironwood Pharmaceuticals	United States	Boston	MA
Kaneka Medical America, LLC	Japan	Osaka	Japan
KnippeRx Inc	United States	Charlestown	IN
Lexicon Pharma Inc.	United States	Woodlands	TX
Lundbeck	United States	Deerfield	IL
Marius Pharmaceuticals, LLC	United States	Raleigh	NC
Mayne Pharma	United States	Raleigh	NC
Merck	United States	Kenilworth	NJ
Myovant Science, Inc	United States	Brisbane	CA
Nestle Healthcare Nutrition, Inc	United States	Bridgewater	NJ
Novartis	Switzerland	Basel	Switzerland
Novugen Pharma	Malaysia	Selangor	Malaysia
OPKO Health	United States	Miami	FL
Otsuka America Pharmaceuticals	Japan	Tokushima	Japan
Palatin Technologies, Inc	United States	Cranbury	NJ

PhathomPharmaceuticals, Inc.	United States	Florham Park	NJ
Revance Therapeutics, Inc	United States	Newark	CA
Rigel Pharmaceuticals, Inc	United States	South San Francisco	CA
RVL Pharmaceuticals, Inc	United States	Bridgewater	NJ
Slate Run	United States	Columbus	OH
Sun Pharmaceutical Industries, Inc (Sun Pharma)	United States	Princeton	NJ
Sunovion Pharmaceuticals Inc	United States	Marlborough	MA
Takeda Pharmaceuticals USA, Inc	United States	Deerfield	IL
Terrain Pharmaceuticals, Inc.	United States	Reno	NV
TEVA	United States	North Whales	PA
TherapeuticsMD, Inc	United States	Boca Raton	FL
Tolmar, Inc.	United States	Fort Collins	CO
Urovant Sciences	United States	Irvine	CA

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0504313	12-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-26-2024

J. KNIPPER AND COMPANY, INC.
1250 PATROL RD
CHARLESTOWN, IN 471118670

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0504313	12-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-26-2024

J. KNIPPER AND COMPANY, INC.
1250 PATROL RD
CHARLESTOWN, IN 471118670

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RJ0504313	12-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
3,3N,4, 5	DISTRIBUTOR	11-26-2024

J. KNIPPER AND COMPANY, INC.
1250 PATROL RD
CHARLESTOWN, IN 471118670

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT

CHANGES

PROMPTLY

REQUESTING MODIFICATIONS TO YOUR
REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

Client#: 1541191 JKNI

ACORD CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 1/15/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer any rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Heather Sherwin
USI Insurance Services, LLC 180 Park Avenue Suite 103 Florham Park, NJ 07932	PHONE (A/C, No, Ext): 973-315-0440 FAX (A/C, No): E-MAIL ADDRESS: heather.sherwin@usi.com
	INSURER(S) AFFORDING COVERAGE — NAIC #
	INSURER A : Federal Insurance Company — 20281
INSURED J. Knipper & Company, Inc. One Healthcare Way Lakewood, NJ 08701	INSURER B :
	INSURER C :
	INSURER D :
	INSURER E :
	INSURER F :

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSR	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	COMMERCIAL GENERAL LIABILITY			35809008	12/10/2024	12/10/2025	EACH OCCURRENCE	$5,000,000
	[X] CLAIMS-MADE [ ] OCCUR						DAMAGE TO RENTED PREMISES (Ea occurrence)	$
	[X] Products Liability						MED EXP (Any one person)	$
	[X] Retro: 10/20/2023			Deductible(s):			PERSONAL & ADV INJURY	$5,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:			$50,000 occ. /			GENERAL AGGREGATE	$
	[X] POLICY [ ] PRO-JECT [ ] LOC			$250,000 agg.			PRODUCTS - COMP/OP AGG	$
	[ ] OTHER:							$
	AUTOMOBILE LIABILITY						COMBINED SINGLE LIMIT (Ea accident)	$
	[ ] ANY AUTO						BODILY INJURY (Per person)	$
	[ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS						BODILY INJURY (Per accident)	$
	[ ] HIRED AUTOS ONLY [ ] NON-OWNED AUTOS ONLY						PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR						EACH OCCURRENCE	$
	[ ] EXCESS LIAB [ ] CLAIMS-MADE						AGGREGATE	$
	[ ] DED [ ] RETENTION $							$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N						[ ] PER STATUTE [ ] OTH-ER	
	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] (Mandatory in NH)	N / A					E.L. EACH ACCIDENT	$
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
A	Professional Liability/E&O Retro: 09/30/2002			35809008	12/10/2024	12/10/2025	$5,000,000 occ/agg Ded: $50,000 each claim	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: NCPDP: 1568560

Evidence of Coverage for:

One Healthcare Way, Lakewood Township, NJ 08701
(See Attached Descriptions)

CERTIFICATE HOLDER

National Council for
Prescription Drug Programs, Inc.
9240 East Raintree Drive
Scottsdale, AZ 85260-7519

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Ulle Scott

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The ACORD name and logo are registered marks of ACORD

TXLCL

DESCRIPTIONS (Continued from Page 1)

1550 Oak Street, Lakewood, NJ 08701
270 Davidson Avenue, Somerset, NJ 08873
1009 Lenox Drive, Lawrenceville, NJ 08648
1250 Patrol Road, Charlestown, IN 47111
160 Chubb Avenue, Suite 305, Lyndhurst, NJ 07071
200 Patrol Road, Suite 300, Jeffersonville, IN 47130
310 Eagles Landing Drive, 330 Eagles Landing Drive, 350 Eagles Landing Drive, Lakeland, FL 33810
2700 Blankenbaker Pkwy, Louisville, KY 40299
5100 Hickory Road, Memphis, TN 38141

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 021143V

Application/License No. _____

J. Knipper and Company, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is One Healthcare Way, Lakewood, NJ 08701 (Address of Applicant/Principal), as PRINCIPAL, and Westfield Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Park Circle, P.O. Box 5001, Westfield Center, Ohio 44251 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on March 1, 2024 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 1st day of March, 2024.

APPLICANT/PRINCIPAL

COMPANY
J. Knipper and Company, Inc.

Authorized Representative

SIGNED and SEALED in the presence of:

Witness Bridget Serrano

Witness Kristina Lutz

SURETY

Westfield Insurance Company

Surety Company's Representative

Robyn Rost, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Karla Luongo

Witness Nicole Kaetzel

Countersigned by:

Nevada Resident Agent

Posted February 20, 2020

ACKNOWLEDGEMENT OF SURETY

State of New Jersey

County of Morris

City of Florham Park

On this 1st day of March in the year 2024 before me personally

Came Robyn Rost to me known, who, being by me duly sworn, did

depose and say that he resides in Florham Park, NJ that he is the Attorney-

In-Fact for Westfield Insurance Company the corporation described

In and which executed the attached instrument; that he knows the seal of the said

corporation; that the seal affixed to the said instrument is such corporate seal;

and that it was so affixed by Order of the Board of Directors of the said corporation,

and that he signed his name thereto by like order.

Notary Public

THOMAS F DORNER SR.
Notary Public, State of New Jersey
My Commission Expires Apr 23, 2028

Corporate Acknowledgement

STATE OF New Jersey

COUNTY OF Ocean

7 **day** March **the year** 2024, **before me** Teresita Weiss, **NOTARY PUBLIC personally appeared** on behalf of J. Knipper and Company, Inc.

personally known to me (or proved to me on the basis of satisfactory evidence) to be the person who executed the within instrument as president (or secretary)or on behalf of the corporation therein named and acknowledged to me that the corporation executed it.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my Official Seal, the day and year first above written.

My Commission expires September 29, 2024

Bridget Serzan

Notary Public, residing at Lakewood, New Jersey

(SEAL)

BRIDGET H. SERZAN
Commission # 50003532
Notary Public, State of New Jersey
My Commission Expires
September 29, 2024

License No. _____

RIDER

To be attached to and form part of Bond No. 021143V.

Issued on behalf of J. Knipper and Company, Inc. as Principal, and in favor of Nevada State Board of Pharmacy as Obligee.

It is agreed that:

☐ 1. The Surety hereby gives its consent to change the Name:

from: _____

to: _____

☐ 2. The Surety hereby gives its consent to change the Address:

from: _____

to: _____

☒ 3. The Surety hereby gives its consent to add the following locations to the above-captioned bond:

1550 Oak Street, Lakewood, NJ 08701

1250 Patrol Road, Charlestown, IN 47111

5100 Hickory Hill Road, Memphis, TN 38141

This rider shall become effective as of April 3, 2025

PROVIDED, however, that the liability of the Surety under the attached bond as changed by this rider shall not be cumulative.

Signed, sealed and dated April 3, 2025.

Westfield Insurance Company

By: Robyn Rost

Robyn Rost Attorney-in-Fact

Accepted: _____ or _____

Obligee Principal

By: _____ By: _____

S-4111 (8/66)

POWER NO. 3120081 01
General Power of Attorney

Westfield Insurance Co.
Westfield National Insurance Co.
Ohio Farmers Insurance Co.
Westfield Center, Ohio

CERTIFIED COPY

Know All Men by These Presents That WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, corporations, hereinafter referred to individually as a "Company" and collectively as "Companies," duly organized and existing under the laws of the State of Ohio, and having their principal offices in Westfield Center, Medina County, Ohio, do by these presents make, constitute and appoint **ROBYN ROST, JOINTLY OR SEVERALLY**
of **RED BANK** and State of NJ its true and lawful Attorney(s)-in-Fact, with full power and authority hereby conferred in their names, place and stead, to execute, acknowledge and deliver **any and all bonds, undertakings, and recognizances; provided, however, that the penal sum of any one such instrument executed hereunder shall not exceed TWENTY MILLION DOLLARS AND NO CENTS ($20,000,000)—**

LIMITATION: THIS POWER OF ATTORNEY CANNOT BE USED TO EXECUTE NOTE GUARANTEE, MORTGAGE DEFICIENCY, MORTGAGE GUARANTEE, OR BANK DEPOSITORY BONDS.

and to bind any of the Companies thereby as fully and to the same extent as if such bonds were signed by the President, sealed with the corporate seal of the applicable Company and duly attested by its Secretary, hereby ratifying and confirming all that the said Attorney(s)-in-Fact may do in the premises. Said appointment is made under and by authority of the following resolution adopted by the Board of Directors of each of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY:

"**BE IT RESOLVED** that the President, any Senior Executive, any Secretary or any Fidelity & Surety Operations Executive or other Executive shall be and is hereby vested with full power and authority to appoint any one or more suitable persons as Attorney(s)-in-Fact to represent and act for and on behalf of the Company subject to the following provisions:

The Attorney-in-Fact may be given full power and authority for and in the name of and on behalf of the Company, to execute, acknowledge and deliver, any and all bonds, recognizances, contracts, agreements of indemnity and other conditional or obligatory undertakings and any and all notices and documents cancelling or terminating the Company's liability thereunder, and any such instruments so executed by any such Attorney-in-Fact shall be as binding upon The Company as if signed by the President and sealed and attested by the Corporate Secretary."

"**BE IT FURTHER RESOLVED** that the signature of any such designated person and the seal of the Company heretofore or hereafter affixed to any power of attorney or any certificate relating thereto by facsimile, and any power of attorney or certificate bearing facsimile signatures or facsimile seal shall be valid and binding upon the Company with respect to any bond or undertaking to which it is attached." (Each adopted at a meeting held on February 8, 2000.)

In Witness Whereof WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY have caused these presents to be signed by their **Senior Executive** and their corporate seals to be hereto affixed this **15TH** day of **NOVEMBER, A.D. 2013**.

Corporate Seals Affixed

WESTFIELD INSURANCE COMPANY
WESTFIELD NATIONAL INSURANCE COMPANY
OHIO FARMERS INSURANCE COMPANY

By: _____
Dennis P. Baus
National Surety Leader and Senior Executive

State of Ohio
County of Medina ss.:

On this **15TH** day of **NOVEMBER** A.D. **2013**, before me personally came **Dennis P. Baus** to me known, who, being by me duly sworn, did depose and say, that he resides in **Wooster, Ohio**, that he is **National Surety Leader and Senior Executive** of WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, the companies described in and which executed the above instrument, that he knows the seals of said Companies; that the seals affixed to said instrument are such corporate seals; that they were so affixed by order of the Board of Directors of said Companies, and that he signed his name thereto by like order.

Notarial Seal Affixed

By _____
William J. Kahelin, Attorney at Law, *Notary Public*
My Commission Does Not Expire (Sec. 147.03 Ohio Revised Code)

State of Ohio
County of Medina ss.:

CERTIFICATE

I, **Frank Carrino**, Secretary of the WESTFIELD INSURANCE COMPANY, WESTFIELD NATIONAL INSURANCE COMPANY, and OHIO FARMERS INSURANCE COMPANY, do hereby certify that the above and foregoing is a true and correct copy of a Power of Attorney, executed by said Companies, which is still in full force and effect; and furthermore, the resolutions of the Board of Directors, set out in the Power of Attorney are in full force and effect.

In Witness Whereof, I have hereunto set my hand and affixed the seal of said Company at Westfield Center, Ohio, this 3rd day of April, A.D. 2025

By _____
Frank Carrino, *Secretary*

BPOAC4A

Financial Statement

December 31, 2023

Westfield Insurance Co.
Westfield Center, Ohio 44251-5001

WESTFIELD INSURANCE COMPANY
BALANCE SHEET

12/31/23
(in thousands)

Assets	
Cash, cash equivalents, and short term investments	34,614
Bonds	1,387,543
Stocks	370,629
Agents' balances and uncollected premiums, net	458,142
Other admitted assets	1,080,285
Total admitted assets	3,331,213
Liabilities	
Reserve for unearned premiums	713,530
Reserve for unpaid losses and loss expenses	1,106,583
Reserve for taxes and other liabilities	304,081
Total liabilities	2,124,194
Capital stock	8,220
Surplus to policyholders	1,198,799
Total surplus	1,207,019
Total liabilities and surplus	3,331,213

State of Ohio
ss:
County of Medina

The undersigned, being duly sworn, says: That he is National Surety Leader - Surety Operations of Westfield Insurance Company, Westfield Center, Ohio; that said Company is a corporation duly organized, existing and engaged in business as a Surety Company by virtue of the Laws of the State of ..... and has duly complied with all the requirements of the laws of said State applicable to said Company and is duly qualified to act as Surety under such laws; that said Company has also complied with and is duly qualified to act as Surety under the Act of Congress approved July 1947, 6 U.S.C. sec. 6-13; and that to the best of his knowledge and belief the above statement is a full, true, and correct statement of the financial condition of the said Company on the 31st day of December, 2023.

Attest:

Frank Carrino

Frank A. Carrino
Group Legal Leader, Secretary

Gary W. Stumper
National Surety Leader
Senior Executive

SEAL

Sworn to before me this 14th day of February A.D. 2024.

David A. Kotnik
Attorney at Law
Notary Public – State of Ohio

NOTARY PUBLIC STATE OF OHIO

My Commission Does Not Expire
Sec. 147.03 Ohio Revised Code

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: J. Knipper and Company, Inc. MDEG License # (if applicable): N/A

Physical Address: 1250 Patrol Road

City: Charlestown State: IN Zip: 47111

Mailing Address (if different from physical address): One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: 732-905-7878 Website: www.knipper.com

Licensing Company Email: Licensing@knipper.com

Section 2: Personal Information

First: Geraldine Middle: Last: Treacy

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☑ F ☐ X

Mailing Address: One Healthcare Way

City: Lakewood State: NJ Zip: 08701

Telephone: [redacted] Email: Licensing@knipper.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order? N/A		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Indiana Wesleyan University			01/16-08/17	
Address		City	State	Zip
4201 S Washington St.		Marion	IN	46953
Diploma/Degree obtained, if any				
Bachelors - Business				
School Name			From - To (MM/YY – MM/YY)	
William Paterson University			01/81-05/81	
Address		City	State	Zip
300 Pompton Road		Wayne	NJ	07470
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Fairleigh Dickinson University			09/79-05/80	
Address		City	State	Zip
1000 River Road		Teaneck	NJ	07666
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Dumont High School			09/78-06/79	
Address		City	State	Zip
101 New Milford Ave.		Dumont	NJ	07628
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY	
Academy of Mount St. Ursula			09/75-06/78	
Address		City	State	Zip
330 Bedford Park Blvd.		Bronx	NJ	10458
Diploma/Degree obtained, if any				
N/A				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/18 - Present	[redacted]	Louisville	KY	[redacted]
08/15-09/18		Louisville	KY	
12/09-08/15		Clifton	NJ	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
J. Knipper and Company, Inc.			08/15 - present	
Business Address		City	State	Zip
1250 Patrol Road		Charlestwon	IN	47111
Phone	Title		Number of Employed Hours	
(732) 905-7878	Senior Vice President, Operations		18,000	
Description of Duties				
Oversee distribution and record keeping for prescription drugs.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	2/18/2020	CO	Denver	Denver
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
2019-3775	Colorado Board of Pharmacy			
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Colorado Board of Pharmacy Claimant	N/A			
Name of Business/Industry/Entity				
J. Knipper and Company, Inc.				

Provide explanation below:

J. Knipper and Company, Inc. was subject to disciplinary action and a penalty in Colorado for delayed notification of a change of designated representative for its 1500 Oak Street, Lakewood, NJ facility. The company has since implemented corrective actions to ensure changes are submitted timely going forward. Provided is a copy of the stipulation and final order issued by the Colorado Board of Pharmacy.

Original Signature (electronic, copies or stamps not accepted)

4/17/2025
Date

I, Geraldine Treacy, **certify that as the MDEG Administrator for**

J. Knipper and Company, Inc.,

that I (initial that you have read and meet the following requirements):

1. ____ Have a high school diploma or its equivalent;
2. ____ Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care; BACHELOR'S DEGREE- BUSINESS
3. ____ Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. ____ Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Geraldine Treacy
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/17/2025
Date

Board Use Only	Date Received: 4/22/25

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler J. Knipper and Company, Inc.

Pharmacy/Wholesaler License # (if applicable) WH02192

Physical Address 1250 Patrol Road

City Charlestown State IN Zip 47111

Mailing Address (if different from physical address) One Healthcare Way

City Lakewood State NJ Zip 08701

Telephone (732) 905-7878 Website https://www.knipper.com/

Licensing Company Email Licensing@knipper.com

Section 2: Personal Information

First Geraldine Middle _____ Last Treacy

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or IT [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address One Healthcare Way

City Lakewood State NJ Zip 08701

Telephone [redacted] Email Licensing@knipper.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.123)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Indiana Wesleyan University			01/16 -08/17	
Address		City	State	Zip
4201 S Washington St		Marion	IN	46953
Diploma/Degree obtained, if any				
Bachelors - Business				
School Name			From - To (MM/YY – MM/YY)	
William Paterson University			01/81-05/81	
Address		City	State	Zip
300 Pompton Road		Wayne	NJ	07470
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Fairleigh Dickinson University			09/79-05/80	
Address		City	State	Zip
1000 River Road		Teaneck	NJ	07666
Diploma/Degree obtained, if any				
N/A				
School Name			From - To (MM/YY – MM/YY)	
Dumont High School			9/78-06/79	
Address		City	State	Zip
101 New Milford Ave		Dumont	NJ	07628
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY	
Academy of Mount St. Ursula			09/75-06/78	
Address		City	State	Zip
330 Bedford Park Blvd		Bronx	NJ	10458
Diploma/Degree obtained, if any				
N/A				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/18-03/25	[redacted]	Louisville	KY	[redacted]
08/15-09/18		Louisville	KY	
12/09-08/15		Clifton	NJ	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
J. Knipper and Company, Inc.			8/2015 - present	
Business Address		City	State	Zip
1250 Patrol Road		Charlestown	IN	47111
Phone	Title		Number of Employed Hours	
(732) 905-7878	Senior Vice President, Operations		~18,000 hours	
Description of Duties				
Oversee distribution and record keeping for prescription drugs.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 3, 2019	2/10/20	CO	Denver	Denver
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
2019-3775	Colorado Board of Pharmacy			
Reason/Charge				
J. Knipper-CO was subject to disciplinary action & penalty in Colorado for delayed notification of change of designated rep for its 15320 Oak St facility				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
~~N~~ Def 3/14/25	Colorado Bd. of Pharmacy	N/A		
Name of Business/Industry/Entity				
J. Knipper and Company, Inc.				

Provide explanation below:

Please see attached Stipulation & Final agency order as well as Closure letter from Colorado Board of Pharmacy.

Original Signature (electronic, copies or stamps not accepted)

3/4/25
Date

I, Geraldine Treacy, **certify that as the designated representative for**

J. Knipper and Company, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. gt gt I am at least 21 years of age;
3. gt gt I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. gt gt I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. gt gt I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. gt gt I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. gt gt I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Geraldine Treacy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/4/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Geraldine Treacy

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/4/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Ocean

I, Geraldine Treacy, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/4/2025

Date

Subscribed and Sworn to before me this 4 day of March, 2025

Notary Public Signature Bridget H. Serzan

BRIDGET H. SERZAN
Notary Public, State of New Jersey
Comm. # 50003532
My Commission Expires 9/29/2029

BRIDGET H. SERZAN
Notary Public, State of New Jersey
Comm. # 50003532
My Commission Expires 9/29/2029

(Seal)

KnipperHEALTH

J. KNIPPER & COMPANY

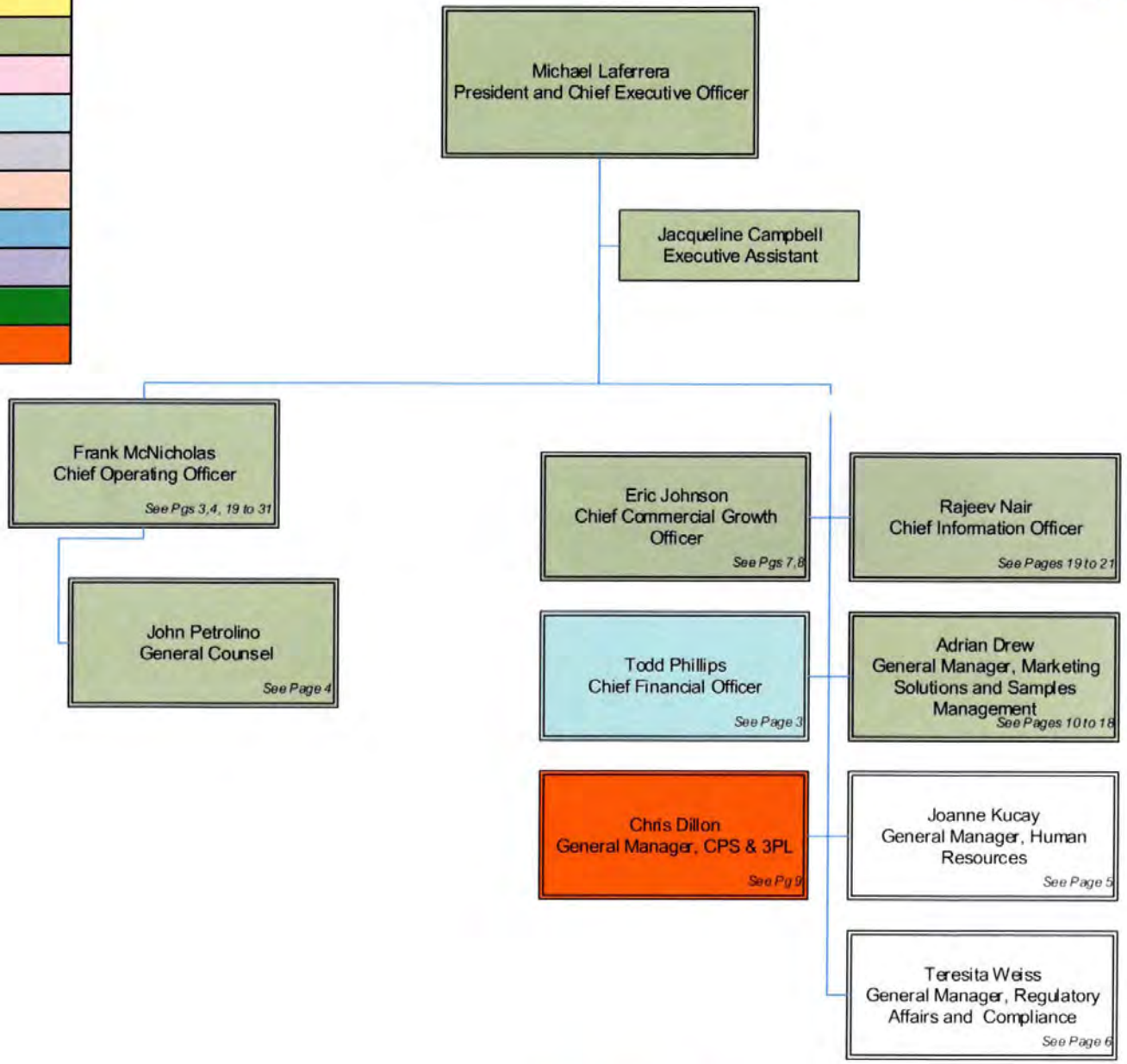
ORGANIZATIONAL CHART

December 31, 2024

CONFIDENTIAL

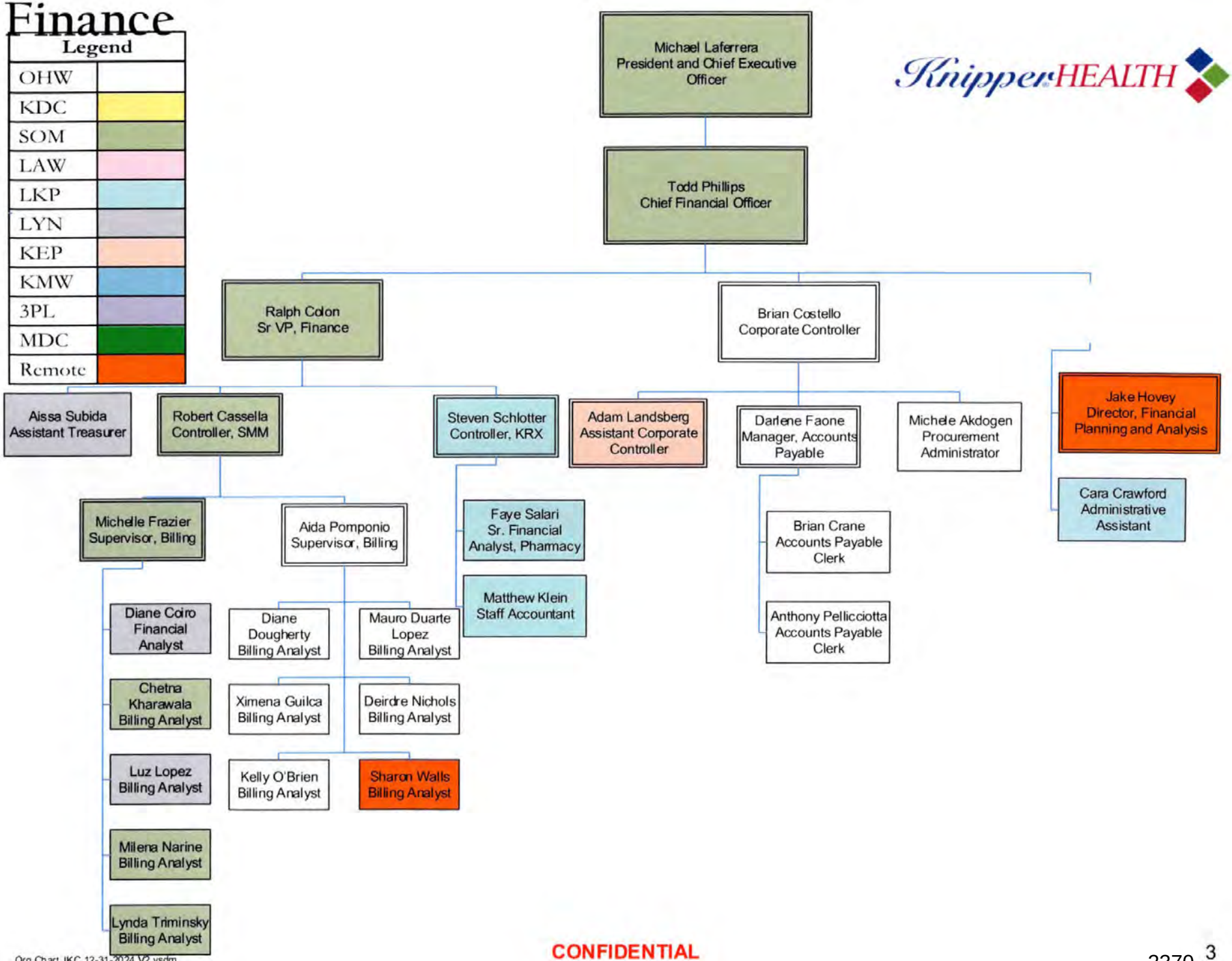
Executive Staff

Legend	
OHW	
KDC	
SOM	
LAW	
LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



Finance

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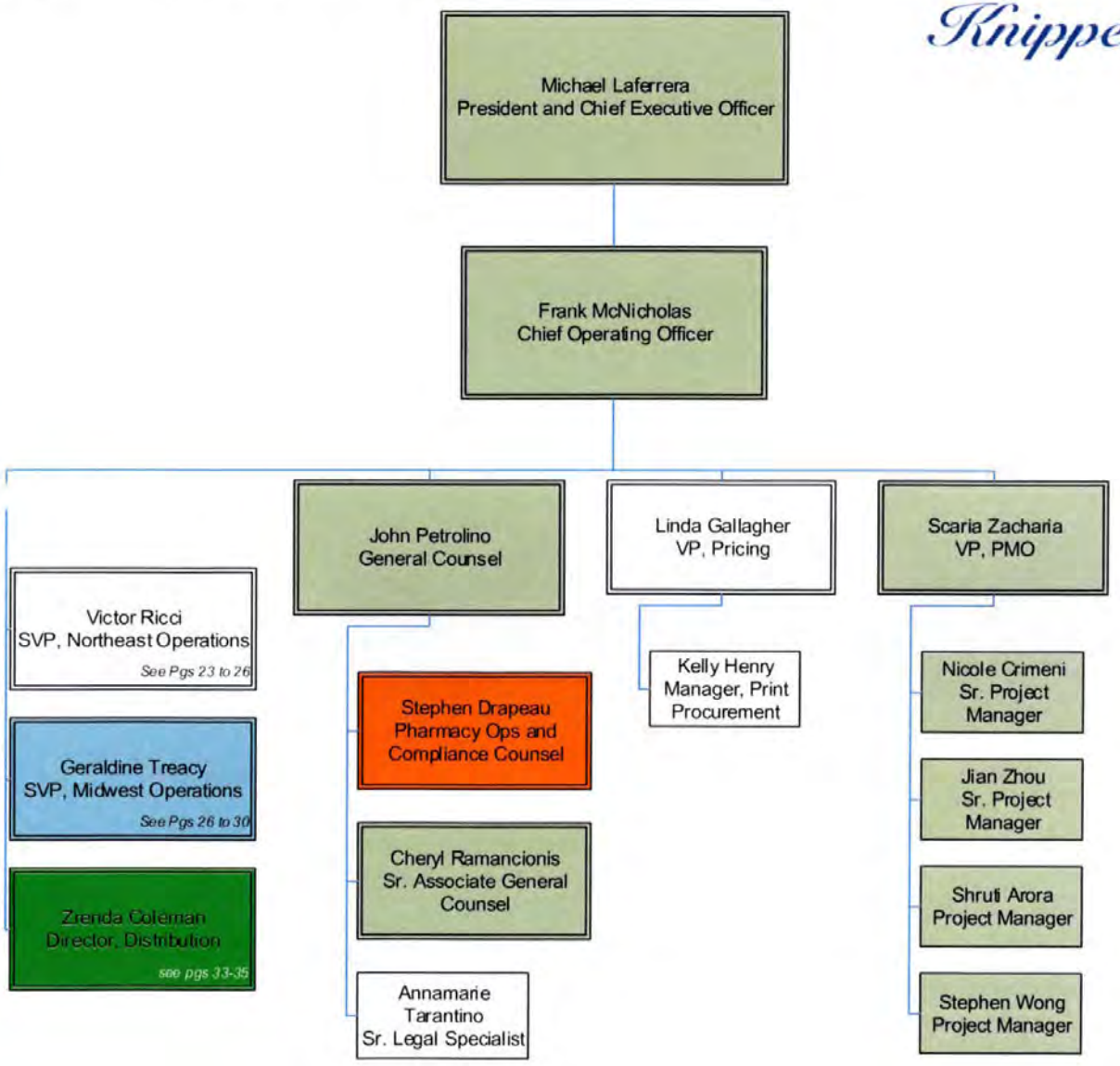


Org Chart JKC 12-31-2024 V2.vsdm

CONFIDENTIAL

Operations, PMO, & Legal

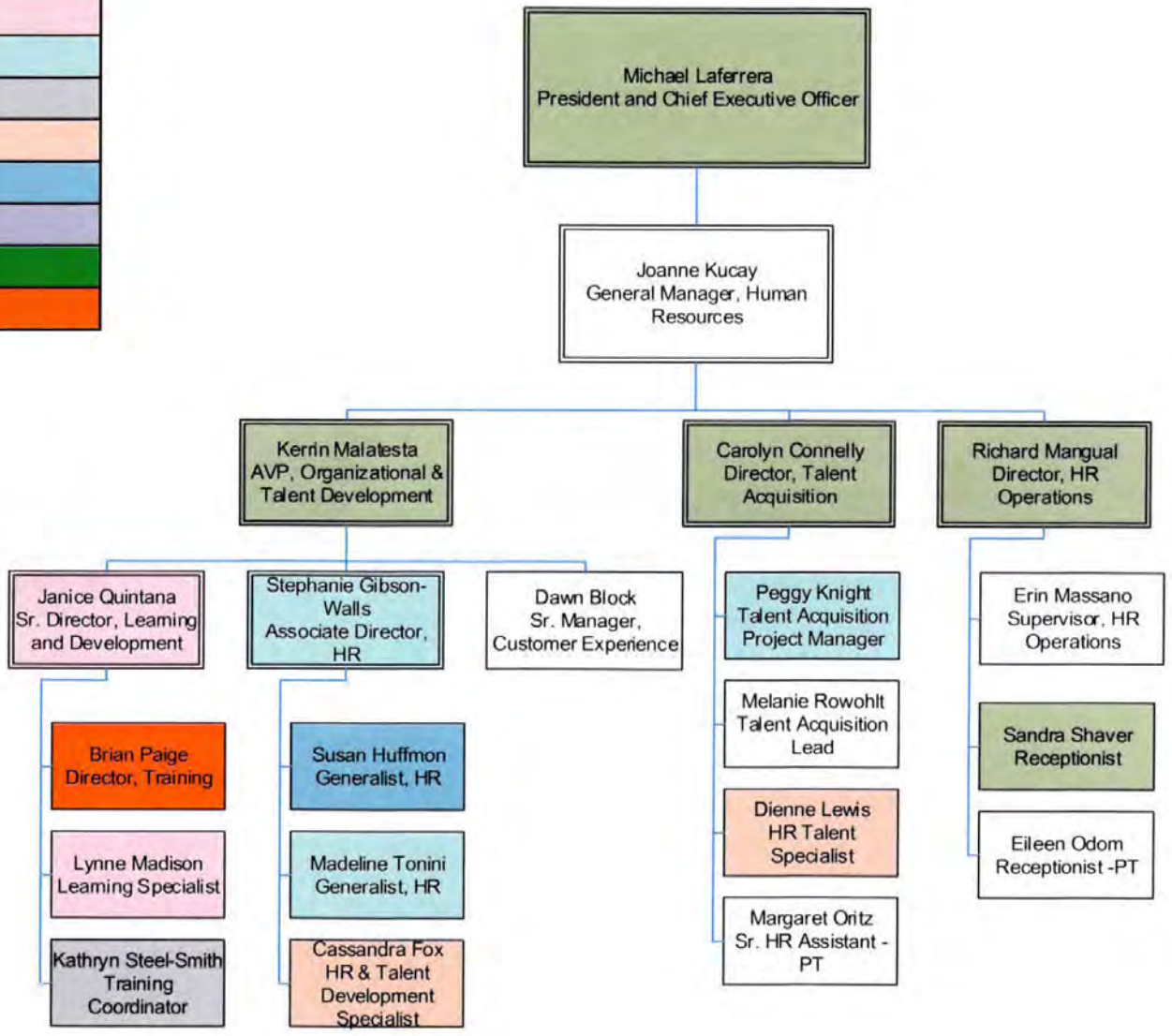
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KEP	
KMW	
3PL	
MDC	
Remote	



CONFIDENTIAL

Human Resources

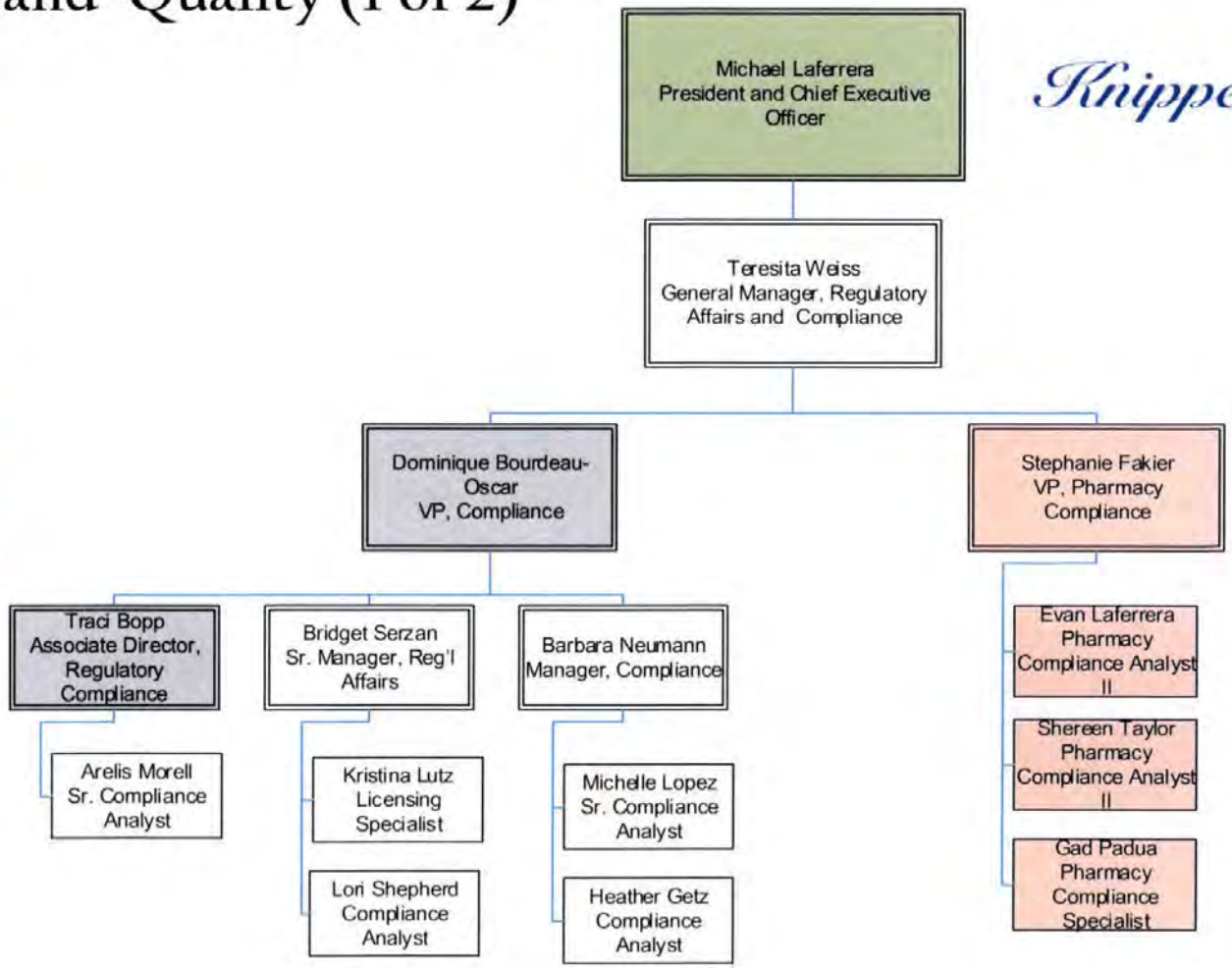
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CONFIDENTIAL

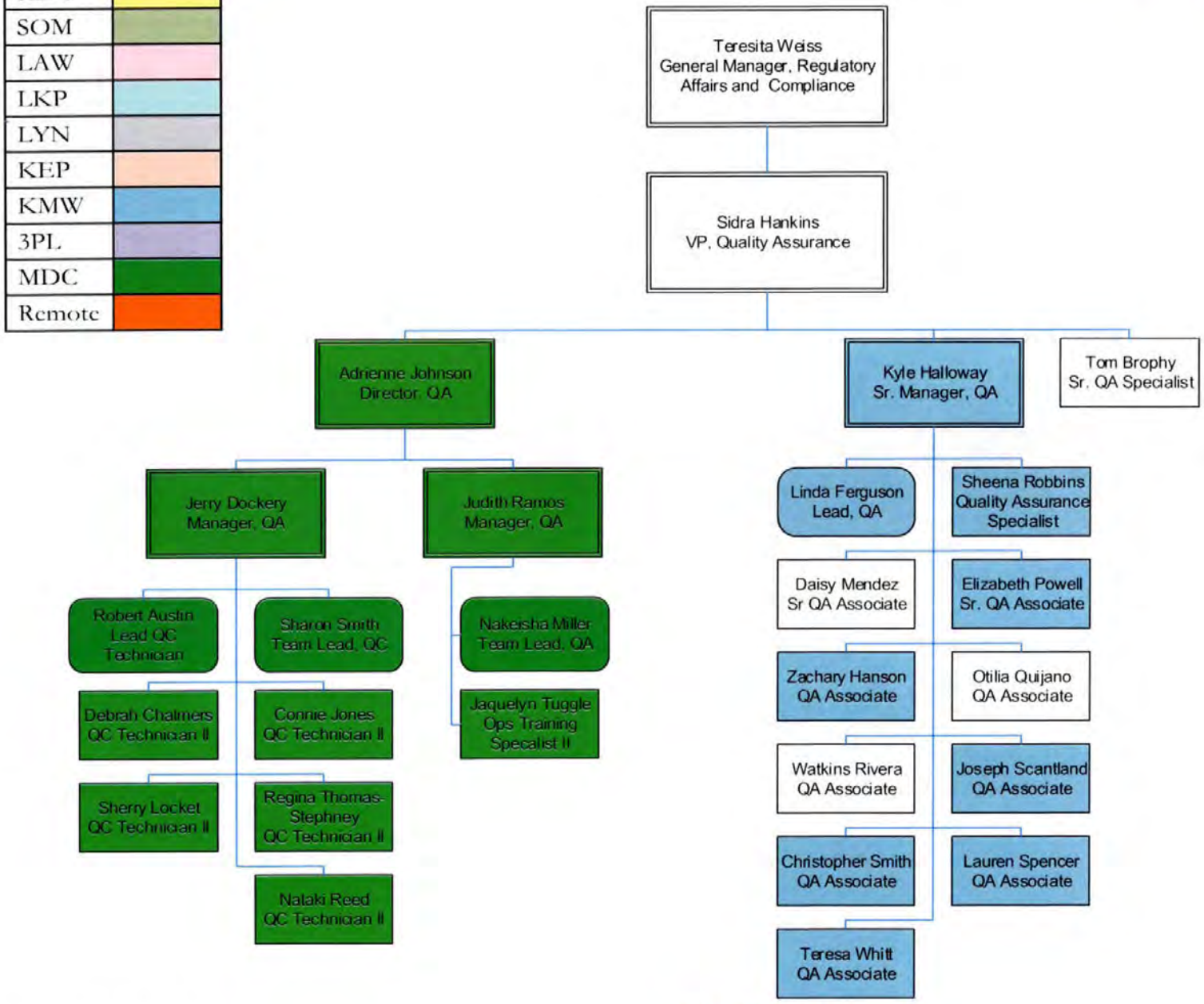
Regulatory and Quality (1 of 2)

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KEP	
KMW	
3PL	
MDC	
Remote	

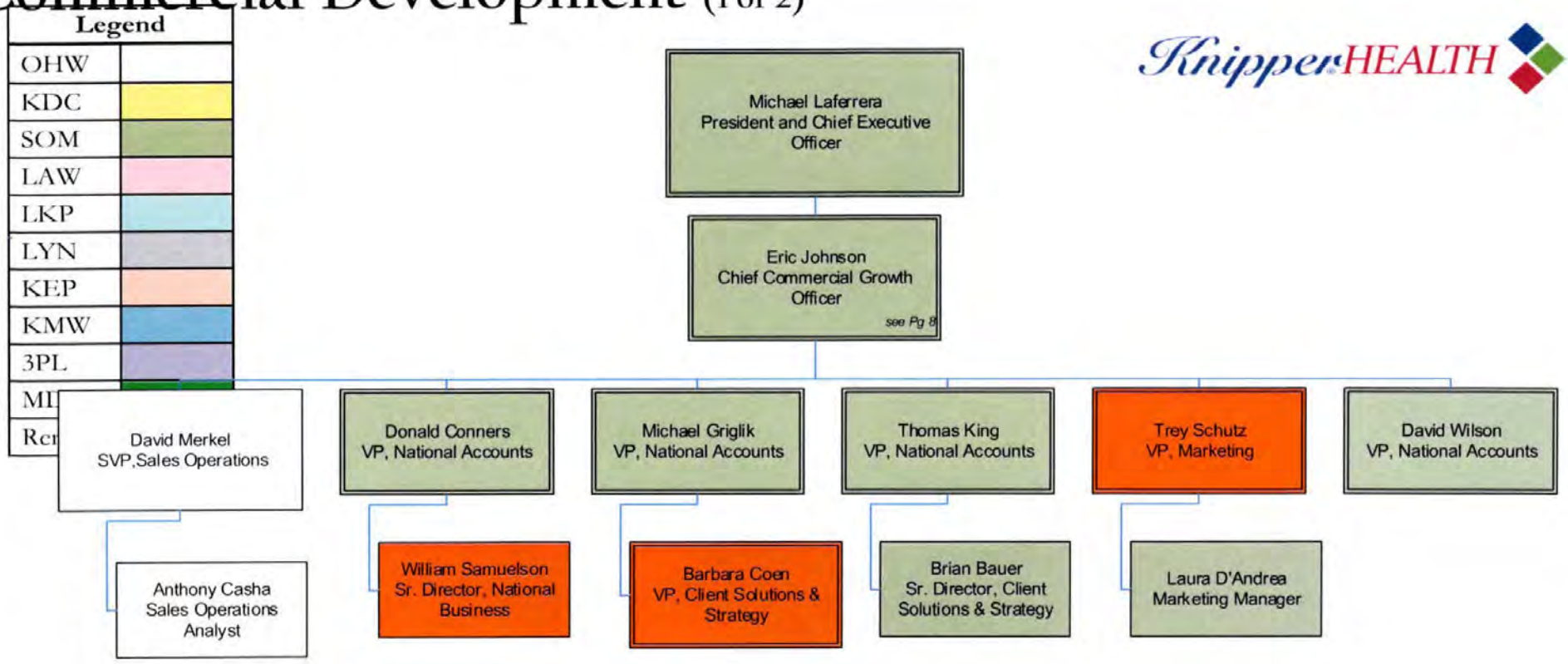


Regulatory and Quality (2 of 2)

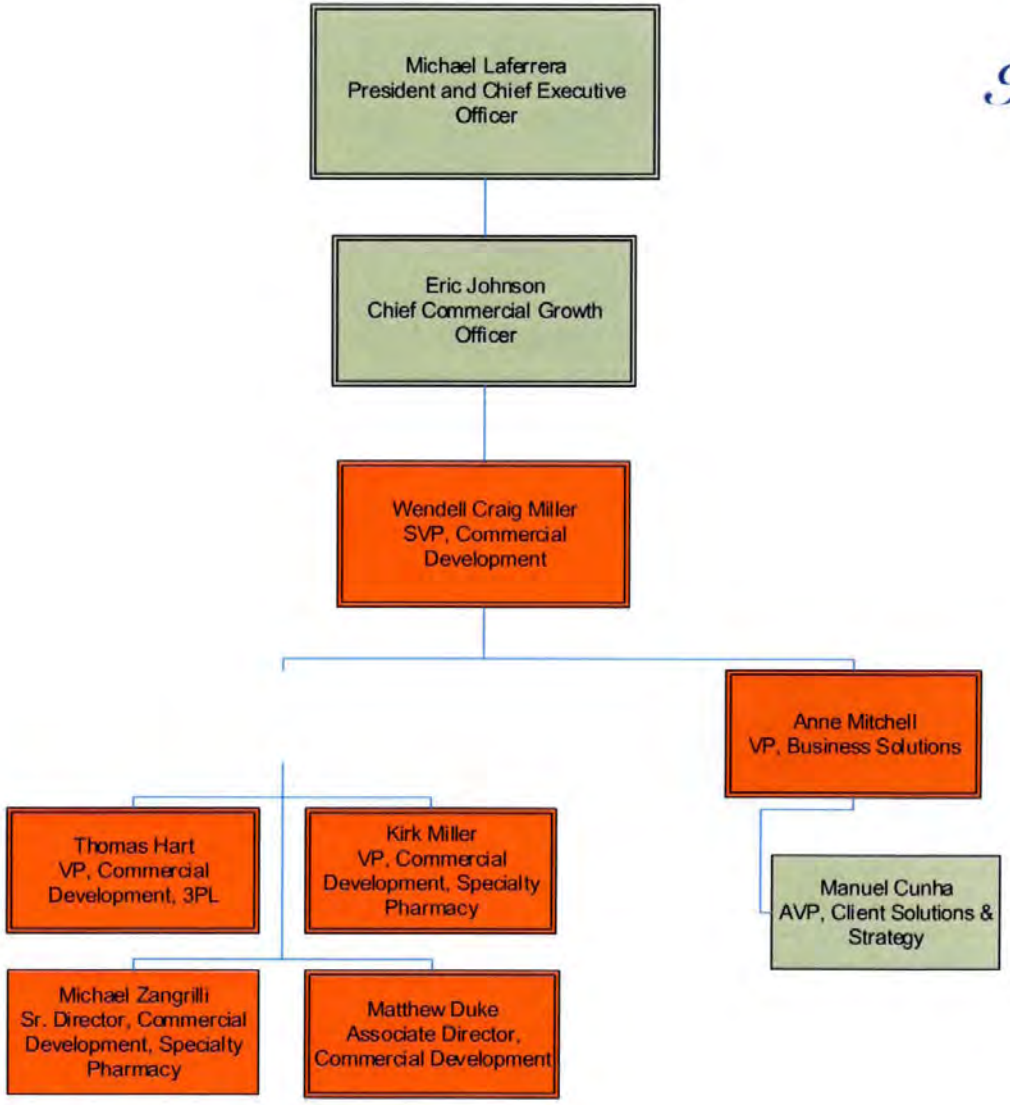
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Remote	



Commercial Development (1 of 2)

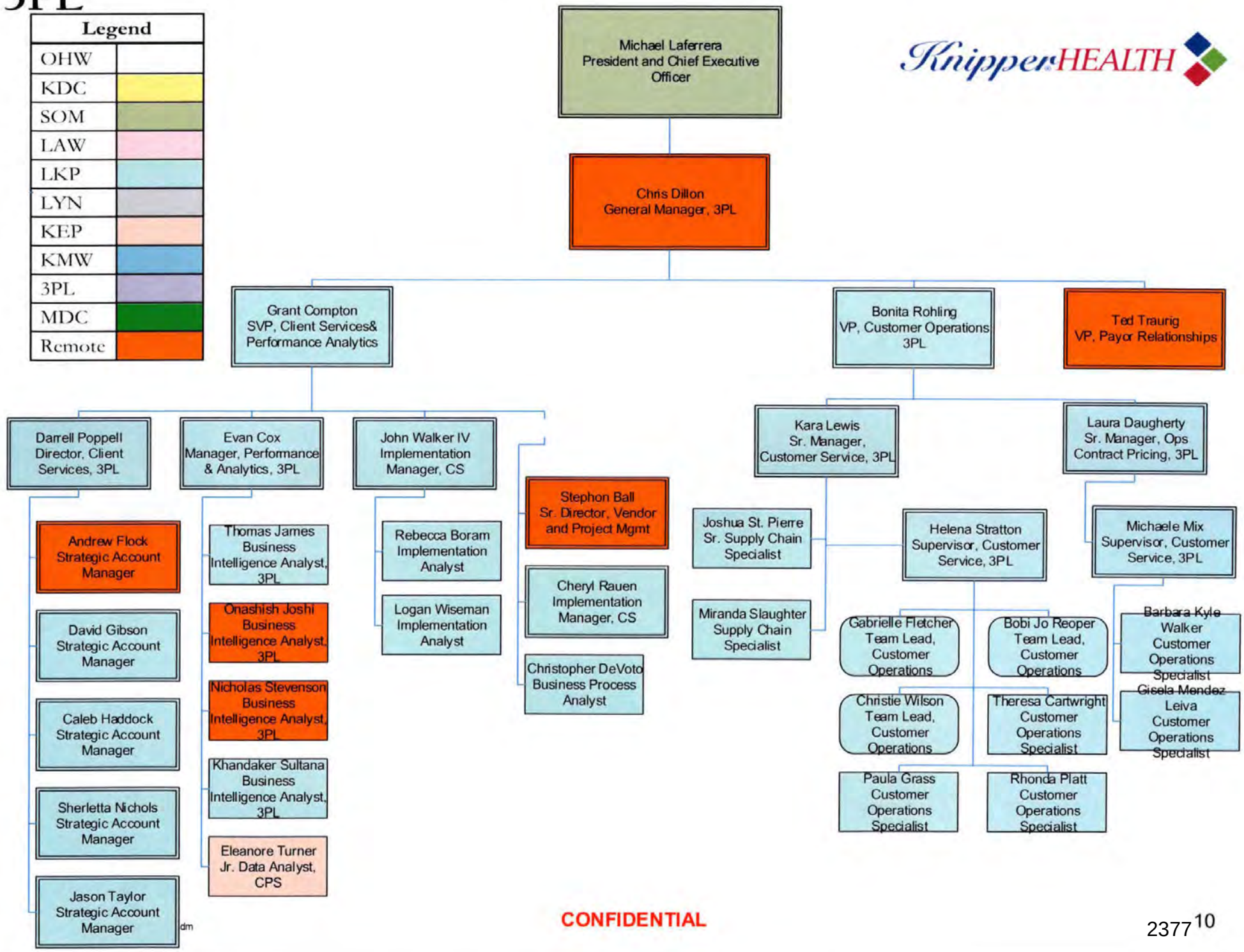


Legend	
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KEP	
KMW	
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MDC	
Remote	



3PL

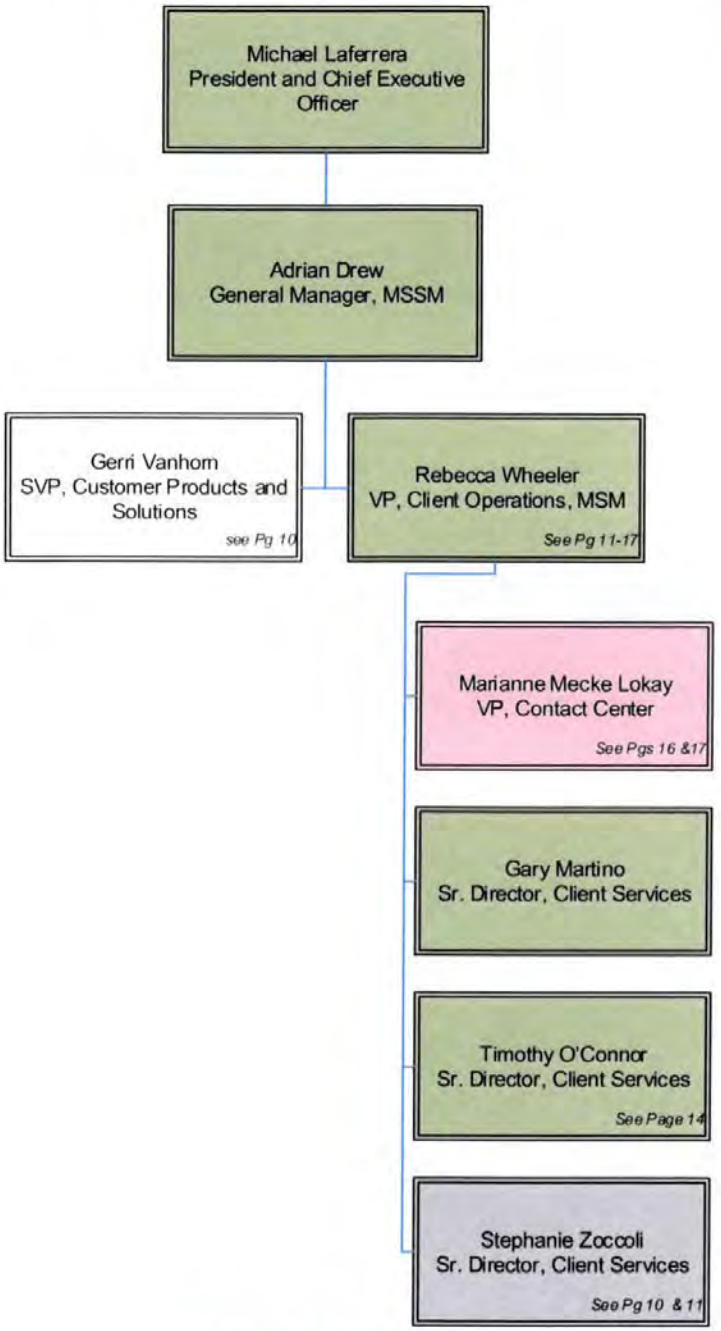
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Remote	



CONFIDENTIAL

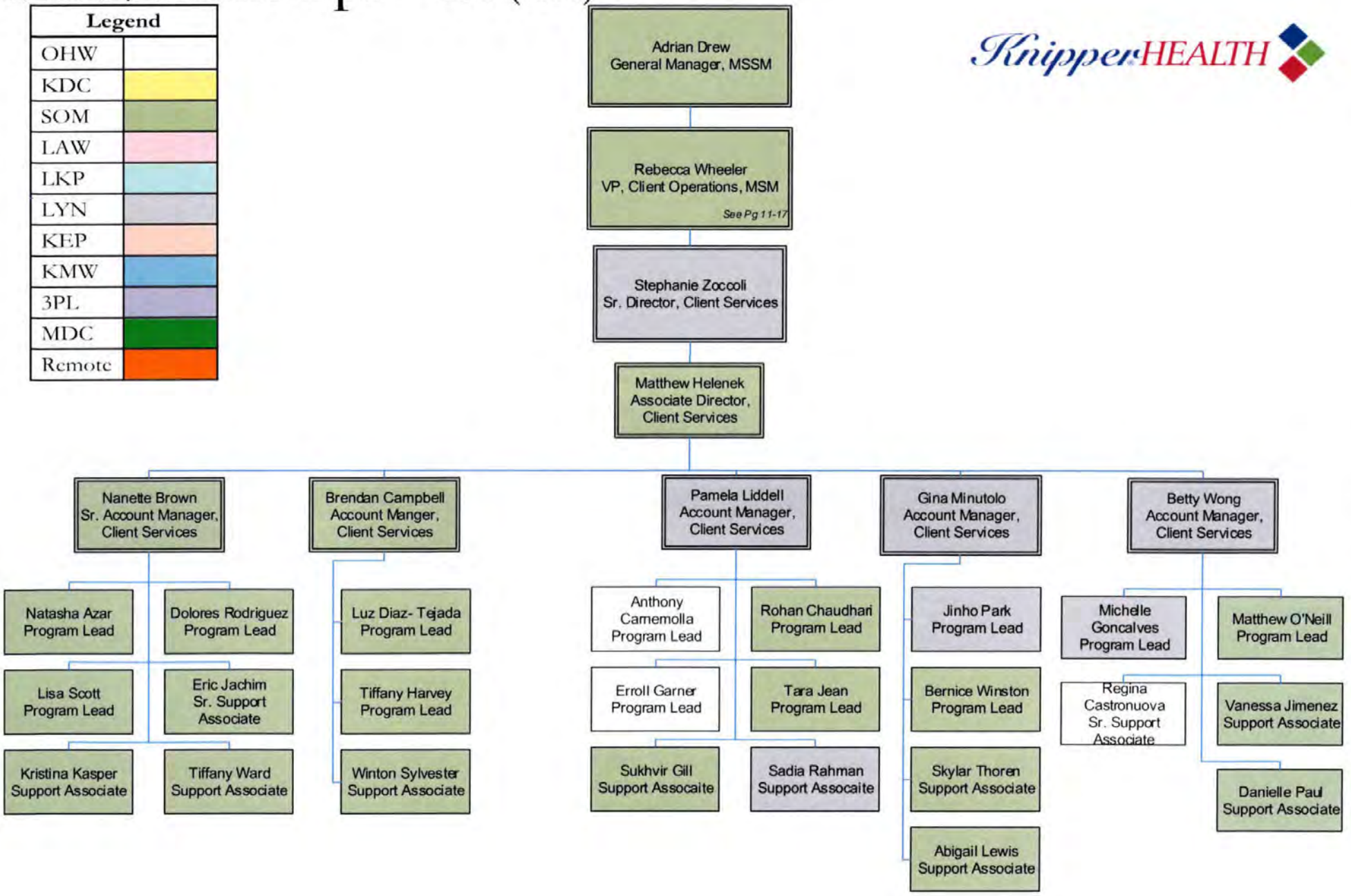
MSM/Client Operations

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3PL	
MDC	
Remote	



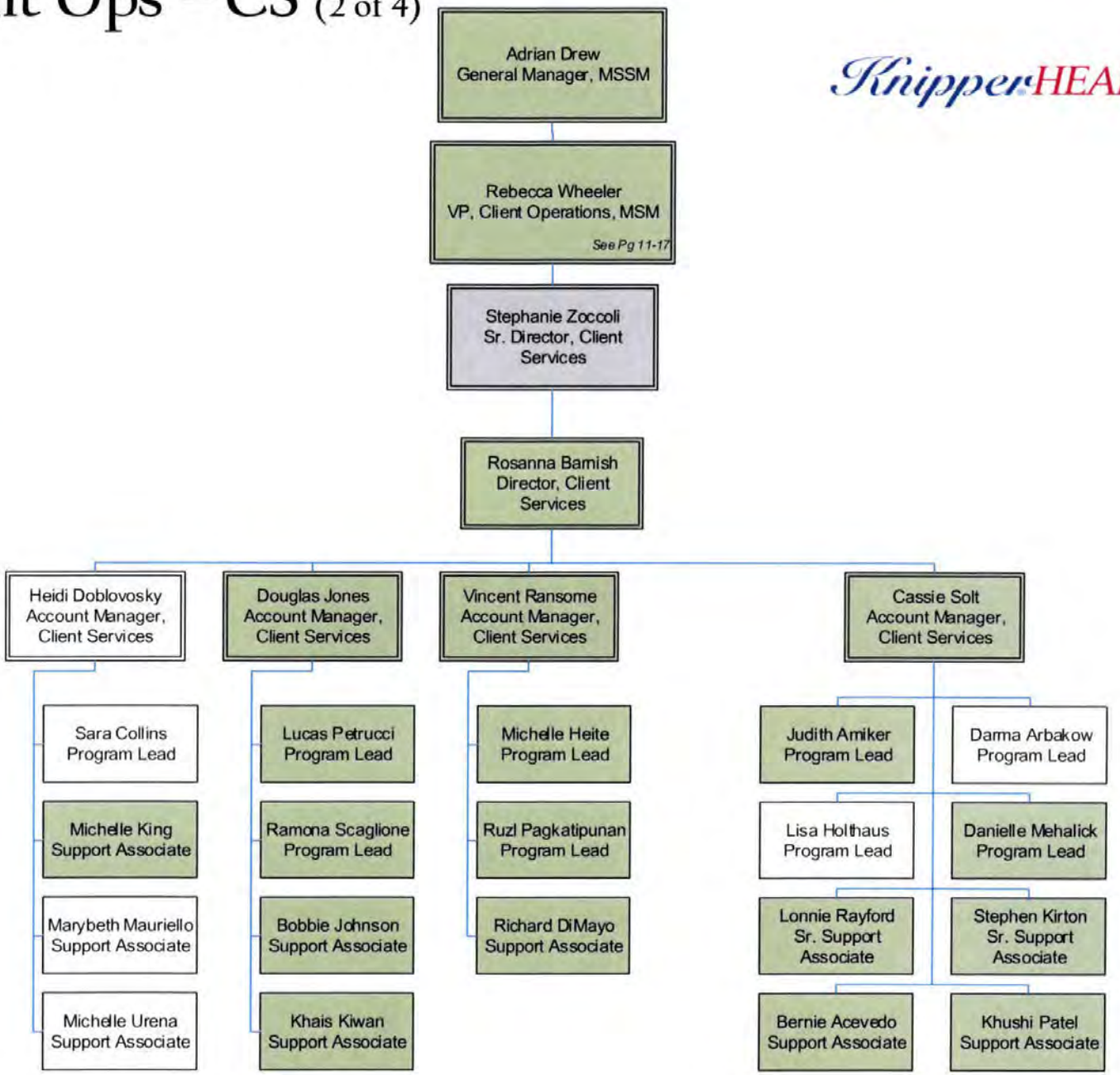
MSM/Client Ops – CS (1 of 5)

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LYN	
KEP	
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3PL	
MDC	
Remote	



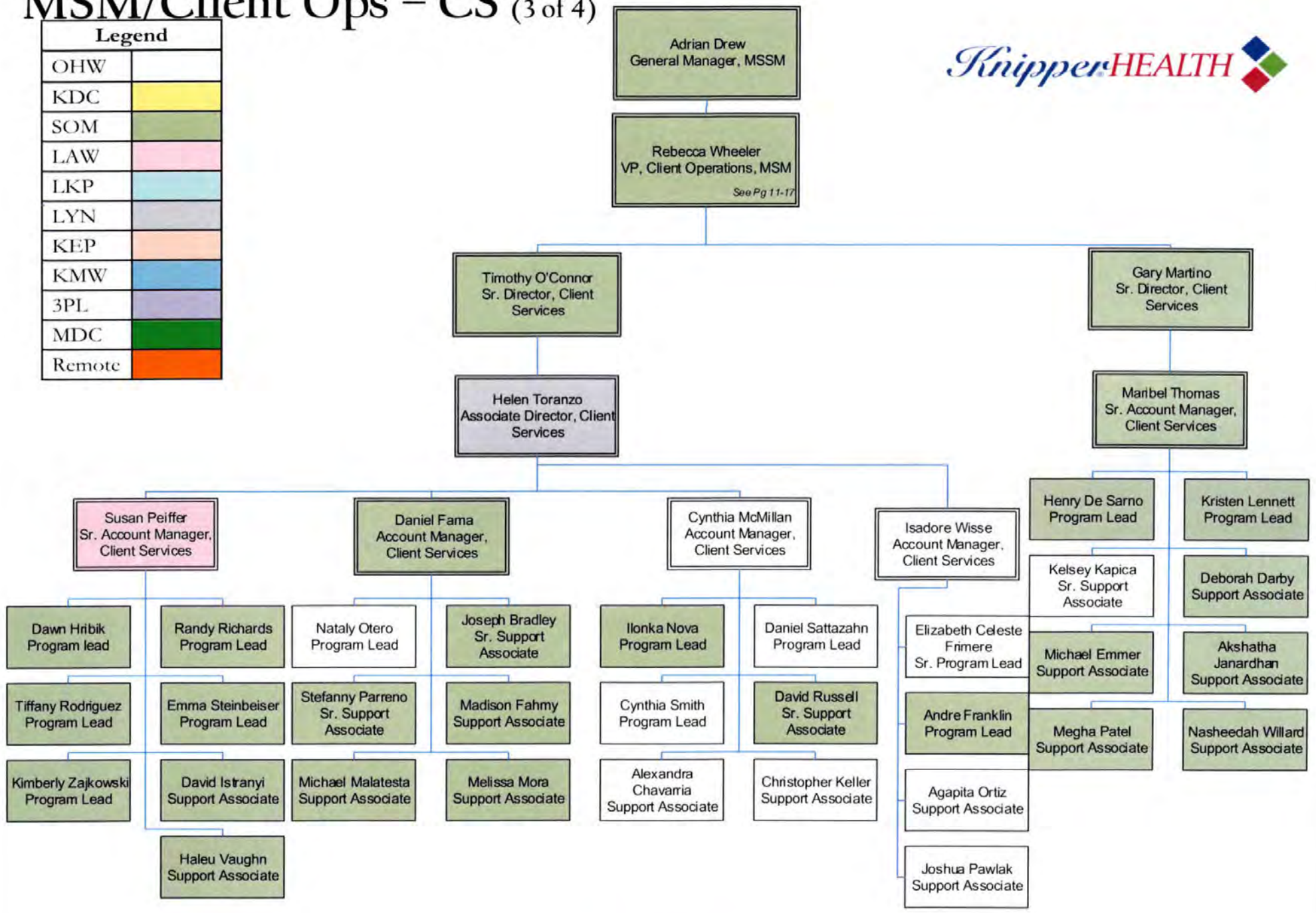
MSM/Client Ops – CS (2 of 4)

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3PL	
MDC	
Remote	



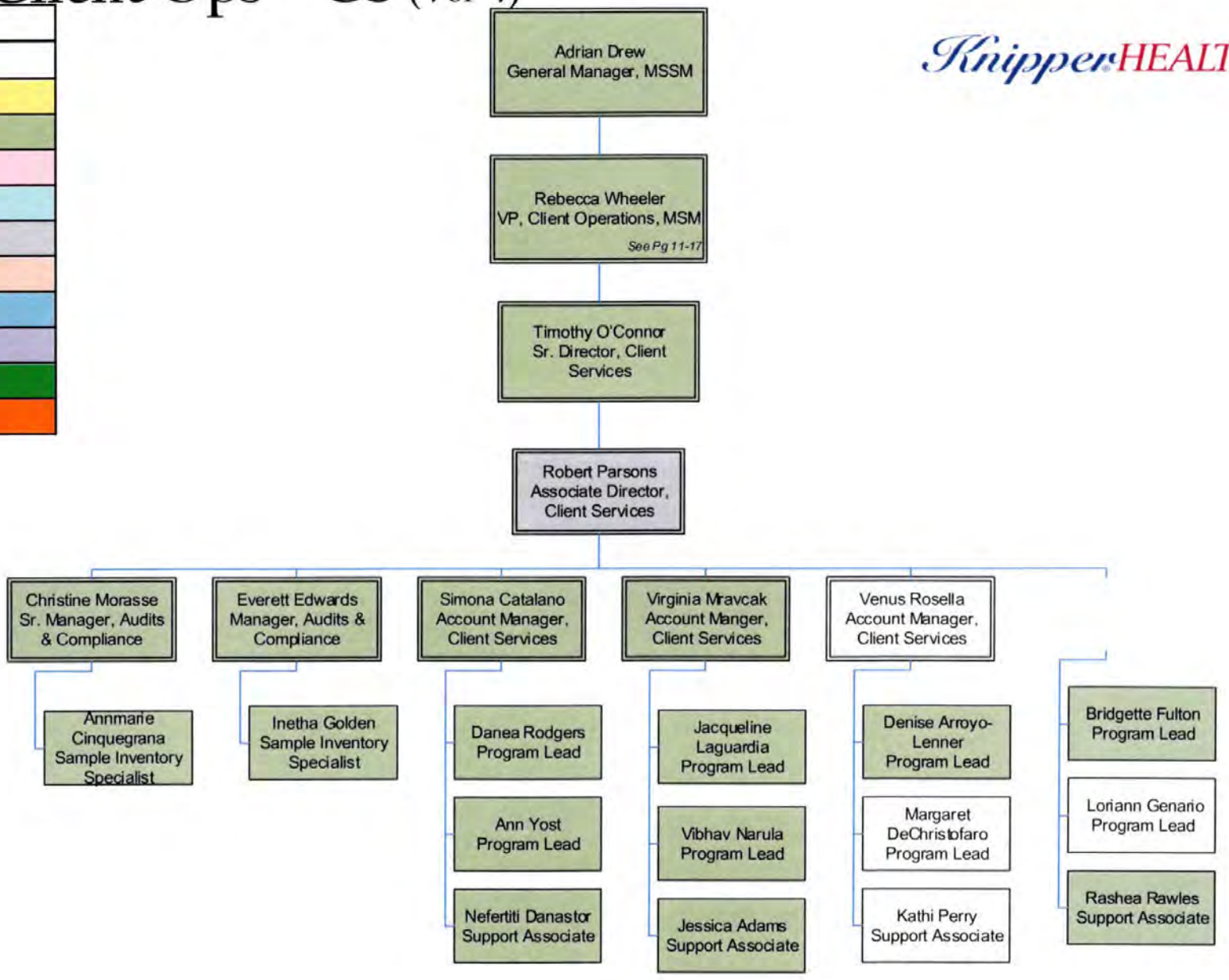
MSM/Client Ops – CS (3 of 4)

Legend	
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3PL	
MDC	
Remote	



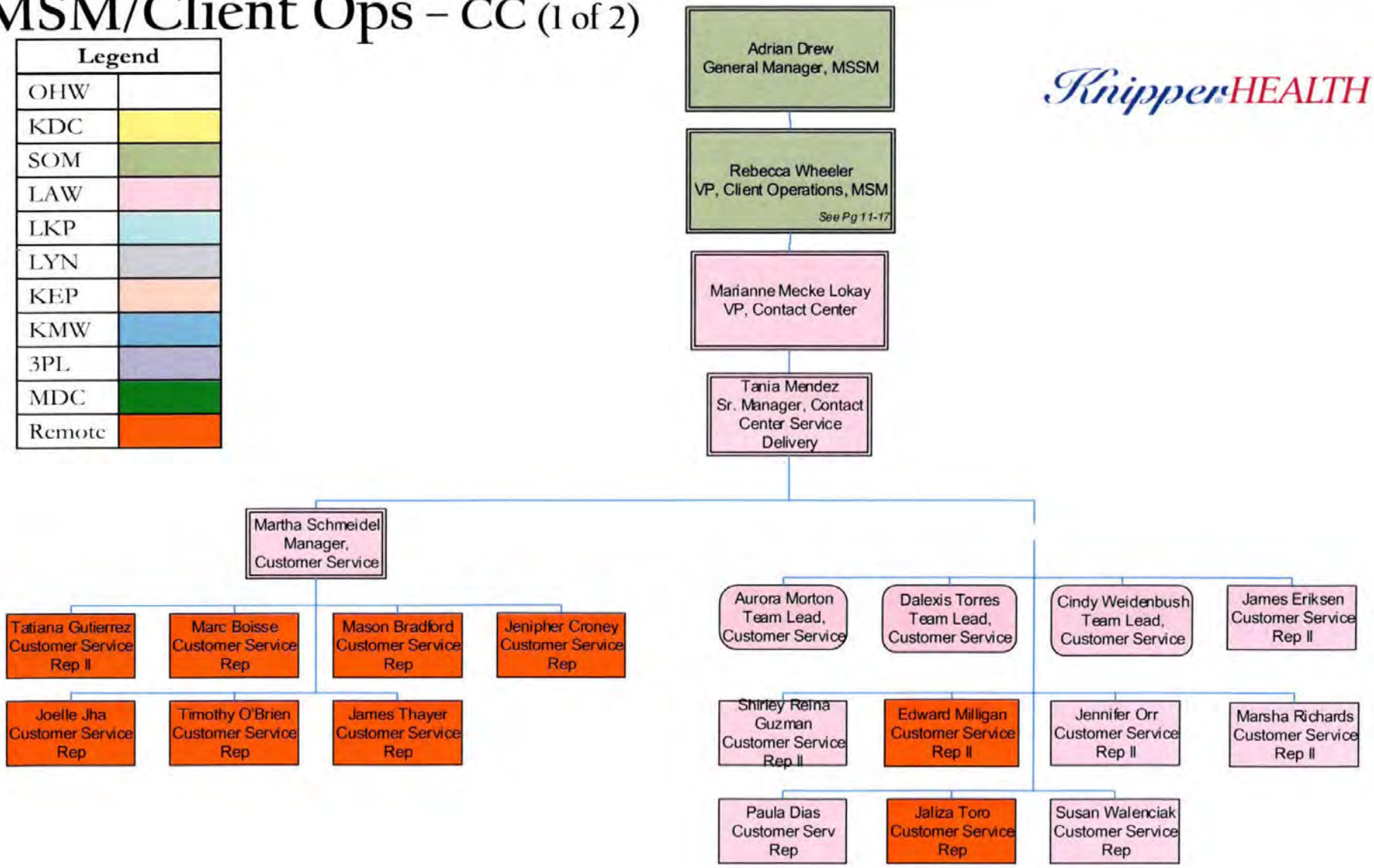
MSM/Client Ops – CS (4 of 4)

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3PL	
MDC	
Remote	



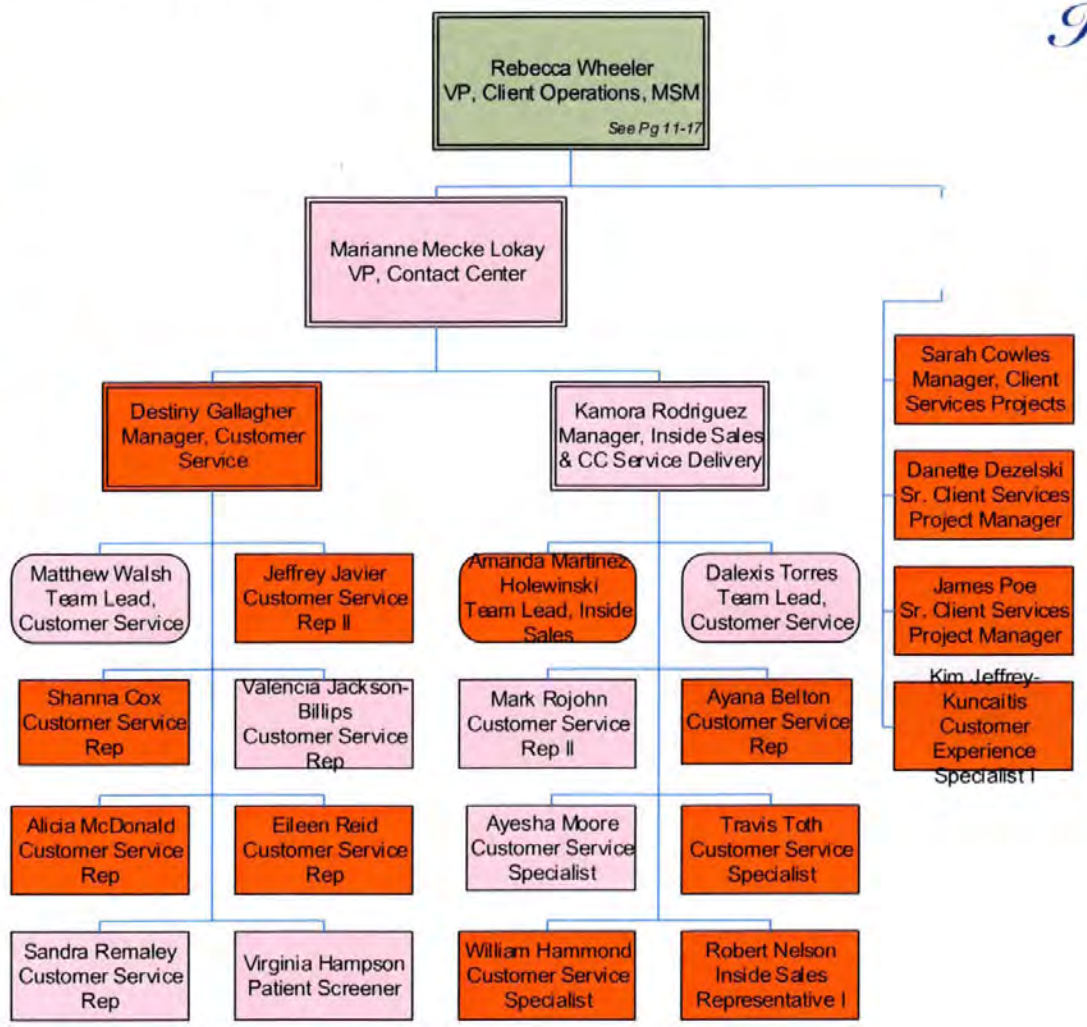
MSM/Client Ops – CC (1 of 2)

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MDC	
Remote	



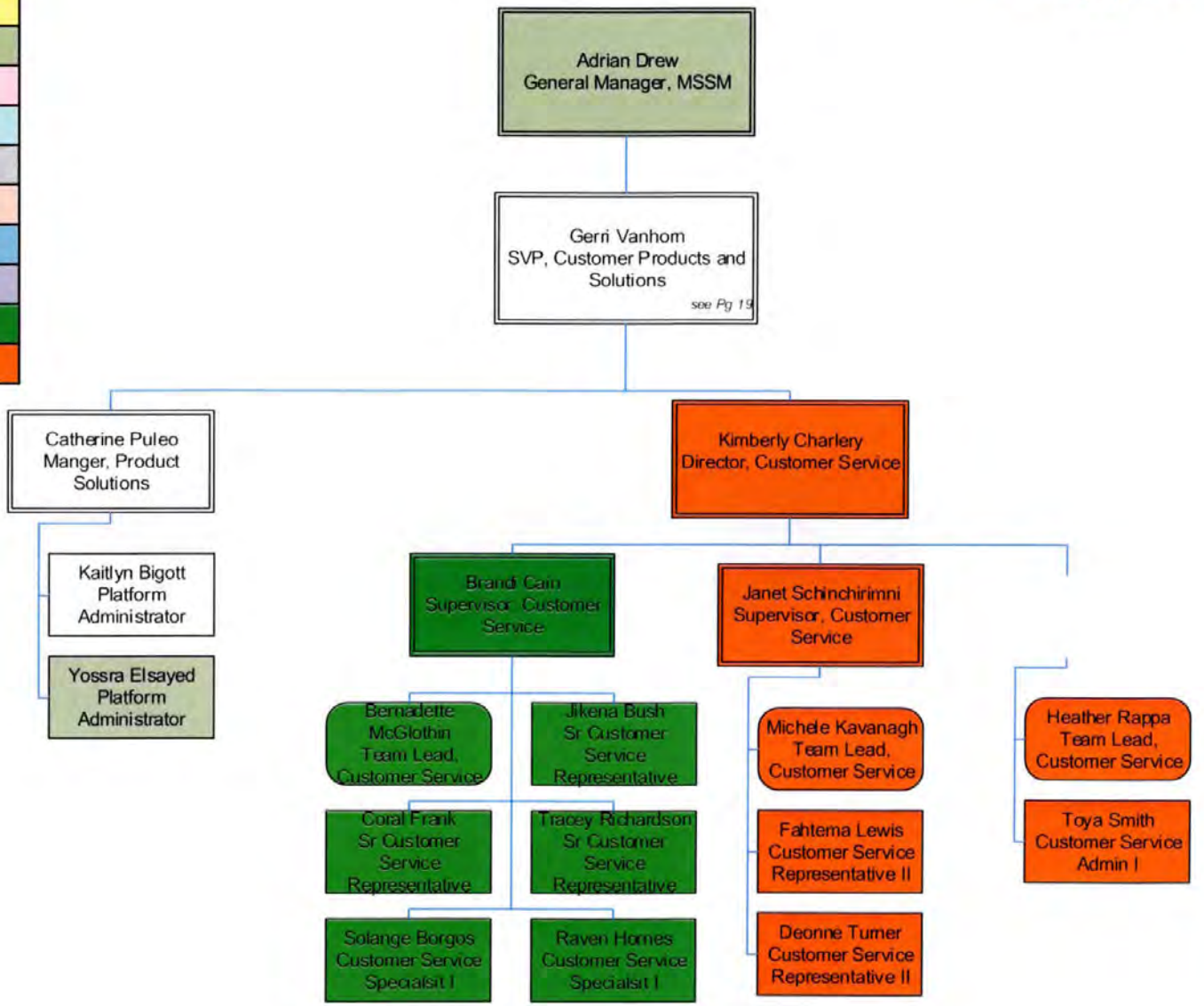
MSM/Client Ops – CC (2 of 2)

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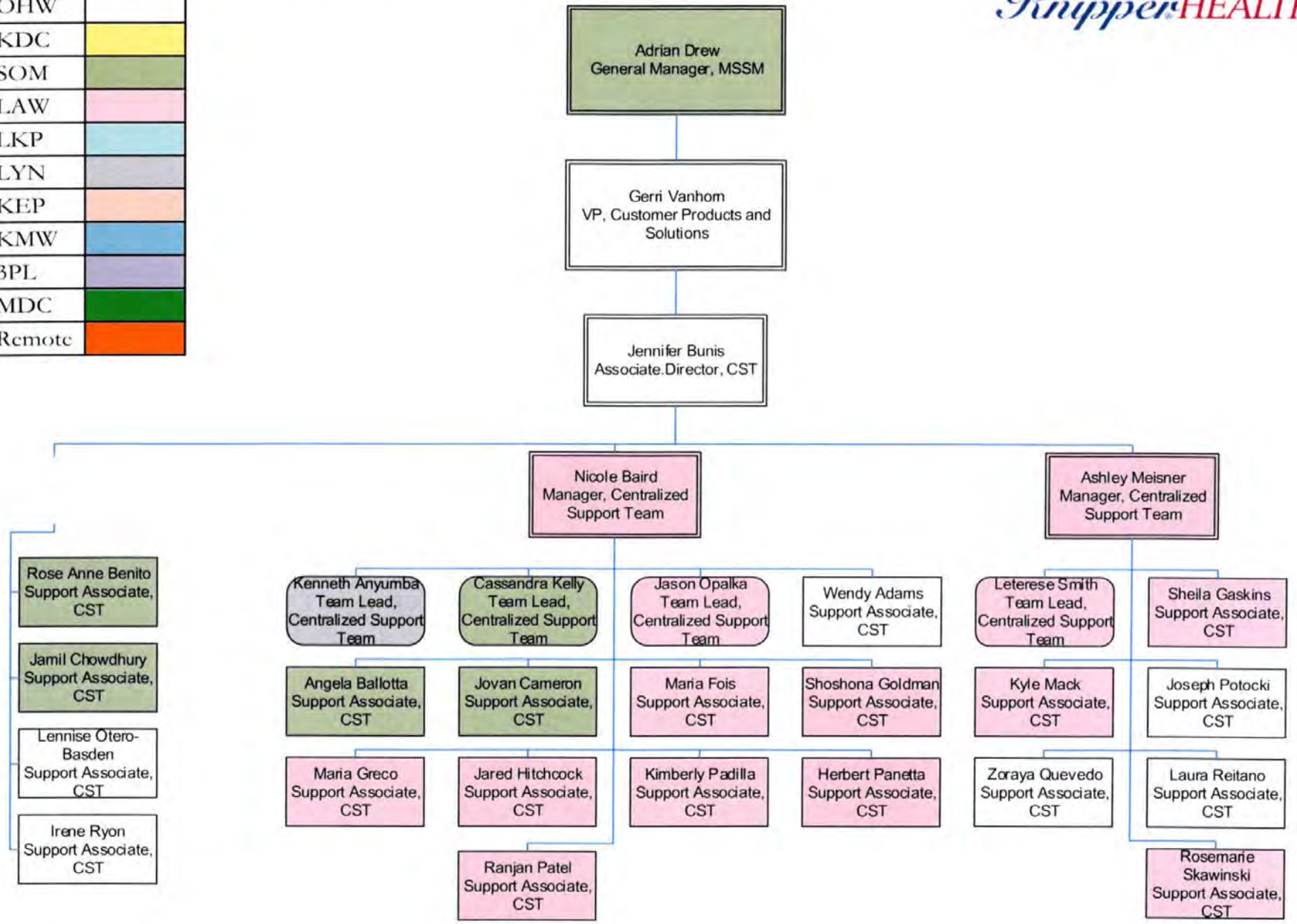
MSM/Client Ops - CST (1 of 2)

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MSM/Client Ops - CST (2 of 2)

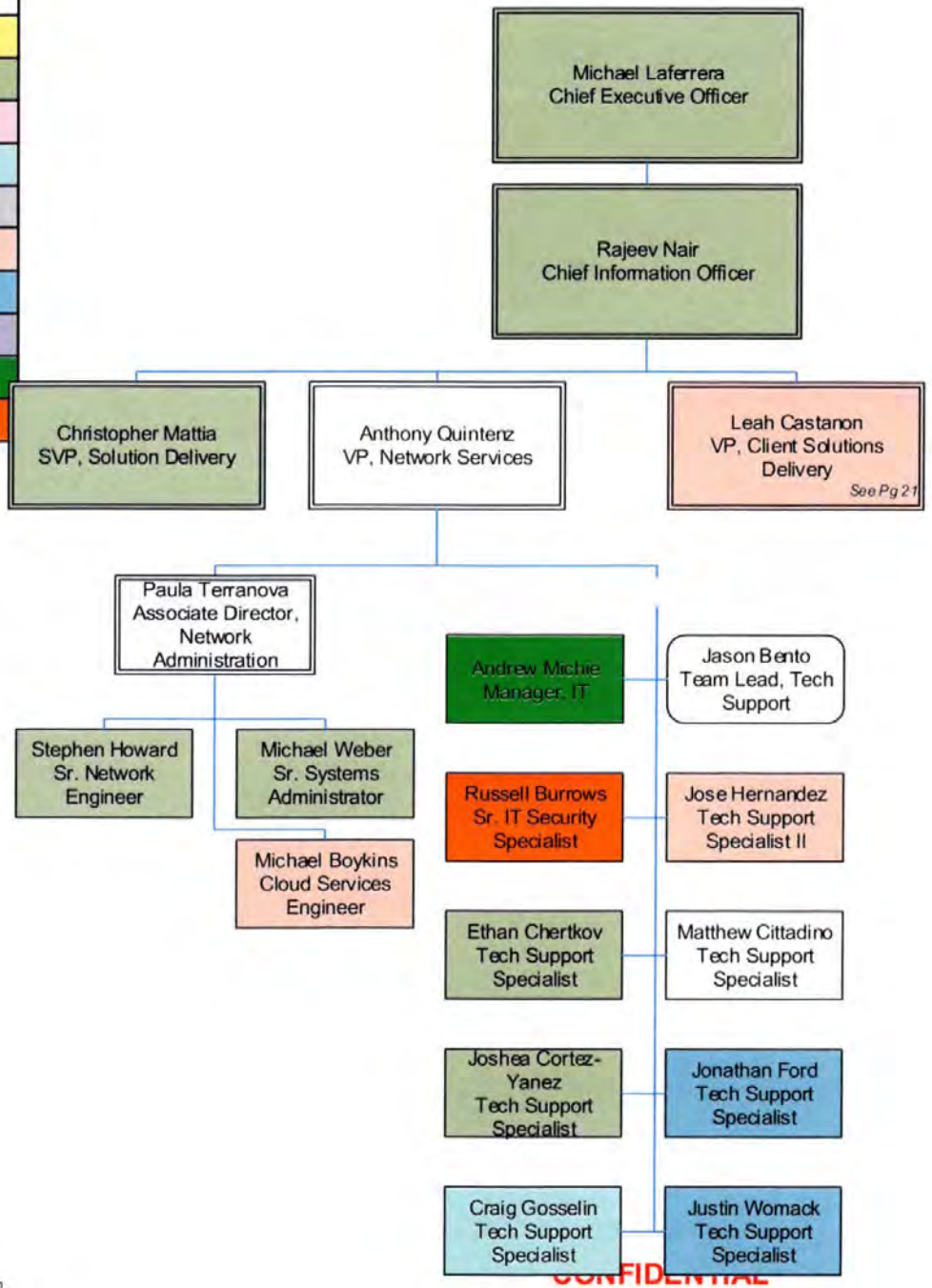
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KMW	
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MDC	
Remote	



CONFIDENTIAL

Information Technology (1 of 3)

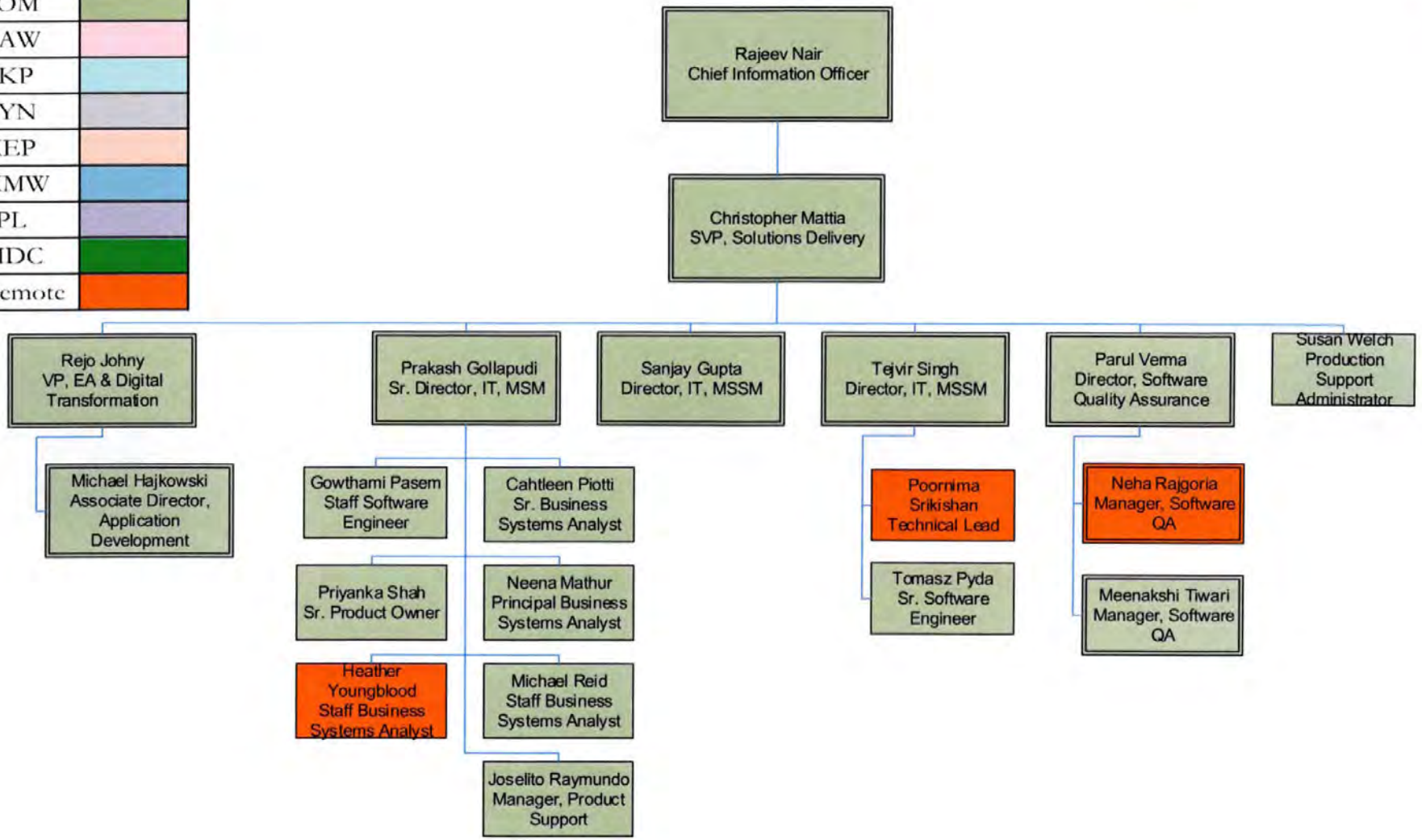
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CONFIDENTIAL

Information Technology (2 of 3)

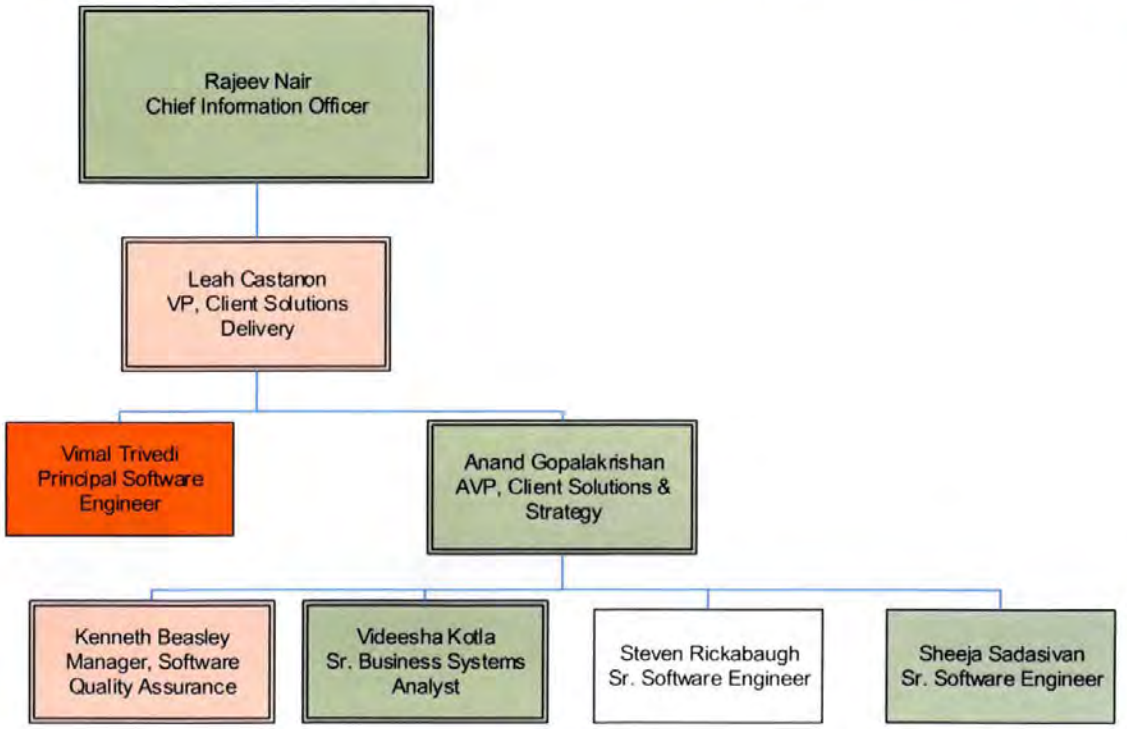
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KEP	
KMW	
3PL	
MDC	
Remote	



Information Technology (3 of 3)

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KEP	
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MDC	
Remote	

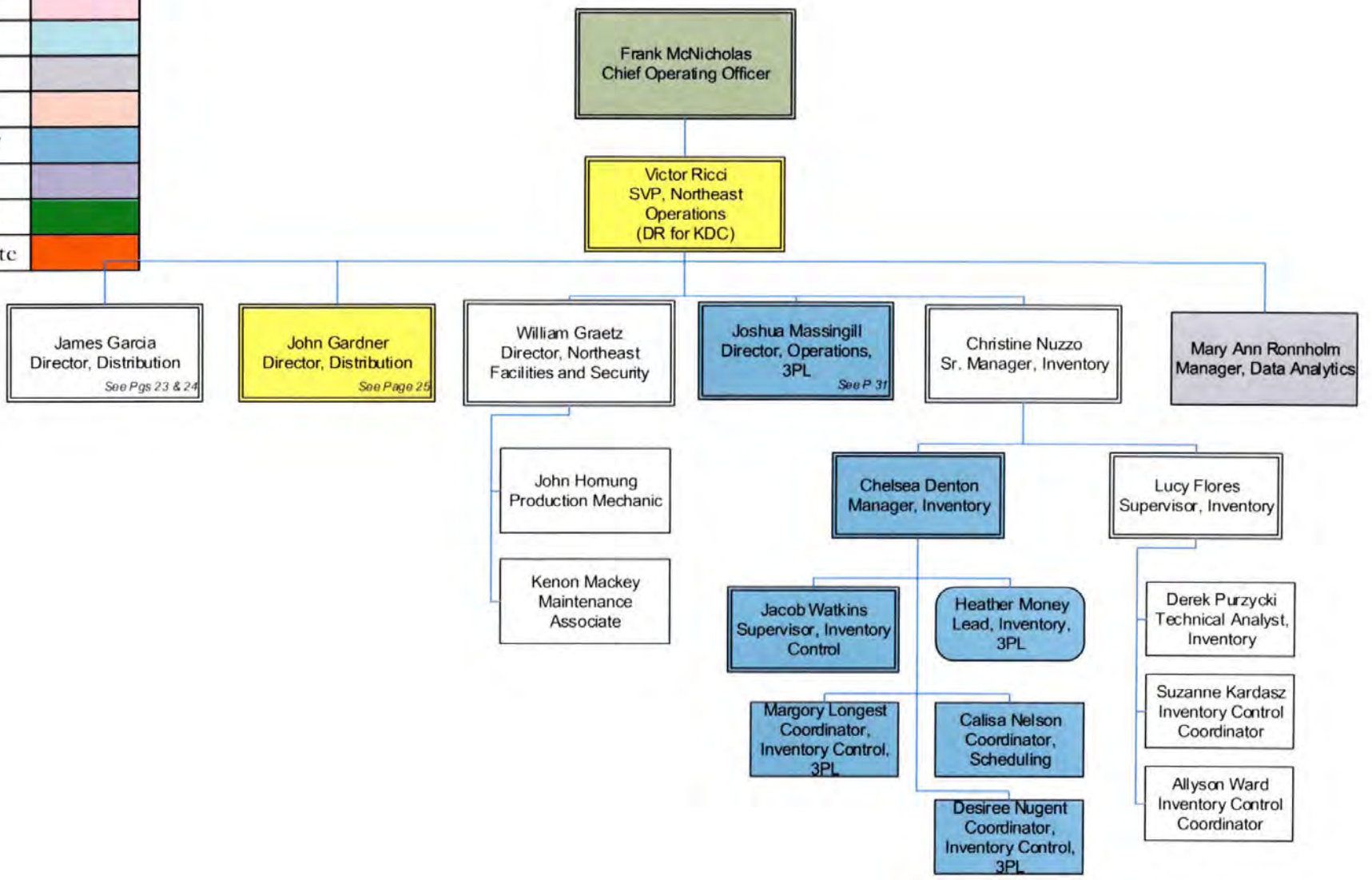
KnipperHEALTH



Operations (1 of 13)

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KEP	
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3PL	
MDC	
Remote	

KnipperHEALTH

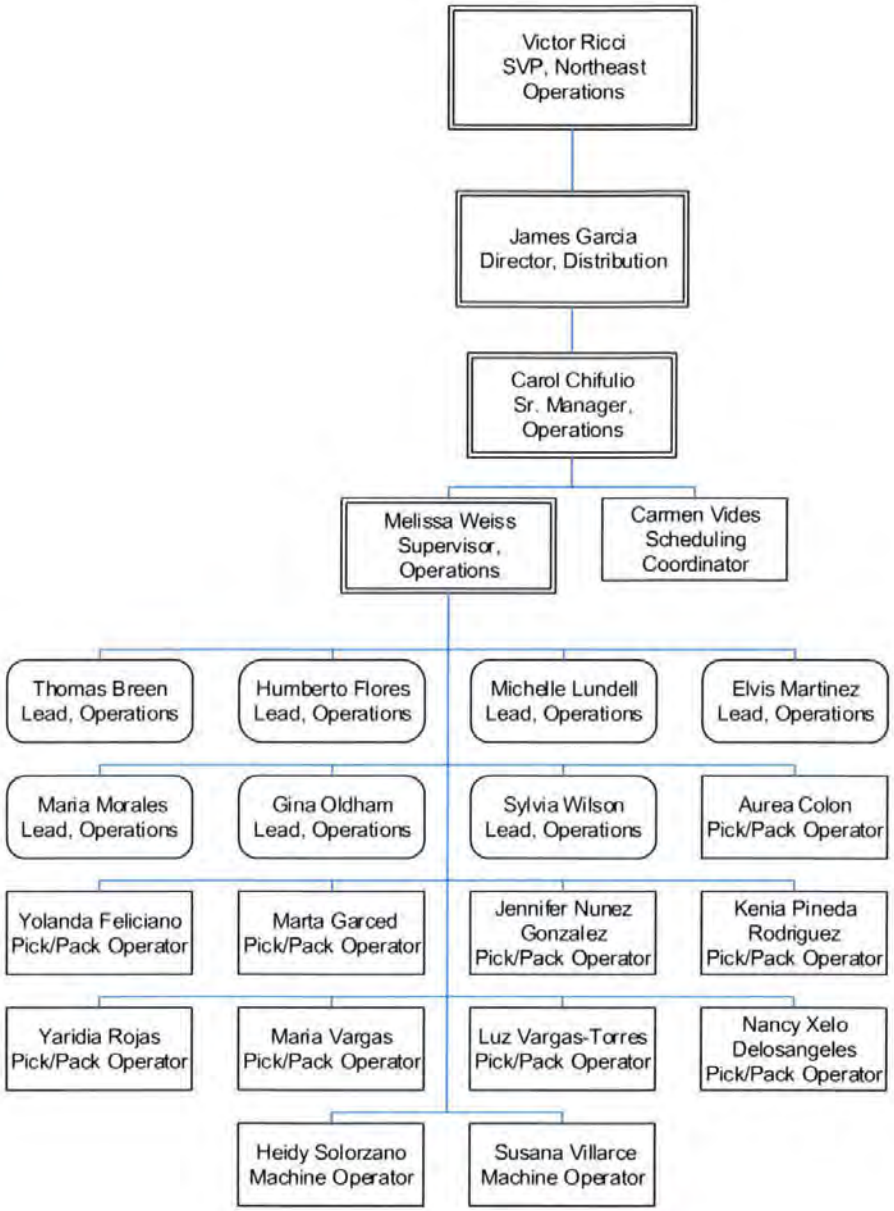


CONFIDENTIAL

Operations (2 of 13)

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MDC	
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KnipperHEALTH

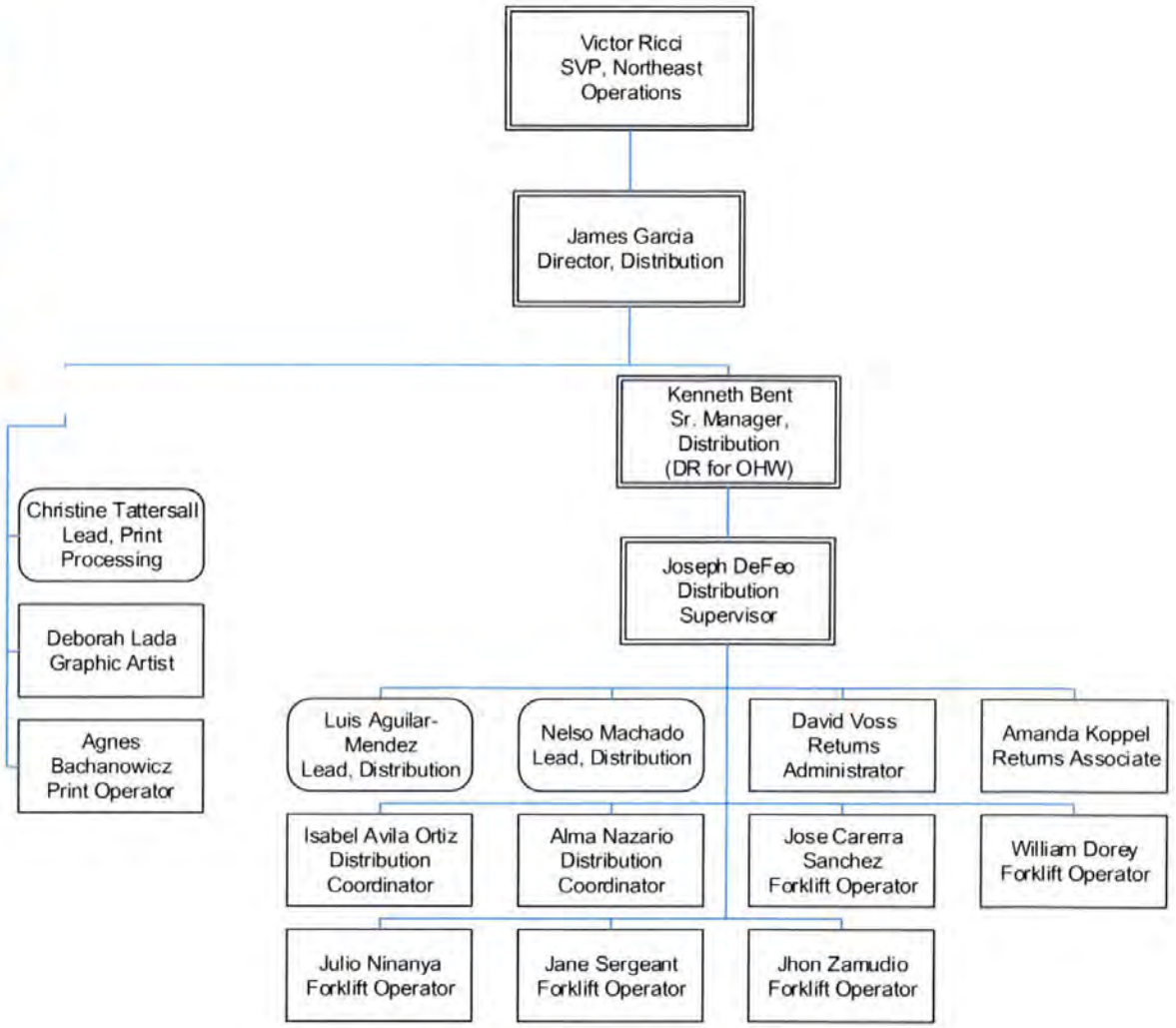


CONFIDENTIAL

Operations (3 of 13)

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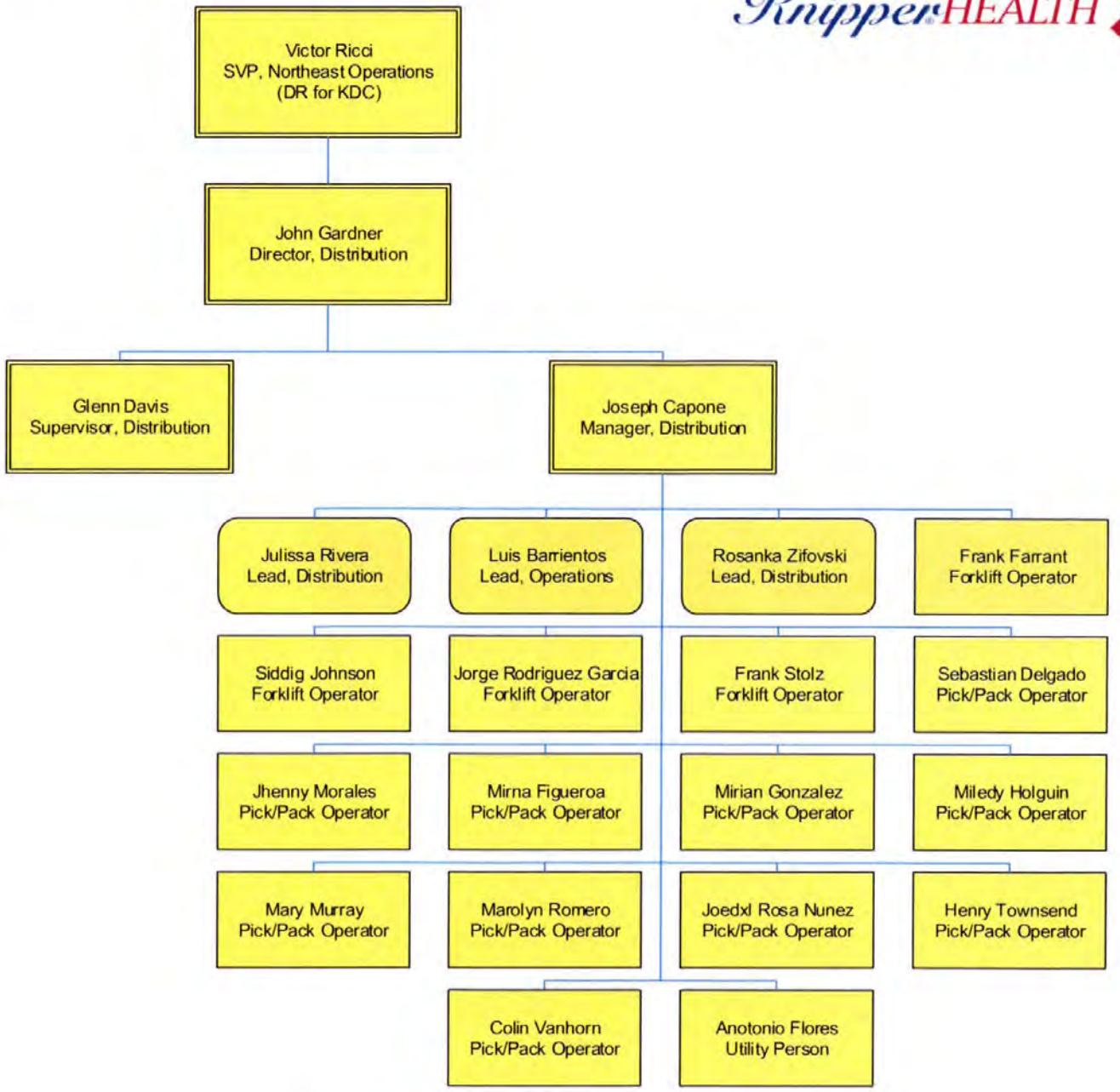
KnipperHEALTH



CONFIDENTIAL

Operations (4 of 13)

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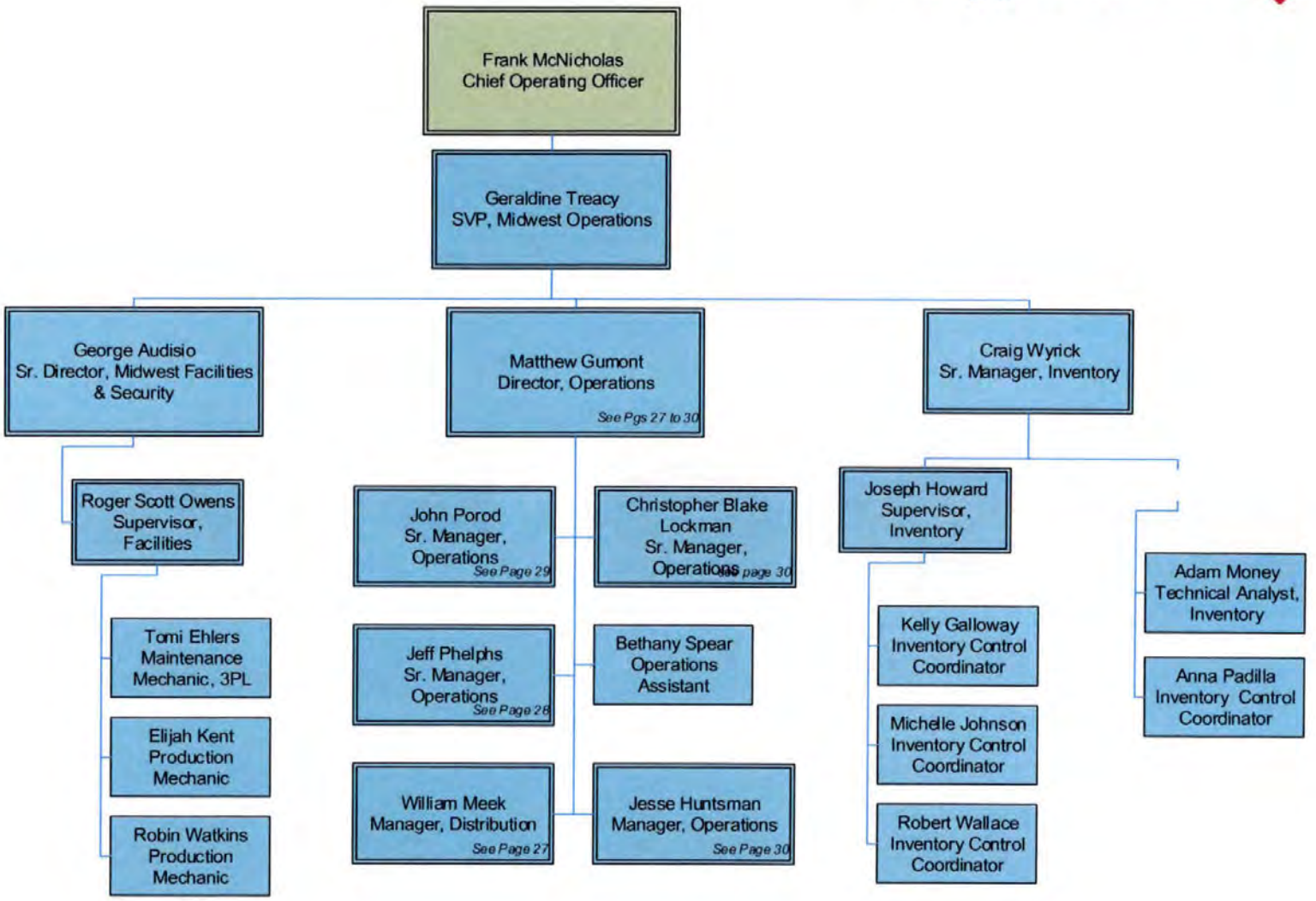


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Operations (5 of 13)

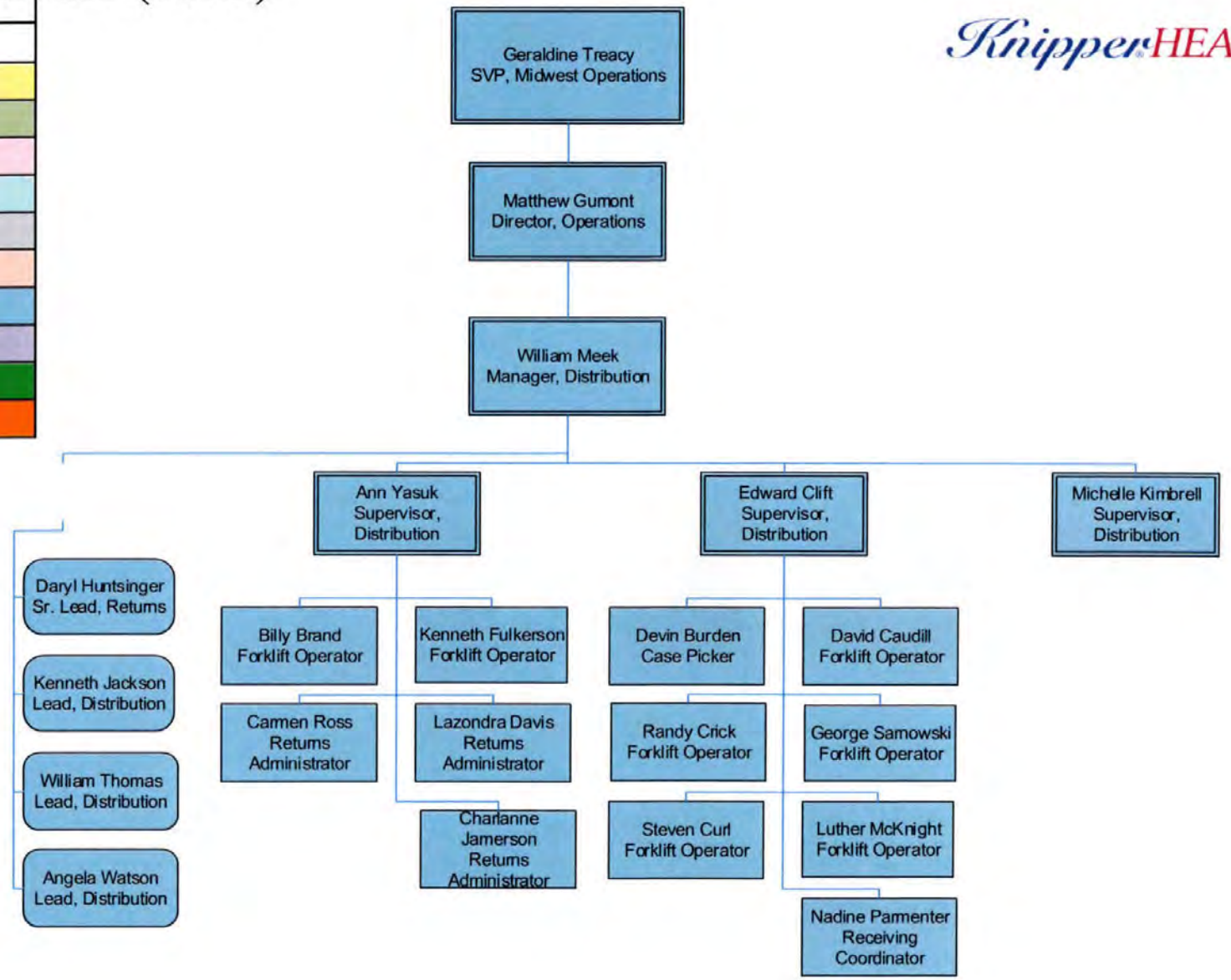
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MDC	
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KnipperHEALTH



Operations (6 of 13)

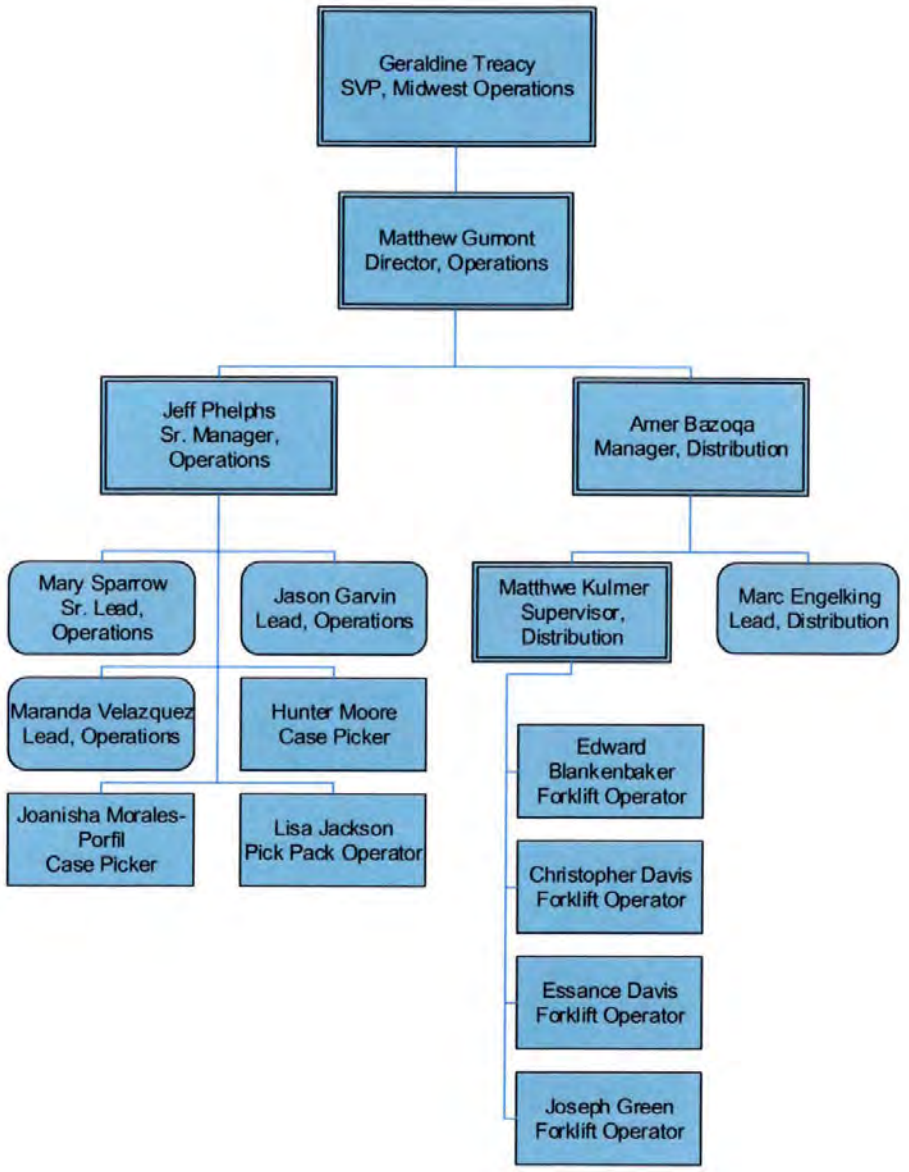
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CONFIDENTIAL

Operations (7 of 13)

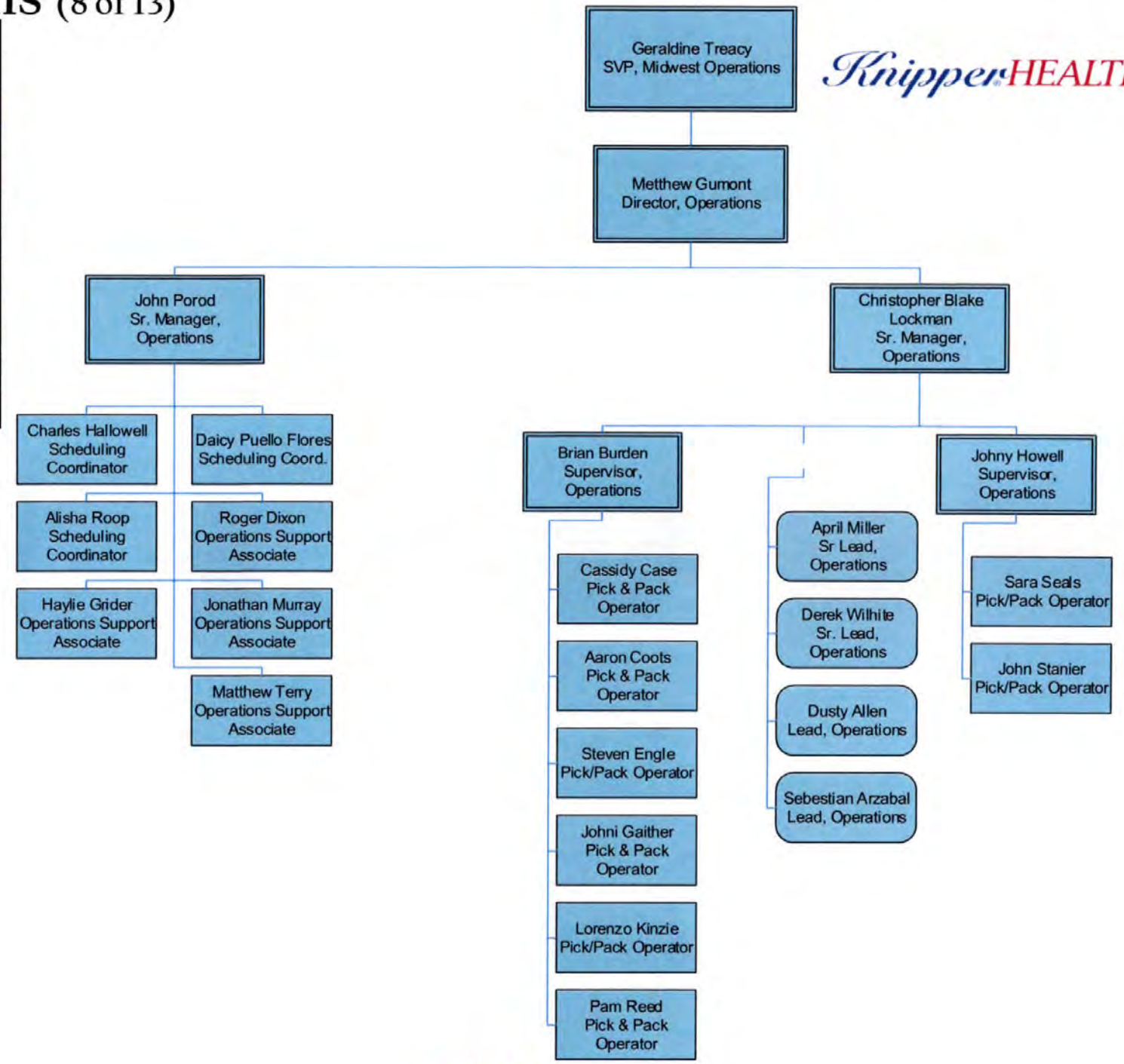
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CONFIDENTIAL

Operations (8 of 13)

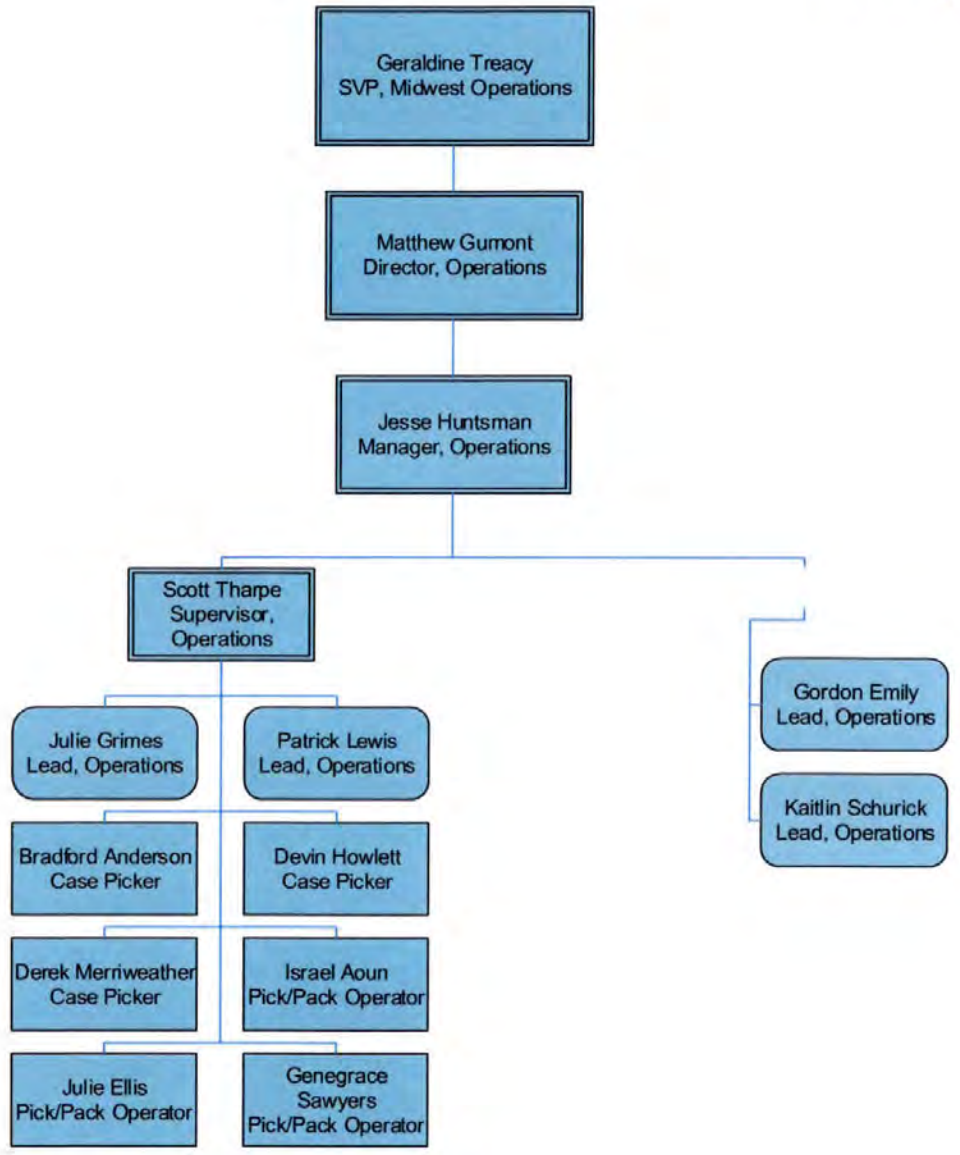
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MDC	
Remote	



CONFIDENTIAL

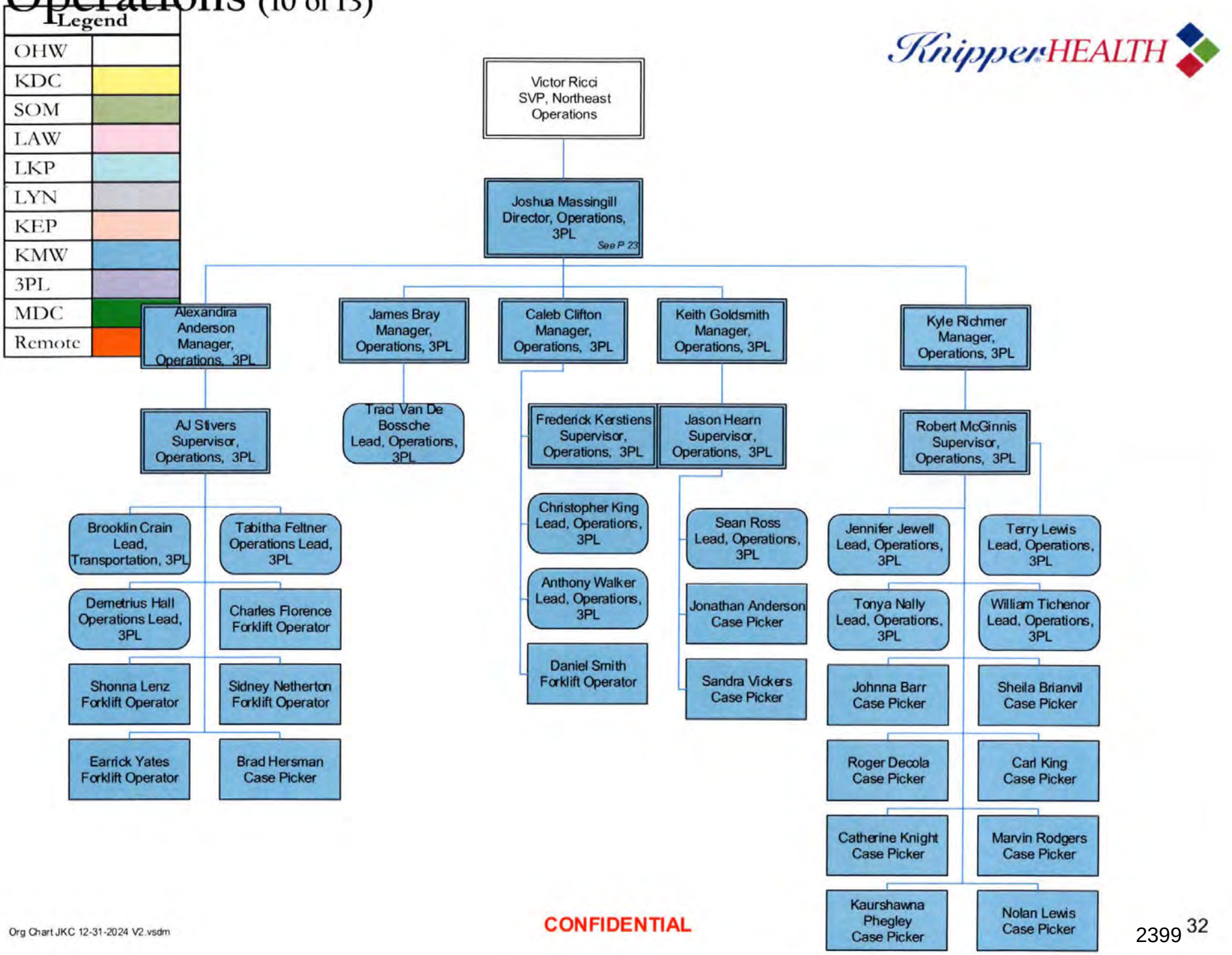
Operations (9 of 13)

Legend	
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MDC	
Remote	



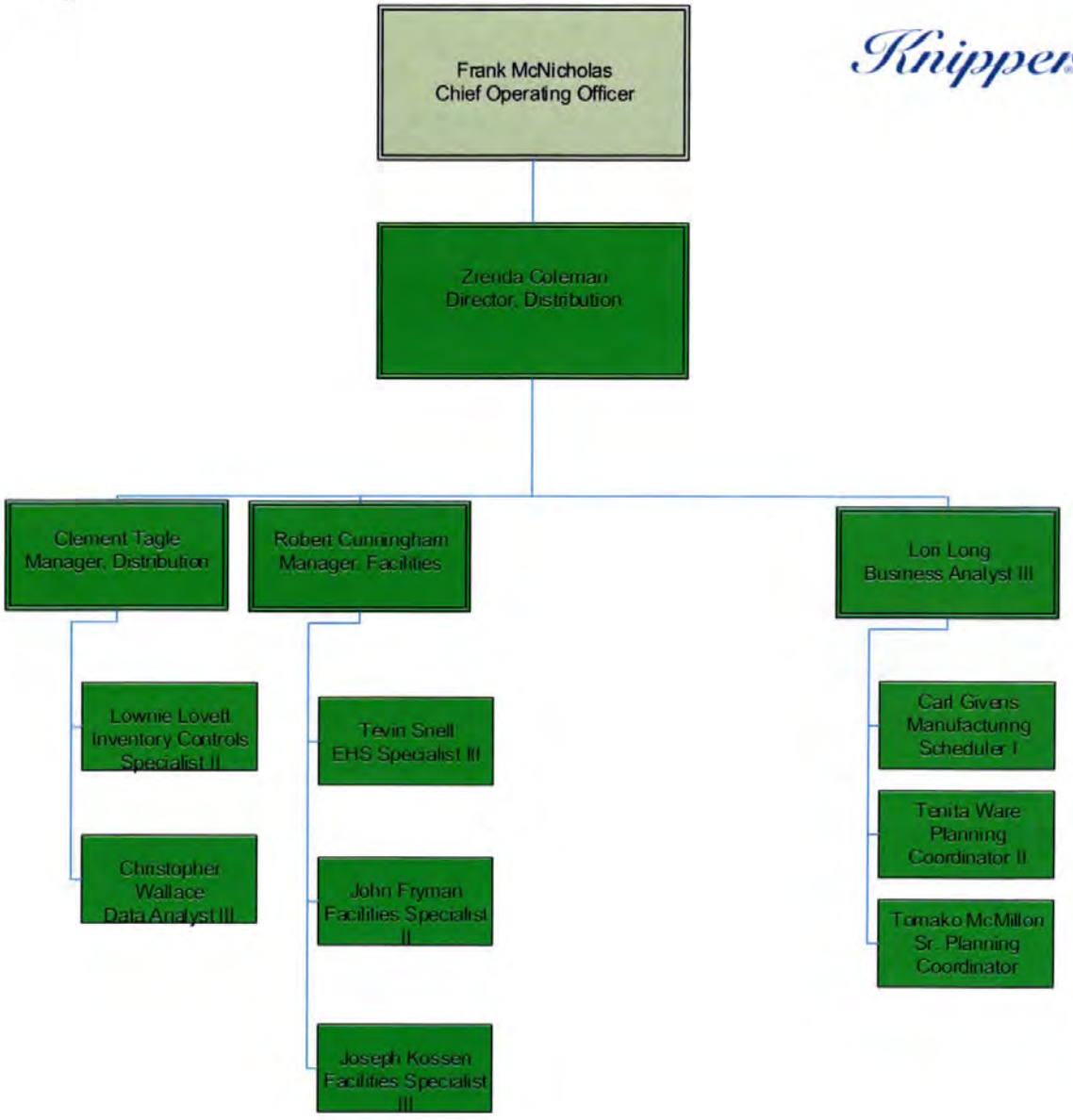
CONFIDENTIAL

Operations (10 of 13)



Operations (11 of 13)

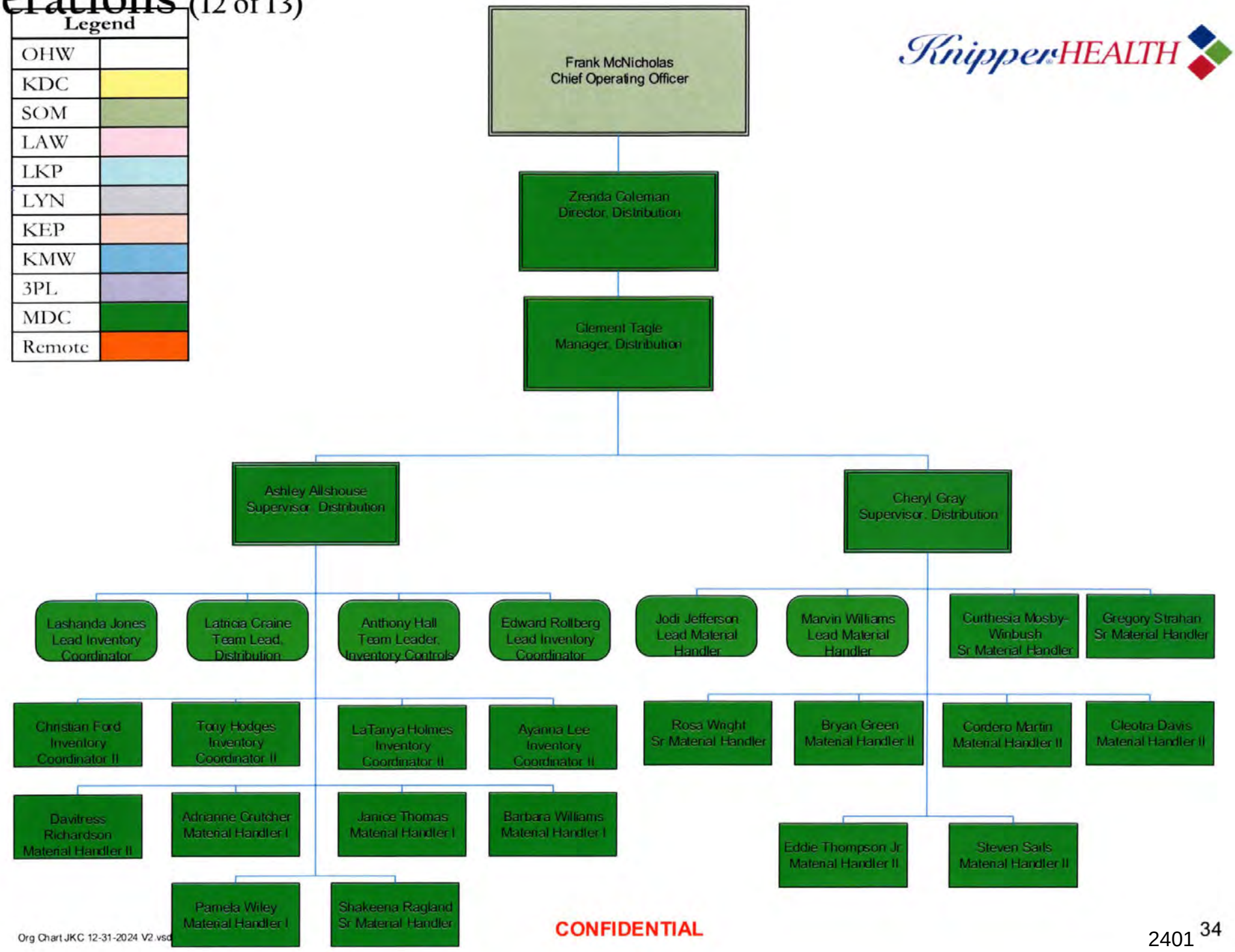
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LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



CONFIDENTIAL

Operations (12 of 13)

Legend	
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KEP	
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MDC	
Remote	

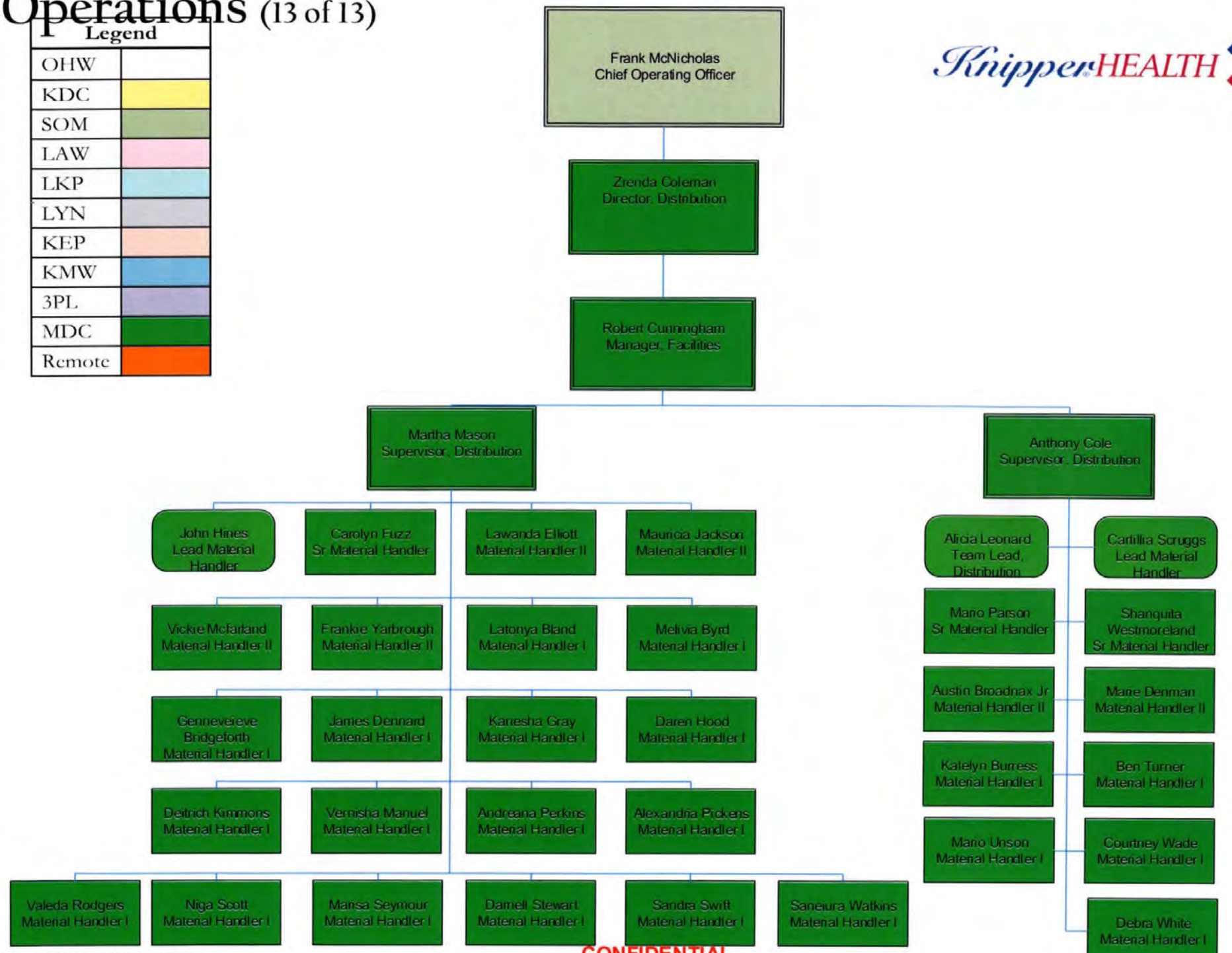


Org Chart JKC 12-31-2024 V2.vsd

CONFIDENTIAL

Operations (13 of 13)

Legend	
OHW	
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SOM	
LAW	
LKP	
LYN	
KEP	
KMW	
3PL	
MDC	
Remote	



Org Chart JKC 12-31-2024 V2.vsdm

CONFIDENTIAL

4YY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH 03267	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Kuehne + Nagel Inc.

Physical Address: 4080 Executive Dr, Suite 100

City: Southaven State: MS Zip: 38672

Mailing Address (if different from physical address): 10 Exchange Place 20th Floor

City: Jersey City State: NJ Zip: 07302

Telephone: 201-413-5500 Website: https://us.kuehne-nagel.com/

Name of Designated Representative (DR): Stephen Berry

Licensing Company Email: qshepharma.us@kuehne-nagel.com DR Email: stephen.berry@kuehne-nagel.

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ [3]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3rd Party Logistics Provider

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # n/a . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/18/2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Cordis
Address: 5452 Betsy Ross Drive City: Santa Clara State: CA Zip: 95054
Name: Embecta Corp
Address: 300 Kimball Drive, Suite 300 City: Parsippany State: NJ Zip: 07054
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York
Parent Company (if any): Kuehne + Nagel Holdings Inc.
Corporation/Organization Name: Kuehne + Nagel Inc.
Mailing Address: 10 Exchange Place 20th Floor
City: Jersey City State: NJ Zip: 07302
Telephone: 201-413-5500 Email: qshepharma.us@kuehne-nagel.com
Contact Person Name: Natalie Martino

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Kuehne + Nagel Inc.

Facility Name

Dan Osterberg

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

11 | 18 | 2024

Date

Board Use Only	Date Received: 12/5/24	Amount: $1000-ck 13450

NABP ACCREDITED
DRUG DISTRIBUTOR

Kuehne + Nagel, Inc

located at

4080 Executive Dr, Southaven, MS 38672

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

11/30/2023 to 11/29/2026
Period of Accreditation

KUEHNE+NAGEL

Owner:
Kuehne + Nagel Investment, LLC
10 Exchange Place 19th floor, Jersey City NJ 07302
FEIN: 22-3176791
100% Ownership

List of Officers:

Marcus Bennett, President/CEO
Date of Birth [redacted]
Social Securit
Home Addres
Home Phone

Dan Osterberg, CFO
Date of Birth [redacted]
Social Securit
Home Addre
Home Phone

Richard J Kaluzinski, Secretary, National Legal Counsel
Date of Birth [redacted]
Social Securit
Home Addre
Home Phone

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	KUEHNE + NAGEL INC.
DOS ID Number:	200052
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/30/1966
Effective Date:	05/01/2023
Statement Status:	CURRENT
Statement Due Date:	06/30/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on September 16, 2024 at 04:29 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100006589450 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

MISSISSIPPI BOARD OF PHARMACY

LICENSE VERIFICATION

The Mississippi Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

Kuehne + Nagel Inc.

Drug Facility

Permit Status:	Active	**Issued Date:**	01/14/2022	**Discipline on File:**	No
Permit #:	18430	**Effective Date:**	12/26/2024	**Discipline Status:**	No Discipline
Classification:	3rd Party Logistics (In-State)	**Expire Date:**	12/31/2025	**Address:**	4080 Executive Drive Suite 100 Southaven, MS 38672

Controlled Substance Registration

No controlled substance registration found!

Public Records

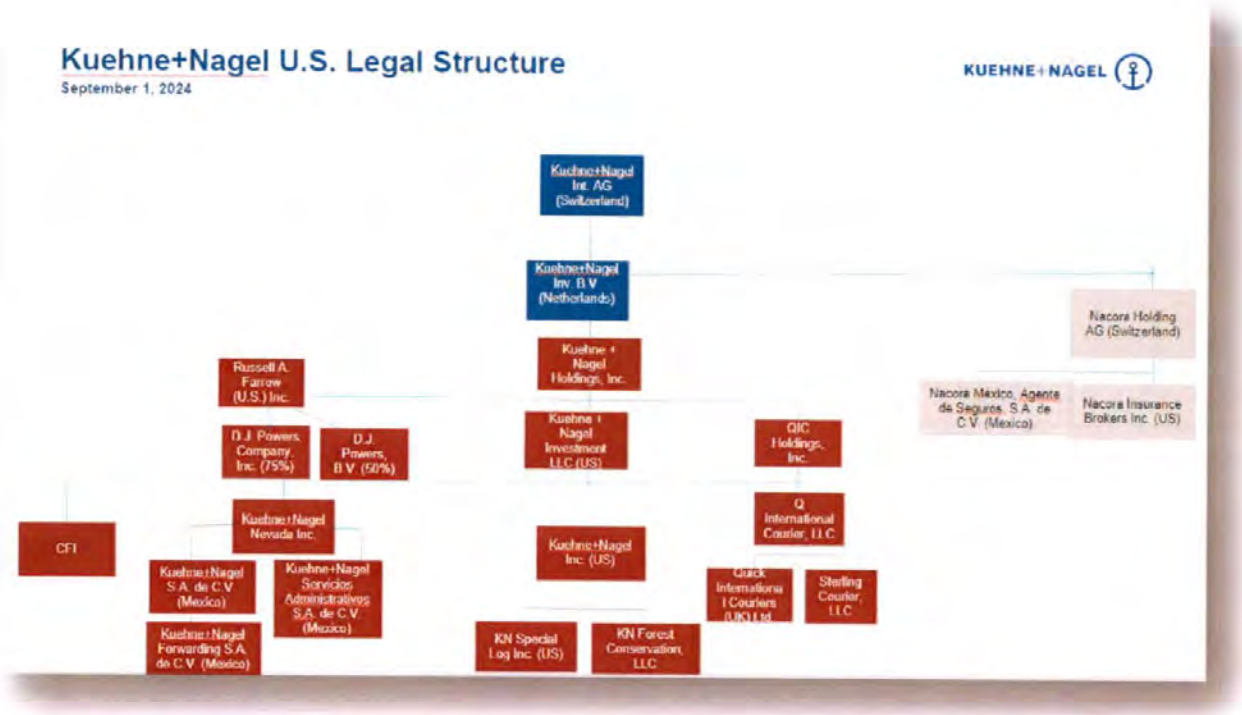
No disciplinary documents were found!

Information loaded from this database is current as of 4/15/2025 12:46:48 PM

KUEHNE+NAGEL

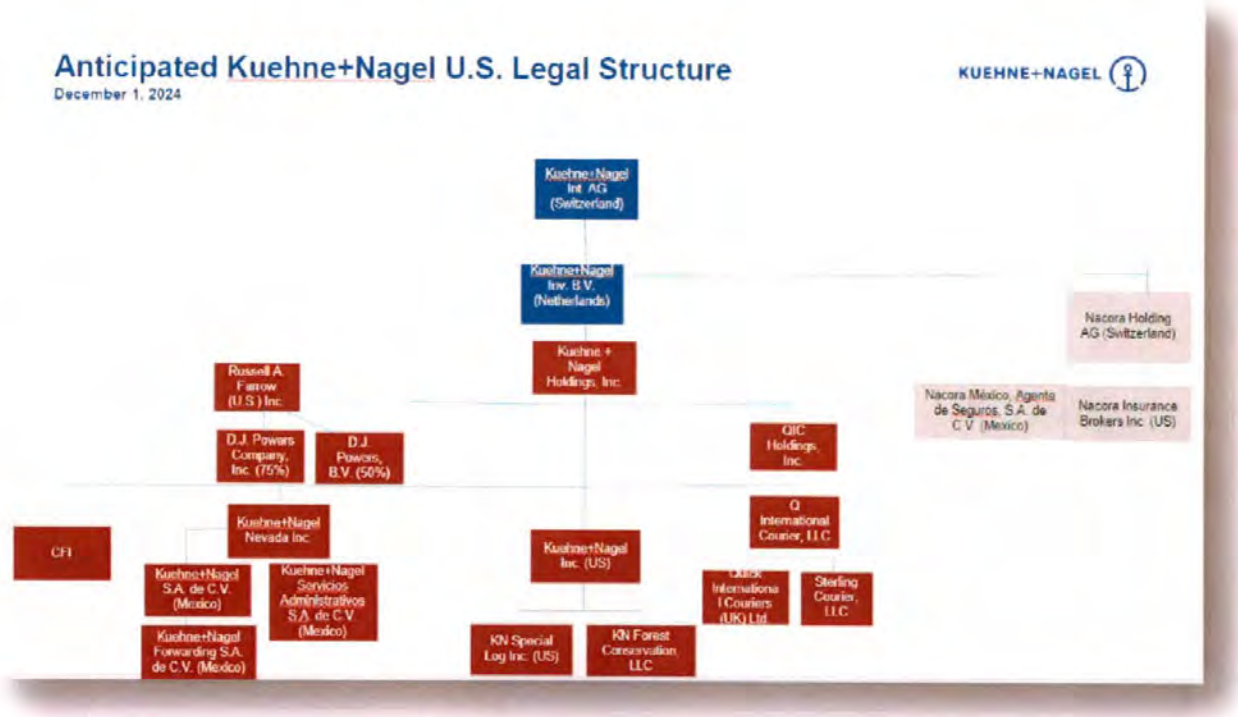
Kuehne+Nagel U.S. Legal Structure

September 1, 2024



Anticipated Kuehne+Nagel U.S. Legal Structure

December 1, 2024



Kuehne + Nagel Inc.

10 Exchange Pl
Floor 20
Jersey City, NJ 07302

Tel.: +1 484.995.6137
ria.philip@kuehne-nagel.com

us.kuehne-nagel.com
www.kuehne-nagel.com

AGREEMENT
AND
PLAN OF MERGER

THIS AGREEMENT AND PLAN OF MERGER, dated as of November 11, 2024 (this "Plan of Merger"), is between Kuehne + Nagel Investment LLC, a New Jersey Limited Liability Company ("Merged LLC"), and Kuehne + Nagel Holdings, Inc., a Delaware corporation ("Surviving Corporation").

W I T N E S S E T H:

WHEREAS, Merged LLC has a single member to wit, the Surviving Corporation; and

WHEREAS, Surviving Corporation is authorized to issue a total of 100 shares of capital stock, consisting of 200 shares of common stock, par value $0.01 per share ("Surviving Corporation Common Stock"), of which, as of the date hereof, 100 shares of Common Stock are issued and outstanding; and

WHEREAS, the sole member and the Managers of the Merged LLC and the Board of Directors of the Surviving Corporation, respectively, approve and deem it advisable that Merged LLC and Surviving Corporation, respectively, consummate the Merger (as defined below).

NOW, THEREFORE, in consideration of the mutual agreements contained in this Plan of Merger, the parties to this Plan of Merger hereby agree that Merged LLC shall be merged (the "Merger") with and into Surviving Corporation in accordance with applicable laws and upon the terms and subject to the conditions set forth as follows:

1. The Merger. At such time agreed between Merged LLC and Surviving Corporation, a certificate of merger evidencing the Merger shall be filed with each of the Office of the Secretary of State of the State of New Jersey pursuant to the Title 42 of the New Jersey Revised Statutes and of the State of Delaware General Corporation Law. The Certificates of Merger shall specify that the Merger shall become effective on December 1, 2024 ("Effective Time"). At the Effective Time, Merged LLC shall be merged with and into Surviving Corporation, and Surviving Corporation shall continue as the surviving corporation. The Surviving Corporation's name shall remain Kuehne + Nagel Holdings, Inc.

2. Certificate of Incorporation and By-laws. The Certificate of Incorporation and By-laws of Surviving Corporation in effect immediately prior to the Effective Time shall be and remain the Certificate of Incorporation and By-laws, respectively, of Surviving Corporation, as the surviving corporation, after the Effective Time, until amended as provided by law.

3. Officers and Directors. From and after the Effective Time, and until they shall have resigned or shall have been legally removed or until their respective successors shall have been elected or appointed and qualified, those persons who are the officers and directors of Surviving Corporation immediately prior to the Effective Time shall be the officers and directors of Surviving Corporation.

4. Effect of the Merger.

4.1 All assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC in and to every type of property (real, personal and mixed) and choses in action, as they exist as of the Effective Time, shall pass and be transferred to and vest in Surviving Corporation, as the surviving corporation, by virtue of the Merger at the Effective Time without any deed, conveyance or other transfer, and all such interests of Surviving Corporation as they exist as of the Effective Time shall remain with Surviving Corporation upon consummation of the Merger. The corporate existence of Surviving Corporation shall continue unaffected and unimpaired upon consummation of the Merger and the separate corporate existence of Merged LLC shall cease at and as of the Effective Time.

4.2 From and after the Effective Time, Surviving Corporation, as the surviving corporation, shall be responsible and liable for all of the liabilities and obligations of Surviving Corporation and Merged LLC existing as of the Effective Time. Any claim existing or action or proceeding pending by or against Surviving Corporation or Merged LLC at the Effective Time may, thereafter, be prosecuted by or against Surviving Corporation, as the surviving corporation, as if the Merger had not taken place or, in connection with any such action or proceeding to which Merged LLC is a party, Surviving Corporation, as the surviving corporation, may be substituted in place of Merged LLC. Neither the rights of creditors nor any liens upon the property of either Surviving Corporation or Merged LLC shall be impaired by reason of the Merger.

5. Effect of Merger on Outstanding Shares.

5.1 *Exchange Ratio*. At the Effective Time, by virtue of the Merger and without any action on the part of the holder thereof, all of the issued and outstanding member shares of the Merged LLC shall be cancelled.

5.2 *Closing of Transfer Books*. At the Effective Time, the membership transfer books of Merged LLC shall be closed and no transfer of shares of Merged LLC membership shall thereafter be made. If, after the Effective Time, certificates representing member shares of Merged LLC are presented to the Surviving Corporation, they shall be canceled in accordance with the terms hereof. At and after the Effective Time, the holders of member shares of Merged LLC Stock shall cease to have any rights as members of Merged LLC.

6. Further Assurances. From time to time after the Effective Time, as and when requested by Surviving Corporation, and to the extent permitted by law, the former managers of Merged LLC and the officers and directors of Surviving Corporation shall execute and deliver such assignments, deeds and other instruments and shall take or cause to be taken such further or other action as shall be necessary in order to consummate the Merger, vest or perfect in or to confirm of record or otherwise to Surviving Corporation, as the surviving corporation, title to, and possession of, all of the assets, rights, privileges, immunities, powers, franchises and interests of Merged LLC and Surviving Corporation in and to every type of property (real, personal and

mixed) and choses in action, and otherwise to carry out the purposes of this Plan of Merger, and the proper officers and directors of Surviving Corporation, as the surviving corporation, are fully authorized to take any and all such action in the name of Merged LLC or Surviving Corporation or otherwise.

7. Termination and Amendment. Prior to the Effective Time, this Plan of Merger may be terminated or amended by the mutual consent of the Managers of Merged LLC and the Board of Directors of Surviving Corporation.

8. Counterparts. This Plan of Merger may be signed in any number of counterparts, each of which shall be deemed an original, and all of which shall be deemed but one and the same instrument.

9. Governing Law. This Plan of Merger shall be governed by and construed in accordance with the laws of the State of New Jersey without giving effect to any choice of law or conflict of law provision or rule (whether of the State of New Jersey or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New Jersey.

IN WITNESS WHEREOF, the parties have duly executed this Plan of Merger as of the date first written above.

KUEHNE + NAGEL INVESTMENT LLC
(Merged LLC)

By: _____
Marcus Bennett, Manager

By: _____
Dan Osterberg, Manager

By: _____
Nadine Jones, Manager

KUEHNE + NAGEL HOLDINGS, INC.
(Surviving Corporation)

By: _____
Name: Dan Osterberg
Title: CFO, Treasurer

List of Licenses-Southhaven

Jurisdiction	Requirement	Number	Issue Date	Expiration
US-AL	Designated Representative	DR0624	1/24/2024	12/31/2024
US-AR	Wholesale Distributor	WD05692	5/9/2022	12/31/2024
US-AZ	Third Party Logistics Provider	L000342	7/22/2022	10/31/2025
US-CA	Third Party Logistics Provider	NPL 1349	8/12/2022	8/1/2025
US-CO	Third Party Logistics Provider	TPLP.0000095	3/25/2024	10/31/2026
US-CT	Wholesaler of Drugs, Cosmetics & Medical Devices	CSW.0005037	7/1/2023	6/30/2025
US-DC	Medical Device Distributor	DCDED01088	8/22/2022	9/30/2025
US-FL	Third Party Logistics Provider	2458	4/8/2024	4/30/2026
US-IA	Limited Distributor - Medical Device Distribution	41554	4/4/2022	12/31/2024
US-IA	Third Party Logistics (3PL) Provider	80213	9/3/2024	3/31/2025
US-IL	Third Party Logistics Provider	278000233	8/21/2024	12/31/2024
US-IN	Third Party Logistics Provider	94000287A	6/4/2024	9/30/2026
US-KS	Third Party Logistics Provider	23-117493	5/12/2022	6/30/2025
US-KY	Third Party Logistics Provider	TPL00405	2/8/2022	6/30/2025
US-LA	Third Party Logistics Provider	10604	4/26/2022	12/31/2024
US-MI	Wholesale Distributor	5306007086	8/17/2022	8/17/2026
US-MN	Third Party Logistics Provider	900246	7/8/2024	10/31/2025
US-MO	Third Party Logistics Provider	2024010119	3/14/2024	10/31/2025
US-MS	Third Party Logistics Provider	18430/16.3	1/14/2022	12/31/2024
US-MT	Wholesale Drug Distributor	PHA-WDD-LIC-88472	7/15/2022	11/30/2025
US-NC	Third Party Logistics Provider	1727	4/26/2024	12/31/2024
US-ND	Third Party Logistics Provider	TPL367	10/25/2022	6/30/2025
US-NH	Manufacturer/Distributor/Wholesaler/Broker	7372	2/7/2022	6/30/2025
US-NM	Third Party Logistics Provider (3PL)	WD20220180	4/19/2024	12/31/2025
US-NV	Wholesaler	WH03267	11/15/2022	10/31/2026
US-OH	Third Party Logistics Provider	170000139	7/11/2024	6/30/2025
US-OK	Third Party Logistics Provider	88-L-7312	3/24/2022	3/31/2025
US-OR	Drug Distribution Agent	DDA-0000573	5/18/2022	9/30/2025
US-PA	Devices-Medical: Manufacturer, Distributor or Retailer	6000010419	2/15/2022	4/30/2025
US-SC	Third Party Logistics Provider	22134	3/8/2024	6/30/2025
US-TN	Third Party Logistics Provider	7891	4/19/2022	4/30/2026
US-TX	Third Party Logistics Provider	1003809	3/18/2024	2/11/2026
US-UT	Pharmacy - Class E	12772231-1714	4/15/2022	9/30/2025
US-VA	Third Party Logistics Providers out of state	242000206	5/9/2022	2/28/2025
US-VT	Third Party Logistics Provider	159.0000232	3/6/2024	7/31/2025
US-WI	Wholesale Distributor of Prescription Drugs	10066 - 45	2/2/2024	5/31/2026
US-WV	Third Party Logistics Provider	3PL0000449	2/1/2024	6/30/2026
US-WY	Third Party Logistics Provider	3PL0159	3/26/2024	6/30/2025

Lexon Insurance Company

November 20, 2024

Nevada Board of Pharmacy

Bond Name: KUEHNE + NAGEL INC.
Bond Number: 413722
Amount: $100,000.00
Effective Date: 10/31/2006

Rider Executed and Effective November 20, 2024

The above referenced bond includes the following K+N facility location to ensure sufficient coverage:

1025 Columbia Rd, Suite 110, Plainfield, IN 46168

4080 Executive Drive, Suite 100, Southaven, MS 38672

2555 USA Parkway, Suite 104, McCarran, NV 89434

324 Half Acre Road, Cranbury, NJ 08512

2532 Whilden Drive, Durham, NC 27713

6005 Freeport Avenue, Suite 103, Memphis, TN 38141

2600 Regent Blvd Dallas, TX 75261

1800 Waters Ridge Drive, Suite 100, Lewisville, TX 75057

Nothing herein contained shall be held to vary, alter or waive or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond or policy, other than as above stated.

Lexon Insurance Company

James Reiss, Attorney in Fact

By:

NEVADA STATE BOARD OF PHARMACY

555 Double Eagle Court #1100
Reno, Nevada 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 0413722

Application/License No. WR00941

Kuehne + Nagel Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 6005 Freeport Ave #J-122, Memphis TN 38141 (Address of Applicant/Principal), as PRINCIPAL, and International Fidelity Insurance Co. (Surety Company), a corporation organized under the laws of the state of New Jersey (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Newark Center, Newark NJ 07102 (Address of Surety), as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on _____ (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in term and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal

may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.

(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.

(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.

(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.

(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.

(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this _____ day of _____, 20____.

APPLICANT/PRINCIPAL

_____
Authorized Representative

SURETY COMPANY

International Fidelity Ins. Co.
Surety Company's Representative

Kevin A. Tattam, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

Benny Munoz
Witness

Martino Sessa
Witness

Countersigned by:

Nevada Resident Agent

NEVADA BONDING AGENCY, INC.
P.O. BOX 60987
LAS VEGAS, NV 89160
PHONE (702) 631-0878
FAX (702) 647-5301

POWER OF ATTORNEY

LX - 015431

Lexon Insurance Company

KNOW ALL MEN BY THESE PRESENTS, that **LEXON INSURANCE COMPANY**, a Texas Corporation, with its principal office in Louisville, Kentucky, does hereby constitute and appoint: Kevin Tattam **********

****

its true and lawful Attorney(s)-In-Fact to make, execute, seal and deliver for, and on its behalf as surety, any and all bonds, undertakings or other writings obligatory in nature of a bond.

This authority is made under and by the authority of a resolution which was passed by the Board of Directors of **LEXON INSURANCE COMPANY** on the 1st day of July, 2003 as follows:

Resolved, that the President of the Company is hereby authorized to appoint and empower any representative of the Company or other person or persons as Attorney-In-Fact to execute on behalf of the Company any bonds, undertakings, policies, contracts of indemnity or other writings obligatory in nature of a bond not to exceed $ 7,100,000.00 Seven million one hundred thousand dollars dollars, which the Company might execute through its duly elected officers, and affix the seal of the Company thereto. Any said execution of such documents by an Attorney-In-Fact shall be as binding upon the Company as if they had been duly executed and acknowledged by the regularly elected officers of the Company. Any Attorney-In-Fact, so appointed, may be removed for good cause and the authority so granted may be revoked as specified in the Power of Attorney.

Resolved, that the signature of the President and the seal of the Company may be affixed by facsimile on any power of attorney granted, and the signature of the Vice President, and the seal of the Company may be affixed by facsimile to any certificate of any such power and any such power or certificate bearing such facsimile signature and seal shall be valid and binding on the Company. Any such power so executed and sealed and certificate so executed and sealed shall, with respect to any bond of undertaking to which it is attached, continue to be valid and binding on the Company.

IN WITNESS THEREOF, **LEXON INSURANCE COMPANY** has caused this instrument to be signed by its President, and its Corporate Seal to be affixed this 2nd day of July, 2003.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

LEXON INSURANCE COMPANY

BY _____
David E. Campbell
President

ACKNOWLEDGEMENT

On this 2nd day of July, 2003, before me, personally came David E. Campbell to me known, who being duly sworn, did depose and say that he is the President of **LEXON INSURANCE COMPANY**, the corporation described in and which executed the above instrument; that he executed said instrument on behalf of the corporation by authority of his office under the By-laws of said corporation.

"OFFICIAL SEAL"
MAUREEN K. AYE
Notary Public, State of Illinois
My Commission Expires 09/21/09

_____
Maureen K. Aye
Notary Public

CERTIFICATE

I, the undersigned, Secretary of **LEXON INSURANCE COMPANY**, A Texas Insurance Company, DO HEREBY CERTIFY that the original Power of Attorney of which the foregoing is a true and correct copy, is in full force and effect and has not been revoked and the resolutions as set forth are now in force.

Signed and Sealed at Lombard, Illinois this 31st Day of Oct., 20 08.

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

_____
Donald D. Buchanan
Secretary

TEL: (201) 653-6100
BOND FAX: (201) 653-7766
MARINE FAX: (201) 533-8611

EMAIL: bond@intlbondmarine.com
marine@intlbondmarine.com

INTERNATIONAL BOND & MARINE BROKERAGE, LTD.
Two Hudson Place • 4th Floor • Hoboken, NJ 07030-5515
www.intlbondmarine.com

October 28, 2008

Via Certified Mail / RRR
7005 1820 00006 2888 3457

Attn: Candy
Nevada State Board of Pharmacy
431 W Plumb Lane
Reno, NV 89509 - 3766

Re: Kuehne + Nagel, Inc.
Pharmaceutical Wholesaler Surety Bond
Bond # 413722

Dear Candy:

Enclosed please find the Change in Surety Rider and power of attorney for the above captioned bond. Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company Bond as of the anniversary date of October 31st, 2008. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount remain unchanged.

If you have any questions or require additional information please feel free to contact our office.

Sincerely,

Shayna Betancourt

Shayna Betancourt
Assistant Surety Manage
International Bond & Ma

Enclosure

SENDER: COMPLETE THIS SECTION

- Complete items 1, 2, and 3. Also complete item 4 if Restricted Delivery is desired.
- Print your name and address on the reverse so that we can return the card to you.
- Attach this card to the back of the mailpiece, or on the front if space permits.

1. Article Addressed to:
Attn Candy
Nevada State board of Pharmacy
431 W Plumb Lane
Reno, NV 89509

COMPLETE THIS SECTION ON DELIVERY

A. Signature X — ☐ Agent ☐ Addressee

B. Received by (Printed Name) L. Hedan — C. Date of Delivery

D. Is delivery address different from item 1? ☐ Yes ☐ No
If YES, enter delivery address below:

NOV 03 2008

3. Service Type
☑ Certified Mail ☐ Express Mail
☑ Registered ☐ Return Receipt for Merchandise
☐ Insured Mail ☐ C.O.D.

4. Restricted Delivery? (Extra Fee) ☐ Yes

2. Article Number (Transfer from service label) 7005 1820 0006 2888 3457

PS Form 3811, February 2004 Domestic Return Receipt 102595-02-M-1540

"SERVING THE

Lexon Insurance Company
(a TX Corporation)
256 Jackson Meadows Drive
Hermitage, TN 37076

Bond Rider

Principal: KUEHNE + NAGEL, INC
Bond Number: 413722
Effective Date of Rider: 10/31/08

Change in Surety

Lexon Insurance Company is substituted for International Fidelity Insurance Company as the bond surety.

Lexon Insurance Company assumes all obligations of the above referenced International Fidelity Insurance Company as of the above referenced effective date of the rider. All other terms and conditions of the bond and any previously issued riders to said bond, including the bond amount, remain unchanged.

Nothing herein contained otherwise shall be held to vary, alter, waive, or extend any of the terms, conditions, provisions, agreements or limitations of the above mentioned Bond.

Lexon Insurance Company
Attorney-in-fact, Kevin A. Tattam 143-48-7151

By: _____

LEXON INSURANCE COMPANY
A TEXAS INSURANCE COMPANY

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Kuehne+Nagel Inc. MDEG License # (if applicable) WH03267

Physical Address 4080 Executive Drive Ste 100

City Southaven State MS Zip 38672

Mailing Address (if different from physical address) 10 Exchange Place 20th Floor

City Jersey City State NJ Zip 07302

Telephone 201-413-5500 Website https://us.kuehne-nagel.com/

Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Stephen Middle Lloyd Last Berry

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Cordova State TN Zip [redacted]

Telephone [redacted] Email stephen.berry@kuehne-nagel.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Alcorn State University		1995-2000	
Address	**City**	**State**	**Zip**
1000 Asu Drive	Lorman	MS	39096
Diploma/Degree obtained, if any			
BS Industrial Technology			

School Name		From - To (MM/YY – MM/YY)	
West Point High School South		08/87-05/89	
Address	**City**	**State**	**Zip**
950 South Eshman Ave	West Point	MS	39773
Diploma/Degree obtained, if any			
High School Diploma-Industrial Arts			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2024 to present	[redacted]	Cordova	TN	[redacted]
03/2020 to 09/2024		Memphis	TN	
08/2017 to 01/2020		Memphis	TN	
05/2012 to 09/2017		Memphis	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)
Kuehne+Nagel Inc.			10/23-present
Business Address	**City**	**State**	**Zip**
4080 Executive Drive Ste 100	Southaven	MS	38672
Phone	**Title**	**Number of Employed Hours**	
201-413-5500	Contract Logistic Quality Supervisor	N/A	
Description of Duties			
N/A Resume			

Business Name			From - To (MM/YY – MM/YY)
Flex Industries			06/22-05/23
Business Address	**City**	**State**	**Zip**
N/A	Memphis	TN	N/A
Phone	**Title**	**Number of Employed Hours**	
N/A	Quality Engineer II	N/A	
Description of Duties	Develops and initiates standards and methods for inspection, testing and evaluation. Devises sampling procedures and designs and develops forms and instructions for recording, evaluating and reporting quality and reliability data. Develops and implements methods and procedures for disposition of discrepant material and devises methods to assess cost and responsibility. Directs workers engaged in measuring and testing product and tabulating data concerning materials, product or process quality and reliability. Compiles and writes training material and conducts training sessions on quality control activities. Supports Product Engineers and Quality Program Managers with customer interfaces as necessary on quality related issues. Assures data availability and integrity for all quality related data. Consolidates and reports quality results. Initiates corrective action requests as needed and tracks to satisfactory completion. Assists with development and implementation of quality audits. Responsible for developing, approving, revising and maintaining quality standards for processing materials and partially finished or finished products. Designs and implements methods and procedures for inspecting, testing and evaluating the precision and accuracy of products and or production equipment. Analyzes reports and returned products and recommends corrective action.		

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

13 Feb 2025
Date

I, Stephen Berry, certify that as the MDEG Administrator for

Kuehne+Nagel Inc.,

that I (initial that you have read and meet the following requirements):

1. SLB Have a high school diploma or its equivalent;
2. SLB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. SLB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. SLB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stephen Berry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

13 Feb 2025
Date

Board Use Only	Date Received:

STEPHEN L. **BERRY**

[redacted]

OBJECTIVE

To find and obtain an engineering or management position in the manufacturing field that suitably challenges my education and experience.

PROFESSIONAL EXPERIENCE

Quality Supervisor

Kuehne + Nagel, October 2023 – Present | Southaven, MS

- Provides leadership and support to quality activities for product handling and distribution operations.
- Drives quality initiates including overseeing the quality auditing process and establishing Process Metrics and KPIs
- Assures accurate review and disposition of non-conforming products including management of product damage, expiry, quarantine, hold, returned goods, and recalls, ensuring that all relevant data is documented and communicated to clients.
- Responsible for monitoring the daily labor, work schedules, and daily attendance of employees.
- Supports and coordinate tasks associated with meetings, presentations, and training as needed.
- Performs inspections and audits as required.
- Investigates overdue and damaged shipments or shortages in shipments for customers.
- Analyzes complaints concerning services rendered. Refer complaints of service failures to designated departments for investigation and updating customers.
- Records and retain meeting minutes.
- Supports the maintenance of the Quality Management System.
- Attends daily, weekly, monthly, and quarterly meetings on quality.
- Determines the Cause of Corrective Action using problem-solving tools.
- Analyzes reports and returned products and recommends corrective action.
- Establishes program to evaluate precision and accuracy of production equipment and testing, measurement and analytical equipment and facilities.
- Approves product, process and equipment qualifications Provides liaison to various regulatory bodies.

Quality Engineer II

Flex Industries, June 2022 – October 2023 | Memphis, TN

- Develops and initiates standards and methods for inspection, testing and evaluation.
- Devises sampling procedures and designs and develops forms and instructions for recording, evaluating and reporting quality and reliability data.
- Develops and implements methods and procedures for disposition of discrepant material and devises methods to assess cost and responsibility.
- Directs workers engaged in measuring and testing product and tabulating data concerning materials, product or process quality and reliability.
- Compiles and writes training material and conducts training sessions on quality control activities.
- Supports Product Engineers and Quality Program Managers with customer interfaces as necessary on quality related issues.

- Assures data availability and integrity for all quality related data.
- Consolidates and reports quality results.
- Initiates corrective action requests as needed and tracks to satisfactory completion.
- Assists with development and implementation of quality audits.
- Responsible for developing, applying, revising and maintaining quality standards for processing materials into partially finished or finished products.
- Designs and implements methods and procedures for inspecting, testing and evaluating the precision and accuracy of products and/or production equipment.
- Analyzes reports and returned products and recommends corrective action.
- Establishes program to evaluate precision and accuracy of production equipment and testing, measurement and analytical equipment and facilities.
- Approves product, process and equipment qualifications Provides liaison to various regulatory bodies.

Quality Assurance Operation Specialist III

Charles Rivers Laboratories, October 2021 – June 2022 | Memphis, TN

- Review manufacturing Batch Production Records (BPRs) and associated supporting documentation including logbooks, Quality Control (QC) testing reports, environmental monitoring reports, etc.
- Perform line clearance and provide general manufacturing support.
- Supports product shipment and receipt of returns.
- Manage raw material review and disposition.
- Manage raw material QA Release Process and Procedure.
- Review Building Management Systems reports.
- Participate in departmental and cross-functional continuous improvement efforts.
- Consistently set a high standard for quality of work.
- Promote a safety mindset through daily actions and communication with team members.
- Issue BPR and labels to Manufacturing.
- Serve as owner of assigned nonconformances, CAPA, change controls, or other quality system documents and collaborate to drive completion.
- Review and approve documents in Master Control.
- Prepare lot packages for disposition decision by management.

Quality Assurance Operation Specialist II

Cognate BioServices, August 2020 – October 2021 | Memphis, TN

- Review manufacturing Batch Production Records (BPRs) and associated supporting documentation including logbooks, Quality Control (QC) testing reports, environmental monitoring reports, etc.
- Perform line clearance and provide general manufacturing support.
- Supports product shipment and receipt of returns.
- Support raw material review and disposition.
- Review Building Management Systems reports.
- Participate in departmental and cross-functional continuous improvement efforts.
- Consistently set a high standard for quality of work.
- Promote a safety mindset through daily actions and communication with team members.
- Issue BPR and labels to Manufacturing.
- Serve as owner of assigned nonconformances, CAPA, change controls, or other quality system documents and collaborate to drive completion.
- Review and approve documents in Master Control.
- Prepare lot packages for disposition decision by management.

Quality Assurance Coordinator

FedEx Trade Network, September 2018 – August 2020 | Memphis, TN

- Review and correct entries based on regulatory requirements such as but not limited to: Free Trade Agreements, Classification, Other Government Agencies, Licenses and Valuations.
- Reviews and research entries to determine if compliant and make changes as necessary to minimize regulatory risk to our customers and FTN as the last point of review prior to submission to CBP.
- Ensures that all decisions made are executed based on Regulatory agency training guidelines and entry processing procedures.
- Performs customers' reviews to ensure entries are filed in accordance with the customers' requirements and specifications within the designated time frames.
- Utilizes Standard Operating Procedures (SOP), Part # databases, customer proprietary systems and applications. Communicates with the appropriate FTN workgroup and/or customers.
- Assesses appropriate level of duties/taxes payable to CBP and/or validates the importance of any special program indicators and terms of sale that may apply.
- Ensures all information obtained during the review of the entry is imaged for record retention purposes using the proper document types.
- Corrects ABI errors to ensure timely submission and payment of entries to CBP.
- Reviews Census Warnings and validate entered data, communicates with the customers and/or solicit additional documentation needed and transmit override code to CBP if necessary.
- Issues referrals in the required format for accurate reporting.
- Corresponds in writing or by telephone with customers, CBP or other governmental agencies at all levels regarding required documentation to resolve issues that could result in fines and penalties.
- Communicates any updates and corrections to databases or profiles to internal and external customers improving customer retention and experience.
- Thorough understanding of the different requirements in systems and processes for each FTN division such as Air & Ocean, Border, CPA and GENEX.

Quality Technician III

Jabil Circuit Inc., June 2018 – September 2018 | Memphis, TN

- Inspects, measures, and tests mechanical, electrical and electromechanical components and assemblies.
- Verifies material conformance to specifications. Interprets company and industrial specifications.
- Gathers and maintains specific records of technical data related to materials, tools, fixtures and processes used in company.
- Creates and maintains inspection plans, logs and reports.
- Compiles reports using information gathered from quality, manufacturing and research projects.
- Develops measurement processes.
- Collects and analyzes data using statistical analysis methods.

Quality Technician

DuNan Precision Manufacturing Inc., January 2017 – September 2017 | Memphis, TN

- Assist with the management of the company's management system based on integration and adaptation of recognized and generally accepted industry practices in accordance with ISO-9001 as far as practicable to company operations.
- Assist with plant quality functions for both existing and new launch programs. Participate in APQP meetings, work with internal and external engineering staff for requirements to operation personnel.
- Apply quality engineering practices and guidance to support project teams and manufacturing operations using Six Sigma tools, FMEA, Process Capability, Process Performance, Cause and Effect diagrams and matrices, measurement system analysis, design of experiments, Process Validation Protocol and Control Plan Development.

- Collect data for product monitoring and measurement systems analyses.
- Collect and manage data for non-conforming and corrective action databases for disposition and resolution.

Quality Control Inspector I/First Article Coordinator

Zimmer Spine, Inc., April 2013 – September 2016 | Memphis, TN

- Utilize overall quality control and first article activities.
- Inspect and test incoming materials, implant devices, instruments and components.
- Utilize inspection tools such as micrometers, calipers, height gages, and optical comparators to assist in the calculations for quality improvement.
- Recommend alternate inspection methods to the quality engineer for quality improvement.
- Assist in closing out CAPA deviations for quality engineers.
- Complete inspection request for company suppliers.
- Maintain and complete internal and supplier corrective action request.
- Perform gage repeatability and reliability studies.
- Maintain accurate documentation during the inspection process to maintain Good Manufacturing Practices.
- Document all activities in a manner complaint with regulatory requirements (QSR, MDD, CMDR, ISO, etc.).

Quality Control Inspector I

Medtronic, Inc., September 2010 – April 2013 | Memphis, TN

- Assure compliance to MSD requirements in inspection and record keeping; Collect inspection data and report results.
- Utilize inspection tools such as micrometers, calipers, height gages, and optical comparators to assist in the calculations for quality improvement.
- Maintain accurate documentation during the inspection process to maintain Good Manufacturing Practices.
- Work with Quality Engineering to drive corrective actions and assure all raw materials received meets specifications.

Quality Technician

Greenlee, Inc., May 2010 – September 2010 | Southaven, MS

- Work with departments to audit and resolve compliance issues; provide recommendation, communication on status of action resolution and bringing to management issues that require attention tracking corrective actions.
- Plan, execute and prepare audit reports.

Quality Technician

Varsity Brands, Inc., April 2008 – June 2009 | Bartlett, TN

- Tested, evaluated, and compared raw materials using technical methods and procedures to ensure that vendors receive quality merchandise.
- Assisted in the development of inspection technique for product.
- Reported to the Quality Manager with analytical color comparison results of recent fabric submits from vendors using Spectra Light III technology.

Technical Service Coordinator

Eka Chemicals, Inc., September 2006 – October 2017 | Columbus, MS

- Lead safety seminars and instructed employees on the appropriate ways to handle high concentration of hydrogen peroxide and sodium chlorate.
- Supervised first fill tank projects and product stewardship evaluations for customers throughout the United States.
- Facilitated all tank and skid unit modifications for safety standards for operating projects by reading blueprints and using measuring equipment such as micrometers, calipers and rulers.
- Responded to emergency calls for sensitive chemical situations involving hydrogen peroxide and sodium chlorate.

EDUCATION

Bachelor of Science in Industrial Technology

Alcorn State University, 1995 – 2000 | Lorman, MS

KEY SKILLS

- Foxfire, MRP, Red Prairie, JD Edwards, Agile/SCRUM, SAP, RF Scanning Technology, GMP, Quality Control, ISO Quality Systems, ISO9001, ISO14001 Environmental Systems, ISO13485, 5S process, Total Quality Management, configuration Management, PPAP, HACCP, JIT, CAPA Process, Root Cause Investigation, FMEA, Lean Manufacturing, Lean Warehousing, Gage R&R, OSHA Standards, DOT Certified, GD&T, ASQ, Quality Planning, Quality Cost, and Assessment. Minitab, Microsoft office products (Word, Excel, Access, PowerPoint and Project)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Kuehne + Nagel Inc.
Pharmacy/Wholesaler License # (if applicable) WH03267
Physical Address 4080 Executive Drive, Suite 100
City Southaven State MS Zip 38672
Mailing Address (if different from physical address) 10 Exchange Place 20th Floor
City Jersey City State NJ Zip 07302
Telephone 201-413-5500 Website https://us.kuehne-nagel.com/
Licensing Company Email qshepharma.us@kuehne-nagel.com

Section 2: Personal Information

First Stephen Middle Lloyd Last Berry
Alias(es, nicknames, name changes, etc.) N/A
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Addre[redacted]
City Cordova State T N Zip [redacted]
Telephone [redacted] Email stephen.berry@kuehne-nagel.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Alcorn State University		1995-2000	
Address	**City**	**State**	**Zip**
1000 Asu Dr	Lorman	MS	39096
Diploma/Degree obtained, if any			
B.S Industrial Technology			

School Name		From - To (MM/YY – MM/YY)	
West Point High School South		08/87 to 05/89	
Address	**City**	**State**	**Zip**
950 South Eshman Ave	West Point	MS	39773
Diploma/Degree obtained, if any			
High School Diploma-Industrial Arts			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2024 to present	[redacted]	Cordova	TN	[redacted]
03/2020 to 09/2024		Memphis	TN	
08/2017 to 01/2020		Memphis	TN	
05/2012 to 09/2017		Memphis	TN	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Kuehne + Nagel Inc.			From - To (MM/YY – MM/YY): 10/23-Present
Business Address: 4080 Executive Drive, Suite 100	City: Southaven	State: MS	Zip: 38672
Phone: 201-413-5500	Title: Contract Logistic Quality Supervisor		Number of Employed Hours: N/A
Description of Duties: N/A Resume			

Business Name: Flex Industries			From - To (MM/YY – MM/YY): 06/22-05/23
Business Address: N/A	City: Memphis	State: TN	Zip: N/A
Phone: N/A	Title: Quality Engineer II		Number of Employed Hours: N/A
Description of Duties: Develops and initiates standards and methods for inspection, testing and evaluation. Devises sampling procedures and designs and develops forms and instructions for recording, evaluating and reporting quality and reliability data. Develops and implements methods and procedures for disposition of discrepant material and devises methods to assess cost and responsibility. Directs workers engaged in measuring and testing product and tabulating data concerning materials, product or process quality and reliability. Compiles and writes training material and conducts training sessions on quality control activities. Supports Product Engineers and Quality Program Managers with customer interfaces as necessary on quality related issues. Assures data availability and integrity for all quality related data. Consolidates and reports quality results. Initiates corrective action requests as needed and tracks to satisfactory completion. Assists with development and implementation of quality audits. Responsible for developing, applying, revising and maintaining quality standards for processing materials into partially finished or finished products. Designs and implements methods and procedures for inspecting, testing and evaluating the precision and accuracy of products and/or production equipment. Analyzes reports and returned products and recommends corrective action.			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer),		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

19 Nov 2024
Date

I, Stephen Berry, **certify that as the designated representative for**

Kuehne + Nagel Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. SLB I am at least 21 years of age;
3. SLB I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. SLB I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. SLB I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. SLB I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. SLB I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Stephen Berry
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

19 Nov 2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Stephen Berry
Print Name (First, Last)

Original Signature (electronic copies or stamps not accepted)

19 Nov 2024
Date

Please have this section completed in the presence of a Notary Public.

State of Mississippi, ss. County of DeSoto

I, Stephen Berry, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

19 Nov 2024
Date

Subscribed and Sworn to before me this 19 day of November.

Notary Public Signature

STATE OF MISSISSIPPI
TREY HOPKINS
NOTARY PUBLIC
ID No. 209658
Comm. Expires
Nov. 29, 2024
DESOTO COUNTY
(Seal)

SOUTHAVEN
EMPLOYEE NAMES
Edna Aguilar
Joshua Allen
Derrick Anderson
Martin Anderson
Eboni Ballard
Brenda Banks
Joshua Bell
Eugene Blue
Jaboris Boatman
Nina Booker
Kendrick Brown
Roger Brown
Terry Butler
Electra Butler
Luz Calderon
Regina Caldwell
Brooks Caldwell
Portia Callicott
Celeste Catron
Kimberly Chapman
Lawrence Clark
Denquarion Conrad
Sharon Craddock
Daron Faulkner
Archie Felston
Makasha Fleming
Nathan Forbes
Anlisia Fry
Percy Gardner
Ronnie Geater
Martire Geraldine
Michelle Gonzalez
Anthony Gonzalez
John Graves
Willie Graves
Olga Gutierrez
Andrea Hampton-Rayborn
Darwante Hardmon
Andrew Harvey
Ceddrick Harwell
Quinton Haynes
Diontez Henry
Jakiel Honorable
Fate Howell

Nachasity Hubbard
Charnese Hudson
Elizabeth Hughes
Brandon Hunter
Maureen Ishmon
Carolyn Jackson
Sharbie Jackson
Anissa Jackson
Jonathan Jenkins
Angel Johnson
Dinastie Johnson
Wonda Johnson
Kenny Johnson
Laquita Jones
Damyon Jones
Tempestt Joyner
Javon Key
Tierra Keys
Ervin Laws
William Lee
Linda Luna
Chasity Maclin
Cheryl Malone
KeAsia McBride
Malik McCain
Olga Mejia
Ana Melendez
Yolonda Mendoza
Birttany Milam
Rodney Miller
Marshall Montgomery
Latreasure Moore
Kelvin Neely
Cairee Nolden
Lakenya Odell
Darsha Odom
Jalia Patterson
Sandra Patton
Nathan Pine
Oscar Price
Victor Procter
Kuerstine Raine
Daniel Rawls
Gregory Redmond
Millie Rodriguez
Mario Saulsberry
Shaderrica Scott

Ezavia Sevire
Vincent Showers
Wilbur Smith
Serverdia Snow
Marcus Strowder
Robert Taylor
Emmanuel Tenniel
Marqueentin Todd
Steven Tolliver
Jayallia Twillie
Barbra Vinson
Gus Walker
Jaylen Wallace
Alexandria White
Marco Whitelaw
Lashockalin Wilks
Joseph Williams
Sandrea Williams
Maurice Williams
Jasmine Williams
Ajecia Willie
Jeffrey Wilson
Anthony Woodard
Irma Woodson
Otha Wright
Maxwell Hennen
Deangelis Nelson
Xavier Wright
Christopher Hardaway
Billy Dasinger
Thomas Brown
Charles Randles
Angelic Garnder
Rodney Yarbrough
Yesenia Perez
Ron Baney
Latricia Parks
Michael Scott
Amber Rubin
Lawrence Davis
Terrell Cordel
Balondemu Olatunji
Linda Williams
Geizi Vera
Tontreall Houston
Daizsha Avery
James Smith jr

Quadrodquiz Carter
Edris Conley
Fuentes-Cortez
Jamie Garrison
Mory Niang
Demetric Pollard
Erin Ballard
Kevin Holland
Herbert Walton
Miguel Rosas
Deonika Dockins
David Giles
Titus James
Erin Harris
Travis Williams
Carl Biddle
Nicolas Triplett
Aubles Buchana
Lucas Smith
Wenona Piniy

Mississippi Board of Pharmacy

Inspection Details

Name
Kuehne + Nagel Inc.

DBA
Kuehne + Nagel Inc.

Address
4080 Executive Drive
Suite 100
Southaven, MS 38672
Desoto

Permit #
18430 [16.3]

CS #
NA - ()

Compounding #

Designated Representative
Aricia Boyd

DEA #:

DEA Expiration:

Inspection Date
09/11/2023

Inspection User
Pugh, Gerald

Assigned To

Comments

None

WDD, 3PL, Vet, Virtual

	Answer	Question
Verify Permits		
1)	Satisfactory	Board of Pharmacy.
		Comments: 18430-16.3
2)	Not Applicable	Controlled Substance.
3)	Not Applicable	DEA.
4)	Not Applicable	FDA.
5)	Satisfactory	Facility is of suitable size and construction and staffed.
		Comments: 263,000
6)	Satisfactory	Is there product in the facility?
		Comments: CORDIS
7)	Satisfactory	Facility is free from any infestation by insects, rodents, birds, etc. (Has SOP).
		Comments: TERMINIX 8-22-2023
Storage & Packaging Areas		
8)	Satisfactory	Lighting.
9)	Satisfactory	Ventilation.
10)	Satisfactory	Sanitation.
11)	Satisfactory	Space.
12)	Satisfactory	Security.
13)	Satisfactory	Equipment.
14)	Satisfactory	Doors locked and access limited.

WDD, 3PL, Vet, Virtual

	Answer	Question
		Comments: BADGE ACCESS
15)	Satisfactory	Sign in and identification required.
16)	Satisfactory	Storage area has designated and clearly marked quarantine areas.
17)	Satisfactory	Storage area is clean and well organized.
18)	Satisfactory	Facility is equipped with working security system suitable for protection against theft or diversion of product and tampering with computer or electronic records.
		Comments: EAGLE EYE
19)	Satisfactory	Shipping and receiving records readily available for inspection.
20)	Satisfactory	Inventories and records of all transactions for all drugs, devices, and/or medical gases are current.
21)	Satisfactory	Temperature and humidity monitoring logs are maintained and current.
22)	Satisfactory	Verification of customer licenses authorizing purchase of drug products.
		Comments: CORPORATE
23)	Satisfactory	Has verified that all suppliers and trading partners are licensed by Mississippi Board of Pharmacy.
		Comments: CORPORATE

Standard Operating Procedures

24)	Satisfactory	Receipt of drugs, and devices.
		Comments: SVQH-100
25)	Satisfactory	Shipping of drugs and devices.
		Comments: WISVQH406
26)	Satisfactory	Inventory and distribution.
		Comments: SVQH-204
27)	Satisfactory	Quality inspection of all incoming and outgoing shipments.
		Comments: SVQH-406
28)	Satisfactory	Product rotation (FIFO).
		Comments: 2823
29)	Satisfactory	Product recalls and withdrawals.
		Comments: 2823
30)	Satisfactory	Return or out of date product Quarantine.
		Comments: 2823
31)	Satisfactory	Complaints and adverse events.

WDD, 3PL, Vet, Virtual

	Answer	Question
		Comments: GUSZQ103 6.1
32)	Not Applicable	DSCSA transaction report.
33)	Satisfactory	Security and crisis handling.
		Comments: 10345
34)	Satisfactory	Validation of customer state licenses and FDA/DEA registration.
		Comments: 10343 CORPORATE
35)	Satisfactory	Notification of theft and diversions.
		Comments: 10345
36)	Satisfactory	Finding of contraband and counterfeit.
		Comments: 10345
37)	Satisfactory	List of agreements with all trading partners.
		Comments: 100604-209
38)	Satisfactory	Is warehouse and storage areas restricted to authorized personnel?
		Comments: BADGE ACCESS
39)	Satisfactory	Is there a training program for all employees including cGMP training (records of)?

Owners/Officers/Responsible Parties

40)	Satisfactory	List of employees with access to product.
		Comments: BADGE ACCESS
41)	Satisfactory	List of employees with access to building after hours.
		Comments: MANAGEMENT

Controlled Substance Handling

42)	Not Applicable	Has current DEA registration.
43)	Not Applicable	Has CS cage/vault and a list of employees with access.

Person Providing Information

Full Name:
ARICIA BOYD

Signature:



4ZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State
Type of Application (check applicable box)	**Wholesaler Business Type (check applicable box)**
☐ New Wholesaler ■ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only) * If making a change, provide current license number: WH 02786	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: PI Services LLC

Physical Address: 2010 Filmore Ave.

City: Erie State: PA Zip: 16506

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: (814) 616-2502 Website: https://pi-svc.com/

Name of Designated Representative (DR): Ashley Ruhland

Licensing Company Email: licensing@blinkhealth.com DR Email: ashley.ruhland@blinkhealth.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Mayne Pharma Commercial LLC
Address: 3301 Benson Dr. Ste 401 City: Raleigh State: NC Zip: 27609
Name: No other suppliers at this time.
Address: City: State: Zip:
Name:
Address: City: State: Zip:
Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Pennsylvania
Parent Company (if any): P.I. Services LLC
Corporation/Organization Name: Blink Health Inc.
Mailing Address: 1407 Broadway, Rm 1910
City: New York State: NY Zip: 10018
Telephone: 646-201-9585 Email: licensing@blinkhealth.com
Contact Person Name: Julie Loftus

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✓	
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

PI Services LLC

Facility Name

Michael Nameth

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

2/19/2025

Date

Board Use Only	Date Received: 3/3/25	Amount: $1000 ck 3170

NABP ACCREDITED
DRUG DISTRIBUTOR

PI Services, LLC

located at

2010 Filmore Avenue, Erie, PA 16506

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

10/20/2023 - 10/19/2026
Period of Accreditation

P.I. Services LLC
(Pennsylvania)
May 3, 2012
1407 Broadway, Suite 1910
New York, NY 10018
FEIN #37-1694004

<table>
<tr><td colspan="2"><u>Ownership Information</u>
Blink Health Inc.
(Delaware)
June 5, 2019
1407 Broadway, Suite 1910
New York, NY 10018
FEIN: 84-2139318
Ownership: 100% of P.I. Services LLC</td></tr>
<tr><td><u>Geoffrey Chaiken</u>
Chief Executive Officer

Business Address:
1407 Broadway, Suite 1910
New York, NY 10018

[redacted]</td><td><u>Michael Nameth</u>
Executive Vice President, Cloud and Specialty Pharmacy

Business Address:
1407 Broadway, Suite 1910
New York, NY 10018

P[redacted]

Ohio Pharmacist #03311863 Issued 8/4/1976
West Virginia Pharmacist #RP0003476 Issued 6/5/1978</td></tr>
</table>

No Officer has an ownership interest in the entity.

Docusign Envelope ID: A1C8EF4A-31CE-462C-BCEC-53EF3B99DA6A

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	P.I. Services LLC
Request Type:	Subsistence Certificate
Request No.:	050125713
Receipt No.:	001407504
Filing Type:	Domestic Limited Liability Company
Filing Subtype:	Limited Liability Company
Initial Filing Date:	April 16, 2012
Status:	Active

Issuance Date: January 29, 2025
File No.: 0004102120

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

P.I. Services LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.

COMMONWEALTH OF PENNSYLVANIA • DEPARTMENT OF STATE •

IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

Certificate of Licensure

Certificate No. 8000002843
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Wholesaler/Distributor

Drug & Device Registration
2525 N. 7th ST.
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

PI SERVICES, LLC
PHARMACY INNOVATION SERVICES
2010 FILMORE AVENUE
ERIE, PA 16506

The above business is registered in the required category to conduct and maintain a facility in accordance with the provisions of the Wholesale Prescription Drug License Act, Act #145, approved December 14, 1992.

Issuance Date: October 04, 2016
Expiration Date: The Last Day of October, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Certificate of Registration

Certificate No. 3000009579
(A certificate starting with a number 4, 5 or 6 does not permit the posession or sale of controlled substances or prescription drugs.)

Category:

Distributor (Prescription)

Drug & Device Registration
2525 N. 7th ST.
SUITE 210D
HARRISBURG, PA 17110
(717) 787-4779

PI SERVICES, LLC
PHARMACY INNOVATION SERVICES
2010 FILMORE AVENUE
ERIE, PA 16506

The above business is registered in the required category to conduct a[illegible] maintain a facility in accordance with the provisions of the Controlled Substance, Drug, Device and Cosmetic Act #64, approved September 9, 1972.

Issuance Date: October 04, 2016
Expiration Date: The Last Day of October, 2025

Jeanne Parisi
Deputy Secretary for Quality Assurance

pennsylvania
DEPARTMENT OF HEALTH

Debra L. Bogen, MD, FAAP
Secretary of Health

NOTE: THIS CERTIFICATE MUST BE POSTED IN A CONSPICUOUS PLACE ON THE PREMISES.

Pennsylvania Department of Health

Pennsylvania Department of Health

Drug, Device and Cosmetic Program

Version 4.0.0

Enter the 10-digit Certificate Number or Registrant's Name (or first few letters).

Lookup

Description of Certificate Categories

You may contact our office at (717) 787-4779 if the Certificate Number/Registrant you are researching is not found.

PI Services, LLC Pharmacy Innovation Services 2010 Filmore Avenue; Erie, PA 16506
Certificate(s): **3000009579** issued: 10/04/2016 expires: 10/31/2025; **8000002843** issued: 10/04/2016 expires: 10/31/2025

The entity noted above holds an active registration and/or license with the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program.

No formal probation, suspension, revocation, or formal disciplinary action has been issued directly by the Pennsylvania Department of Health Drug, Device, and Cosmetic (DDC) program against the aforementioned specific registration and/or license. Contact the DDC program with any further questions at (717) 787-4779 or email: ra-ddc@pa.gov

Back to DD&C Home

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Assembly Version 4.0.0.0

Database Version Could not retrieve database version. Check that the database is registered as a Data-tier Application.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. CMS0390681

Application/License No. _____

PI Services LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2010 Filmore Ave., Erie, PA 16506 (Address of Applicant/Principal), as PRINCIPAL, and RLI Insurance Company (Surety Company), a corporation organized under the laws of the state of IL (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 9025 N. Lindbergh Drive, Peoria, IL 61615 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on February 21, 2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

Posted February 20, 2020

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 21st day of February, 2025.

APPLICANT/PRINCIPAL

PI Services LLC
COMPANY

By: _____
Authorized Representative

SURETY

RLI Insurance Company

By: _____
Surety Company's Representative

Charissa D. Wilson, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

_____
Witness

_____
Witness

SIGNED and SEALED in the presence of:

_____
Witness Joshua Eichem

_____
Witness Cassidy D. Palic

Countersigned by:

N/A
Nevada Resident Agent

Posted February 20, 2020

POWER OF ATTORNEY

RLI Insurance Company
Contractors Bonding and Insurance Company

9025 N. Lindbergh Dr. Peoria, IL 61615
Phone: 800-645-2402

Bond No. CMS0390681

Know All Men by These Presents:

That this Power of Attorney is not valid or in effect unless attached to the bond which it authorizes, but may be detached by the approving officer if desired.

That this Power of Attorney may be effective and given to either or both of **RLI Insurance Company** and **Contractors Bonding and Insurance Company**, required for the applicable bond.

That **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, each Illinois corporations (as applicable), each authorized and licensed to do business in all states and the District of Columbia do hereby make, constitute and appoint: **Charissa D. Wilson** in the City of Overland Park, State of KS, it's true and lawful Agent and Attorney in Fact, with full power and authority hereby conferred upon him/her to sign, execute, acknowledge and deliver for and on its behalf as Surety, in general, any and all bonds and undertakings in an amount not to exceed Seventy Five Million Dollars ($75,000,000) for any single obligation, and specifically for the following described bond.

Principal: PI Services LLC

Obligee: Nevada State Board of Pharmacy

RLI Insurance Company and **Contractors Bonding and Insurance Company**, as applicable, have each further certified that the following is a true and exact copy of a Resolution adopted by the Board of Directors of each such corporation, and now in force, to-wit:

> **"All bonds, policies, undertakings, Powers of Attorney or other obligations of the Corporation shall be executed in the corporate name of the Corporation by the President, Secretary, any Assistant Secretary, Treasurer, or any Vice President, or by such other officers as the Board of Directors may authorize. The President, any Vice President, Secretary, any Assistant Secretary, or the Treasurer may appoint Attorneys in Fact or Agents who shall have authority to issue bonds, policies or undertakings in the name of the Corporation. The corporate seal is not necessary for the validity of any bonds, policies, undertakings, Powers of Attorney or other obligations of the Corporation. The signature of any such officer and the corporate seal may be printed by facsimile or other electronic image."**

IN WITNESS WHEREOF, **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, as applicable, have caused these presents to be executed by its respective Sr. Vice President with its corporate seal affixed this 24th day of January, 2024.

RLI INSURANCE COMPANY CORPORATE SEAL ILLINOIS

CONTRACTORS BONDING AND INSURANCE COMPANY CORPORATE SEAL ILLINOIS

RLI Insurance Company
Contractors Bonding and Insurance Company

Eric Raudins — Sr. Vice President

State of Ohio
County of Cuyahoga } SS

On this 24th day of January, 2024, before me, a Notary Public, personally appeared Eric Raudins, who being by me duly sworn, acknowledged that he signed the above Power of Attorney as the aforesaid officer of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, and acknowledged said instrument to be the voluntary act and deed of said corporation.

By: Jill A. Scott
Jill A. Scott — Notary Public

JILL A SCOTT
Notary Public
State of Ohio
My Comm. Expires
September 22, 2025

CERTIFICATE

I, the undersigned officer of **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company**, do hereby certify that the attached Power of Attorney is in full force and effect and is irrevocable; and furthermore, that the Resolution of the Company as set forth in the Power of Attorney, is now in force. In testimony whereof, I have hereunto set my hand and the seal of the **RLI Insurance Company** and/or **Contractors Bonding and Insurance Company** this 21st day of February, 2025.

RLI Insurance Company
Contractors Bonding and Insurance Company

By: Jeffrey D Fick
Jeffrey D Fick — Corporate Secretary

A00A1124

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler PI Services LLC

Pharmacy/Wholesaler License # (if applicable) WH02786

Physical Address 2010 Filmore Ave.

City Erie State PA Zip 16506

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email licensing@blinkhealth.com

Section 2: Personal Information

First Ashley Middle Elizabeth Last Ruhland

Alias(es, nicknames, name changes, etc.) Ashley Elizabeth Allender

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address [redacted]

City Erie State PA Zip [redacted]

Telephone [redacted] Email ashley.ruhland@blinkhealth.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Lake Erie College of Osteopathic Medicine (LECOM)		08/13 - 05/16	
Address	**City**	**State**	**Zip**
1858 W Grandview Blvd	Erie	PA	16509
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Clarion University of Pennsylvania		08/09 - 05/13	
Address	**City**	**State**	**Zip**
840 Wood St	Clarion	PA	16214
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
DuBois Central Catholic		08/05 - 06/09	
Address	**City**	**State**	**Zip**
200 Central Christian Road	DuBois	PA	15801
Diploma/Degree obtained, if any			
High school diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/19 -present	[redacted]	Erie	PA	[redacted]
09/17-07/19		Erie	PA	
09/16-09/17		Elizabethtown	PA	
08/13-08/16		Erie	PA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
PI Services LLC			11/20 - Present	
Business Address		**City**	**State**	**Zip**
2010 Filmore Ave.		Erie	PA	16506
Phone	**Title**		**Number of Employed Hours**	
814-616-2502	Designated Representative		~ 4160	
Description of Duties				
On-board pharmacies and vendors. Supervise warehouse manage with: ordering product, processing customer orders, drug storage. Manage inventory of commercial drugs and OTC products. Maintain compliance with state and fed laws.				

Business Name			From - To (MM/YY – MM/YY)	
Pharmacy Innovations			08/19 - present	
Business Address		**City**	**State**	**Zip**
2936 W 17th St.		Erie	PA	16505
Phone	**Title**		**Number of Employed Hours**	
814-838-2102	Staff Pharmacist		~ 4500	
Description of Duties				
Assist physicians with their patient's medications. Counsel patients. Supervise technicians. Handle + resolve customer issues + questions.				

Business Name			From - To (MM/YY – MM/YY)	
Rite Aid Pharmacy			09/17 - 07/19	
Business Address		**City**	**State**	**Zip**
353 East 6th Street		Erie	PA	16507
Phone	**Title**		**Number of Employed Hours**	
814-455-2910	Staff Pharmacist		~ 3780	
Description of Duties				
Assist customers with medical-related issues. Provide healthcare counseling + immunizations. Supervise the work done by staff.				

Business Name			From - To (MM/YY – MM/YY)	
Rite Aid Pharmacy			06/16 - 09/17	
Business Address		**City**	**State**	**Zip**
330 Cumberland Pkwy		Mechanicsburg	PA	17005
Phone	**Title**		**Number of Employed Hours**	
717-796-7685	Staff Pharmacist		~ 2590	
Description of Duties				
" " "				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Ashley Ruhland, **certify that as the designated representative for**

PI Services LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AR I am at least 21 years of age;
3. AR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ashley Ruhland

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/14/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ashley Ruhland

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/14/25

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Erie

I, Ashley Ruhland, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/14/25

Date

Subscribed and Sworn to before me this 14th day of January, 2025.

Jordyn L Froehlich

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Jordyn L. Froehlich, Notary Public
Erie County
My Commission Expires October 24, 2027
Commission Number 1434765

(Seal)

PI Services LLC
2010 Filmore Ave. Erie, PA 16506

Employee list

Name	Position
Ashley Ruhland	Designated Representative
Allison Breese	Warehouse Manager

4AAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: UPS Supply Chain Solutions, Inc.

Physical Address: 7 Gateway Blvd.

City: Pedricktown State: NJ Zip: 08067

Mailing Address (if different from physical address): 7 Gateway Blvd.

City: Pedricktown State: NJ Zip: 08067

Telephone: 856-351-6619 Website: www.ups.com

Name of Designated Representative (DR): Roger M. McLaughlin, Jr.

Licensing Company Email: ralicensing@ups.com DR Email: rogermclaughlin@ups.com

Entities the Wholesaler will Serve (✓ all applicable)	**Products to be Handled or Wholesaled (✓ all applicable)**	**Type of Wholesaling (✓ all applicable)**
■ Pharmacies ■ Practitioners ■ Hospitals ■ Wholesalers ■ Veterinarians ☐ Others:	■ Dangerous Drugs ☐ Controlled Substances ■ [a]Medical devices, equipment, supplies, gases ■ Others: Prescription Human & Veterinary drugs Over the Counter (OTC) Human & Veterinary drugs	☐ Manufacturer ☐ Repacker ☐ Reverse Distributor ☐ Warehouse ☐ Retail pharmacy wholesale distributor ■ Others: 3PL

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? see attachment# 1		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:
see attachment# 1

Original Signature (electronic, copies or stamps not accepted)

24 Mar 2021
Date

Disciplinary Statement
UPS Supply Chain Solutions, Inc. ("UPS SCS")

WHOLESALE LICENSE

Matters Related to Colorado Order
1645 Satellite Blvd, Duluth, GA

Final

As previously disclosed by UPS Supply Chain Solution, Inc. (UPS SCS), to your agency in 2010, the Colorado Board of Pharmacy's Stipulation and Final Agency Order ("Colorado Order") was effective October 18, 2010, with regard to UPS SCS's Duluth, GA facility's Colorado Out-of-State Wholesaler License # WHO-7462. UPS SCS's Duluth facility did not file Colorado's required notice of change of Designated Representative within Colorado's required 14-day timeframe to file such notice. UPS SCS implemented corrective actions and has successfully completed the terms of the Colorado order. Please note, UPS SCS's Colorado Out-of-State Wholesaler License # WHO-7462 was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Colorado Case No. 2011-000273 documentation related to the Colorado Order on file with the UPS SCS Regulatory Affairs Department.

Final

On November 15, 2011, UPS SCS informed your agency of the Iowa Board of Pharmacy's (IBoP) action concerning Iowa Wholesale Drug License #5820 and which became effective November 11, 2011. This Iowa Stipulation and Consent Order (the "Iowa Order") relates to the Colorado Order and the untimely filing of notice regarding the Colorado Order to the IBoP. UPS SCS has successfully completed the terms of the Iowa Order and Iowa Wholesale Drug License #5820 has not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Iowa Case No. 2010-162 documentation on file with the UPS SCS Regulatory Affairs Department. Note: This Iowa matter is a spin-off of the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is **not** based on an independent set of facts.

Final

On October 18, 2013, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the underlying Colorado matter summarized above, which was executed by the Michigan BOP on October 9, 2013 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two thousand five hundred dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is not based on an independent set of facts.

PHARMACY LICENSE

Matters Related to Kentucky Agreed Orders
1860 Outer Loop Road, Louisville, KY

Final

UPS SCS dispenses medical devices, including diabetes-related pumps, to consumers from its Kentucky licensed pharmacy facility. Not all states recognize the Durable Medical Equipment or Home Medical Equipment provider category for entities that dispense medical devices rather than drugs. Those states that do not recognize these categories require a non-resident or out of state pharmacy permit for dispensing medical devices. Accordingly, UPS SCS obtained a home-state pharmacy permit in Kentucky and numerous non-resident pharmacy permits and DME/HME permits in other states. On September 12, 2012, the Kentucky Board of Pharmacy ("KYBoP") and UPS SCS executed final Agreed Orders relating to minor violations under Kentucky Administrative Regulations 2:270 and Kentucky Revised Statutes Sec. 315.121(6) in connection with late filing of pharmacy technician registrations at UPS SCS's Louisville, Kentucky facility (the "Kentucky Orders"). UPS SCS and the KYBoP agreed to address the Kentucky Orders informally by entering in the aforementioned Agreed Orders in lieu of the KYBoP filing a formal complaint. UPS SCS self-reported this action to your agency on September 18, 2012. UPS SCS takes this and all regulatory matters seriously and has implemented corrective action. Moreover, UPS SCS has instituted internal safeguards to ensure that applicable regulatory compliance is maintained in the future. UPS SCS's Kentucky pharmacy license (Kentucky Pharmacy License #P07277) remains current and in good standing and was not and has not been restricted, modified, revoked, or limited in any way.

Final

On May 14, 2013, UPS SCS informed your agency of the Texas Board of Pharmacy's (TXBoP) action concerning UPS SCS Texas Class E Nonresident Pharmacy License #26160 and which became effective May 7, 2013. As already disclosed to you, on May 14, 2013, the Texas Board of Pharmacy (TXBoP) and UPS SCS executed a final Agreed Board Order (the "Texas Order") relating to the above-mentioned Kentucky Pharmacy License Agreed Orders. Pursuant to the Texas Agreed Board Order, the TXBoP reprimanded UPS SCS's Nonresident Pharmacy License. The Texas Board of Pharmacy did not levy a fine or any other penalty on the License. The License was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Texas Agreed Board Order # L-13-004 on file with the UPS SCS Regulatory Affairs Department. Note: The Texas Order is directly related to the Kentucky pharmacy license matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is **not** based on an independent set of facts.

Final

On April 22, 2014, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the Kentucky Order summarized above, which was adopted by the Michigan BOP on April 9, 2014 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two hundred fifty dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Kentucky matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is not based on an independent set of facts.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2011-000273

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATION OF UPS SUPPLY CHAIN SOLUTIONS, INC., REGISTRATION NO. WHO-7462,

Respondent.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and UPS Supply Chain Solutions, Inc. ("Respondent") to resolve all matters pertaining to Board Case Number 2011-000273, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, its registration as a non-resident prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Respondent was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on December 8, 2008, being issued registration number WHO-7462, and has been so registered at all times relevant to this disciplinary action.

3. Respondent does not contest these findings and hereby waives any further proof in this proceeding before the Board regarding the following findings.

4. Respondent failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, forty-six (46) days transpired between the date the previous designated representative ceased the position and the date the application and fee were received.

5. Respondent states and affirms that it was never without the proper oversight of a designated representative but failed to timely submit the change application to the Board because of human error. Further, Respondent states and affirms that it has identified the cause of the error and has implemented corrective actions.

6. Respondent does not contest that the conduct described above constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drug.

12-22-802. Wholesaler license requirements

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3) (VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

Regulation 15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803. And

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

(b) Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

Regulation 15.01.14 Change of name, location, or ownership, or designated representative

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

7. The Board finds and concludes, and Respondent agrees, that based upon the above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-22-125.2(5), C.R.S., Respondent shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent shall submit all future applications detailing a change in designated representative and fee to the Board within fourteen (14) days of the previous designated representative ceasing the position.

10. **Other Requirements.** Respondent acknowledges and agrees that, as a condition of this Final Agency Order, Respondent shall:

a. promptly pay all Respondent's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Respondent enters into this Final Agency Order freely and voluntarily, whether or not Respondent has consulted with legal counsel. Respondent acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

d. to appeal this Final Agency Order.

Respondent freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent to the sanctions imposed herein.

12. **Acknowledgments.** Respondent has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent

_____ Dated: 10/1/10
Authorized Representative / Title

Subscribed and sworn to before me in the County of Fulton, State of Georgia, this 1 day of October, 2010 by Daniel Silvernale, authorized representative of UPS Supply Chain Solutions, Inc.

My commission expires: Sept 21, 2013

DALE BANKS NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES SEPT 21 2013 Notary Public

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18th day of October, 2010.

State Board of Pharmacy

BY: _____
Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 29th day of September 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097
(via email: joyroberts@ups.com)

/s/ John Steele
John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of October 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097

Catie Hangiost
Agent of the Board

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	Case No. 2010-162
Wholesale Drug License of	)	
UPS SUPPLY CHAIN	)	**STIPULATION**
SOLUTIONS, L.L.C.,	)	**AND CONSENT**
License No. 5820	)	**ORDER**
Respondent	)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), The Iowa Board of Pharmacy (hereinafter, the "Board") and UPS Supply Chain Solutions, L.L.C. (hereinafter, "Respondent"), have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on September 13, 2011, and the licensee disciplinary proceeding related to the charges shall be resolved without a hearing, as the Board and Respondent have agreed to the following Stipulation and Consent Order:

1. Respondent's license to operate a wholesale drug business was renewed November 19, 2010, as evidenced by Wholesale Drug License Number 5820, recorded in the permanent records of the Board.

2. Wholesale Drug License Number 5820 issued to and held by Respondent is current and in force until December 31, 2011.

3. The Board has jurisdiction over the parties and the subject matter herein.

4. A Statement of Charges was filed against Respondent on September 13, 2011. The Statement of Charges alleges Respondent violated the pharmacy laws of the State of Colorado and failed to timely report the violation to the Board.

5. The records of the investigation indicate that Respondent has successfully

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completed the terms of the Colorado Stipulation and Final Agency Order.

6. Respondent has chosen not to contest the allegations set forth in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of $1000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulation and Consent Order. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

8. The Board does not mandate any further corrective action.

9. Respondent agrees to obey all federal and state laws, rules, and regulations substantially related to the operation of a wholesale drug business.

10. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend Respondent's Iowa license to operate a wholesale drug business or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

11. This Stipulation and Consent Order is the resolution of a contested case. By entering into this stipulation, Respondent waives all rights to a contested case

hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

12. This Stipulation and Consent Order is a proposed settlement subject to approval by a majority of the full Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

13. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by UPS Supply Chain Solutions, L.L.C., to the Iowa Board of Pharmacy for its consideration on this 21st day of October 2011.

UPS SUPPLY CHAIN SOLUTIONS, L.L.C.,
Respondent
By DANIEL SILVERNALE, Vice President, Finance and Healthcare Compliance

Subscribed and sworn to before me by Daniel Silvernale, who has stated to me that he is the VP, Finance & Healthcare Compliance of UPS Supply Chain Solutions, L.L.C., and is authorized to sign this Stipulation and Consent Order on behalf of UPS Supply Chain Solutions, L.L.C., on this 21st day of October 2011.

LINDA P BOWDEN NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES AUGUST 30, 2015

Linda P. Bowden
NOTARY PUBLIC IN AND FOR THE STATE OF GEORGIA

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 11th day of November 2011.

SUSAN FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

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STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Numbers: 53-06-002764
53-15-027264

File Number: 53-10-118763
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 23, 2011, charging UPS Supply Chain Solutions Inc., hereafter Respondent Wholesaler, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true for the purposes of this Consent Order and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Wholesaler is FINED in the amount of $2,500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Bureau of Health Care Services, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-10-118763.**

IT IS FURTHER ORDERED that in the event Respondent violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 10/9/13

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Wholesaler understands and intends that by signing this Stipulation, Respondent Wholesaler is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Wholesaler is waiving the right to appear with an attorney and such witnesses as Respondent Wholesaler may desire to present a defense to said charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Subsequent to the adverse actions, Respondent Wholesaler submitted information about steps implemented by Respondent Wholesaler, in the state of Colorado, to ensure that this type of action will not recur, including establishing strategy groups and tactical teams which ensure regulations are met and all locations are compliant. Respondent Wholesaler indicated that a single manager coordinates the local teams to ensure all information is consistently distributed. No patient safety issues were involved in Respondent Wholesaler's actions.
>
> Respondent Wholesaler was cooperative in resolution of this matter. Respondent Wholesaler has been licensed in the state of Michigan since 2008 and has no other complaints against its license.

4. Patricia A. Smeelink, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Wholesaler and the Department and may be entered as the final order of the Disciplinary Subcommittee in said cause.

CONTINUED ON NEXT PAGE

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Wholesaler and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 8-7-13

AGREED TO BY:

Daniel Silvernale, Vice President
Authorized Representative for
UPS Supply Chain Solutions Inc.
Respondent Wholesaler

Dated: 6/28/13

Approved as to form by:

Max R. Hoffman, Jr.
Attorney for Respondent Wholesaler (P67550)

This is the last page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-10-118763, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

BH/PB

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 11-0062A

IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS, INC.

AGREED ORDER

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions, Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that numerous technicians worked on various dates in 2010, without being timely registered with the Board. The Respondent assured the technicians that it would take care of ensuring they were properly registered. Respondent subsequently properly registered the technicians. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).

(b) The technicians that worked without being appropriately registered with the Board were: Chelsea Hutchins, Alisha Netherton, Brittany Barger, Lauren Fisher, Karen Millay, Meghan Rae Yates, Michelle Green, Amanda Gracie, Faith Joway, Taylor Parker, Manoj Bhandari, Jonathan Pruitt, Whitney Wilson, Dustin R. Harris, Fabrice Mboya, Lauren Howell, Coco Boards, Benjamin Bickett, Jessica Horlander, Jason Cope, William Robert Bennett Jr, Thomas Hicks, Nimo Muhumed Mohamud, Harold Keith Newcom, Rodrick G Parrish, Johnathan Borho, Antoya Blackburn, Jonathan Graves, and Leilani Roach.

(c) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by

entering into this Agreed Order, in lieu of the Board filing a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $2900.00 ($100 per technician) payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

9/12/12
Date

UPS Supply Chain Solutions, Inc.
Respondent

8/14/12
Date

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 11-0061A

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IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS INC.

AGREED ORDER

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that Sherry Rich worked as a pharmacy technician from April 1, 2010 through November 19, 2010, without being timely registered with the Board. The Respondent assured Ms. Rich that it would take care of ensuring she was properly registered. Respondent subsequently properly registered Ms. Rich with the Board. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).

(b) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $125.00 payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky

Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President — Date 8/12/12
Kentucky Board of Pharmacy

UPS Supply Chain Solutions Inc. — Date 8/14/12
Respondent

AGREED BOARD ORDER #L-13-004

RE: IN THE MATTER OF
UPS SUPPLY CHAIN SOLUTIONS, INC.
(CLASS E NONRESIDENT
PHARMACY LICENSE #26160)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy ("Board") the matter of Class E nonresident pharmacy license number 26160 issued to UPS Supply Chain Solutions, Inc. ("Respondent"), 1860 Outer Loop Road, Louisville, Kentucky 40219.

On September 8, 2012, Respondent self-reported to the Board the entry of two Agreed Orders by the Kentucky Board of Pharmacy, as described below in Counts (1) and (2).

By letter dated February 22, 2013, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

> Section 565.002 (a)(13); and Section 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011), as alleged in the Counts below.

The conduct described in the Kentucky Board of Pharmacy's Agreed Orders is substantially similar to conduct described in:

> Section 565.002(a)(3); and Section 568.002(a) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011); and
>
> Section 297.3(a)(1) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012).

COUNTS

(1) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0061A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that from April through November of 2010, the pharmacy allowed an unregistered individual to perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $125.

(2) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0062A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that, on various dates in 2010, the pharmacy allowed twenty-nine (29) unregistered individuals to

perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $2900.

An informal conference was held in the office of the Texas State Board of Pharmacy on April 2, 2013. Phillip Vowels, R.Ph., Pharmacist-in-Charge of Respondent; Sue Young, Director, Global Healthcare Compliance, for Respondent; Amy Carney, Regulatory Affairs Manager, for Respondent; Maureen O'Brien, Senior Quality Assurance Manager, for Respondent; Emily Johnson, Legal Counsel for Respondent; Hannah Heck, Legal Counsel for Respondent; and Michelle Williams, Legal Counsel for Respondent, appeared via teleconference. The informal conference was heard by a Board panel comprised of: Jeanne D. Waggener, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Stacy E. Martyak, Staff Attorney, was also in attendance.

By signing this Order, Daniel Silvernale, Vice President, for and on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that Respondent's license is hereby reprimanded.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 7th day of May, 2013.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Daniel Silvernale, Vice President of UPS Supply Chain Solutions, Inc.

APPROVED AS TO FORM:

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Number: 53-01-008968

File Number: 53-13-129412
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 27, 2013, charging UPS Supply Chain Solutions Inc., hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and argument were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true, for purposes of this Consent Order, and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly, IT IS HEREBY ORDERED, that for the cited violation of the Public Health Code, Respondent Pharmacy is REPRIMANDED.

IT IS FURTHER ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $250.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order made payable to the state of Michigan, and the check or money order shall clearly display the file number **53-13-129412.**

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 4/9/14

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Respondent Pharmacy acknowledges the Kentucky Board of Pharmacy disciplinary action which precipitated the Complaint.

4. Harvey Schmidt, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

CONTINUED ON NEXT PAGE

6. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department Licensing and
Regulatory Affairs

Dated: 1-29-14

AGREED TO BY:

UPS Supply Chain Solutions Inc.
Respondent

Dated: 1/21/14

This is the final page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-13-129412, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

PB

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: BioMerieux, Inc.
Address: 515 Colorow Drive City: Salt Lake City State: UT Zip: 84108

Name: Ferring Production, Inc.
Address: 100 Interpace Parkway City: Parsippany State: NJ Zip: 07054

Name: Quidel Corporation
Address: 9975 Summer Ridge Road City: San Diego State: CA Zip: 92121

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address: N/A
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

26-Mar-2025

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): United Parcel Service of America, Inc.
Corporation/Organization Name: UPS Supply Chain Solutions, Inc.
Mailing Address: 12380 Morris Road
City: Alpharetta State: GA Zip: 30005
Telephone: 678-746-4100 Email: ralicensing@ups.com
Contact Person Name: Felix Chang

Section 6: Partnership

Partnership Name:
Mailing Address:
City: N/A State: Zip:
Telephone: Email:
Contact Person Name:

26-Mar-2025

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address: N/A
City: State: Zip:
Telephone: Email:

26-Mar-2025

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:	✔	
1. Copy of Certification see attachment# 2 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/. see attachment# 3		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** see attachment# 4	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** see attachment# 5		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** see attachment# 6	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ see attached		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** see attachment# 7	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** see attachment# 8	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ see attached	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/Fingerprint%20Submission%20Instructions%20-%20Effective%2001.01.2024.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

UPS Supply Chain Solutions, Inc.

Facility Name

Roger M. McLaughlin, Jr.

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

24 March 2025

Date

Board Use Only	Date Received: 3/31/25	Amount: $1000 CK 1149

NABP ACCREDITED
DRUG DISTRIBUTOR

UPS Supply Chain Solutions, Inc

located at

7 Gateway Blvd, Pedricktown, NJ 08067

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Attachment# 2

Carlene Colasanti

From: vawd@nabp.pharmacy
Sent: Tuesday, March 4, 2025 4:42 PM
To: Carlene Colasanti
Cc: Deborah Robertson; Casey Criswell
Subject: [EXTERNAL] NABP Drug Distributor Accreditation: Approved - UPS Supply Chain Solutions, Inc, Pedricktown, NJ
Attachments: 115033240_NABP Certificate.pdf

CAUTION! This email originated outside of the organization. Please do not open attachments or click links from an unknown or suspicious origin.

Hello Carlene,

On behalf of the National Association of Boards of Pharmacy® (NABP®), I extend to you our sincere appreciation for choosing our organization to serve UPS Supply Chain Solutions, Inc located at 7 Gateway Blvd, Pedricktown, NJ 08067. NABP is pleased to inform you that your facility has successfully met the Drug Distributor Accreditation requirements.

Congratulations on achieving NABP Drug Distributor Accreditation. The details of your accreditation are as follows:

- **Accredited Entity:** UPS Supply Chain Solutions, Inc
- **Address:** 7 Gateway Blvd, Pedricktown, NJ 08067
- **Accreditation Period:** 02/27/2025 – 02/26/2028
- **Accreditation Contact:** Carlene Colasanti; ccolasanti@ups.com
- The Drug Distributor Accreditation Certificate is attached; please review the information on the certificate to ensure that it is correct.

We look forward to continuing working with you and your facility. If you have any questions, please contact us via phone at 847/391-4539 or via email at vawd@nabp.pharmacy.

Cordially,

Ann Luecking
She, Her, Hers
Accreditation Analyst
847/391-4539

National Association of Boards of Pharmacy
1600 Feehanville Dr, Mount Prospect, IL 60056
www.nabp.pharmacy [nabp.pharmacy]



[pulse.pharmacy]

UPS Supply Chain Solutions, Inc.
12380 Morris Road
Alpharetta, GA 30005
Phone ~ (678) 746 4100
State of Incorporation: Delaware
Date of Incorporation: 8/29/88
FEIN ~ 94-3083515

Name/Title	Work Address	Work Phone	Work Fax	Email
John Bolla **President**	12380 Morris Road Alpharetta, GA 30005	(919) 455-8564	(678) 746-8650	jbolla@ups.com
Felix Chang **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-3452	(678) 746-8650	fxchang@ups.com
Seth Bruckner **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-7413	(678) 746-8650	sbruckner@ups.com
William M. Jacques **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-8718	(678) 746-8650	wjacques@ups.com
Jeremiah (Jay) Blanton **Vice President**	12380 Morris Road Alpharetta, GA 30005	(502) 500-0427	(678) 746-8650	jblanton@ups.com

Parent Company Information:
United Parcel Service of America, Inc.
55 Glenlake Parkway NE
Atlanta, GA 30328
P ~ (404) 828 6022
FEIN ~ 95-1732075
State/Date of Incorporation ~ DE 5/9/30

Attachment# 4

Organizational Chart
UPS SUPPLY CHAIN SOLUTIONS, INC.



THIS REPORT IS SUBMITTED IN CONFIDENCE AND APPLICABLE EXEMPTIONS TO THE FREEDOM OF INFORMATION ACT ARE TO BE INVOKED TO WITHHOLD IT FROM PUBLIC DISCLOSURE

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "UPS SUPPLY CHAIN SOLUTIONS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE SEVENTH DAY OF MARCH, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "UPS SUPPLY CHAIN SOLUTIONS, INC." WAS INCORPORATED ON THE TWENTY-NINTH DAY OF AUGUST, A.D. 1988.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

2170882 8300

SR# 20250970388

Authentication: 203111541

Date: 03-07-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

Attachment# 8

State of New Jersey
DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL AND OCCUPATIONAL HEALTH SERVICE
PO BOX 369
TRENTON, N.J. 08625-0369
www.nj.gov/health

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

JUDITH M. PERSICHILLI, RN, BSN, MA
Commissioner

September 12, 2022

Re: Third Party Logistics Providers

Per H.R. 3204, DQSA, Uniform National Policy, Sec. 585 (b)(2) New Jersey does not regulate third-party logistics providers as wholesale distributors. To qualify for a wholesale drug or medical device registration, a facility must conduct regulated wholesale distribution or manufacturing activity as defined in N.J.A.C. 8:21-3A.3, therefore New Jersey does not issue or require registration of third party logistics providers.

Sincerely,
Eric B. Lieberman, Esq.
Project Coordinator, Wholesale Drug Project
Public Health and Food Protection Program

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 1400503

Application/License No. _____

UPS Supply Chain Solutions, Inc. (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 7 Gateway Blvd, Pedricktown, NJ 08067 (Address of Applicant/Principal), as PRINCIPAL, and Great American Insurance Company (Surety Company), a corporation organized under the laws of the state of Ohio (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 301 E. 4th Street, Cincinnati, OH 45202 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 03/29/2017 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 29 day of March, 2017.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company's Representative

Lisa Gelsomino, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 4/11/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Liberty Mutual Insurance Co. Nat'l Ins Northeast
500 N 3rd St, Suite 300
Wausau, WI 54403

www.LibertyMutual.com

CONTACT NAME:
PHONE (A/C, No, Ext): **FAX (A/C, No):**
E-MAIL ADDRESS: CMeCertProduction@LibertyMutual.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Liberty Mutual Fire Insurance Company	23035
INSURER B : LM Insurance Corporation	33600
INSURER C : Liberty Insurance Corporation	42404
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
UPS SUPPLY CHAIN SOLUTIONS, INC.
12380 MORRIS ROAD
ALPHARETTA GA 30005

COVERAGES **CERTIFICATE NUMBER:** 84813791 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	✓ COMMERCIAL GENERAL LIABILITY			TB2-C21-095741-135	1/1/2025	1/1/2026	EACH OCCURRENCE	$ 1,000,000
A	☐ CLAIMS-MADE ✓ OCCUR			TB2-C21-095741-145	1/1/2025	1/1/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$
B				TB5-C21-095741-155	1/1/2025	1/1/2026	MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 1,000,000
	✓ POLICY ☐ PRO-JECT ☐ LOC						PRODUCTS - COMP/OP AGG	$ 1,000,000
	OTHER:							$
A	AUTOMOBILE LIABILITY			AI2-C21-092036-025	1/1/2025	1/1/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
A	✓ ANY AUTO			AI2-C21-092036-585	1/1/2025	1/1/2026	BODILY INJURY (Per person)	$
A	☐ OWNED AUTOS ONLY ☐ SCHEDULED AUTOS			AI2-C21-092036-945	1/1/2025	1/1/2026	BODILY INJURY (Per accident)	$
B	☐ HIRED AUTOS ONLY ☐ NON-OWNED AUTOS ONLY			AI5-C21-092036-875	1/1/2025	1/1/2026	PROPERTY DAMAGE (Per accident)	$
								$
	☐ UMBRELLA LIAB ☐ OCCUR						EACH OCCURRENCE	$
	☐ EXCESS LIAB ☐ CLAIMS-MADE						AGGREGATE	$
	☐ DED ☐ RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N			WC5-C25-095741-295	1/1/2025	1/1/2026	✓ PER STATUTE ☐ OTH-ER	
B	ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? N	N / A		WA5-C2D-095741-305	1/1/2025	1/1/2026	E.L. EACH ACCIDENT	$ 1,000,000
C	(Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below			WA7-C2D-095741-325	1/1/2025	1/1/2026	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: 3101 Pond Station Road Louisville, KY 40272; Healthcare Facility 2425 Universal Way Louisville, KY 40219; 7 Gateway Blvd., Pedricktown, NJ, 08067

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Joshua Cleveland

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AGENCY CUSTOMER ID: 2-004105

LOC #: _____

ADDITIONAL REMARKS SCHEDULE

Page ____ of ____

AGENCY	NAMED INSURED
Liberty Mutual Insurance Co. Nat'l Ins Northeast	UPS SUPPLY CHAIN SOLUTIONS, INC. 12380 MORRIS ROAD ALPHARETTA GA 30005
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 **FORM TITLE:** Certificate of Liability Insurance (03/16)

HOLDER: Nevada State Board of Pharmacy

ADDRESS: 985 Damonte Ranch Parkway, Suite 206 Reno NV 89521

If changes/revisions to this certificate are necessary, you may email your request to CMeCertProduction@libertymutual.com.

If you no longer require this certificate and do not need on an annual basis, please email the certificate to our office and instruct us to delete from our database.

ACORD 101 (2008/01) © 2008 ACORD CORPORATION. All rights reserved.

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ATTACHMENT

84613791 | 2-004105 | 1/25-1/26 UPS SCS All Lines - 1M | Erin Celing | 4/11/2025 9:44:00 AM (CDT) | Page 2 of 2

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: UPS Supply Chain Solutions, Inc. MDEG License # (if applicable): TBD

Physical Address: 7 Gateway Blvd.

City: Pedricktown State: NJ Zip: 08067

Mailing Address (if different from physical address): *same as physical address*

City: State: Zip:

Telephone: 856-351-6619 Website: www.ups.com

Licensing Company Email: ralicensing@ups.com

Section 2: Personal Information

First: Roger Middle: M. Last: McLaughlin, Jr.

Alias(es, nicknames, name changes, etc.): N/A

Date of Birt[redacted] SSN or ITIN[redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address[redacted]

City: Rising Sun State: MD Zip[redacted]

Telephone[redacted] Email: rogermclaughlin@ups.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Delcastle Vo-Tech		1978 - 1981	
Address	**City**	**State**	**Zip**
1417 Newport Road	Wilmington	DE	19804
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

26 March 2025

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2007 - present	[redacted]	Rising Sun	MD	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City N/A	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

26 Mar - 2025

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			01/25 - present	
Business Address		**City**	**State**	**Zip**
7 Gateway Blvd.		Pedricktown	NJ	08067
Phone	**Title**		**Number of Employed Hours**	
856-351-6619	Supervisor, Distribution Operations		477	
Description of Duties				
see attachment# 9				

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			01/23 - 12/24	
Business Address		**City**	**State**	**Zip**
2235 Route 322, Suite 100		Woolwich Township	NJ	08085
Phone	**Title**		**Number of Employed Hours**	
N/A (building closed)	Facility Manager		4,698	
Description of Duties				
see attachment# 9				

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			1/21 - 12/22	
Business Address		**City**	**State**	**Zip**
7 Gateway Blvd.		Pedricktown	NJ	08067
Phone	**Title**		**Number of Employed Hours**	
856-351-6619	Facility Operations Manager		2,340	
Description of Duties				
see attachment# 9				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

26 Mar-2025

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties	N/A			

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

26-Mar-2025

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
N/A				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

24 Mar 2025

Date

I, Roger M. McLaughlin, Jr., **certify that as the MDEG Administrator for**

UPS Supply Chain Solutions, Inc., 7 Gateway Blvd., Pedricktown, NJ, 08067,

that I (initial that you have read and meet the following requirements):

1. RMM Have a high school diploma or its equivalent;
2. RMM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RMM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RMM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roger M. McLaughlin, Jr.
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

24 Mar 2025
Date

Board Use Only	Date Received: 3/31/25

Roger M McLaughlin Jr
[redacted]

Objective

To continue my career within UPS SCS and allow me to utilize my Management, Supervision and Administrative skills to benefit mutual growth and success.

Skills Profile

Troubleshooter skilled at researching and solving system and supply chain issues effectively.

Communications skills demonstrated through professional, verbal and writing abilities, client relations, employee training and the ability to produce reports and correspondence.

Often noted by other managers, supervisors, client and staff for a "Job Well Done" for completing assignments on time and assisting others with issues that they may be facing.

Proficient in system applications of SAP, LMS, RCS, Windows, Microsoft office, Internet applications, and E-Mail.

Education

Graduated from DelCastle Vo-Tech High School in June 1981

Work History

UPS Supply Chain Solutions – Pedricktown NJ – NJOMN January 2025 til Present

Assistant Operations Manager

Assisting supervisors with completing the daily matrix goals completed within the timeframe as outlined in the contract with the client.

Assisting QA/RA with any facility related issues that would need to be resolved. These would include any Nonconformance's and Change

Controls that need to be addressed and processes put in place to resolve them.

Assisting new supervisors in adjusting to their new roles as they transition from hourly positions to supervisor positions.

Guiding the supervisors on procedures that need to be completed for Human Resources.

Assisting with any operational issues that may arise and need to be addressed.

Complete daily scorecards with information that is sent over to the client on a consistent basis.

Responsible for ensuring that the cycle counts are completed in the facility. This allows us to remain within the goals set by the clients KPIs.

UPS Healthcare – Woolwich TWP NJ – NJ322 January 2023 – December 2024

Facility Operations Manager

Responsible for managing the daily operations of the Woolwich NJ facility. As a third-party distributor, we are responsible for the distribution of the client's materials, which consist of medical devices. My daily responsibilities also include the reporting of everything related to the financials for the building.

Developing the supervisors within the facility so that they become more knowledgeable of the healthcare environment and the expectations required as such.

Continue to develop the supervisors by increasing their knowledge of what it takes for them to get to the next level of management. This is done through one-on-one conversations with the supervisors along with training being assigned to them through UPS University.

Responsible for all communications with the client that is located at the facility. Making sure that all requests are handled timely and in an appropriate manner.

Continuing to hold monthly meetings with the supervisors on the productivity in their areas and holding their teams accountable for their individual productivity and attendance.

Working with QA to ensure all things regarding eQMS are current and continue to move forward in the process. This is so we minimize tasks assigned to the management team going late.

Making sure that all things facility related are taken care of, i.e.. maintenance, equipment, sanitation, etc.

Currently the Designated Representative (DR) for the Woolwich TWP location.

Continue to be the backup 3PL DR for the Swedesboro NJ location.

I am responsible for the inventory accuracy of the facility to meet the clients KPIs. This includes cycle counts, replenishments, and recording of damaged material daily.

UPS Supply Chain Solutions – Pedricktown NJ – NJOMN January 2021 – December 2022

Facility Operations Manager

Responsible for managing the daily operations of the Pedricktown NJ facility. As a third-party distributor, we are responsible for the distribution of the client's materials, which consist of medical devices. My daily responsibilities also include the reporting of everything related to the financials for the building.

Developing the supervisors within the facility so that they become more knowledgeable of the healthcare environment and the expectations required as such.

Continue to develop the supervisors by increasing their knowledge of what it takes for them to get to the next level of management. This is done through one-on-one conversations with the supervisors along with training being assigned to them through UPS University.

Responsible for all communications with the client that is located at the facility. Making sure that all requests are handled timely and in an appropriate manner.

Continuing to hold monthly meetings with the supervisors on the productivity in their areas and holding their teams accountable for their individual productivity and attendance.

Working with QA to ensure all things regarding eQMS are current and continue to move forward in the process. This is so we minimize tasks assigned to the management team going late.

Making sure that all things facility related are taken care of, ie. maintenance, equipment, sanitation, etc.

Currently the back up 3PL DR for the Swedesboro NJ location.

I am responsible for the inventory accuracy of the facility in order to meet the clients KPIs. This includes cycle counts, replenishments, and recording of damaged material on a daily basis.

UPS Supply Chain Solutions – Pedricktown NJ – NJOMN March 2020 – December 2020

Distribution Associate Manager

Managing the supervisors and training them on all tasks that have been assigned to them.

Developing the supervisors within the international area so that they become more knowledgeable of the healthcare environment and the expectations required as such. This would be inclusive of the handling of the medical devices that we are currently distributing for the client.

Responsible for working with the International Team to increase the Order Accuracy percent effective. In January 2020 they were at (96.8%) and as of November 3, 2020, we were at (99.7%).

Taken on some additional responsibilities such as the Pedricktown Daily reporting that is reported to senior management within UPS HLD. Holding the Morning Management Meeting with all the management team within the Pedricktown facility. Continue to work with the Administrative Staff on finances and productivity reports to ensure that they are accurate. Continue to work with Corporate Security to get the security system here in Pedricktown functioning properly.

Developed the Monthly Personnel Performance presentation that is now being used by all the supervisors/managers in Pedricktown.

Continue to develop the supervisors within the International Area to the point where they are setting the example on what needs to be in holding associates accountable to their productivity.

UPS Supply Chain Solutions – Swedesboro NJ – NJLGN July 2017 – February 2020

Assistant Operations Manager

Managing the supervisors with completing tasks as assigned by the facility manager.

Assisting supervisors with completing the daily matrix goals completed within the timeframe as outlined in the contract with the client.

Assisting QA/RA with any facility related issues that would need to be resolved. These would include any NonConformances and Change Controls that need to be addressed and processes put in place to resolve them.

Assisting new supervisors in adjusting to their new roles as they transition from hourly positions to supervisor positions.

Guiding the supervisors on procedures that need to be completed for Human Resources.

Assisting the facility manager with any operational issues that may arise and need to be addressed.

Complete daily scorecards with information that is sent over to the client on a consistent basis.

Responsible for ensuring that the cycle counts were completed in the facility. This allowed us to remain within the goals of the clients KPIs.

Completed the necessary training for the California 3PL Designated Representative in January 2019. On 5/1/2019, I became the Designated Representative for the Swedesboro NJ (NJLGN) location.

UPS Supply Chain Solutions – Swedesboro NJ – NJLGN June 2016 – July 2017

Sr Operations Supervisor

Assisting other supervisors with completing tasks as assigned by the facility manager.

Assisting supervisors with completing the daily operation of achieving the goal of having the order volume completed each day.
Assisting QA/RA with any facility related issues that would need to be resolved. Those would include any NonConformance Reports that need to be addressed and processes put in place to resolve them.

Assisting new supervisors in adjusting to their new roles as they transition from hourly positions to supervisor positions.

Guiding the supervisors on procedures that need to be completed for Human Resources.

Assisting HR and operations with completing interviews for potential new employees.

Assisting the CHSP committee on what issues need to be documented on the appropriate forms. Coming up with ideas on how to make them a successful team. Providing them with ideas to ensure the entire warehouse participates in CHSP and not just those that are on the team.

UPS Supply Chain Solutions – Newark DE – DENWK Sep 2015 - June 2016

Sr Warehouse Supervisor

Responsible for ensuring that all pharmaceutical orders that were received daily for multiple clients were processed and shipped each day.

Responsible for receiving department – this was to ensure that all materials that were received and put away within the time constraints that were agreed upon by each client.

Responsible for the shipping department – this was to ensure that any LTL shipments that were received are processed. Also contacting the various carriers to arrange a pickup time for each of the shipments.

Responsible for the controlled area within the warehouse. This would include the handling of controlled substances and the documentation that was required to be sent back to the DEA on a monthly basis.

Responsible for making sure all client invoices are paid for the services being performed for each of the various clients.

Responsible for maintaining the facility as the only representative in the facility on a daily basis. (Acting as the Facility Manager)

Responsible for making sure that all projects for the closing of the facility are taken care of that are assigned to me. This is to ensure a smooth transition of the clients and their materials to other facilities within UPS Supply Chain Solutions.

Training associates on new versions of SOPs/Work Instructions and any corporate mandated trainings required.

Assisting QA/RA with any facility related issues that would need to be resolved. Those would include any Non-Conformance Reports that need to be addressed and processes put in place to resolve them.

UPS Supply Chain Solutions – Newark DE – DELAK – May 2012 – Sep 2015

MDM Supervisor

Responsible for productions needs in SAP, which consists of assisting the MDM team with maintaining the Customer Master, Material Master, License Verification process.

Assisting the MDM team with troubleshooting issues and errors that may arise on a daily basis on all areas within SAP.

Training the MDM team on any new functions that may be developed within SAP so that they can be applied to any new or existing client's database

Ensure training has been completed for conversion and onboarding clients with the upload templates that UPS uses to upload the client's data within SAP.

Coordinate calls and meetings with internal and external customers to ensure processes that have been developed are followed.

Currently responsible for creating client profiles for any new onboarding client and reviewing with the clients before go-live.

Currently responsible for conversion clients that are currently in the LMS and will be converted over to the SAP/GHOS system.

UPS Supply Chain Solutions – Newark DE – DENWK – Nov 2006 – May 2012

Shared Services Supervisor

Responsible for the File Admin area of creating and maintaining client information within the LMS system to include (Customer Master, Material Master, Vendor Listing, Customer License Information, Pricing and Contracts, etc.).

Responsible for the Returns Department to ensure that all returns that are needed to be processed are done so within the time constraints that the clients and UPS have agreed to.

The returns department is responsible for processing of credits and debits as required for each customer that has sent a return back to UPS SCS.

UPS Supply Chain Solutions – Newark DE – Sept 1999 to Nov 2006

Warehouse Supervisor

Responsible for ensuring that all pharmaceutical orders that were received on a daily from multiple clients were processed and shipped on a daily basis.

Responsible for receiving department – this was to ensure that all materials that were received and put away within the time constraints that were agreed upon by each client.

Responsible for the shipping department – this was to ensure that any LTL orders that were received were processed, and the carriers contacted to arrange a pick-up time for each of the orders.

Responsible for the controlled area within the warehouse. This would include the handling of controlled substances and the documentation that was required to be sent back to the DEA on a monthly basis.

Livingston Healthcare/UPS SCS – Newark DE – Aug 1997 to Sept 1999

Warehouse Associate/Team Lead

Duties including picking packing and shipping of pharmaceutical orders for multiple clients daily.

Forklift driver responsibilities included the putting away of materials and moving of the material to the picking line timely as to not hinder the picking process.

Use multiple shipping systems to include UPS Worldship and FedEx Systems.

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: UPS Supply Chain Solutions, Inc.
Pharmacy/Wholesaler License # (if applicable): TBD
Physical Address: 7 Gateway Blvd.
City: Pedricktown State: NJ Zip: 08067
Mailing Address (if different from physical address): *same as physical address*
City: State: Zip:
Telephone: 856-351-6619 Website: www.ups.com
Licensing Company Email: ralicensing@ups.com

Section 2: Personal Information

First: Roger Middle: M. Last: McLaughlin, Jr.
Alias(es, nicknames, name changes, etc.): N/A
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X
Mailing Address: [redacted]
City: Rising Sun State: MD Zip: [redacted]
Telephone: [redacted] Email: rogermclaughlin@ups.com
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name
Delcastle Vo-Tech
From - To (MM/YY – MM/YY)
1978 - 1981
Address
1417 Newport Road
City
Wilmington
State
DE
Zip
19804
Diploma/Degree obtained, if any
Diploma

School Name
From - To (MM/YY – MM/YY)
Address
City
State
Zip
Diploma/Degree obtained, if any

School Name
From - To (MM/YY – MM/YY)
Address
City
State
Zip
Diploma/Degree obtained, if any

School Name
From - To (MM/YY – MM/YY)
Address
City
State
Zip
Diploma/Degree obtained, if any

School Name
From - To (MM/YY – MM/YY
Address
City
State
Diploma/Degree obtained, if any

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
9/2007 - present	[redacted]	Rising Sun	MD	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City		Zip
From - To (MM/YY – MM/YY)	Address	City		Zip
From - To (MM/YY – MM/YY)	Address	City		Zip
From - To (MM/YY – MM/YY)	Address	City		Zip
From - To (MM/YY – MM/YY)	Address	City		Zip
From - To (MM/YY – MM/YY)	Address	City		Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			01/25 - present	
Business Address		**City**	**State**	**Zip**
7 Gateway Blvd.		Pedricktown	NJ	08067
Phone	**Title**		**Number of Employed Hours**	
856-351-6619	Supervisor, Distribution Operations		477	
Description of Duties				
see attachment# 9				

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			01/23 - 12/24	
Business Address		**City**	**State**	**Zip**
2235 Route 322, Suite 100		Woolwich Township	NJ	08085
Phone	**Title**		**Number of Employed Hours**	
N/A (building closed)	Facility Manager		4,698	
Description of Duties				
see attachment# 9				

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			1/21 - 12/22	
Business Address		**City**	**State**	**Zip**
7 Gateway Blvd.		Pedricktown	NJ	08067
Phone	**Title**		**Number of Employed Hours**	
856-351-6619	Facility Operations Manager		2,340	
Description of Duties				
see attachment# 9				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				
N/A				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

(1) 26-Nov-2025

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

N/A

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

26-Mar-2025

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge		N/A		
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

26 Mar 2025

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

24 Mar 2025
Date

I, Roger M. McLaughlin, Jr., **certify that as the designated representative for**

UPS Supply Chain Solutions, Inc., 7 Gateway Blvd., Pedricktown, NJ, 08067,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ____ I am at least 21 years of age;
3. ____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Roger M. McLaughlin, Jr.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

24 Mar 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Roger M. McLaughlin, Jr.

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

26 Mar 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Delaware, ss. County of New Castle

I, Roger M. McLaughlin, Jr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

26 Mar 2025

Date

Subscribed and Sworn to before me this 26th day of March, 2025

Carlene L. Colasanti

Notary Public Signature

(Seal)

Attachment# 7

Employee Listing

Name	Access level
*bishop, david	Employee
*burrell, noah timothy	Employee
*collazo, johnathan	Employee
*collins, everett	Employee
*diggs, bruce	Employee
*georges, esdras	Employee
*hunt, richard	Employee
*ingram, arthur	Employee
*kelley, olivia	Employee
*martinez-cruz, yadser	Employee
*massengill, darryl	Employee
*mccarrie, matthew	Employee
*mckenzie, merrick	Employee
*muhsin, mohammed	Employee
*murphey, erin	Employee
*murray, delaine	Employee
*nipe, jullian	Employee
*patterson-hawkins, jaydon	Employee
*reynoso, bryan juarez	Employee
*robinson, zamir	Employee
*santiago, juan	Employee
*smith, jerome	Employee
*white, alecio	Employee
abdur rahmaan, shareefah	Employee
akinola, ayodeji	Employee
bacon, william	Employee
bennett, rodney	Employee
bosch, james	Employee
brown, marlon	Employee
burton, brittany	Employee
campbell, tevin	Employee
chiodi, brian	Employee
collins, james	Employee
collins, kimberly	Employee
cruz valle, william abraham	Employee
curtis, alyssa	Employee
dickey, jonathon	Employee
duffield, bradley	Employee
faust, maurice	Supervisor
freso, william	Employee
gallaher, angel	Employee
george, erik	Employee

guzman ferreiras, yuleydy	Employee
halpin, robert	Employee
harasta, stephen	Employee
hayes, charles	Employee
hickman, ken	Supervisor
hickman, michael	Supervisor
hobbs, talaihia	Employee
holloway, terrence	Employee
iannacone, mark	Employee
jackson ortega, jackine	Employee
jones, alan	Employee
kelley, clifford	Employee
kelley, jordan	Employee
klepka, david	Employee
labbree, william	Employee
leftridge, carita	Employee
lloyd, dawn	Employee
loomis, stephen	Employee
mcclintock, derrick	Employee
mcdonald, raymond	Employee
mckenzie, beverly	Employee
mendez, amelia	Employee
miranda, bryan	Employee
okoro, ebere	Employee
ortega, ivan	Employee
parker, david	Employee
parks, brian	Employee
perez, kylie	Employee
perkins, jamison	Employee
ponce perez, magaly	Employee
rivaldo, jose	Employee
robertson, deborah	Supervisor
robertson, scott	Employee
robinson, swantiya	Employee
romero maysonet, luis	Employee
romero saborido, david	Employee
salamanca, neychaliz	Employee
santiago, bermarit	Employee
sehrawat, daksh	Employee
smith, bradley	Employee
smith, christen	Employee
taraschi, terry	Employee
thornton, carl	Employee
tillett, darnell	Employee

timchal, grant	Employee
traina, thomas	Employee
tyrol, william	Employee
valdez, albania	Employee
valle, yanira	Employee
vassallo, nicholas	Employee
vassallo, ray	Employee
wata, claude	Employee
watson, william	Employee
wilson, keyonne	Employee
wilson, tasha	Employee
wine, melinda	Employee
zea zea, nubia	Employee
zidor, wawens	Employee
Rizzo, David	Supervisor
McLaughlin, Roger	Supervisor
Hastings, Allen	Supervisor
Esterly, Jake	Manager

4BBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (05/12/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Axia Medical Solutions

Physical Address: 10691 King William Dr

City: Dallas State: TX Zip: 75220

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 866-494-4466 Website: www.axiamedicalsolutions.com

Name of Designated Representative (DR): Ryan Arvo

Licensing Company Email: licensing@axiamedicalsolutions.c DR Email: licensing@axiamedicalsolutions.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	☐ Others:	■ Warehouse
☐ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Amy Dang

Original Signature (electronic, copies or stamps not accepted)

2/3/25

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Wellgistics
Address: 358 Eagles Landing Dr City: Lakeland State: FL Zip: 78738
Name: Masters Drug Company
Address: 3600 Pharma Way City: Lebanon State: OH Zip: 45036
Name: Strides Pharmaceuticals
Address: 2 Tower Center BLVD STE 1102 City: East Brunswick State: NJ Zip: 08816
Name: Rising Pharmaceuticals
Address: 2 Tower Center BLVD Ste 1401 City: East Brunswick State: NJ Zip: 08816

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
~~Telephone:~~ 806-640-8223 ~~Email:~~ Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California
Parent Company (if any):
Corporation/Organization Name: Axia Medical Solutions LLC
Mailing Address: 10691 King William Dr
City: Dallas State: TX Zip: 75220
Telephone: 806-640-8223 Email: licensing@axiamedicalsolutions.com
Contact Person Name: Amy Dang

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Axia Medical Solutions LLC

Facility Name

Amy Dang

Print Name of Authorized Person Submitting Application

Original Signature of Authorized Person (copies or stamps not accepted)

2/3/25

Date

Board Use Only	Date Received: _____ Amount: _____

Axia Medical Solutions LLC:

List all Officers and Directors:

Amy Dang

List all shareholders and their percent ownership:

Amy Dang 100%

Officers/Directors/Partners information ; List all percent ownership

Amy Lou Dang, home address [redacted] ownership = 100%, sole officer

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	AXIA MEDICAL SOLUTIONS, LLC
Entity No.:	200324210144
Registration Date:	08/28/2003
Entity Type:	Limited Liability Company - CA
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of January 28, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 289800328

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at bizfileOnline.sos.ca.gov.

- Please contact Drugs and Food Safety Licensing Branch at (512) 834-6727 immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **https://www.dshs.texas.gov/drug-manufacturers-distributors/applications-forms-drug-manufacturers-distributor**
- Please submit written notice if you close or sell your business. You can email us at drugs-foodsafety@dshs.texas.gov.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drugs and Food Safety Licensing Branch at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

RYAN ARVO
210 FREEDOM TR
FORNEY TX 75126

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

AXIA MEDICAL SOLUTIONS LLC

10691 KING WILLIAM DR
DALLAS, TX 75220

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003995
Expires: September 19, 2026

NON-TRANSFERABLE

Commissioner

519094

TEXAS Health and Human Services | Texas Department of State Health Services

License Details

"License" means a license, certificate, registration, permit, or other form of authorization, including a renewal of the authorization, that a person must obtain to practice or engage in a particular business, occupation, or profession, or a facility must obtain before a particular business, occupation, or profession is practiced or engaged in within the facility. A "License Rank" is the level of license; a "License Modifier" provides additional information on the scope of the license.

A license may have one or two statuses. The first status is normally "Current" which means the license is in good standing. If the first status is "Expired" or "Null and Void", or if either status shows "Inactive", the licensee may not practice in the profession and/or operate as a licensed business.

For more information regarding this license, including any disciplinary information displayed below, please contact the appropriate board or program office. A list of DSHS licensing board and programs may be found at: http://www.dshs.state.tx.us/Licensee-Registrant-Permittee.aspx or click the link at the bottom of this page.

Press "Previous Record" to display the previous license.

Press "Next Record" to display the next license.

Press "Search Results" to return to the Search Results list.

Press "New Search Criteria" to do another search of this type.

Press "New Search" to start a new search.

License Number: 1003995 ***Current Date: 01/28/2025 11:31 AM***

Name:	AXIA MEDICAL SOLUTIONS LLC
License Type:	Prescription Drug Distributor
License Status:	Current
Expiry Date:	09/19/2026
Effective Rank Date:	12/13/2024
Modifier(s):	Own Label Dist Prescription Non Prescrpt Third Party Logistics Provider

Addresses

Physical Loc	Address	AXIA MEDICAL SOLUTIONS LLC 10691 KING WILLIAM DR DALLAS , TX DALLAS 75220 US
Mailing Address	Address	RYAN ARVO FORNEY , TX ROCKWALL 75126 US

Food & Drug Owner

Licensee's Role	Food & Drug License
Related Party Role	Food & Drug Owner

Related Party Name	License	Address
AXIA MEDICAL SOLUTIONS LLC	Owner #A073451 Status: Current Expiration Date:	CARLSBAD , CA OUT OF STATE/UNKNOWN 92011 US

Previous Record | Next Record | Search Results | New Search Criteria | New Search | Print

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. PB11562514110

Application/License No. _____

Axia Medical Solutions LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 10691 King William Dr, Dallas TX 75220 (Address of Applicant/Principal), as PRINCIPAL, and PHILADELPHIA INDEMNITY INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of Pennsylvania (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is One Bala Plaza, Suite 100, Bala Cynwyd, PA 19004 - 0950 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 2/01/2025 (Effective Date).

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS
639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 30th day of January, 2025.

APPLICANT/PRINCIPAL

COMPANY

Authorized Representative

SURETY

Surety Company's Representative

Ryan Tash, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Witness

Witness

Countersigned by:

Nevada Resident Agent

PHILADELPHIA INDEMNITY INSURANCE COMPANY
One Bala Plaza, Suite 100
Bala Cynwyd, PA 19004-0950

Power of Attorney

KNOW ALL PERSONS BY THESE PRESENTS: That **PHILADELPHIA INDEMNITY INSURANCE COMPANY** (the Company), a corporation organized and existing under the laws of the Commonwealth of Pennsylvania, does hereby constitute and appoint **Ryan Tash, & Susan Fournier of Surety Solutions Insurance Services, Inc.** its true and lawful Attorney-in-fact with full authority to execute on its behalf bonds, undertakings, recognizances and other contracts of indemnity and writings obligatory in the nature thereof, issued in the course of its business and to bind the Company thereby, in an amount not to exceed **$50,000,000.**

This Power of Attorney is granted and is signed and sealed by facsimile under and by the authority of the following Resolution adopted by the Board of Directors of PHILADELPHIA INDEMNITY INSURANCE COMPANY on the 14th of November 2016.

RESOLVED: That the Board of Directors hereby authorizes the President or any Vice President of the Company: (1) Appoint Attorney(s) in Fact and authorize the Attorney(s) in Fact to execute on behalf of the Company bonds and undertakings, contracts of indemnity and other writings obligatory in the nature thereof and to attach the seal of the Company thereto; and (2) to remove, at any time, any such Attorney-in-Fact and revoke the authority given. And, be it

FURTHER RESOLVED: That the signatures of such officers and the seal of the Company may be affixed to any such Power of Attorney or certificate relating thereto by facsimile, and any such Power of Attorney so executed and certified by facsimile signatures and facsimile seal shall be valid and binding upon the Company in the future with respect to any bond or undertaking to which it is attached.

IN TESTIMONY WHEREOF, PHILADELPHIA INDEMNITY INSURANCE COMPANY HAS CAUSED THIS INSTRUMENT TO BE SIGNED AND ITS CORPORATE SEALTO BE AFFIXED BY ITS AUTHORIZED OFFICE THIS 5TH DAY OF OCTOBER 2024.

(Seal)

John Glomb, President & CEO
Philadelphia Indemnity Insurance Company

On this 5th day of October, 2024 before me came the individual who executed the preceding instrument, to me personally known, and being by me duly sworn said that he is the therein described and authorized officer of the **PHILADELPHIA INDEMNITY INSURANCE COMPANY**; that the seal affixed to said instrument is the Corporate seal of said Company; that the said Corporate Seal and his signature were duly affixed.

Commonwealth of Pennsylvania - Notary Seal
Vanessa Mckenzie, Notary Public
Delaware County
My commission expires November 3, 2028
Commission number 1366394
Member, Pennsylvania Association of Notaries

Notary Public: Vanessa McKenzie

residing at: Linwood, PA

My commission expires: November 3, 2028

I, Edward Sayago, Corporate Secretary of PHILADELPHIA INDEMNITY INSURANCE COMPANY, do hereby certify that the foregoing resolution of the Board of Directors and the Power of Attorney issued pursuant thereto on the 5th day October 2024 are true and correct and are still in full force and effect. I do further certify that John Glomb, who executed the Power of Attorney as President, was on the date of execution of the attached Power of Attorney the duly elected President of PHILADELPHIA INDEMNITY INSURANCE COMPANY.

In Testimony Whereof I have subscribed my name and affixed the facsimile seal of each Company this 30 day of January, 20 25

Edward Sayago, Corporate Secretary
PHILADELPHIA INDEMNITY INSURANCE COMPANY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Axia Medical Solutions

Pharmacy/Wholesaler License # (if applicable): TX 1003895

Physical Address: 10691 King William Dr

City: Dallas State: TX Zip: 75220

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 866-494-4466 Website: www.axiamedicalsolutions.com

Licensing Company Email: licensing@axiamedicalsolutions.com

Section 2: Personal Information

First: Ryan Middle: Michael Last: Arvo

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Addr[redacted]

City: Forney State: TX Zip: 75126

Telephone: [redacted] Email: rarvo@axiamedicalsolutions.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Poteet High School		08/03 - 05/07	
Address	City	State	Zip
1020 FM1470	Poteet	TX	78065
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Texas Tech University		08/07 - 05/09	
Address	City	State	Zip
2500 Broadway W	Lubbock	TX	79409
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Brookhaven College		08/11 - 09/13	
Address	City	State	Zip
3939 Valley View Ln	Farmers Branch	TX	75244
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/19 - present	[redacted]	Forney	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
03/17 - 01/19		Forney	TX	
From - To (MM/YY – MM/YY)		City	State	
1/15 - 3/17		Mesquite	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Axia Medical Solutions			10/24- present	
Business Address		**City**	**State**	**Zip**
10691 King William Dr		Dallas	TX	75220
Phone	**Title**		**Number of Employed Hours**	
866-494-4466	Purchasing Director		720	
Description of Duties				
Purchasing, Procurement, Inventory Management, Returns, Quarantine, SOPs				

Business Name			From - To (MM/YY – MM/YY)	
Prodigy Health			12/21 - 10/23	
Business Address		**City**	**State**	**Zip**
7901 E Riverside Dr STE 125		Austin	TX	78744
Phone	**Title**		**Number of Employed Hours**	
512-693-4376	Purchasing Lead		4160	
Description of Duties				
Assist with the purchasing, Procurement, Inventory Management, Returns, Quarantine, SOPs				

Business Name			From - To (MM/YY – MM/YY)	
Mockingbird Pharma			05/19 - 12/21	
Business Address		**City**	**State**	**Zip**
2351 Merritt Dr		Garland	TX	75041
Phone	**Title**		**Number of Employed Hours**	
972-591-0598	Warehouse Associate		5560	
Description of Duties				
Management of warehouse, picking, packing, shipping, returns, DSCSA, comply with all state and federal guidelines				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Ryan Arvel

Original Signature (electronic, copies or stamps not accepted)

2/5/2025

Date

I, Ryan Arvo, **certify that as the designated representative for**

Axia Medical Solutions LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RA I am at least 21 years of age;
3. RA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ryan Arvo

Print Name (First, Last)

Ryan Arvo

Original Signature (electronic, copies or stamps not accepted)

2/5/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Arvo

Print Name (First, Last)

Ryan Arvo

Original Signature (electronic, copies or stamps not accepted)

2/5/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Dallas

I, Ryan Arvo, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ryan Arvo

Original Signature

2/5/2025

Date

Subscribed and Sworn to before me this 3rd day of February.

Luis Melendez

Notary Public Signature

LUIS ANGEL MELENDEZ
Notary Public, State of Texas
Comm. Expires 12-17-2028
Notary ID 132823195
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Axia Medical Solutions

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Wholesale TX license #1003995

Physical Address: 10691 King William Dr

City: Dallas State: TX Zip: 75220

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 866-494-4466 Website: www.axiamedicalsolutions.com

Licensing Company Email: licensing@axiamedicalsolutions.com

Section 2: Personal Information

First: Amy Middle: Lou Last: Dang

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Austin State: TX Zip: [redacted]

Telephone: [redacted] Email: licensing@axiamedicalsolutions.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Caprock High School		08/90- 05/94	
Address	City	State	Zip
3001 E 34th Ave	Amarillo	TX	79103
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Amarillo College		08/94 - 05/97	
Address	City	State	Zip
2201 S Washington St #2411	Amarillo	TX	79109
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/24 - present	[redacted]	Austin	TX	[redacted]
12/19 - 2/24		Cedar Park	TX	
04/17 - 12/19		Richardson	TX	
01/15-04/17		Rockwall	TX	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Axia Medical Solutions			06/23- present
Business Address	**City**	**State**	**Zip**
10691 King William Dr	Dallas	TX	75220
Phone	**Title**		
866-494-4466	Owner/Officer		
Description of Duties			
Strategy, Finance, Management of staff, HR, payroll, compliance, reporting			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

2/3/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Amy Dang

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/2/25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Dallas

I, Amy Dang, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/3/25

Date

Subscribed and Sworn to before me this 3rd day of February

Notary Public Signature

LUIS ANGEL MELENDEZ
Notary Public, State of Texas
Comm. Expires 12-17-2028
Notary ID 132823195

Employee List

Axia Medical Solutions LLC

10691 King William Dr, Dallas TX 75220

Ryan Arvo

Myles Conway

Luis Melendez

Amy Dang

Trent Walker

4CCC

PHo 4619

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Chewy Wholesale DFW5, LLC

Physical Address: 7243 Grady Niblo Road, Suite 110

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as Physical Address

City: _____ State: _____ Zip: _____

Telephone: 469-554-7840 Website: N/A

Name of Designated Representative (DR): Vicky Tran

Licensing Company Email: pharmacylicensing@chewy.com DR Email: vtran@chewy.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	☐ Controlled Substances	☐ Repacker
☐ Hospitals	☐ [a]Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	■ Others: Over the counter drugs	☐ Warehouse
■ Veterinarians		■ Retail pharmacy wholesale distributor
☐ Others:		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Zoetis US LLC
Address: 1950 W. Oak Circle City: Marietta State: GA Zip: 30062
Name: Elanco
Address: 2500 Innovation Way City: Greenfield State: IN Zip: 46140
Name: PetIQ
Address: 530 Fentress Blvd City: Daytona Beach State: FL Zip: 32114
Name: The Harvard Drug Group
Address: 5960 E. Shelby Drive City: Memphis State: TN Zip: 38141

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): Chewy Pharmacy Texas Holding, LLC
Corporation/Organization Name: Chewy Wholesale DFW5, LLC
Mailing Address: 7700 W. Sunrise Blvd.
City: Plantation State: FL Zip: 33322
Telephone: 877-977-3879 Email: pharmacylicensing@chewy.com
Contact Person Name: Magan Wagner

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.**	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Chewy Wholesale DFW5, LLC

Facility Name

Brent Yoder

Print Name of Authorized Person Submitting Application

Brent E. Yoder

Original signature of Authorized Person (copies or stamps not accepted)

10/29/2024

Date

Board Use Only	Date Received: 11/1/24	Amount: $1000 EC ✓

Chewy Wholesale DFW5, LLC

Owner:
Chewy Wholesale DFW5, LLC
7700 W Sunrise Blvd.
Plantation, FL 33322
100% Owner

Corporate Officers:

Name	Title / Percent of Ownership	Business Address
Ornel Cotera	President, 0%	7700 W Sunrise Blvd. Plantation, FL 33322
Brent Yoder	Vice President, 0%	2506 Boylston Court, Zionsville, IN 46077

Delaware

The First State

I, JEFFREY W. BULLOCK, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "CHEWY WHOLESALE DFW5, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE THIRTY-FIRST DAY OF MAY, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "CHEWY WHOLESALE DFW5, LLC" WAS FORMED ON THE THIRTIETH DAY OF MARCH, A.D. 2023.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

Jeffrey W. Bullock, Secretary of State

7381583 8300

SR# 20242670789

Authentication: 203599265

Date: 05-31-24

You may verify this certificate online at corp.delaware.gov/authver.shtml

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application for Registration for Chewy Wholesale DFW5, LLC (file number 805061040), a DELAWARE, USA, Foreign Limited Liability Company (LLC), was filed in this office on May 16, 2023.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on May 07, 2024.

Jane Nelson
Secretary of State

chewy | Health

October 31, 2024

Chewy Wholesale DFW5, LLC does not hold a DEA registration, FDA registration, or a Controlled Substance registration and therefore does not dispense any controlled substances.

Regards,

Magan Wagner
Licensing & Accreditation Manager
mwagner6@chewy.com

- Please contact this office immediately if any information on this license is incorrect.
- This license must be displayed at the address licensed.
- The license renewal application and fee are due every two years BEFORE the anniversary date. Please note that it is the responsibility of the license holder to remit the licensure fee before the expiration date, whether a payment notice is received or not. Failure to submit the renewal fee before the expiration date will result in a $100.00 delinquency fee for each location and must be remitted before the license will be issued.
- A license that is amended, including a change of name, ownership, legal entity, or a notification of a change in the location of a licensed place of business will require submission of new application and fee. Applications for these changes can be downloaded from our website at **www.dshs.texas.gov**.
- Please submit written notice if you close or sell your business.
- If you have any questions or desire additional information concerning the application process or this license, please contact the Drug and Device Business Filing and Verification Unit at (512) 834-6727. In order to serve you better, DSHS would like you to complete the short online survey at: **https://www.surveymonkey.com/r/RLUsurvey**. The information you provide will assist DSHS in its efforts to continually improve and become more responsive to the needs of its customers. Thank you in advance for your cooperation.

CHEWY WHOLESALE DFW5 LLC
7243 GRADY NIBLO RD STE 110
DALLAS TX 75236

TEXAS DEPARTMENT OF STATE HEALTH SERVICES
REGULATORY LICENSING UNIT

CHEWY WHOLESALE DFW5 LLC

7243 GRADY NIBLO RD STE 110
DALLAS, TX 75236

Pursuant to Health and Safety Code Chapter 431 (Food, Drug, Device, and Cosmetic Act) and Title 25 of the Texas Administrative Code, and in reliance on statements and representations made by licensee, the licensee shall be subject to all applicable rules, regulations and orders of the Texas Department of State Health Services now or hereafter in effect. The above licensee is authorized to engage in the following activities:

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

License # 1003722
Expires: June 5, 2025

NON-TRANSFERABLE

Commissioner

517468

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206
Reno, NV 89521
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 285073764

Application/License No. _____

CHEWY WHOLESALE DFW5, LLC (Applicant/Principal), doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 7243 Grady Niblo Road, Suite 110 Dallas, TX 75236 (Address of Applicant/Principal), as PRINCIPAL, and LIBERTY MUTUAL INSURANCE COMPANY (Surety Company), a corporation organized under the laws of the state of MA (State of Incorporation) and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 175 Berkeley Street Boston, MA 02116 (Address of Surety) as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on April 10, 2024.

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 10th day of April, 2024.

APPLICANT/PRINCIPAL
CHEWY WHOLESALE DFW5, LLC

COMPANY

B & E. Yoder
Authorized Representative

SURETY
LIBERTY MUTUAL INSURANCE COMPANY

Surety Company's Representative

Bartlomiej Siepierski, Attorney-in-fact
print name

SIGNED and SEALED in the presence of

Witness

Witness

SIGNED and SEALED in the presence of

Witness Karolina Zawadzka

Witness Ann Formhals

Countersigned by

Nevada ~~Resident~~ Non-Resident Agent: Christopher P. Trona

Revised February 01, 2021

Liberty Mutual SURETY

This Power of Attorney limits the acts of those named herein, and they have no authority to bind the Company except in the manner and to the extent herein stated.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

Certificate No: **8211417-285057**

POWER OF ATTORNEY

KNOWN ALL PERSONS BY THESE PRESENTS: That The Ohio Casualty Insurance Company is a corporation duly organized under the laws of the State of New Hampshire, that Liberty Mutual Insurance Company is a corporation duly organized under the laws of the State of Massachusetts, and West American Insurance Company is a corporation duly organized under the laws of the State of Indiana (herein collectively called the "Companies"), pursuant to and by authority herein set forth, does hereby name, constitute and appoint, Aaron D. Griffin; Aerie Walton; Bartlomiej Stepierski; Christina L. Sandoval; Christopher P. Troha; Corinne Chapman; Dartonya Wright; Derek J. Elston; James B. McTaggart; Jean Torres; Jennifer L. Jakaitis; Jessica B. Dempsey; Judith A. Lucky-Eftimov; Kristin L. Hannigan; Melissa L. Fortier; Nicholas Kertesz; Rachel Fore; Richard Casas; Roger Paraison; Samantha Chierici; Sandra M. Winsted; Susan A. Welsh; Tara A. Maquinto; Therese M. Jackson

all of the city of Chicago state of IL each individually if there be more than one named, its true and lawful attorney-in-fact to make, execute, seal, acknowledge and deliver, for and on its behalf as surety and as its act and deed, any and all undertakings, bonds, recognizances and other surety obligations, in pursuance of these presents and shall be as binding upon the Companies as if they have been duly signed by the president and attested by the secretary of the Companies in their own proper persons.

IN WITNESS WHEREOF, this Power of Attorney has been subscribed by an authorized officer or official of the Companies and the corporate seals of the Companies have been affixed thereto this 26th day of February, 2024.

Liberty Mutual Insurance Company
The Ohio Casualty Insurance Company
West American Insurance Company

By: _____
David M. Carey, Assistant Secretary

State of PENNSYLVANIA
County of MONTGOMERY ss

On this 26th day of February, 2024 before me personally appeared David M. Carey, who acknowledged himself to be the Assistant Secretary of Liberty Mutual Insurance Company, The Ohio Casualty Company, and West American Insurance Company, and that he, as such, being authorized so to do, execute the foregoing instrument for the purposes therein contained by signing on behalf of the corporations by himself as a duly authorized officer.

IN WITNESS WHEREOF, I have hereunto subscribed my name and affixed my notarial seal at Plymouth Meeting, Pennsylvania, on the day and year first above written.

Commonwealth of Pennsylvania - Notary Seal
Teresa Pastella, Notary Public
Montgomery County
My commission expires March 28, 2025
Commission number 1126044
Member, Pennsylvania Association of Notaries

By: _____
Teresa Pastella, Notary Public

This Power of Attorney is made and executed pursuant to and by authority of the following By-laws and Authorizations of The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company which resolutions are now in full force and effect reading as follows:

ARTICLE IV – OFFICERS: Section 12. Power of Attorney.
Any officer or other official of the Corporation authorized for that purpose in writing by the Chairman or the President, and subject to such limitation as the Chairman or the President may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Corporation to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact, subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Corporation by their signature and execution of any such instruments and to attach thereto the seal of the Corporation. When so executed, such instruments shall be as binding as if signed by the President and attested to by the Secretary. Any power or authority granted to any representative or attorney-in-fact under the provisions of this article may be revoked at any time by the Board, the Chairman, the President or by the officer or officers granting such power or authority.

ARTICLE XIII – Execution of Contracts: Section 5. Surety Bonds and Undertakings.
Any officer of the Company authorized for that purpose in writing by the chairman or the president, and subject to such limitations as the chairman or the president may prescribe, shall appoint such attorneys-in-fact, as may be necessary to act in behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations. Such attorneys-in-fact subject to the limitations set forth in their respective powers of attorney, shall have full power to bind the Company by their signature and execution of any such instruments and to attach thereto the seal of the Company. When so executed such instruments shall be as binding as if signed by the president and attested by the secretary.

Certificate of Designation – The President of the Company, acting pursuant to the Bylaws of the Company, authorizes David M. Carey, Assistant Secretary to appoint such attorneys-in-fact as may be necessary to act on behalf of the Company to make, execute, seal, acknowledge and deliver as surety any and all undertakings, bonds, recognizances and other surety obligations.

Authorization – By unanimous consent of the Company's Board of Directors, the Company consents that facsimile or mechanically reproduced signature of any assistant secretary of the Company, wherever appearing upon a certified copy of any power of attorney issued by the Company in connection with surety bonds, shall be valid and binding upon the Company with the same force and effect as though manually affixed.

I, Renee C. Llewellyn, the undersigned, Assistant Secretary, The Ohio Casualty Insurance Company, Liberty Mutual Insurance Company, and West American Insurance Company do hereby certify that the original power of attorney of which the foregoing is a full, true and correct copy of the Power of Attorney executed by said Companies, is in full force and effect and has not been revoked.

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the seals of said Companies this 10th day of April, 2024.

By: _____
Renee C. Llewellyn, Assistant Secretary

LMS-12873 LMIC OCIC WAIC Multi Co 02/21

Not valid for mortgage, note, loan, letter of credit, currency rate, interest rate or residual value guarantees.

For bond and/or Power of Attorney (POA) verification inquiries, please call 610-832-8240 or email HOSUR@libertymutual.com.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Chewy Wholesale DFW5, LLC

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 7243 Grady Niblo Road, Suite 110

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as Physical Address

City: State: Zip:

Telephone: 469-554-7840 Website: N/A

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Vicky Middle: Thu Last: Tran

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ■ F ☐ X

Mailing Address: [redacted]

City: Dallas State: TX Zip: [redacted]

Telephone: 469-554-7840 Email: vtran@chewy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Kentucky		08/2008-05/2012	
Address	City	State	Zip
338 Lexington Ave.	Lexington	KY	40508
Diploma/Degree obtained, if any			
Bachelor's of Science			

School Name		From - To (MM/YY – MM/YY)	
Paul Laurence Dunbar		08/2004-05/2008	
Address	City	State	Zip
1600 Man o' War Blvd	Lexington	KY	40513
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
11/1/23 - present	[redacted]	Dallas	TX	[redacted]
10/1/23 - 10/31/23		Dallas	TX	
9/1/23 - 9/30/23		Dallas	TX	
10/1/20 - 8/31/23		Lexington	KY	
8/2/18 - 9/30/20		Louisville	KY	
5/31/14 - 8/1/18		Lexington	KY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Chewy Wholesale DFW5, LLC			09/01/2023 - Current	
Business Address		**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 110		Dallas	TX	75236
Phone	**Title**		**Number of Employed Hours**	
469-554-7840	Designated Representative		2,240 Hours	
Description of Duties				
Maintain & manage inventory, drug storage, policies, & distribution operations. Institute & maintain compliance to all state & federal regulations.				

Business Name			From - To (MM/YY – MM/YY)	
Chewy Pharmacy, LLC			08/15/2018 - 8/31/2023	
Business Address		**City**	**State**	**Zip**
11403 Bluegrass Pkwy., Suite 650		Louisville	KY	40299
Phone	**Title**		**Number of Employed Hours**	
786-320-7111	Pharmacist		9,600 Hours	
Description of Duties				
Approving, dispensing & record keeping prescriptions. Also supervised pharmacy technicians & on-boarded new pharmacist.				

Business Name			From - To (MM/YY – MM/YY)	
TriHealth Rehabilitation Hospital			10/1/2018 - 05/31/2022	
Business Address		**City**	**State**	**Zip**
2155 Dana Ave		Cincinnati	OH	45207
Phone	**Title**		**Number of Employed Hours**	
513-601-0600	Pharmacist		820 Hours	
Description of Duties				
Approving, dispensing & record keeping prescriptions				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I, Vicky Tran, **certify that as the designated representative for**

Chewy Wholesale DFW5, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. VT I am at least 21 years of age;
3. VT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. VT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. VT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. VT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. VT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Vicky, Tran

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/23/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Vicky, Tran

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/23/24

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Dallas

I, Vicky Tran, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/23/24

Date

Subscribed and Sworn to before me this 23 day of October 2024

Notary Public Signature

HILDA FLORES
Notary Public
STATE OF TEXAS
My Comm. Exp. 10-27-27
Notary ID # 13203472-4

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Wholesale DFW5, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 7243 Grady Niblo Road, Suite 110

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as Physical Address

City: _____ State: _____ Zip: _____

Telephone: 469-554-7840 Website: N/A

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Ornel Middle: Andrew Last: Cotera

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Addre[redacted]

City: Plantation State: FL Zip: [redacted]

Telephone[redacted] Email: ocotera@chewy.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mast Academy		06/96 - 05/00	
Address	**City**	**State**	**Zip**
3979 Rickenbacker Causeway	Miami	FL	33149
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/00 - 08/06	
Address	**City**	**State**	**Zip**
205 Fletcher Drive	Gainesville	FL	32611
Diploma/Degree obtained, if any			
B.S Economics			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/19 - Current	[redacted]	Deerfield	FL	[redacted]
From - To (MM/YY – MM/YY)		City	State	
10/09 - 05/19		Deerfield	FL	
From - To (MM/YY – MM/YY)		City	State	
03/11 - 11/14		Matawan	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Chewy, Inc.			09/15 - Current	
Business Address		**City**	**State**	**Zip**
7700 W Sunrise Blvd.		Plantation	FL	33322
Phone	**Title**			
786-320-7111	President, Category Management			
Description of Duties				
Monitor & oversee Chewy Pharmacy, Compounding, OTC, F&T and the practice hub business teams.				

Business Name			From - To (MM/YY – MM/YY)	
Office Dept			11/14 - 09/15	
Business Address		**City**	**State**	**Zip**
6600 N. Military Trail		Boca Raton	FL	33487
Phone	**Title**			
561-438-4800	Sr. Category Manager			
Description of Duties				
Managed assortment for digital storage category.				

Business Name			From - To (MM/YY – MM/YY)	
Hess Corp.			06/07 - 11/14	
Business Address		**City**	**State**	**Zip**
1 Hess Plaza		Woodbridge	NJ	07095
Phone	**Title**			
732-750-6888	Category Manager			
Description of Duties				
Managed store assortment for convenience stores.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

7/2/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ornel Cotera

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

7/2/24

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Ornel Cotera, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

7/2/24

Date

Subscribed and Sworn to before me this 2nd day of July 2024

Peralta

Notary Public Signature

STACY PERALTA
Notary Public - State of Florida
Commission # HH 488949
My Comm. Expires Feb 5, 2028
Bonded through National Notary Assn.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Chewy Wholesale DFW5, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 7243 Grady Niblo Road, Suite 110

City: Dallas State: TX Zip: 75236

Mailing Address (if different from physical address): Same as Physical Address

City: State: Zip:

Telephone: 469-554-7840 Website: N/A

Licensing Company Email: pharmacylicensing@chewy.com

Section 2: Personal Information

First: Brent Middle: Edward Last: Yoder

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Zionsville State: IN Zip: [redacted]

Telephone: [redacted] Email: byoder@chewy.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Massachusetts Institute of Technology		06/11-05/13	
Address	**City**	**State**	**Zip**
1 Amherst St	Cambridge	MA	02142
Diploma/Degree obtained, if any			
Masters of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts Institute of Technology		06/11-05/13	
Address	**City**	**State**	**Zip**
1 Amherst St	Cambridge	MA	02142
Diploma/Degree obtained, if any			
Masters of Systems Engineering			

School Name		From - To (MM/YY – MM/YY)	
Georgia Institute of Technology		08/99-05/04	
Address	**City**	**State**	**Zip**
311 Ferst Drive	Atlanta	GA	30332
Diploma/Degree obtained, if any			
BS Industrial Engineering			

School Name		From - To (MM/YY – MM/YY)	
Crete-Monee High School		08/95-05/99	
Address	**City**	**State**	**Zip**
1515 W Exchange St	Crete	IL	60417
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2015-06/2024	[redacted]	Zionsville	IN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/2013-03/2015		Indianapolis	IN	
From - To (MM/YY – MM/YY)		City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Chewy Pharmacy DFW8, LLC			03/23 - Current
Business Address	**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 100	Dallas	TX	75236
Phone	**Title**		
469-554-7870	Vice President		
Description of Duties			
Vice President			

Business Name			From - To (MM/YY – MM/YY)
Chewy Wholesale DFW5, LLC			03/23 - Current
Business Address	**City**	**State**	**Zip**
7243 Grady Niblo Road, Suite 110	Dallas	TX	75236
Phone	**Title**		
469-554-7840	Vice President		
Description of Duties			
Vice President			

Business Name			From - To (MM/YY – MM/YY)
Chewy Pharmacy MCO4, LLC			06/23 - Current
Business Address	**City**	**State**	**Zip**
3376 NW 35th Avenue Road	Ocala	FL	34475
Phone	**Title**		
352-820-7412	Vice President		
Description of Duties			
Vice President			

Business Name			From - To (MM/YY – MM/YY)
Chewy.com			10/22-06/23
Business Address	**City**	**State**	**Zip**
1974 Innovation Blvd	Clayton	IN	46118
Phone	**Title**		
317-539-8549	Sr. Director, Pharmacy Operations		
Description of Duties			
Operational director responsible for the fulfillment operations of pharmacy orders			

Business Name			From - To (MM/YY – MM/YY)
Chewy.com			02/21-10/22
Business Address	**City**	**State**	**Zip**
1974 Innovation Blvd	Clayton	IN	46118
Phone	**Title**		
317-539-8549	Sr. Director, FC Design and Infrastructure		
Description of Duties			
Responsible for the design, installation, and maintenance of Chewy.com fulfillment assets.			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Chewy.com			3/20-2/21
Business Address	**City**	**State**	**Zip**
1974 Innovation Blvd.	Clayton	IN	46118
Phone	**Title**		
317-539-8549	Sr. Director, FC Quality, Customer Experience, and Learning and Development		

Description of Duties

Responsible for fulfillment network quality, SOX compliance, and customer experience. Additionally responsible for developing and executing learning programs for exempt and non exempt employees.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			1/17-2/19
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Director, Reliability and Maintenance Engineering		

Description of Duties

Responsible for the support and maintenance of mechanical, pneumatic, and electrical assets in North, Central, and South America.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			01/17-02/19
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Regional Operations Director		

Description of Duties

Responsible for the fulfillment activities for Amazon.com orders from six warehouses in IN, VA, TN, KY.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			01/15-01/17
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Director of Operations		

Description of Duties

Responsible for the fulfillment activities for Amazon.com orders from a single warehouse in Whitestown, IN.

Business Name			From - To (MM/YY – MM/YY)
Amazon.com			01/14-01/15
Business Address	**City**	**State**	**Zip**
4255 Anson Blvd	Whitestown	IN	46075
Phone	**Title**		
317-769-8011	Sr. Operations Manager		

Description of Duties

Responsible for outbound shipping activities for Amazon.com orders from a single warehouse in Whitestown, IN

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
N/A				
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

B. ✝ E Yoder
Original Signature (electronic, copies or stamps not accepted)

6/27/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brent Yoder

Print Name (First, Last)

B + E Yoder

Original Signature (electronic, copies or stamps not accepted)

6/27/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Hamilton

I, BRENT YODER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

B + E. Yoder

Original Signature

6/27/2024

Date

Subscribed and Sworn to before me this 27th day of June 2024.

Paul H Sloan

Notary Public Signature

PAUL H SLOAN, III
Notary Public - Seal
Boone County - State of Indiana
Commission Number NP0672999
My Commission Expires Sep 15, 2031

(Seal)

Chewy Wholesale DFW5, LLC_Employee List

Name	Title
Vicky Tran	Designated Representative

4DDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?		☐ Nevada ■ Out-of-State
Type of Application (check applicable box)		**Wholesaler Business Type (check applicable box)**
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH _____	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: Correct Rx Pharmacy Services, Inc.

Physical Address: 1352 Charwood Road, Suite C

City: Hanover State: Maryland Zip: 21076

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: (443) 557-0100 Website: www.correctrxpharmacy.com

Name of Designated Representative (DR): Jill R. Molofsky, RPh

Licensing Company Email: info@correctrxpharmacy.com DR Email: jmolofsky@correctrxpharmacy.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
☐ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
☐ Practitioners	■ Controlled Substances	☐ Repacker
☐ Hospitals	☐ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
☐ Wholesalers	☐ Others:	☐ Warehouse
☐ Veterinarians		■ Retail pharmacy wholesale distributor
■ Others: Correctional Facilities		☐ Others:

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

November 14, 2024
Date

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Cencora
Address: 1 W 1st Ave City: Conshohocken State: PA Zip: 19428
Name: Covis
Address: 200 Connell Dr., Suite 3200 City: Berkeley Heights State: NJ Zip: 07922
Name: Healthsource Distributors, LLC
Address: 7200 Rutherford Road, Suite 150 City: Windsor Mill State: MD Zip: 21244
Name: Jams Rx
Address: 4811 Lyons Technology Pkwy, Units 23 City: Coconut Creek State: FL Zip: 33073

Section 4: Publicly Traded Corporation

State of Incorporation: N/A
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Maryland
Parent Company (if any): N/A
Corporation/Organization Name: Correct Rx Pharmacy Services, Inc.
Mailing Address: 1352 Charwood Road, Suite C
City: Hanover State: Maryland Zip: 21076
Telephone: (443) 557-0100 Email: jmolofsky@correctrxpharmacy.com
Contact Person Name: Jill R. Molofsky, RPh

Section 6: Partnership

Partnership Name: N/A
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

Owner's Name: N/A
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✓
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✓
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List the top four corporation shareholders and their percent ownership.**	✓			
• **List of all corporation shareholders and their percent ownership.**		✓		
• **List of all partners and their percent ownership.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months**.	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances**	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only)	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.**	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)**	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/.		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

Correct Rx Pharmacy Services, Inc.

Facility Name

Ellen H. Yankellow, PharmD

Print Name of Authorized Person Submitting Application

Ellen H. Yankellow

Original signature of Authorized Person (copies or stamps not accepted)

November 14, 2024

Date

Board Use Only	Date Received: _____	Amount: Check # 041506

Correct Rx Pharmacy Services, Inc.
1352 Charwood Road, Suite C
Hanover, Maryland 21076
Phone 443-557-0100 Fax 443-557-0333

CORPORATE OFFICERS/DIRECTORS/SHAREHOLDER

President/Director/Shareholder: 44.22% Ellen H. Yankellow, PharmD

[redacted]

Shareholder: 34% Martin Yankellow 2021 Irrevocable Trust

[redacted]

Secretary/Director/Shareholder: 13.4% Jill R. Molofsky, RPh

[redacted]

Treasurer/Director/Shareholder: 8.38% Martin L. Yankellow

[redacted]

STATE OF MARYLAND
Department of Assessments and Taxation

I, DANIEL K. PHILLIPS OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF THE STATE OF MARYLAND, DO HEREBY CERTIFY THAT THE DEPARTMENT, BY LAWS OF THE STATE, IS THE CUSTODIAN OF THE RECORDS OF THIS STATE RELATING TO THE FORFEITURE OR SUSPENSION OF CORPORATIONS, OR THE RIGHTS OF CORPORATIONS TO TRANSACT BUSINESS IN THIS STATE, AND THAT I AM THE PROPER OFFICER TO EXECUTE THIS CERTIFICATE.

I FURTHER CERTIFY THAT CORRECT RX PHARMACY SERVICES, INC. (D07326721), INCORPORATED APRIL 18, 2003, IS A CORPORATION DULY INCORPORATED AND EXISTING UNDER AND BY VIRTUE OF THE LAWS OF MARYLAND AND THE CORPORATION HAS FILED ALL
ANNUAL REPORTS REQUIRED, HAS NO OUTSTANDING LATE FILING PENALTIES ON THOSE REPORTS, AND HAS A RESIDENT AGENT. THEREFORE, THE CORPORATION IS AT THE TIME OF THIS CERTIFICATE IN GOOD STANDING WITH THIS DEPARTMENT AND DULY AUTHORIZED TO EXERCISE ALL THE POWERS RECITED IN ITS CHARTER OR CERTIFICATE OF INCORPORATION, AND TO TRANSACT BUSINESS IN MARYLAND.

IN WITNESS WHEREOF, I HAVE HEREUNTO SUBSCRIBED MY SIGNATURE AND AFFIXED THE SEAL OF THE STATE DEPARTMENT OF ASSESSMENTS AND TAXATION OF MARYLAND AT BALTIMORE ON THIS AUGUST 07, 2024.

Daniel K. Phillips
Director

700 East Pratt Street, 2nd Flr, Ste 2700, Baltimore, Maryland 21202
Telephone Baltimore Metro (410) 767-1344 / Outside Baltimore Metro (888) 246-5941
MRS (Maryland Relay Service) (800) 735-2258 TT/Voice

Online Certificate Authentication Code: ySQWGAs3C0qQs5iFpI68Tw
To verify the Authentication Code, visit http://dat.maryland.gov/verify

153842

State of Maryland

153842

DEPARTMENT OF HEALTH

THE MARYLAND STATE BOARD OF PHARMACY
CERTIFIES THAT Correct Rx Pharmacy Services
IS A REGISTERED Active
Distributor (exp.: 05/31/2025)

SIGNATURE OF BEARER

IN ACCORDANCE WITH THE HEALTH OCCUPATIONS ARTICLE OF THE ANNOTATED CODE OF MARYLAND

LIC. REG. PERM. NO.	EXPIRATION DATE
D01558	05/31/2025

SECRETARY MDH

WHERE REQUIRED BY LAW THIS MUST BE CONSPICUOUSLY DISPLAYED IN OFFICE TO WHICH IT APPLIES

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0632441	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	07-08-2024

CORRECT RX PHARMACY SERVICES, INC.
1352 CHARWOOD RD STE C
HANOVER, MD 210763125

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
RC0632441	08-31-2025	$1850

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	DISTRIBUTOR	07-08-2024

CORRECT RX PHARMACY SERVICES, INC.
1352 CHARWOOD RD STE C
HANOVER, MD 210763125

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. 30BSBJH2516

Application/License No. _____

Correct Rx Pharmacy Services Inc.^^^^^^^ _____, doing or intending to do business as a
Applicant/Principal
pharmaceutical wholesaler, whose address for purposes of service is
1352-C Charwood Road, Hanover, MD 21076 _____, as
Address of Applicant/Principal
PRINCIPAL, and Hartford Fire Insurance Company _____, a
Surety Company
corporation organized under the laws of the state of Connecticut _____
State of Incorporation
and authorized to transact a general surety business in the State of

Nevada, whose address for purposes of service is
One Hartford Plaza, Hartford, CT 06115 _____ as
Address of Surety
SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on November 14, 2024^^^^^^^^^^.
Effective Date

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.
(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this ^14th^^day of November, ^2024.

APPLICANT/PRINCIPAL

Correct Rx Pharmacy Services Inc.

Authorized Representative

SURETY COMPANY

Hartford Fire Insurance Company

Surety Company's Representative

Joelle L LaPierre ^^ +Attorney-in-fact

print name

SIGNED and SEALED in the presence of:

Witness

Witness

SIGNED and SEALED in the presence of:

Carrie Robinson

Witness

Witness

Countersigned by:

NOT REQUIRED

Nevada Resident Agent

POWER OF ATTORNEY

Direct Inquiries, Bond Authenticity and Claims to:
THE HARTFORD
BOND, T-14
One Hartford Plaza
Hartford, Connecticut 06155
Bond.Claims@thehartford.com
call: **888-266-3488** *or fax:* **860-757-5835**

KNOW ALL PERSONS BY THESE PRESENTS THAT:

Agency Name: BLUE RIDGE RISK PARTNERS LLC
Agency Code: 30-720522

- [X] **Hartford Fire Insurance Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Casualty Insurance Company**, a corporation duly organized under the laws of the State of Indiana
- [ ] **Hartford Accident and Indemnity Company**, a corporation duly organized under the laws of the State of Connecticut
- [ ] **Hartford Insurance Company of the Midwest**, a corporation duly organized under the laws of the State of Indiana

having their home office in Hartford, Connecticut (hereinafter collectively referred to as the "Companies") do hereby make, constitute and appoint
Joelle L LaPierre
of Lake Mary, Florida,
its true and lawful Attorney-in-Fact, to sign its name as surety(ies) only as delineated above by, and to execute, seal and acknowledge the following bond, undertaking, contract or written instrument:

Bond No. 30BSBJH2516
Naming Correct Rx Pharmacy Services Inc. as Principal,
and Nevada State Board of Pharmacy as Obligee,
in the amount of See Bond Form(s) on behalf of Company in its business of guaranteeing the fidelity of persons, guaranteeing the performance of contracts and executing or guaranteeing bonds and undertakings required or permitted in any actions or proceedings allowed by law.

In Witness Whereof, and as authorized by a Resolution of the Board of Directors of the Companies on May 23, 2016 the Companies have caused these presents to be signed by its Assistant Vice President and its corporate seals to be hereto affixed, duly attested by its Assistant Secretary. Further, pursuant to Resolution of the Board of Directors of the Companies, the Companies hereby unambiguously affirm that they are and will be bound by any mechanically applied signatures applied to this Power of Attorney.

Phyllis A. Clark, Assistant Secretary

Joelle L. LaPierre, Assistant Vice President

STATE OF FLORIDA
COUNTY OF SEMINOLE } **ss.** Lake Mary

On this 1st day of March, 2024, before me personally came Joelle L. LaPierre, to me known, who being by me duly sworn, did depose and say: that (s)he resides in Seminole County, State of Florida; that (s)he is the Assistant Vice President of the Companies, the corporations described in and which executed the above instrument; that (s)he knows the seals of the said corporations; that the seals affixed to the said instrument are such corporate seals; that they were so affixed by authority of the Boards of Directors of said corporations and that (s)he signed his/her name thereto by like authority.

Mariluz Arce
My Commission HH 287363
Expires July 13, 2026

I, the undersigned, Assistant Vice President of the Companies, DO HEREBY CERTIFY that the above and foregoing is a true and correct copy of the Power of Attorney executed by said Companies, which is still in full force effective as of November 14, 2024.

Signed and sealed in Lake Mary, Florida.

Keith D. Dozois, Assistant Vice President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Correct Rx Pharmacy Services, Inc.

Pharmacy/Wholesaler License # (if applicable): D01558 (Maryland)

Physical Address: 1352 Charwood Road, Suite C

City: Hanover State: Maryland Zip: 21076

Mailing Address (if different from physical address): (Same)

City: State: Zip:

Telephone: 443-557-0100 Website: www.correctrxpharmacy.com

Licensing Company Email: info@correctrxpharmacy.com

Section 2: Personal Information

First: Jill Middle: Lisa Last: Molofsky

Alias(es, nicknames, name changes, etc.): Rosenfeld (Maiden name)

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Pikesville State: Maryland Zip: [redacted]

Telephone: 443-557-0100 Email: jmolofsky@correctrxpharmacy.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland School of Pharmacy		09/78-05/81	
Address	**City**	**State**	**Zip**
20 N. Pine Street	Baltimore	MD	21201
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Maryland, College Park		09/76-06/78	
Address	**City**	**State**	**Zip**
7736 Baltimore Avenue	College Park	MD	20742
Diploma/Degree obtained, if any			
N/A - Prepharmacy school requisites			

School Name		From - To (MM/YY – MM/YY)	
Pikesville High School		09/73 - 06/76	
Address	**City**	**State**	**Zip**
7621 Labyrinth Road	Pikesville	MD	21208
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/19 - Present	[redacted]	Pikesville	MD	[redacted]
From - To (MM/YY – MM/YY)		City	State	
07/89 - 09/19		Owings Mills	MD	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Correct Rx Pharmacy Services, Inc.			04/03 - Present	
Business Address		**City**	**State**	**Zip**
1352 Charwood Road, Suite C		Hanover	MD	21076
Phone	**Title**		**Number of Employed Hours**	
(443) 557-0100	Vice President and Secretary		41,000	
Description of Duties				
Supervise medication record keeping, storage, and shipments to our clients. Ensure all wholesaler activities abide by applicable state and federal law. Review and update policies and oversee staff training and credentialing.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/14/2024
Date

I, Jill R. Molofsky, **certify that as the designated representative for**

Correct Rx Pharmacy Services, Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jill R. Molofsky

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/14/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jill R. Molofsky

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/14/2024

Date

Please have this section completed in the presence of a Notary Public.

State of MARYLAND, ss. County of Anne Arundel

I, Jill R. Molofsky, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/14/2024

Date

Subscribed and Sworn to before me this 14 day of November, 2024

Tyrina Ann Hardiman

Notary Public Signature

Commission ends Jan 15, 2027



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Correct Rx Pharmacy Services, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): D01558 (Maryland)

Physical Address: 1352 Charwood Road, Suite C

City: Hanover State: MD Zip: 21076

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: (443) 557-0100 Website: www.correctrxpharmacy.com

Licensing Company Email: info@correctrxpharmacy.com

Section 2: Personal Information

First: Jill Middle: Rosenfeld Last: Molofsky

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Pikesville State: MD Zip: [redacted]

Telephone: [redacted] Email: jmolofsky@correctrxpharmacy.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland School of Pharmacy		09/78-05/81	
Address	City	State	Zip
20 N. Pine Street	Baltimore	MD	21201
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Maryland College Park		09/76-06/78	
Address	City	State	Zip
7736 Baltimore Avenue	College Park	MD	20742
Diploma/Degree obtained, if any			
N/A - Prepharmacy school requisites			

School Name		From - To (MM/YY – MM/YY)	
Pikesville High School		09/73-06/76	
Address	City	State	Zip
7621 Labyrinth Road	Pikesville	MD	21208
Diploma/Degree obtained, if any			
Maryland High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/19-Present	[redacted]	Pikesville	MD	[redacted]
From - To (MM/YY – MM/YY)		City	State	
07/89-09/19		Owings Mills	MD	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Correct Rx Pharmacy Services, Inc.			04/18/2003 - Present
Business Address	**City**	**State**	**Zip**
1352 Charwood Road, Suite C	Hanover	MD	21076
Phone	**Title**		
(443) 557-0100 ext. 248	President and CEO		

Description of Duties

Supervise medication record keeping, storage, and shipments to our clients. Ensure all wholesale distributor activities abide by applicable state and federal law. Review and update policies and oversee staff training and credentialing.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/14/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jill R. Molofsky

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

November 14, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of MARYLAND, ss. County of Anne Arundel

I, Jill Molofsky, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

11/14/24

Date

Subscribed and Sworn to before me this 14 day of November, 2024

Notary Public Signature



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Correct Rx Pharmacy Services, Inc.

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): D01558 (Maryland)

Physical Address: 1352 Charwood Road, Suite C

City: Hanover State: MD Zip: 21076

Mailing Address (if different from physical address): Same

City: State: Zip:

Telephone: (443) 557-0100 Website: www.correctrxpharmacy.com

Licensing Company Email: info@correctrxpharmacy.com

Section 2: Personal Information

First: Ellen Middle: Hersberger Last: Yankellow

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Lutherville State: MD Zip: [redacted]

Telephone: [redacted] Email: eyankellow@correctrxpharmacy.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Maryland School of Pharmacy		01/92 - 01/96	
Address	**City**	**State**	**Zip**
20 N. Pine Street	Baltimore	MD	21201
Diploma/Degree obtained, if any: Doctor of Pharmacy (PharmD)			

School Name		From - To (MM/YY – MM/YY)	
University of Maryland School of Pharmacy		06/70 - 06/73	
Address	**City**	**State**	**Zip**
20 N. Pine Street	Baltimore	MD	21201
Diploma/Degree obtained, if any: Bachelor of Science in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Patapsco High School		09/66 - 06/68	
Address	**City**	**State**	**Zip**
8100 Wise Avenue	Baltimore	MD	21222
Diploma/Degree obtained, if any: Maryland High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/12 - Present	[redacted]	Lutherville	MD	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Correct Rx Pharmacy Services, Inc.			04/18/2003 - Present
Business Address	**City**	**State**	**Zip**
1352 Charwood Road, Suite C	Hanover	MD	21076
Phone	**Title**		
(443) 557-0100 ext. 248	President and CEO		
Description of Duties			
Performs all functions as President, negotiates and signs all contracts, responsible for all business development, oversee pharmacy operations and business administration (finance, clinical, purchasing, etc.), customer relations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

11/15/2014
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ellen H. Yankellow

Print Name (First, Last)

Ellen H. Yankellow

Original Signature (electronic, copies or stamps not accepted)

November 14, 2024

Date

Please have this section completed in the presence of a Notary Public.

State of MARYLAND, ss. County of Anne Arundel

I, ELLEN H Yankellow, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Ellen H. Yankellow

Original Signature

11/14/2024

Date

Subscribed and Sworn to before me this 14 day of November, 2024

Tyrina Ann Hardeman

Notary Public Signature

Commission Expires Jan 15, 2027



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Correct Rx Pharmacy Services, Inc.

Pharmacy/MDEG/Wholesaler License # (if applicable) D01558 (Maryland)

Physical Address 1352 Charwood Road, Suite C

City Hanover State MD Zip 21076

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone (443) 557-0100 Website www.correctrxpharmacy.com

Licensing Company Email info@correctrxpharmacy.com

Section 2: Personal Information

First Martin Middle Lee Last Yankellow, Jr.

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Chicago State IL Zip [redacted]

Telephone [redacted] Email myankellow@correctrxpharmacy.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Chicago Kent School of Law		1998-2001	
Address	**City**	**State**	**Zip**
565 W Adams Street	Chicago	IL	60661
Diploma/Degree obtained, if any			
Juris Doctor			

School Name		From - To (MM/YY – MM/YY)	
Hiram College		1994-1998	
Address	**City**	**State**	**Zip**
11715 Garfield Road	Hiram	OH	44234
Diploma/Degree obtained, if any			
Bachelor in History			

School Name		From - To (MM/YY – MM/YY)	
Loyola Blakefield High School		1990-1994	
Address	**City**	**State**	**Zip**
500 Chestnut Avenue	Towson	MD	21204
Diploma/Degree obtained, if any			
Maryland High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/2011 - Present	[redacted]	Chicago	IL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Correct Rx Pharmacy Services, Inc.			2006 - Present	
Business Address		**City**	**State**	**Zip**
1352 Charwood Road, Suite C		Hanover	MD	21076
Phone	**Title**			
(443) 557-0100	Vice President / Treasurer			
Description of Duties				
Collaborate with all management tiers to oversee contract reviews, policy development, employee orientation and training, and served as a central resource for addressing a wide range of legal inquiries. By staying updated on regulatory requirements and leveraging our company's collective clinical, legal, and business expertise, I provided managers and supervisors with information that ensured robust corporate governance and regulatory adherence .				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/6/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Martin Yankellow
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

February 6, 2025
Date

Please have this section completed in the presence of a Notary Public.

State of Maryland, ss. County of Anne Arundel

I, Martin L. Yankellow, Jr., being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

February 6, 2025
Date

Subscribed and Sworn to before me this 6th day of February 2025

Rachael Allen Campbell
Notary Public Signature

My commission expires December 26, 2028.

RACHAEL ALLEN CAMPBELL
NOTARY
PUBLIC
BALTIMORE COUNTY, MD

Correct Rx Pharmacy Services, Inc.
1352 Charwood Road, Suite C
Hanover, Maryland 21076
D01558

List of Employees:

Ellen H. Yankellow
Jill R. Molofsky
Joseph A. DeMino
Kathy Kniess

4EEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Wholesaler Application

Non-Refundable $1,000 Fee

Rev (08/17/2022)

Where is the facility located?	☐ Nevada ■ Out-of-State

Type of Application (check applicable box)		Wholesaler Business Type (check applicable box)
■ New Wholesaler ☐ Ownership Change* ☐ Name Change* ☐ Location Change* (in-state only)	* If making a change, provide current license number: WH N/A	☐ Publicly Traded (complete sections 1, 2, 3, 4, 8, 9) ■ Non-Publicly Traded (complete sections 1, 2, 3, 5, 8, 9) ☐ Partnership (complete sections 1, 2, 3, 6, 8, 9) ☐ Sole Owner (complete sections 1, 2, 3, 7, 8, 9)

Section 1: General Information

Facility Name: UPS Supply Chain Solutions, Inc.

Physical Address: 2425 Universal Way

City: Louisville State: KY Zip: 40219

Mailing Address (if different from physical address): 2425 Universal Way

City: Louisville State: KY Zip: 40219

Telephone: 502-961-4032 Website: www.ups.com

Name of Designated Representative (DR): Ryan Mascio

Licensing Company Email: ralicensing@ups.com DR Email: rmasico@ups.com

Entities the Wholesaler will Serve (✓ all applicable)	Products to be Handled or Wholesaled (✓ all applicable)	Type of Wholesaling (✓ all applicable)
■ Pharmacies	■ Dangerous Drugs	☐ Manufacturer
■ Practitioners	☐ Controlled Substances	☐ Repacker
■ Hospitals	■ *Medical devices, equipment, supplies, gases	☐ Reverse Distributor
■ Wholesalers	■ Others: Prescription Human & Veterinary drugs Over the Counter (OTC) Human & Veterinary drugs	☐ Warehouse
■ Veterinarians		☐ Retail pharmacy wholesale distributor
☐ Others:		■ Others: 3PL

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
SEE ATTACHMENT #1		
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with at least 10% interest or partners with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-5, you have marked "YES" to in section 2 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3 . **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:
SEE ATTACHMENT #1

Original Signature (electronic, copies or stamps not accepted)

10-Aug-2024
Date

Disciplinary Statement
UPS Supply Chain Solutions, Inc. ("UPS SCS")

WHOLESALE LICENSE

Matters Related to Colorado Order
1645 Satellite Blvd, Duluth, GA

Final
As previously disclosed by UPS Supply Chain Solution, Inc. (UPS SCS), to your agency in 2010, the Colorado Board of Pharmacy's Stipulation and Final Agency Order ("Colorado Order") was effective October 18, 2010, with regard to UPS SCS's Duluth, GA facility's Colorado Out-of-State Wholesaler License # WHO-7462. UPS SCS's Duluth facility did not file Colorado's required notice of change of Designated Representative within Colorado's required 14-day timeframe to file such notice. UPS SCS implemented corrective actions and has successfully completed the terms of the Colorado order. Please note, UPS SCS's Colorado Out-of-State Wholesaler License # WHO-7462 was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Colorado Case No. 2011-000273 documentation related to the Colorado Order on file with the UPS SCS Regulatory Affairs Department.

Final
On November 15, 2011, UPS SCS informed your agency of the Iowa Board of Pharmacy's (IBoP) action concerning Iowa Wholesale Drug License #5820 and which became effective November 11, 2011. This Iowa Stipulation and Consent Order (the "Iowa Order") relates to the Colorado Order and the untimely filing of notice regarding the Colorado Order to the IBoP. UPS SCS has successfully completed the terms of the Iowa Order and Iowa Wholesale Drug License #5820 has not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Iowa Case No. 2010-162 documentation on file with the UPS SCS Regulatory Affairs Department. Note: This Iowa matter is a spin-off of the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is **not** based on an independent set of facts.

Final
On October 18, 2013, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the underlying Colorado matter summarized above, which was executed by the Michigan BOP on October 9, 2013 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two thousand five hundred dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Colorado matter summarized above. It is based on the same underlying facts that gave rise to the Colorado matter. It is not based on an independent set of facts.

PHARMACY LICENSE

Matters Related to Kentucky Agreed Orders
1860 Outer Loop Road, Louisville, KY

Final

UPS SCS dispenses medical devices, including diabetes-related pumps, to consumers from its Kentucky licensed pharmacy facility. Not all states recognize the Durable Medical Equipment or Home Medical Equipment provider category for entities that dispense medical devices rather than drugs. Those states that do not recognize these categories require a non-resident or out of state pharmacy permit for dispensing medical devices. Accordingly, UPS SCS obtained a home-state pharmacy permit in Kentucky and numerous non-resident pharmacy permits and DME/HME permits in other states. On September 12, 2012, the Kentucky Board of Pharmacy ("KYBoP") and UPS SCS executed final Agreed Orders relating to minor violations under Kentucky Administrative Regulations 2:270 and Kentucky Revised Statutes Sec. 315.121(6) in connection with late filing of pharmacy technician registrations at UPS SCS's Louisville, Kentucky facility (the "Kentucky Orders"). UPS SCS and the KYBoP agreed to address the Kentucky Orders informally by entering in the aforementioned Agreed Orders in lieu of the KYBoP filing a formal complaint. UPS SCS self-reported this action to your agency on September 18, 2012. UPS SCS takes this and all regulatory matters seriously and has implemented corrective action. Moreover, UPS SCS has instituted internal safeguards to ensure that applicable regulatory compliance is maintained in the future. UPS SCS's Kentucky pharmacy license (Kentucky Pharmacy License #P07277) remains current and in good standing and was not and has not been restricted, modified, revoked, or limited in any way.

Final

On May 14, 2013, UPS SCS informed your agency of the Texas Board of Pharmacy's (TXBoP) action concerning UPS SCS Texas Class E Nonresident Pharmacy License #26160 and which became effective May 7, 2013. As already disclosed to you, on May 14, 2013, the Texas Board of Pharmacy (TXBoP) and UPS SCS executed a final Agreed Board Order (the "Texas Order") relating to the above-mentioned Kentucky Pharmacy License Agreed Orders. Pursuant to the Texas Agreed Board Order, the TXBoP reprimanded UPS SCS's Nonresident Pharmacy License. The Texas Board of Pharmacy did not levy a fine or any other penalty on the License. The License was not and is not restricted, modified, revoked or limited in any way. UPS SCS has a copy of the Texas Agreed Board Order # L-13-004 on file with the UPS SCS Regulatory Affairs Department. Note: The Texas Order is directly related to the Kentucky pharmacy license matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is **not** based on an independent set of facts.

Final

On April 22, 2014, UPS SCS informed your agency of the Consent Order and Stipulation between the Michigan Board of Pharmacy (BOP) and UPS SCS based on the Kentucky Order summarized above, which was adopted by the Michigan BOP on April 9, 2014 (the "Michigan Order"). As previously disclosed to you, pursuant to this Consent Order, UPS SCS paid a fine of two hundred fifty dollars. The Consent Order and Stipulation specifically provided that "no patient safety issues were involved," and the BOP did not impose any other penalty. UPS SCS's Michigan licenses have not been restricted, modified, revoked, or limited in any way. Note: The Michigan Order is directly related to the Kentucky matter summarized above. It is based on the same underlying facts that gave rise to the Kentucky matter. It is not based on an independent set of facts.

BEFORE THE STATE BOARD OF PHARMACY

STATE OF COLORADO

Case No. 2011-000273

STIPULATION AND FINAL AGENCY ORDER

IN THE MATTER OF DISCIPLINARY PROCEEDING REGARDING THE NON-RESIDENT PRESCRIPTION DRUG WHOLESALER REGISTRATION OF UPS SUPPLY CHAIN SOLUTIONS, INC., REGISTRATION NO. WHO-7462,

Respondent.

IT IS HEREBY STIPULATED AND AGREED by and between the Colorado State Board of Pharmacy ("Board") and UPS Supply Chain Solutions, Inc. ("Respondent") to resolve all matters pertaining to Board Case Number 2011-000273, as follows:

FINDINGS AND CONCLUSIONS

1. The Board has jurisdiction over Respondent, its registration as a non-resident prescription drug wholesaler, and the subject matter of this Stipulation and Final Agency Order ("Final Agency Order") pursuant to the provisions of the Pharmaceuticals and Pharmacists Act at Title 12, Article 22, C.R.S.

2. Respondent was originally registered as an non-resident prescription drug wholesaler in the State of Colorado on December 8, 2008, being issued registration number WHO-7462, and has been so registered at all times relevant to this disciplinary action.

3. Respondent does not contest these findings and hereby waives any further proof in this proceeding before the Board regarding the following findings.

4. Respondent failed to timely submit an application to the Board detailing a change in designated representative and fee. In this case, forty-six (46) days transpired between the date the previous designated representative ceased the position and the date the application and fee were received.

5. Respondent states and affirms that it was never without the proper oversight of a designated representative but failed to timely submit the change application to the Board because of human error. Further, Respondent states and affirms that it has identified the cause of the error and has implemented corrective actions.

6. Respondent does not contest that the conduct described above constitutes violations of the following sections of the Colorado Revised Statutes and Board Regulations:

12-22-125. Unprofessional conduct - grounds for discipline.

(1) The board may suspend, revoke, refuse to renew, or otherwise discipline any license or registration issued by it, after a hearing held in accordance with the provisions of this section, upon proof that the licensee or registrant:

(c) Has violated:

(I) Any of the provisions of this part 1, including but not limited to any acts in section 12-22-126;

(II) The lawful rules of the board; or

(III) Any state or federal law pertaining to drug.

12-22-802. Wholesaler license requirements

(2)(b) An applicant for a license shall pay any reasonable fee required by the accreditation body or the board and comply with any rules promulgated by the board;

(3) (VII) The name of the applicant's designated representative for the facility, the fingerprints of the designated representative, and a personal information statement for the designated representative that includes information as required by the board, including but not limited to the information in subsection (5) of this section; and

(5)(i) Update all of the information required in this part 8 whenever changes occur.

Regulation 15.01.11 Minimum required information for registration.

a. The following minimum information shall be required from each wholesaler as part of the registration:

(8) The name of the applicant's designated representative, who must meet the following requirements:

(a) Be at least twenty-one years of age;

(b) Have at least three years of full-time employment history with a pharmacy or a wholesaler in a capacity related to the dispensing and distribution of and the recordkeeping related to prescription drugs;

(c) Be employed by the applicant in a full-time managerial position;

(d) Be actively involved in and aware of the actual daily operation of the wholesaler;

(e) Be physically present at the facility of the applicant during regular business hours, except when the absence of the designated representative is authorized, including, but not limited to, sick leave and vacation leave;

(f) Serve in the capacity of a designated representative for only one applicant or wholesaler at a time, except where more than one licensed wholesaler is co-located in the same facility and the wholesalers are members of an affiliated group as defined by section 1504 of the federal "Internal Revenue code of 1986."

(g) Not have any convictions under federal, state, or local law relating to wholesale or retail prescription drug distribution or controlled substances;

(h) Not have an felony convictions pursuant to federal, state, or local law; and

(i) Undergo a background check as required by CRS 12-22-803. And

(9) Wholesalers that distribute animal drugs exclusively are exempt from the requirements of 15.01.11(a)(8).

(b) Changes in any information in section 15.01.11 shall be submitted to the Colorado Board of Pharmacy within fourteen calendar days thereof.

Regulation 15.01.14 Change of name, location, or ownership, or designated representative

c. Any change in the designated representative of a wholesaler shall be reported to the board on a form supplied by the board within 14 calendar days of such change. The incoming designated representative must undergo the required background check.

7. The Board finds and concludes, and Respondent agrees, that based upon the above-described violations of the Pharmaceuticals and Pharmacists Act and relevant rules and regulations, the following discipline is just and appropriate under the circumstances.

TERMS OF DISCIPLINE

8. **Fine with Surcharge.** Pursuant to §12-22-125.2(5), C.R.S., Respondent shall pay a fine of Five Thousand Dollars and No Cents ($5,000.00). Respondent understands and acknowledges that, pursuant to §24-34-108, C.R.S., the Executive Director of the Department of Regulatory Agencies shall impose an additional surcharge of 10% of this fine. Respondent shall therefore pay a total amount of Five Thousand Five Hundred Dollars and No Cents ($5,500.00). The total amount shall be payable to the State of Colorado and shall be remitted in one lump sum to be included when Respondent submits this signed Final Agency Order to the Board.

9. **Compliance.** Respondent shall submit all future applications detailing a change in designated representative and fee to the Board within fourteen (14) days of the previous designated representative ceasing the position.

10. **Other Requirements.** Respondent acknowledges and agrees that, as a condition of this Final Agency Order, Respondent shall:

a. promptly pay all Respondent's own fees and costs associated with this Final Agency Order;

b. comply fully with this Final Agency Order; and

c. comply fully with the Pharmacists and Pharmaceuticals Act, all Board rules and regulations, and any other state and federal laws and regulations related to pharmacists and pharmaceuticals in the State of Colorado.

11. **Advisements and Waivers.** Respondent enters into this Final Agency Order freely and voluntarily, whether or not Respondent has consulted with legal counsel. Respondent acknowledges its understanding that it has the following rights:

a. to have formal notice of hearing and charges served upon it;

b. to respond to said formal notice of charges;

c. to have a formal disciplinary hearing pursuant to Sections 12-22-125 and 12-22-125.2(2)(a), C.R.S.; and

d. to appeal this Final Agency Order.

Respondent freely **waives** these rights, and acknowledges that such waiver is made voluntarily in consideration for the Board's limiting the action taken against Respondent to the sanctions imposed herein.

12. **Acknowledgments.** Respondent has read this Final Agency Order in its entirety and acknowledges, whether or not Respondent has consulted with legal counsel, that Respondent understands its legal consequences and agrees that none of its terms or conditions are unconscionable. Respondent is not relying on any statements, promises or representations from the Board other than as may be contained in this Final Agency Order. Respondent further acknowledges that it is not entering into this Final Agency Order under any duress.

13. **Violations.** Time is of the essence in this Final Agency Order. It is the responsibility of Respondent to take all appropriate steps to comply fully with this Final Agency Order. Respondent acknowledges and agrees that any violation of this Final Agency Order shall constitute a willful violation of a lawful Board order, may be sanctioned as provided under §12-22-125.2(4), C.R.S., and may be sufficient grounds for additional discipline, including but not limited to revocation of Respondent's registration. The pendency of any suspension or disciplinary action arising out of an alleged violation of this Final Agency Order shall not affect the obligation of Respondent to comply with all terms and conditions of this Final Agency Order.

14. **Integration and Severability.** Upon execution by all parties, this Final Agency Order shall represent the entire and final agreement of and between the parties. In the event any provision of this Final Agency Order is deemed invalid or unenforceable by a court of law, it shall be severed and the remaining provisions of this Final Agency Order shall be given full force and effect.

15. **Public Record.** Upon execution by all parties, this Final Agency Order shall be a public record, maintained in the custody of the Board.

16. **Effective Date.** This Final Agency Order shall become effective upon signature by a Board representative.

ACCEPTED AND AGREED BY

Respondent

Authorized Representative / Title

Dated: 10/1/10

Subscribed and sworn to before me in the County of Fulton, State of Georgia, this 1 day of October, 2010 by Daniel Silvernale, authorized representative of UPS Supply Chain Solutions, Inc.

My commission expires: Sept 21, 2013

DALE BANKS NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES SEPT 21 2013

FINAL AGENCY ORDER

WHEREFORE, the within Stipulation and Final Agency Order is approved, accepted, and hereby made an Order of the Board.

Done and effective this 18th day of October, 2010.

State Board of Pharmacy

BY: Wendy Anderson

Wendy Anderson
Program Director

CERTIFICATE OF MAILING

This is to certify that I have duly mailed the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 29th day of September 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097
(via email: joyroberts@ups.com)

/s/ John Steele
John C. Steele

CERTIFICATE OF SERVICE

This is to certify that I have duly served the within **STIPULATION AND FINAL AGENCY ORDER** upon all parties herein by depositing copies of same in the United States mail, first class postage prepaid, at Denver, Colorado, this 18th day of October 2010, addressed as follows:

UPS Supply Chain Solutions, Inc.
Attn: Joy Roberts
1645 Satelite Blvd.
Duluth, GA 30097

Catie Haugiust
Agent of the Board

BEFORE THE IOWA BOARD OF PHARMACY

Re:	)	Case No. 2010-162
Wholesale Drug License of	)	
UPS SUPPLY CHAIN	)	**STIPULATION**
SOLUTIONS, L.L.C.,	)	**AND CONSENT**
License No. 5820	)	**ORDER**
Respondent	)	

Pursuant to Iowa Code §§ 17A.10 and 272C.3(4) (2011), The Iowa Board of Pharmacy (hereinafter, the "Board") and UPS Supply Chain Solutions, L.L.C. (hereinafter, "Respondent"), have agreed to settle a contested case currently on file with the Board. The Statement of Charges filed against Respondent on September 13, 2011, and the licensee disciplinary proceeding related to the charges shall be resolved without a hearing, as the Board and Respondent have agreed to the following Stipulation and Consent Order:

1. Respondent's license to operate a wholesale drug business was renewed November 19, 2010, as evidenced by Wholesale Drug License Number 5820, recorded in the permanent records of the Board.

2. Wholesale Drug License Number 5820 issued to and held by Respondent is current and in force until December 31, 2011.

3. The Board has jurisdiction over the parties and the subject matter herein.

4. A Statement of Charges was filed against Respondent on September 13, 2011. The Statement of Charges alleges Respondent violated the pharmacy laws of the State of Colorado and failed to timely report the violation to the Board.

5. The records of the investigation indicate that Respondent has successfully

RECEIVED
OCT 28 2011
IOWA BOARD OF PHARMACY

completed the terms of the Colorado Stipulation and Final Agency Order.

6. Respondent has chosen not to contest the allegations set forth in the Statement of Charges and acknowledges that the allegations, if proven in a contested case proceeding, would constitute grounds for the discipline described herein.

7. Upon the Board's approval of this Stipulation and Consent Order, Respondent shall be assessed a civil penalty in the amount of $1000. The civil penalty payment shall be made by check, payable to the Treasurer of Iowa and mailed to the executive director of the Board within 10 days after Respondent's receipt of notice of the Board's approval of this Stipulation and Consent Order. All civil penalty payments shall be deposited into the State of Iowa general fund. Upon the Board's receipt of the civil penalty, this disciplinary proceeding shall be concluded without further order of the Board.

8. The Board does not mandate any further corrective action.

9. Respondent agrees to obey all federal and state laws, rules, and regulations substantially related to the operation of a wholesale drug business.

10. Should Respondent violate or fail to comply with any of the terms or conditions of this Stipulation and Consent Order, the Board may initiate action to revoke or suspend Respondent's Iowa license to operate a wholesale drug business or to impose other licensee discipline as authorized by Iowa Code chapters 272C and 155A (2011), and 657 Iowa Administrative Code § 36.1.

11. This Stipulation and Consent Order is the resolution of a contested case. By entering into this stipulation, Respondent waives all rights to a contested case

hearing on the allegations contained in the Statement of Charges, and waives any objections to this Stipulation and Consent Order.

12. This Stipulation and Consent Order is a proposed settlement subject to approval by a majority of the full Board. If the Board fails to approve this Stipulation and Consent Order, it shall be of no force or effect to either party. If the Board approves this Stipulation and Consent Order, it shall be the full and final resolution of this matter.

13. The Board's approval of this Stipulation and Consent Order shall constitute a FINAL ORDER of the Board in a disciplinary action.

This Stipulation and Consent Order is voluntarily submitted by UPS Supply Chain Solutions, L.L.C., to the Iowa Board of Pharmacy for its consideration on this 21st day of October 2011.

UPS SUPPLY CHAIN SOLUTIONS, L.L.C.,
Respondent
By DANIEL SILVERNALE, Vice President, Finance and Healthcare Compliance

Subscribed and sworn to before me by Daniel Silvernale, who has stated to me that he is the VP, Finance + Healthcare Compliance of UPS Supply Chain Solutions, L.L.C., and is authorized to sign this Stipulation and Consent Order on behalf of UPS Supply Chain Solutions, L.L.C., on this 21st day of October 2011.

Linda P Bowden
NOTARY PUBLIC IN AND FOR THE STATE OF GEORGIA

LINDA P BOWDEN NOTARY PUBLIC FULTON COUNTY, GEORGIA MY COMMISSION EXPIRES AUGUST 30, 2015

This Stipulation and Consent Order is accepted by the Iowa Board of Pharmacy on this 11th day of November 2011.

SUSAN FREY, Chairperson
Iowa Board of Pharmacy
400 SW Eighth Street, Suite E
Des Moines, Iowa 50309-4688

cc: Scott M. Galenbeck
Assistant Attorney General
Office of the Attorney General
Hoover State Office Building
Des Moines, Iowa 50319

UPS Supply-settle 9-11.doc

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Numbers: 53-06-002764
53-15-027264

File Number: 53-10-118763
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 23, 2011, charging UPS Supply Chain Solutions Inc., hereafter Respondent Wholesaler, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true for the purposes of this Consent Order and constitute a violation of section 17768(2)(d) of the Public Health Code, supra.

Accordingly,

IT IS HEREBY ORDERED that for the cited violation of the Public Health Code, Respondent Wholesaler is FINED in the amount of $2,500.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Bureau of Health Care Services, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909**. The fine shall be paid by check or money order, made payable to the State of Michigan, and the check or money order shall clearly display file number **53-10-118763.**

IT IS FURTHER ORDERED that in the event Respondent violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 10/9/13

MICHIGAN BOARD OF PHARMACY

By _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Wholesaler neither admits nor denies the facts alleged in the Complaint dated September 23, 2011, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Wholesaler understands and intends that by signing this Stipulation, Respondent Wholesaler is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Wholesaler is waiving the right to appear with an attorney and such witnesses as Respondent Wholesaler may desire to present a defense to said charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Subsequent to the adverse actions, Respondent Wholesaler submitted information about steps implemented by Respondent Wholesaler, in the state of Colorado, to ensure that this type of action will not recur, including establishing strategy groups and tactical teams which ensure regulations are met and all locations are compliant. Respondent Wholesaler indicated that a single manager coordinates the local teams to ensure all information is consistently distributed. No patient safety issues were involved in Respondent Wholesaler's actions.
>
> Respondent Wholesaler was cooperative in resolution of this matter. Respondent Wholesaler has been licensed in the state of Michigan since 2008 and has no other complaints against its license.

4. Patricia A. Smeelink, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in the foregoing Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Wholesaler and the Department and may be entered as the final order of the Disciplinary Subcommittee in said cause.

CONTINUED ON NEXT PAGE

6. This proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Wholesaler and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department of Licensing and
Regulatory Affairs

Dated: 8-7-13

AGREED TO BY:

Daniel Silvernale, Vice President
Authorized Representative for
UPS Supply Chain Solutions Inc.
Respondent Wholesaler

Dated: 6/28/13

Approved as to form by:

Max R. Hoffman, Jr.
Attorney for Respondent Wholesaler (P67550)

This is the last page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-10-118763, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

BH/PB

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 11-0062A

IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS, INC.

AGREED ORDER

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions, Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that numerous technicians worked on various dates in 2010, without being timely registered with the Board. The Respondent assured the technicians that it would take care of ensuring they were properly registered. Respondent subsequently properly registered the technicians. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).
(b) The technicians that worked without being appropriately registered with the Board were: Chelsea Hutchins, Alisha Netherton, Brittany Barger, Lauren Fisher, Karen Millay, Meghan Rae Yates, Michelle Green, Amanda Gracie, Faith Joway, Taylor Parker, Manoj Bhandari, Jonathan Pruitt, Whitney Wilson, Dustin R. Harris, Fabrice Mboya, Lauren Howell, Coco Boards, Benjamin Bickett, Jessica Horlander, Jason Cope, William Robert Bennett Jr, Thomas Hicks, Nimo Muhumed Mohamud, Harold Keith Newcom, Rodrick G Parrish, Johnathan Borho, Antoya Blackburn, Jonathan Graves, and Leilani Roach.
(c) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by

entering into this Agreed Order, in lieu of the Board filing a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $2900.00 ($100 per technician) payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

9/12/12
Date

UPS Supply Chain Solutions, Inc.
Respondent

8/14/12
Date

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 11-0061A

KY BOARD OF PHARMACY
RECEIVED
2012 AUG 29 P 1:18

IN RE: PHARMACY PERMIT NO. P07277 HELD BY UPS SUPPLY CHAIN SOLUTIONS INC.

AGREED ORDER

Come the parties, the Kentucky Board of Pharmacy ("the Board") and UPS Supply Chain Solutions Inc. ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Respondent is a pharmacy in the Commonwealth of Kentucky, having been assigned pharmacy permit no. P07277.

(2) (a) An investigation of Respondent's pharmacy revealed that Sherry Rich worked as a pharmacy technician from April 1, 2010 through November 19, 2010, without being timely registered with the Board. The Respondent assured Ms. Rich that it would take care of ensuring she was properly registered. Respondent subsequently properly registered Ms. Rich with the Board. Nonetheless, the Respondent was in violation of KRS 315.121(1)(g).

(b) The above facts subject Respondent to discipline pursuant to KRS 315.121(1) (h).

(3) Respondent takes compliance with KRS 315 seriously and as part of its corporate compliance program presented to the Board a detailed corrective action plan intended to ensure on-going compliance with KRS 315.121(1)(g).

(4) This matter is considered a violation pursuant to KRS 315.121(6) and 201 KAR 2:270.

(5) The Board and Respondent have agreed to address this matter informally by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $125.00 payable by September 5, 2012. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky

Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) By entering into this Agreed Order, Respondent expressly acknowledges that Respondent was fully and completely informed of Respondent's right to due process, that Respondent fully understands those rights, and that Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(C) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP"), and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy

8/12/12
Date

UPS Supply Chain Solutions Inc.
Respondent

8/14/12
Date

AGREED BOARD ORDER #L-13-004

RE: IN THE MATTER OF
UPS SUPPLY CHAIN SOLUTIONS, INC.
(CLASS E NONRESIDENT
PHARMACY LICENSE #26160)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy ("Board") the matter of Class E nonresident pharmacy license number 26160 issued to UPS Supply Chain Solutions, Inc. ("Respondent"), 1860 Outer Loop Road, Louisville, Kentucky 40219.

On September 8, 2012, Respondent self-reported to the Board the entry of two Agreed Orders by the Kentucky Board of Pharmacy, as described below in Counts (1) and (2).

By letter dated February 22, 2013, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Section 565.002 (a)(13); and Section 565.002(c) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011), as alleged in the Counts below.

The conduct described in the Kentucky Board of Pharmacy's Agreed Orders is substantially similar to conduct described in:

Section 565.002(a)(3); and Section 568.002(a) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2011); and

Section 297.3(a)(1) of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2012).

COUNTS

(1) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0061A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that from April through November of 2010, the pharmacy allowed an unregistered individual to perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $125.

(2) On or about September 12, 2012, the Kentucky Board of Pharmacy entered an Agreed Order in case number 11-0062A against the Kentucky pharmacy permit number P07277 held by UPS Supply Chain Solutions, Inc. The Order was based on allegations that, on various dates in 2010, the pharmacy allowed twenty-nine (29) unregistered individuals to

perform duties of a pharmacy technician without being registered with the Kentucky Board of Pharmacy. The Order imposed an administrative penalty of $2900.

An informal conference was held in the office of the Texas State Board of Pharmacy on April 2, 2013. Phillip Vowels, R.Ph., Pharmacist-in-Charge of Respondent; Sue Young, Director, Global Healthcare Compliance, for Respondent; Amy Carney, Regulatory Affairs Manager, for Respondent; Maureen O'Brien, Senior Quality Assurance Manager, for Respondent; Emily Johnson, Legal Counsel for Respondent; Hannah Heck, Legal Counsel for Respondent; and Michelle Williams, Legal Counsel for Respondent, appeared via teleconference. The informal conference was heard by a Board panel comprised of: Jeanne D. Waggener, R.Ph., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Stacy E. Martyak, Staff Attorney, was also in attendance.

By signing this Order, Daniel Silvernale, Vice President, for and on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that Respondent's license is hereby reprimanded.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 7th day of May, 2013.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Daniel Silvernale, Vice President of UPS Supply Chain Solutions, Inc.

APPROVED AS TO FORM:

Kerstin B. Arnold, General Counsel
Texas State Board of Pharmacy

STATE OF MICHIGAN
DEPARTMENT OF LICENSING AND REGULATORY AFFAIRS
BUREAU OF HEALTH CARE SERVICES
BOARD OF PHARMACY
DISCIPLINARY SUBCOMMITTEE

In the Matter of

UPS SUPPLY CHAIN SOLUTIONS INC.
License Number: 53-01-008968

File Number: 53-13-129412
CONSENT ORDER AND STIPULATION

CONSENT ORDER

WHEREAS, an Administrative Complaint, hereafter Complaint, was issued on September 27, 2013, charging UPS Supply Chain Solutions Inc., hereafter Respondent Pharmacy, with having violated section 17768(2)(d) of the Public Health Code, 1978 PA 368, as amended; MCL 333.1101 et seq; and

WHEREAS, Respondent neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee of the Michigan Board of Pharmacy, hereafter Disciplinary Subcommittee, shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and argument were presented in support of the allegations; and

WHEREAS, the Disciplinary Subcommittee has reviewed the Stipulation and, based upon the matters asserted therein, agrees that the public interest is best served by resolution of the outstanding Complaint; now, therefore,

IT IS HEREBY FOUND that the facts alleged in the Complaint are true, for purposes of this Consent Order, and constitute a violation of section 17768(2)(d) of the Public Health Code, supra:

Accordingly, IT IS HEREBY ORDERED, that for the cited violation of the Public Health Code, Respondent Pharmacy is REPRIMANDED.

IT IS FURTHER ORDERED that for the cited violation of the Public Health Code, Respondent Pharmacy is FINED in the amount of $250.00 to be paid to the State of Michigan within 60 days of the effective date of this Order.

IT IS FURTHER ORDERED that the fine shall be mailed to the **Department of Licensing and Regulatory Affairs, Enforcement Division, Sanction Monitoring, P.O. Box 30189, Lansing, MI 48909.** The fine shall be paid by check or money order made payable to the state of Michigan, and the check or money order shall clearly display the file number **53-13-129412.**

IT IS FURTHER ORDERED that in the event Respondent Pharmacy violates any provision of this Order, the Disciplinary Subcommittee may proceed to take disciplinary action pursuant to 1996 AACS, R 338.1632 and section 16221(h) of the Public Health Code, supra.

CONTINUED ON NEXT PAGE

IT IS FURTHER ORDERED that this Order shall be effective 30 days from the date signed by the Disciplinary Subcommittee, as set forth below.

Dated: 4/9/14

MICHIGAN BOARD OF PHARMACY

By: _____
Chairperson, Disciplinary Subcommittee

STIPULATION

1. Respondent Pharmacy neither admits nor denies the facts alleged in the Complaint dated September 27, 2013, but agrees that the Disciplinary Subcommittee shall treat the allegations as true, which finding shall have the same force and effect for purposes of this Consent Order as if evidence and arguments were presented in support thereof.

2. Respondent Pharmacy understands and intends that by signing this Stipulation Respondent Pharmacy is waiving the right, pursuant to the Public Health Code, the rules promulgated thereunder, and the Administrative Procedures Act of 1969, 1969 PA 306, as amended; MCL 24.201 et seq, to require the Department of Licensing and Regulatory Affairs, hereafter Department, to prove the charges set forth in the Complaint by presentation of evidence and legal authority, and Respondent Pharmacy is waiving the right to appear with an attorney and such witnesses as Respondent Pharmacy may desire to present a defense to the charges.

3. Factors taken into consideration in the formulation of the within Consent Order are as follows:

> Respondent Pharmacy acknowledges the Kentucky Board of Pharmacy disciplinary action which precipitated the Complaint.

4. Harvey Schmidt, R.Ph., a member of the Michigan Board of Pharmacy who supports this proposal, and the Department's representative are both free to discuss this matter with the Disciplinary Subcommittee and recommend acceptance of the resolution set forth in this Consent Order.

5. The foregoing Consent Order is approved as to form and substance by Respondent Pharmacy and the Department and may be entered as the final order of the Disciplinary Subcommittee in this cause.

CONTINUED ON NEXT PAGE

6. The foregoing proposal is conditioned upon acceptance by the Disciplinary Subcommittee, Respondent Pharmacy and the Department expressly reserving the right to further proceedings without prejudice should the Consent Order be rejected.

AGREED TO BY:

Carole H. Engle, Director
Bureau of Health Care Services
Department Licensing and
Regulatory Affairs

Dated: 1-29-14

AGREED TO BY:

UPS Supply Chain Solutions Inc.
Respondent

Dated: 1/21/14

This is the final page of a Consent Order and Stipulation in the matter of UPS Supply Chain Solutions Inc., File Number 53-13-129412, before the Disciplinary Subcommittee of the Michigan Board of Pharmacy, consisting of five pages, this page included.

PB

Section 3: List the top four suppliers your company has been associated with in regards to pharmaceutical products that were sold, dispensed or distributed within the last year.

Name: Exact Sciences
Address: 5505 Endeavor Lane City: Madison State: WI Zip: 53719

Name: Dexcom
Address: 8046 East Ray Road City: Mesa State: AZ Zip: 85212

Name:
Address: City: State: Zip:

Name:
Address: City: State: Zip:

Section 4: Publicly Traded Corporation

State of Incorporation:
Parent Company (if any):
Corporation Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

N/A
QSM 27-Sept-2024

Section 5: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware
Parent Company (if any): United Parcel Service of America, Inc.
Corporation/Organization Name: UPS Supply Chain Solutions, Inc.
Mailing Address: 12380 Morris Road
City: Alpharetta State: GA Zip: 30005
Telephone: 678-746-4100 Email: ralicensing@ups.com
Contact Person Name: Felix Chang

Section 6: Partnership

Partnership Name:
Mailing Address:
City: State: Zip:
Telephone: Email:
Contact Person Name:

Section 7: Sole Owner

N/A
QSM 27-Sept-2024

Owner's Name:
Business Name:
Business Address:
City: State: Zip:
Telephone: Email:

Section 8: NABP Accreditation/FDA Registration	Yes	No
Is your company Drug Distributor or VAWD Accredited by NABP? If yes, provide:		✔
1. Copy of Certification 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		
Is your company licensed as a Manufacturer by the FDA? If yes, provide:		✔
1. Copy of FDA registration 2. Copy of a bond in an amount of $25,000 made payable to the state of Nevada. This must be current to maintain a Nevada wholesaler registration. Complete the **Surety Bond form** at http://bop.nv.gov/Services/newapps/Business/.		

Section 9: Provide the following documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.** SEE ATTACHMENT #2	✓	✓		
• **List the top four corporation shareholders and their percent ownership.** N/A	✓			
• **List of all corporation shareholders and their percent ownership.** SEE ATTACHMENT #3		✓		
• **List of all partners and their percent ownership.** N/A			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **12 months.** SEE ATTACHMENT #4	✓	✓	✓	✓
• **Designated Representative form** must be completed by the Designated Representative. Access form at http://bop.nv.gov/Services/newapps/Business/ SEE ATTACHED		✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner owning more than 10% of the business stocks/shares. Access form at http://bop.nv.gov/Services/newapps/Business/ N/A		✓	✓	✓
• **Copy of DEA certificate if handling controlled substances** N/A	✓	✓	✓	✓
• **Copy of current SEC 10K or 8K** (First 15 pages only) N/A	✓			
• **List containing each employee, agent, independent contractor, consultant, guardian, personal representative, lender or holder of indebtedness of the applicant.** SEE ATTACHMENT #5	✓	✓	✓	✓
• **Copy of your license, certification, permit or registration issued to your wholesaler business** from the regulatory board or licensing authority of the state or territory in which the wholesaler is located. **(REQUIRED FOR OUT-OF-STATE WHOLESALERS, if applicable)** SEE ATTACHMENT #6	✓	✓	✓	✓
• [a]**Medical Devices, Equipment and Gases (MDEG) Administrator form** must be completed if the business will wholesale medical devices, equipment, supplies, gases, including hypodermic devices. (NAC 639.6957). Access form at https://bop.nv.gov/Services/newapps/Business/ SEE ATTACHED	✓	✓	✓	✓
• **If providing [a]Medical Devices, Equipment and Gases (MDEG), supply a copy of proof of insurance (NAC 639.6957).** The MDEG wholesaler shall maintain liability insurance of at least one million dollars ($1,000,000.00). SEE ATTACHMENT #7	✓	✓	✓	✓
ONLY Complete below if your company is NOT accredited by NABP and/or FDA registered (see Section 8)				
• **Submit Fingerprints** following instructions found at: SEE ATTACHED http://bop.nv.gov/uploadedFiles/bopnvgov/content/Services/newapps/7.1.2019.Fingerprint%20Submission%20Instructions.pdf.		✓	✓	✓
• **Copy of a bond in an amount of $100,000** made payable only to the State of Nevada. This must be current to maintain a Nevada Wholesaler registration. Complete the **Surety Bond form** at: http://bop.nv.gov/Services/newapps/Business/. SEE ATTACHED		✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline. I further certify compliance with NRS 639.590 and NAC 639.594 as applicable.

UPS Supply Chain Solutions, Inc.

Facility Name

RYAN MASCIO

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

10-Aug-2024

Date

Board Use Only	Date Received: 10/2/24	Amount: $1000-ck 1137964

Organizational Chart
UPS SUPPLY CHAIN SOLUTIONS, INC.



THIS REPORT IS SUBMITTED IN CONFIDENCE AND APPLICABLE EXEMPTIONS TO THE FREEDOM OF INFORMATION ACT ARE TO BE INVOKED TO WITHHOLD IT FROM PUBLIC DISCLOSURE

UPS Supply Chain Solutions, Inc.
12380 Morris Road
Alpharetta, GA 30005
Phone ~ (678) 746 4100
State of Incorporation: Delaware
Date of Incorporation: 8/29/88
FEIN ~ 94-3083515

Name/Title	Work Address	Work Phone	Work Fax	Email
John Bolla **President**	12380 Morris Road Alpharetta, GA 30005	(919) 455-8564	(678) 746-8650	jbolla@ups.com
Felix Chang **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-3452	(678) 746-8650	fxchang@ups.com
Seth Bruckner **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-7413	(678) 746-8650	sbruckner@ups.com
William M. Jacques **Vice President**	12380 Morris Road Alpharetta, GA 30005	(678) 746-8718	(678) 746-8650	wjacques@ups.com
Jeremiah (Jay) Blanton **Vice President**	12380 Morris Road Alpharetta, GA 30005	(502) 500-0427	(678) 746-8650	jjblanton@ups.com

Parent Company Information:
United Parcel Service of America, Inc.
55 Glenlake Parkway NE
Atlanta, GA 30328
P ~ (404) 828 6022
FEIN ~ 95-1732075
State/Date of Incorporation ~ DE 5/9/30

ATTACHMENT #2

ATTACHMENT #4

State Of Delaware

Entity Details

4/10/2024 4:07:50PM

File Number:	2170882	Incorporation Date / Formation Date:	8/29/1988
Entity Name:	UPS SUPPLY CHAIN SOLUTIONS, INC.		
Entity Kind:	Corporation	Entity Type:	General
Residency:	Domestic	State:	DELAWARE
Status:	Good Standing	Status Date:	8/29/1988

Registered Agent Information

Name:	CORPORATION SERVICE COMPANY		
Address:	251 LITTLE FALLS DRIVE		
City:	WILMINGTON	Country:	
State:	DE	Postal Code:	19808
Phone:	302-636-5401		

COMMONWEALTH OF KENTUCKY

KENTUCKY BOARD OF PHARMACY

State Office Building Annex, Suite 300
125 Holmes Street
Frankfort KY 40601

LICENSE/PERMIT: Third Party Logistic

NUMBER: TPL00470

EFFECTIVE DATE: 05/01/2024

EXPIRATION DATE: 06/30/2025

Issued to:
UPS SUPPLY CHAIN SOLUTIONS, INC

2425 UNIVERSAL WAY
LOUISVILLE, KY 40219

License/Permit must be posted in public view.

The official status of this license/permit can be verified at www.pharmacy.ky.gov.

The facility above is hereby licensed or permitted at the above address, and is subject to the rules and regulations of the Kentucky Board of Pharmacy.

rmascio@ups.com

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/19/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Liberty Mutual Insurance Co. Nat'l Ins Northeast
500 N 3rd St, Suite 300
Wausau, WI 54403

www.LibertyMutual.com

CONTACT NAME:
PHONE (A/C, No, Ext):
FAX (A/C, No):
E-MAIL ADDRESS: CMeCertProduction@LibertyMutual.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Liberty Mutual Fire Insurance Company	23035
INSURER B : LM Insurance Corporation	33600
INSURER C : Liberty Insurance Corporation	42404
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
UPS SUPPLY CHAIN SOLUTIONS, INC.
12380 MORRIS ROAD
ALPHARETTA GA 30005

COVERAGES **CERTIFICATE NUMBER:** 83158117 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	✓ COMMERCIAL GENERAL LIABILITY			TB2-C21-095741-135	1/1/2025	1/1/2026	EACH OCCURRENCE	$ 1,000,000
A	CLAIMS-MADE ✓ OCCUR			TB2-C21-095741-145	1/1/2025	1/1/2026	DAMAGE TO RENTED PREMISES (Ea occurrence)	$
B				TB5-C21-095741-155	1/1/2025	1/1/2026	MED EXP (Any one person)	$
							PERSONAL & ADV INJURY	$ 1,000,000
	GEN'L AGGREGATE LIMIT APPLIES PER:						GENERAL AGGREGATE	$ 1,000,000
	✓ POLICY PRO-JECT LOC						PRODUCTS - COMP/OP AGG	$ 1,000,000
	OTHER							$
A	AUTOMOBILE LIABILITY			AI2-C21-092036-025	1/1/2025	1/1/2026	COMBINED SINGLE LIMIT (Ea accident)	$ 1,000,000
A	✓ ANY AUTO			AI2-C21-092036-585	1/1/2025	1/1/2026	BODILY INJURY (Per person)	$
A	OWNED AUTOS ONLY / SCHEDULED AUTOS			AI2-C21-092036-945	1/1/2025	1/1/2026	BODILY INJURY (Per accident)	$
B	HIRED AUTOS ONLY / NON-OWNED AUTOS ONLY			AI5-C21-092036-875	1/1/2025	1/1/2026	PROPERTY DAMAGE (Per accident)	$
								$
	UMBRELLA LIAB OCCUR						EACH OCCURRENCE	$
	EXCESS LIAB CLAIMS-MADE						AGGREGATE	$
	DED RETENTION $							$
B	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y/N			WC5-C25-095741-295	1/1/2025	1/1/2026	✓ PER STATUTE OTH-ER	
B	ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? N	N/A		WA5-C2D-095741-305	1/1/2025	1/1/2026	E.L. EACH ACCIDENT	$ 1,000,000
C	(Mandatory in NH)			WA7-C2D-095741-325	1/1/2025	1/1/2026	E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
	If yes, describe under DESCRIPTION OF OPERATIONS below						E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

RE: New Facility addition in Louisville, KY | Universal Way 2425 Universal Way Louisville, KY 40219.

CERTIFICATE HOLDER

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno NV 89521

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE
Joshua Cleveland

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AGENCY CUSTOMER ID: 2-004105

LOC #:

ADDITIONAL REMARKS SCHEDULE

Page ____ of ____

AGENCY	NAMED INSURED
Liberty Mutual Insurance Co. Nat'l Ins Northeast	UPS SUPPLY CHAIN SOLUTIONS, INC. 12380 MORRIS ROAD ALPHARETTA GA 30005
POLICY NUMBER	
CARRIER / NAIC CODE	EFFECTIVE DATE:

ADDITIONAL REMARKS

THIS ADDITIONAL REMARKS FORM IS A SCHEDULE TO ACORD FORM,

FORM NUMBER: 25 **FORM TITLE:** Certificate of Liability (03/16)

HOLDER: Nevada State Board of Pharmacy

ADDRESS: 985 Damonte Ranch Parkway, Suite 206 Reno NV 89521

If changes/revisions to this certificate are necessary, you may email your request to CMeCertProduction@libertymutual.com.

If you no longer require this certificate and do not need on an annual basis, please email the certificate to our office and instruct us to delete from our database.

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NEVADA STATE BOARD OF PHARMACY

431 W Plumb Lane
Reno, NV 89509
(775) 850-1440
Fax: (775) 850-1444

PHARMACEUTICAL WHOLESALER SURETY BOND

Bond No. F208744

Application/License No. _____

UPS Supply Chain Solutions, Inc.
Applicant/Principal
doing or intending to do business as a pharmaceutical wholesaler, whose address for purposes of service is 2425 Universal Way
Address of Applicant/Principal
Louisville, KY 40219, as PRINCIPAL, and Great American Insurance Company
Surety Company
, a corporation organized under the laws of the state of Ohio
State of Incorporation
and authorized to transact a general surety business in the State of Nevada, whose address for purposes of service is 2425 Universal Way Louisville, KY 40219
Address of Surety
as SURETY, are held and firmly bound unto the State of Nevada and to the Nevada State Board of Pharmacy for the penal sum of ONE HUNDRED THOUSAND DOLLARS ($100,000.00), for which payment we bind ourselves, our heirs, executors, administrators, successors and assigns jointly and severally, by these presents. This bond term shall become effective on 08/16/2024
Effective Date
.

WHEREAS, the provisions of Nevada Revised Statutes (NRS) 639.515 require that the Applicant/Principal file or have on file with the Nevada State Board of Pharmacy (Board) a bond in the sum of $100,000.00 payable to the Nevada State Board of Pharmacy and this bond is executed and tendered in accordance therewith. This bond secures payment of any administrative fines imposed by the Board pursuant to NRS 639.255 and any costs incurred by the Board regarding the license of Applicant/Principal that are impose pursuant to NRS 622.400 or 622.410 which the Applicant/Principal fails to pay.

THIS BOND is subject to the following conditions:

(1) This bond shall be deemed continuous in form and shall remain in full force and effect and shall run concurrently with the license period for which the license is granted and each and every succeeding license period or periods for which said Applicant/Principal may be licensed, after which liability hereunder shall cease except as to any liability or indebtedness therefore incurred or accrued hereunder.

(2) This bond is executed by the Applicant/Principal and the Surety to comply with the provisions of NRS 639.515 and said bond shall be subject to all of the terms and provisions thereof.
(3) The Surety, its successors and assigns, are jointly and severally liable on the obligations of the bond.
(4) The limitations of the liability of the Surety and the conditions of the bond are set forth in NRS 639.515. Any claim by the Board may be made directly to the Surety and need not be preceded by the filing of any action in a proper court. Payment of any such claim shall be payable to the Nevada State Board of Pharmacy.
(5) The aggregate liability of the Surety hereunder on all claims whatsoever shall not exceed the penal sum of this bond in any event.
(6) This bond may not be cancelled by the Surety without first giving the Board written notice at least thirty days in advance of any intent to cancel the bond.
(7) The Applicant/Principal and Surety may be served with notices, papers and other documents at the addresses given above.

I certify or declare under penalty of perjury, under the laws of the State of Nevada, that I have executed the foregoing bond on behalf of the Surety under an unrevoked power of attorney.

In witness whereof, each party to this bond has caused it to be executed on this 16th day of August, 2024.

APPLICANT/PRINCIPAL

Authorized Representative

SURETY COMPANY

Surety Company' s Representative

Michael S Brown, Attorney-in-fact
print name

SIGNED and SEALED in the presence of:

Witness Jeiani Laureano

Witness

SIGNED and SEALED in the presence of:

Christina Rinozzi
Witness

Witness

Countersigned by:

Nevada Resident Agent

GREAT AMERICAN INSURANCE COMPANY®

Administrative Office: 301 E 4TH STREET • CINCINNATI, OHIO 45202 • 513-369-5000 • FAX 513-723-2740

The number of persons authorized by
this power of attorney is not more than one

Bond No. F208744

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS: That the GREAT AMERICAN INSURANCE COMPANY, a corporation organized and existing under and by virtue of the laws of the State of Ohio, does hereby nominate, constitute and appoint the person or persons named below its true and lawful attorney-in-fact, for it and in its name, place and stead to execute on behalf of the said Company, as surety, the specific bond, undertaking or contract of suretyship referenced herein; provided that the liability of the said Company on any such bond, undertaking or contract of suretyship executed under this authority shall not exceed the limit stated below. The bond number on this Power of Attorney must match the bond number on the bond to which it is attached or it is invalid.

Name	Address	Limit of Power
Michael S Brown	200 N. Martingale Rd., Suite 700 Schaumburg, IL 60173	$100000---

IN WITNESS WHEREOF the GREAT AMERICAN INSURANCE COMPANY has caused these presents to be signed and attested by its appropriate officers and its corporate seal hereunto affixed this 16th day of August , 2024

Attest

GREAT AMERICAN INSURANCE COMPANY

Assistant Secretary

Divisional Senior Vice President

MARK VICARIO (877-377-2405)

STATE OF OHIO, COUNTY OF HAMILTON - ss:

On this 16th day of August , 2024 , before me personally appeared MARK VICARIO, to me known, being duly sworn, deposes and says that he resides in Cincinnati, Ohio, that he is a Divisional Senior Vice President of the Bond Division of Great American Insurance Company, the Company described in and which executed the above instrument; that he knows the seal of the said Company; that the seal affixed to the said instrument is such corporate seal; that it was so affixed by authority of his office under the By-Laws of said Company, and that he signed his name thereto by like authority.

SUSAN A KOHORST
Notary Public
State of Ohio
My Comm. Expires
May 18, 2025

This Power of Attorney is granted by authority of the following resolutions adopted by the Board of Directors of Great American Insurance Company by unanimous written consent dated June 9, 2008.

RESOLVED: That the Divisional President, the several Divisional Senior Vice Presidents, Divisional Vice Presidents and Divisonal Assistant Vice Presidents, or any one of them, be and hereby is authorized, from time to time, to appoint one or more Attorneys-in-Fact to execute on behalf of the Company, as surety, any and all bonds, undertakings and contracts of suretyship, or other written obligations in the nature thereof; to prescribe their respective duties and the respective limits of their authority; and to revoke any such appointment at any time.

RESOLVED FURTHER: That the Company seal and the signature of any of the aforesaid officers and any Secretary or Assistant Secretary of the Company may be affixed by facsimile to any power of attorney or certificate of either given for the execution of any bond, undertaking, contract of suretyship, or other written obligation in the nature thereof, such signature and seal when so used being hereby adopted by the Company as the original signature of such officer and the original seal of the Company, to be valid and binding upon the Company with the same force and effect as though manually affixed.

CERTIFICATION

I, STEPHEN C. BERAHA, Assistant Secretary of Great American Insurance Company, do hereby certify that the foregoing Power of Attorney and the Resolutions of the Board of Directors of June 9, 2008 have not been revoked and are now in full force and effect.

Signed and sealed this 16th day of August , 2024

Assistant Secretary

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: UPS Supply Chain Solutions, Inc. MDEG License # (if applicable): N/A

Physical Address: 2425 Universal Way

City: Louisville State: KY Zip: 40219

Mailing Address (if different from physical address): 2425 Universal Way

City: Louisville State: KY Zip: 40219

Telephone: 502-961-4032 Website: www.ups.com

Licensing Company Email: ralicensing@ups.com

Section 2: Personal Information

First: Ryan Middle: Thomas Last: Mascio

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☐ F ☐ X

Mailing Address: [redacted]

City: Radcliff State: KY Zip: [redacted]

Telephone: [redacted] Email: rmascio@ups.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Kentucky Adult Education			2004	
Address		City	State	Zip
500 Metro Street		Frankfort	KY	40601
Diploma/Degree obtained, if any				
GED				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

N/A
Ows 27-Sept-2024

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/19 - Present	[redacted]	Radcliff	KY	[redacted]
03/17 - 03/19		Newark	DE	
05/12 - 02/17		Lawrenceville	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A
Ows 27-Sept-2024

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, Inc.			05/21 to 08/24	
Business Address		**City**	**State**	**Zip**
5071 S. Preston Highway		Shepherdsville	KY	40165
Phone	**Title**		**Number of Employed Hours**	
678-702-1217	Distribution Supervisor II		6,850	
Description of Duties				
Distribution Supervisor II overseeing inbound and outbound of pharmaceuticals and medical devices				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

NDA
Dec 27 Sept 2024

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A
as of 27-sept-2024

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

28-Sep-2024
Date

I, Ryan Mascio, **certify that as the MDEG Administrator for**

2425 Universal Way, Louisville, KY 40219,

that I (initial that you have read and meet the following requirements):

1. RM Have a high school diploma or its equivalent;
2. RM Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. RM Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. RM Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan Mascio
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

26-Sep-2024
Date

Board Use Only	Date Received: 10/2/24

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: UPS Supply Chain Solutions, Inc.

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 2425 Universal Way

City: Louisville State: KY Zip: 40219

Mailing Address (if different from physical address): Same as Above

City: State: Zip:

Telephone: 502-961-4032 Website: www.ups.com

Licensing Company Email: ralicensing@ups.com

Section 2: Personal Information

First: Ryan Middle: Thomas Last: Mascio

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Radcliff State: KY Zip: [redacted]

Telephone: [redacted] Email: rmascio@ups.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Kentucky Adult Education			2004	
Address		City	State	Zip
500 Mero Street		Frankfort	KY	40601
Diploma/Degree obtained, if any				
GED				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

N/A
Aug 27 - Sept - 2024

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/19-Present	[redacted]	Radcliff	KY	[redacted]
03/17-03/19		Newark	DE	
05/12-02/17		Lawrenceville	GA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

N/A
Aug 27 - Sept - 2024

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
UPS Supply Chain Solutions, INC			05/21-08/24	
Business Address		City	State	Zip
5071 S. Preston Highway		Shepherdsville	KY	40165
Phone	Title		Number of Employed Hours	
678-702-1217	Distribution Supervisor II		6850	
Description of Duties				
Distribution Supervisor II overseeing inbounding and out bounding of pharmaceuticals and med devices.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A
Does not apply - Sept-2024

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address			State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

N/A
OW 27-Sept 2024

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

N/A
Dec 27-Sept-2024

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

16-Aug-2024
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
11/15/2006	11/16/2006	KY	Elizabethtown	Hardin
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
KYA0447002	State Police Elizabethtown (KYKSP0400)			
Reason/Charge				
See attachment 1				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Ryan Mascio	N/A			
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Regarding an arrest in 2006 related to traffic violations, specifically operating a motor vehicle that was not insured, not registered, and while my driver's license was suspended due to failure to attend traffic school.

At the time, I made a series of poor decisions regarding my responsibilities as a driver. My license had been suspended due to missed school for prior traffic citations, and unfortunately, I did not take the necessary steps to resolve the situation in a timely manner. Additionally, the vehicle I was operating was not properly registered or insured, which further compounded the issue.

Since then, all obligations and fines have been resolved, and my driver's license has been fully restored.

Original Signature (electronic, copies or stamps not accepted)

31-Jan-2025
Date

U.S. Department of Justice
Federal Bureau of Investigation
Criminal Justice Information Services Division
Clarksburg, WV 26306

DATE: 09-06-2024

RYAN THOMAS MASCIO
[redacted]

The Criminal Justice Information Services (CJIS) Division of the Federal Bureau of Investigation has completed the following fingerprint submission:

Subject Name

RYAN THOMAS MASCIO

Search Completed Result 09-06-2024 E2024250000000312001

A SEARCH OF THE FINGERPRINTS PROVIDED BY THIS INDIVIDUAL HAS REVEALED PRIOR ARREST DATA AT THE FBI. THIS DOES NOT PRECLUDE FURTHER CRIMINAL HISTORY AT THE STATE OR LOCAL LEVEL.

Social Security number: XXX-XX-7428

The result of the above response is only effective for the date the submission was originally completed. For more updated information, please submit new fingerprints of the subject.

In order to protect Personally Identifiable Information, as of August 17, 2009, FBI policy has changed to no longer return the fingerprint cards. This form will serve as the FBI's official response.

This Identity History Summary (IdHS) is provided pursuant to 28 CFR 16.30-16.34 solely for you to conduct a personal review and/or obtain a change, correction, or updating of your record. **This IdHS is not provided for the purpose of licensing or employment or any other purpose enumerated in 28 CFR 20.33.**

Any questions may be addressed to the Customer Service Group at (304) 625-5590. You may also visit the Web site at www.fbi.gov for further instructions.

Chris Ormerod
Section Chief
Biometric Services Section
Criminal Justice Information
Services Division

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

USFPID09Z
TCN PNJF20240906131346000002964843

THE FBI IDENTIFIED YOUR TEN-PRINT SUBMISSION WHICH CONTAINED THE FOLLOWING DESCRIPTORS:

NAME MASCIO,RYAN THOMAS

SEX	RACE	BIRTH DATE	HEIGHT	WEIGHT	EYES	HAIR
[redacted]						

STATE ID
NULL

BIRTH PLACE
[redacted]

CITIZENSHIP
UNITED STATES

OTHER BIRTH DATES	SCARS-MARKS-TATTOOS	SOCIAL SECURITY	MISC NUMBERS
NONE	NONE	[redacted]	NONE

ALIAS NAME(S)
NONE

END OF COVER SHEET

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

USFPID09Z NCN E2024250000000312001

BECAUSE ADDITIONS OR DELETIONS MAY BE MADE AT ANY TIME, A NEW COPY SHOULD BE REQUESTED WHEN NEEDED FOR SUBSEQUENT USE.

THIS RECORD IS SUBJECT TO THE
FOLLOWING USE AND DISSEMINATION RESTRICTIONS

UNDER PROVISIONS SET FORTH IN TITLE 28, CODE OF FEDERAL REGULATIONS (CFR), SECTION 50.12, BOTH GOVERNMENTAL AND NONGOVERNMENTAL ENTITIES AUTHORIZED TO SUBMIT FINGERPRINTS AND RECEIVE FBI IDENTIFICATION RECORDS MUST NOTIFY THE INDIVIDUALS FINGERPRINTED THAT THE FINGERPRINTS WILL BE USED TO CHECK THE CRIMINAL HISTORY RECORDS OF THE FBI. IDENTIFICATION RECORDS OBTAINED FROM THE FBI MAY BE USED SOLELY FOR THE PURPOSE REQUESTED AND MAY NOT BE DISSEMINATED OUTSIDE THE RECEIVING DEPARTMENT, RELATED AGENCY OR OTHER AUTHORIZED ENTITY. IF THE INFORMATION ON THE RECORD IS USED TO DISQUALIFY AN APPLICANT, THE OFFICIAL MAKING THE DETERMINATION OF SUITABILITY FOR LICENSING OR EMPLOYMENT SHALL PROVIDE THE APPLICANT THE OPPORTUNITY TO COMPLETE, OR CHALLENGE THE ACCURACY OF, THE INFORMATION CONTAINED IN THE FBI IDENTIFICATION RECORD. THE DECIDING OFFICIAL SHOULD NOT DENY THE LICENSE OR EMPLOYMENT BASED ON THE INFORMATION IN THE RECORD UNTIL THE APPLICANT HAS BEEN AFFORDED A REASONABLE TIME TO CORRECT OR COMPLETE THE INFORMATION, OR HAS DECLINED TO DO SO. AN INDIVIDUAL SHOULD BE PRESUMED NOT GUILTY OF ANY CHARGE/ARREST FOR WHICH THERE IS NO FINAL DISPOSITION STATED ON THE RECORD OR OTHERWISE DETERMINED. IF THE APPLICANT WISHES TO CORRECT THE RECORD AS IT APPEARS IN THE FBI'S CJIS DIVISION RECORDS SYSTEM, THE APPLICANT SHOULD BE ADVISED THAT THE PROCEDURES TO CHANGE, CORRECT OR UPDATE THE RECORD ARE SET FORTH IN TITLE 28, CFR, SECTION 16.34.

- FBI IDENTIFICATION RECORD -

WHEN EXPLANATION OF A CHARGE OR DISPOSITION IS NEEDED, COMMUNICATE DIRECTLY WITH THE AGENCY THAT FURNISHED THE DATA TO THE FBI.

END OF PART 1 - PART 2 TO FOLLOW

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

USFPID09Z NCN E2024250000000312001
PART 2

- FBI IDENTIFICATION RECORD - FBI UCN-862885NC9

NAME	FBI UCN	DATE REQUESTED
MASCIO,RYAN THOMAS	862885NC9	2024/09/06

SEX	RACE	BIRTH DATE	HEIGHT	WEIGHT	EYES	HAIR
[redacted]						

BIRTH PLACE
[redacted]

PATTERN CLASS
LS LS LS LS LS LS LS LS LS LS

CITIZENSHIP
UNITED STATES

1-ARRESTED OR RECEIVED 2006/11/15 SID- KYA0447002
AGENCY-STATE POLICE ELIZABETHTOWN (KYKSP0400)
AGENCY CASE-

FINGERPRINT INFORMATION
BSI/1000063823151
PRINT DATE/2006/11/16

CHARGE 1-OPERATING ON SUSPENDED/REVOKED OPERATORS LIC
CHARGE 2-NO/EXPIRED REGISTRATION PLATES
CHARGE 3-NO/EXPIRED KENTUCKY REGISTRATION RECEIPT
CHARGE 4-FAIL OF OWN TO MAINT REQ INSUR/SEC 1ST OFF

COURT-STATE POLICE ELIZABETHTOWN (KYKSP0400)
CHARGE-MRD/OPERATING ON SUS OR REV OPER LICENSE
MRD/DISMISSAL BY MOTION OF PROSECUTOR
CHARGE-MRD/NO REGISTRATION PLATES
MRD/GUILTY
CHARGE-MRD/NO REGISTRATION RECEIPT
MRD/GUILTY
CHARGE-MRD/FAILURE OF OWNER TO MAINTAIN REQUIRED INS/SEC,
MRD/GUILTY 500.00

END OF PART 2 - PART 3 TO FOLLOW

UNITED STATES DEPARTMENT OF JUSTICE
FEDERAL BUREAU OF INVESTIGATION
CRIMINAL JUSTICE INFORMATION SERVICES DIVISION
CLARKSBURG, WV 26306

USFPID09Z
PART 3

NCN E2024250000000312001

- FBI IDENTIFICATION RECORD - FBI UCN-862885NC9

RECORD UPDATED 2024/09/06

ALL ENTRIES CONTAINED IN THIS FBI RECORD ARE BASED ON FINGERPRINT COMPARISONS AND PERTAIN TO THE SAME INDIVIDUAL.

THE USE OF THIS RECORD IS REGULATED BY LAW. IT IS PROVIDED FOR OFFICIAL USE ONLY AND MAY BE USED ONLY FOR THE PURPOSE REQUESTED.

I, Ryan Mascio, **certify that as the designated representative for**

2425 Universal Way, Louisville, KY 40219,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RM I am at least 21 years of age;
3. RM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Ryan Mascio

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

16-Aug-2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ryan, Mascio
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

16-Aug-2024
Date

Please have this section completed in the presence of a Notary Public.

State of Delaware, ss. County of New Castle

I, Ryan Mascio, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

16-Aug-2024
Date

Subscribed and Sworn to before me this 16th day of Aug 2024

Amy Frances Mueller
Notary Public Signature

(Seal)

EMPLOYEES

ATTACHMENT #5

UPS Supply Chain Solutions, Inc.
2425 Universal Way
Louisville, KY 40219

LAST NAME	FIRST NAME	TITLE
Mascio	Ryan	Supervisor, Distribution Operations
Hodges	Taylor	Supervisor, Distribution Operations
Diop	Charles	Supervisor, Distribution Operations
Gee	Zion	Senior Warhouse, Distribution Operations

4FFF

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			■ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Adelia Compounding, LLC

Physical Address: 1801 Royal Lane, Ste 500

City: Farmers Branch State: TX Zip: 75229

Mailing Address (if different from physical address): 1401 Valley Rd., 4th Floor

City: Wayne State: NJ Zip: 07470

Telephone: 866-596-9595 Toll Free # (NAC 639.708, NRS 639.23286): 866-596-9595

Fax: 866-607-4545 Contact Email: adeliapharmacy@basichi.com

Website: https://basichomeinfusion.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Allan Tsao

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24253

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Allan Tsao	NV Pharmacist Registration #: 24253
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): BCDI BHI Intermediate 2, LP

Corporation/Organization Name: Adelia Compounding, LLC

Mailing Address: 1401 Valley Rd., 4th Floor

City: Wayne State: NJ Zip: 07470

Telephone: 201-475-0500 Email: adeliapharmacy@basichi.com

Contact Person Name: Allan Tsao

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Adelia Compounding, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Jeffrey Foreman

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

1/15/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Foreman

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

1/5/2025

Date

Board Use Only	Date Received: 2/18/25	Amount: $500cc

ADELIA
COMPOUNDING

Adelia Compounding
1801 Royal Lane, Suite 500
Farmers Branch, TX 75229

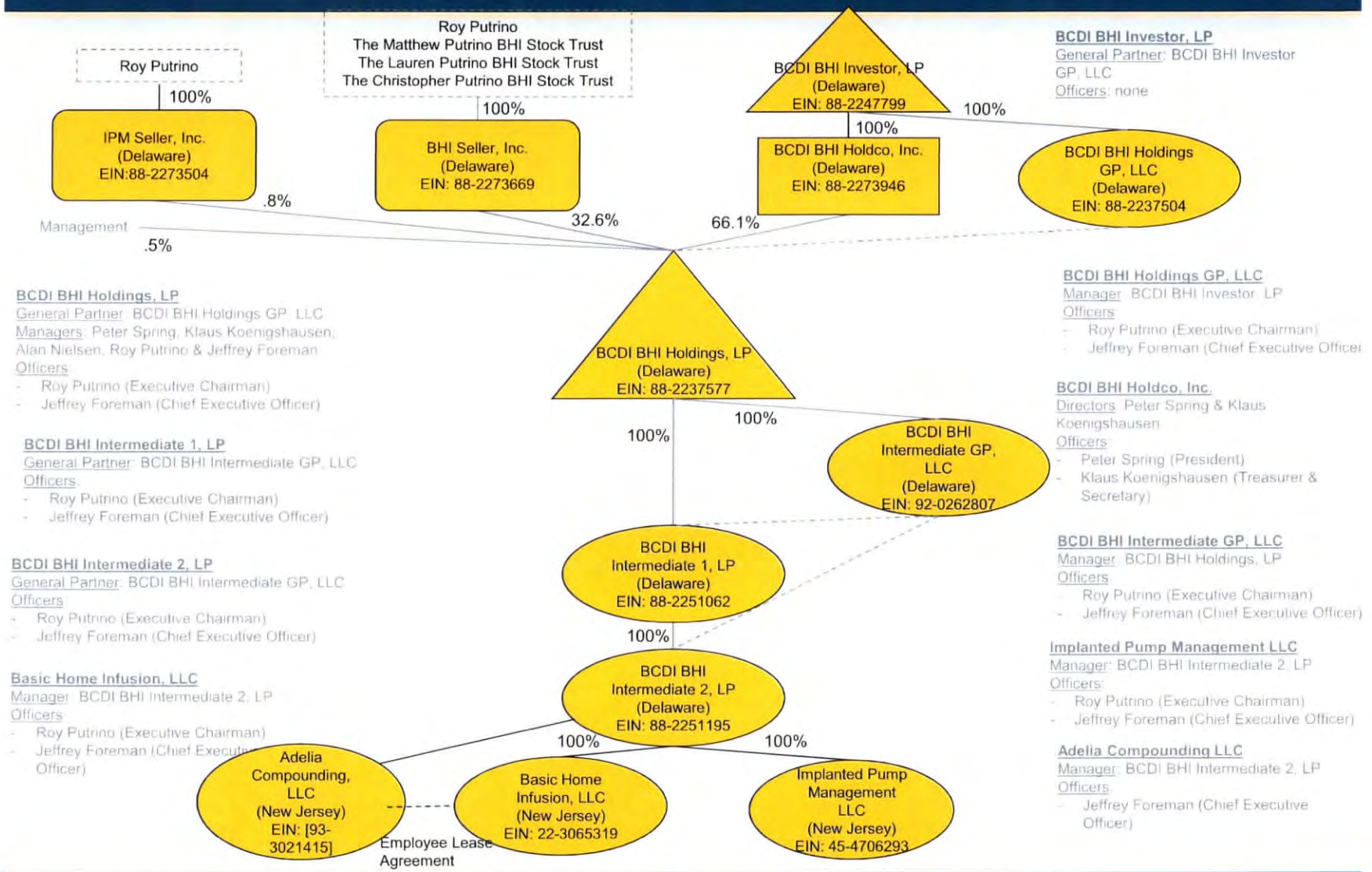
Adelia Compounding LLC Officer

Name: Jeffrey Foreman

Title: CEO

Business Address: 1401 Valley Rd., 4th Floor, Wayne, NJ 07470

Organization Structure



Mailing Addresses

BCDI BHI Investor, LP
Mailing Address: c/o Bain Capital Double Impact, 200 Clarendon St. FL 41, Boston, MA 02116

BCDI BHI Holdings, GP, LLC
Mailing Address: c/o Bain Capital Double Impact, 200 Clarendon St. FL 41, Boston, MA 02116

BCDI BHI Holdco, Inc.
Mailing Address: c/o Bain Capital Double Impact, 200 Clarendon St. FL 41, Boston, MA 02116

BHI Seller, Inc.
Mailing Address: c/o Roy Putrino, 1401 Valley Road, Wayne, NJ 07470

IPM Seller, Inc.
Mailing Address: c/o Roy Putrino, 1401 Valley Road, Wayne, NJ 07470

BCDI BHI Holdings, LP
Mailing Address: c/o Basic Home Infusion, 1401 Valley Road, Wayne, NJ 07470

BCDI BHI Intermediate GP, LLC
Mailing Address: c/o Basic Home Infusion, 1401 Valley Road, Wayne, NJ 07470

BCDI BHI Intermediate 1, LP
Mailing Address: c/o Basic Home Infusion, 1401 Valley Road, Wayne, NJ 07470

BCDI BHI Intermediate 2, LP
Mailing Address: c/o Basic Home Infusion, 1401 Valley Road, Wayne, NJ 07470

Basic Home Infusion, LLC
Mailing Address: c/o Basic Home Infusion, 1401 Valley Road, Wayne, NJ 07470

Implanted Pump Management LLC
Mailing Address: c/o Basic Home Infusion, 1401 Valley Road, Wayne, NJ 07470

Adelia Compounding LLC
Mailing Address: 1401 Valley Road, Wayne NJ 07470

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

ADELIA COMPOUNDING, LLC
0451012897

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on August 22, 2023.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATION SERVICE COMPANY
PRINCETON SOUTH CORPORATE CENTER,
SUITE 160, 100 CHARLES EWING BLVD
EWING, NJ 08628

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 5th day of February, 2025

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6161368588

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Adelia Compounding, LLC

Pharmacy/Wholesaler License # (if applicable):

Physical Address: 1801 Royal Lane, Ste 500

City: Farmers Branch State: TX Zip: 75229

Mailing Address (if different from physical address): 1401 Valley Rd., 4th Floor

City: Wayne State: NJ Zip: 07470

Telephone: 866-596-9595 Website: https://basichomeinfusion.com/

Licensing Company Email: adeliapharmacy@basichi.com

Section 2: Personal Information

First: Allan Middle: Cheehao Last: Tsao

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Houston - College of Pharmacy		08/91 - 05/94	
Address	**City**	**State**	**Zip**
4302 University Dr.	Houston	TX	77074
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of the Ozarks		09/89 - 07/91	
Address	**City**	**State**	**Zip**
415 N. College Avenue	Clarksville	AR	72830
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
02/17 - Current				
From - To (MM/YY – MM/YY)				
10/08 - 02/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Adelia Compounding, LLC			04/24 - Current	
Business Address		**City**	**State**	**Zip**
1801 Royal Lane, Ste 500		Farmers Branch	TX	75229
Phone	**Title**		**Number of Employed Hours**	
866-596-9595	Director of Pharmacy - Texas		1560	
Description of Duties				
Ensures compliance, quality, & efficiency in sterile intrathecal compounding while managing licensure, risk mitigation, and staff leadership. Oersee KPIs, financials strateg, epartmental collaboration to drive operational excellence & growth.				

Business Name			From - To (MM/YY – MM/YY)	
Pantherx Rare Pharmacy			06/23 - 04/24	
Business Address		**City**	**State**	**Zip**
24 Summit Park Dr		Pittsburgh	PA	15275
Phone	**Title**		**Number of Employed Hours**	
855-726-8479	Infusion Program Director		1730	
Description of Duties				
Oversaw newly established infusion services, ensuring compliance, efficiency, and patient care. Maintain relationships with nursing partners risk, developed policy and procedures related to infusion services & performance metrics.				

Business Name			From - To (MM/YY – MM/YY)	
AmeriSourceBergen - USBioServices Specialty Pharmacy			10/16 - 10/22	
Business Address		**City**	**State**	**Zip**
5025 Plano Parkway		Carrollton	TX	75010
Phone	**Title**		**Number of Employed Hours**	
888-518-7246	Infusion Program Director		12480	
Description of Duties				
Responsible and oversaw IVIG, hemophilia, and specialty infusion services, ensuring compliance, efficiency, and patient care while managing licensure, staff development, risk, and program growth.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

January 31, 2025

Date

I, Allan Tsao, **certify that as the designated representative for**

Adelia Compounding, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. AT I am at least 21 years of age;
3. AT I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. AT I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. AT I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. AT I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. AT I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Allan Tsao
[redacted]

Original Signature (electronic, copies or stamps not accepted)

January 31, 2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Allan Tsao [redacted]

Print Name (Fi

Original Signature (electronic, copies or stamps not accepted)

2-12-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Dallas

I, Allan C. Tsao, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or rev [redacted] registration, permit, certificate or certification for which I am applying for.

Original Signature

2-12-2025

Date

Subscribed and Sworn to before me this 12 day of February 2025

Notary Public Signature

ALYZEI SOTO
Notary Public, State of Texas
Comm. Expires 08-18-2025
Notary ID 133276658

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Adelia Compounding, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 1801 Royal Lane, Ste 500

City: Farmers Branch State: TX Zip: 75229

Mailing Address (if different from physical address): 1401 Valley Rd., 4th Floor

City: Wayne State: NJ Zip: 07470

Telephone: 866-596-9595 Website: https://basichomeinfusion.com/

Licensing Company Email: adeliapharmacy@basichi.com

Section 2: Personal Information

First: Jeffrey Middle: David Last: Foreman

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From To (MM/YY - MM/YY)
Calumet High School		09/81 - 05/85
Address	**City**	**State / Zip**
57070 Mine St.	Calumet	MI 49913
Diploma/Degree obtained, if any		
HS Diploma		

School Name		From To (MM/YY - MM/YY)
Michigan Technological University		09/85 - 05/86
Address	**City**	**State / Zip**
1400 Townsend Dr.	Houghton	MI 49931
Diploma/Degree obtained, if any		

School Name		From To (MM/YY - MM/YY)
Ferris State University		09/86 - 05/90
Address	**City**	**State / Zip**
1201 State St.	Big Rapids	MI 49307
Diploma/Degree obtained, if any		
BS Pharmacy		

School Name		From To (MM/YY - MM/YY)
Address	**City**	**State / Zip**
Diploma/Degree obtained, if any		

School Name		From To (MM/YY - MM/YY)
Address	**City**	**State / Zip**
Diploma/Degree obtained, if any		

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From To (MM/YY - MM/YY)	Address	City	State	Zip
05/24 - present	[redacted]			
07/15 - 07/24				
01/12 - 08/19				
From To (MM/YY - MM/YY)	Address	City	State	Zip
From To (MM/YY - MM/YY)	Address	City	State	Zip
From To (MM/YY - MM/YY)	Address	City	State	Zip
From To (MM/YY - MM/YY)	Address	City	State	Zip
From To (MM/YY - MM/YY)	Address	City	State	Zip
From To (MM/YY - MM/YY)	Address	City	State	Zip
From To (MM/YY - MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From To (MM/YY - MM/YY)
Basic Home Infusion LLC			06/22 - Present
Business Address	**City**	**State**	**Zip**
1401 Valley Rd	Wayne	NJ	
Phone	**Title**		
888-822-7428	Chief Executive Officer		

Description of Duties

Responsible overseeing Basic Home Infusion LLC & Implanted Pump Management LLC A leading nationwide provider of infusion & targeted drug delivery/intrathecal therapy services consisting of sterile compounding & nursing services

Business Name			From To (MM/YY - MM/YY)
Comprehensive Pharmacy Services LLC (Now CPS Solutions, LLC)			04/19 - 03/22
Business Address	**City**	**State**	**Zip**
655 Metro Place South Suite 450	Dublin	OH	43017
Phone	**Title**		
800-968-6962	Group Presicent		

Description of Duties

Responsible for overseeing all of CPS business unit operations including pharmacy management solutions consulting solutions telepharmacy solutions as well as ambulatory & specialty pharmacy solutions including oversight of Thergy

Business Name			From To (MM/YY - MM/YY)
Healthcare Entrepreneur/Investor Advisor – Frazier Healthcare			02/18 - 03/19
Business Address	**City**	**State**	**Zip**
601 Union St, Suite 3200	Seattle	WA	98101
Phone	**Title**		
206-621-7200	Operating Partner		

Description of Duties

Conducted due diligence on dozens of companies in three theses surrounding veterinary meds pharma distribution and pharmacy services

Business Name			From To (MM/YY - MM/YY)
Smith Drug Company/Burlington Drug Company			03/15 - 02/18
Business Address	**City**	**State**	**Zip**
9098 Fairforest Rd	Spartanburg	SC	29301
Phone	**Title**		
800-572-1216	President		

Description of Duties

Transitioned & transformed business into a service & solutions-oriented company to replace product-based model Led strategic initiatives involving IntegraiRx HealthWise Pharmacy programs & solutions Rx Sourcing Strategies GPO & Pha

Business Name			From To (MM/YY - MM/YY)
Walgreen Company			01/11 - 03/15
Business Address	**City**	**State**	**Zip**
108 Wilmot Rd	Deerfield	IL	60015
Phone	**Title**		
847-914-2500	Div VP Brand & Generic Pharmaceutical Purchasing 2013-15 Div VP Brand Rx Wh		

Description of Duties

Pharmaceutical Sourcing

Continue on next page if additional space is needed

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/11/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jeffrey Foreman

Print Name [redacted]

Original Signature (electronic, copies or stamps not accepted)

2/11/2025

Date

Please have this section completed in the presence of a Notary Public.

State of ILLINOIS, ss. County of Lake

I, Jeffrey Foreman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

2/11/2025

Date

Subscribed and Sworn to before me this 11 day of February, 2025

Notary Public Signature

LISA PAINTER
Official Seal
Notary Public - State of Illinois
My Commission Expires Sep 13, 2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Adelia Compounding, LLC

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 1801 Royal Lane, Ste 500

City: Farmers Branch State: TX Zip: 75229

Mailing Address (if different from physical address): 1401 Valley Rd., 4th Floor

City: Wayne State: NJ Zip: 07470

Telephone: 866-596-9595 Toll Free # (NAC 639.708, NRS 639.23286): 866-596-9595

Fax: 866-607-4545 Contact Email: adeliapharmacy@basichi.com

Website: https://basichomeinfusion.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Allan Tsao

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24253

Name of Person with direct knowledge of compounding procedures: Allan Tsao

Email of Person with direct knowledge of compounding procedures: [redacted]

Telephone of Person with direct knowledge of compounding procedures: 866-596-9595

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☑ Low ☑ Medium ☑ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☑ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Adelia Compouding specialized in Intrathecal therapy services, the sterile compounded products may include but not limited to the followings:

Intrathecal Pain Management Medications:
Morphine
Hydromorphone
Bupivacaine
Clonidine

Intrathecal Spasticity Management Medication:
Baclofen

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☑ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:

N/A

6. What laboratory performs this additional testing?

Name: White Rock Medical Center Laboratory

Address: 9440 Poppy Drive

City: Dallas State: TX Zip: 75218

Telephone: 214-324-6100

7. What is your procedure for visual inspection of compounded sterile products?

Each compounded sterile product undergoes a thorough visual inspection under appropriate lighting to check for particulate matter, discoloration, and container integrity. Any discrepancies are documented, and the product is quarantined until further evaluation.

8. How often do you perform glove fingertip and medial fill testing?

Glove fingertip testing is conducted initially during training and semi-annually thereafter. Media-fill testing is performed semi-annually, however we also perform these testings as needed

9. What is your policy if an employee fails a glove fingertip or media-fill test?

If an employee fails a glove fingertip or media-fill test, they are immediately removed from compounding duties. The individual undergoes retraining in aseptic techniques, followed by re-evaluation and testing. Compounding privileges are reinstated only upon successful completion of these steps.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

Initial Training:
Comprehensive education on USP <797> guidelines, aseptic techniques, and facility protocols.
Hands-on training in gowning, gloving, and compounding procedures.
Initial competency assessments, including written tests and practical evaluations.

Annual Training:
Refresher courses on aseptic techniques and updated protocols.
Annual competency assessments to ensure ongoing proficiency.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Primary Engineering Controls (PECs):
Cleaned at the beginning of each shift, before each batch, and every 30 minutes during continuous compounding using sterile 70% Isopropyl Alcohol (IPA).

Secondary Engineering Controls (SECs):
Daily: Work surfaces and floors are cleaned with a disinfectant solution.
Monthly: Walls, ceilings, and storage shelving are cleaned with a sporicidal agent to prevent microbial contamination.

12. Who performs the sterile compounding process at your facility?

Licensed pharmacists and trained pharmacy technicians who have demonstrated competency in sterile compounding procedures.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The Pharmacist-in-Charge (PIC) holds ultimate responsibility for the sterile compounding process, ensuring compliance with all regulatory standards and overseeing staff performance.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Compounded sterile products are shipped using temperature-controlled packaging with ice packs to maintain required storage conditions. Shipments are scheulded for overnight delivery to minimize the duration of transport.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A – Adelia Compounding does not perform sterile hazardous drug compounding		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

Cmmerically available solution ingredients are always preferred. If/when prescribed ingredients are not available in solution, then the pharmacy will perform high risk compounding of Baclofen, Bupivacaine, Morphine, Hydromorphone, & Clonidine.

2. What sterilization methods are utilized at your facility?

Aseptic processing techniques are employed during compounding to maintain sterility

3. Does your facility utilize biological indicators? ☑ Yes ☐ No

4. If yes, describe how they are utilized:

Biological indicators are used to monitor the effectiveness of sterilization processes.

They are placed in test loads during sterilization cycles and incubated to confirm the absence of microbial growth, ensuring the reliability of the sterilization method.

These testings are performed routinely as part of our quality assurance program and as needed in response to environmental monitoring data, process deviations, or facility changes.

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Allan Tsao

Name of Person who Completed the Form

Director of Pharmacy

Title

[redacted]

Signature (copies or stamps not accepted)

February 4, 2025

Date

Board Use Only	Date Received: 2/18/25	Date Approved: _____	Approved By: _____

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *ADELIA COMPOUNDING,LLC* License Number:

Class of License: *AS*

Inspection Information

Type: *Compliance* Purpose: *Pre-Inspection*

Date: *10/08/2024* Arrival Time: *10:00 AM* Departure Time: *11:30 AM*

Action Taken: *Pre-Inspection*

General Comments:

Pre-Inspection Checklist

Verify Owner/Owner's Representative ID — *Yes*

Name	Title
: *Allan Tsao*	: *Owner's Representative*

Verify PIC ID — *Yes*

Name	Title
: *Tanya Stephens*	: *PIC*

1. The prescription department has adequate space for the size and scope of the pharmaceutical services provided by the pharmacy. — *Yes*

2. Fixtures (i.e. shelving, countertops, etc.) for the storage of drugs, equipment, and supplies necessary to operate a pharmacy are installed. — *Yes*

Comment

1 balance on site

3. Electrical supply exists. — *Yes*

4. A sink with hot and cold running water available exclusive of the restroom facilities. — *Yes*

5. Pharmacy arranged in an orderly fashion and kept clean. — *Yes*

6. The prescription department is complete and contains the following required equipment and supplies including, but not limited to: — *Yes*

6a. data processing system including a printer or comparable equipment; — *Yes*

6b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration; — *Yes*

6c. adequate supply of child-resistant, light-resistant, tight, and, if applicable, glass containers; *Not Applicable*

6d. adequate supply of prescription labels with name, address, and telephone number of the pharmacy; *Yes*

Comment

Ensure that software is programmed to include all required information including the complete address.

6e. appropriate equipment necessary for the proper preparation of prescription drug orders; *Yes*

6f. metric-apothecary weight and measure conversion charts; *Yes*

Comment

Ensure that a metric-apothecary conversion chart is available (for example, on the computer desktops).

6g. if the pharmacy serves the public, the word "pharmacy" or similar word or symbol, as determined by the board, is displayed in a prominent place on the front of the pharmacy. *Not Applicable*

7. A reference library is on site and current: *Yes*

Comment

Pharmacy has online references available.

7a. Texas Pharmacy Laws and Regulations (publication year: _____) *Yes*

Publication Year
: *2024*

7b. Drug Interactions Reference (publication year: _____) *Yes*

Publication Year
: *Online*

7c. General Information Reference (publication year: _____) *Yes*

Publication Year
: *Online*

7d. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (if the pharmacy is compounding non-sterile preparations) *Yes*

7e. General reference text on veterinary drugs (if the pharmacy dispenses veterinary prescriptions) *Not Applicable*

7f. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center. *Yes*

8.If the pharmacy is compounding sterile preparations, the following references are also required: *Yes*

8a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding Sterile Preparations *Yes*

8b. Chapter 71 of the USP/NF concerning Sterility Tests *Yes*

8c. Chapter 85 of the USP/NF concerning Bacterial Endotoxins Test	*Yes*
8d. Chapter 1163 of the USP/NF concerning Quality Assurance in Pharmaceutical Compounding	*Yes*
8e. Handbook on Injectable Drugs (publication year: _____)	*Yes*

Publication Year
: *Online*

8f. Specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy (e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs)	*Yes*

Comment

Ensure that the pharmacy has access to a reference specific for the scope of pharmacy services (i.e., extended stability of compounded preparations).

9. Security Requirements can be met to assure the pharmacy will be locked by key, combination, or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site.	*Yes*
10. Pharmacy has basic alarm system with the off-site monitoring and perimeter and motion sensors. (Alarm must be activated). *If your city requires an alarm permit, provide a copy of the permit.	*Yes*
11. Written policies and procedures/SOPs for the pharmacy's security system that meet the requirements of Rule 291.33(b)(2)(E)	*Yes*
12. An area suitable for confidential patient counseling, if the pharmacy serves the general public	*Not Applicable*
13. If compounding sterile preparations, the pharmacy has controlled area that meets the requirements in Rule 291.133 (d)(6)(A) if the pharmacy is compounding low-risk and medium-risk preparations or Rule291.133(d)(6)(B) if high-risk preparations are being compounded.	*Yes*

Comment

Ensure that all viable samples demonstrate no actionable growth prior to compounding for patient use.

14. Certified primary engineering control device (e.g., laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators).	*Yes*
15. Certified clean room(s) (e.g. ante area, buffer area).	*Yes*

Discussion Items

The requirements of TSBP Rule 291.11 and Section 565.0591 of the Pharmacy Act regarding the operation of a pharmacy within 6 months of becoming licensed.	*Yes*
Corresponding Responsibility and the Red Flags checklist using references from the DEA RPh Manual, the Texas Controlled Substances Act, and TSBP Rules 291.29 and 291.34 (b).	*Yes*
Pharmacy will need to conduct an opening inventory on the first day of business.	*Yes*

Pharmacy will need to report all controlled substances to the PMP as required. *Yes*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and

- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).

Tanya Stephens

Tanya Stephens PIC #39669

Terri Burrows

TEXAS STATE BOARD OF PHARMACY

Re:	Adelia Compounding, LLC
Address:	1801 Royal Lane, Suite 500 Farmers Branch, Texas 75229
License No.:	35502
Date Issued:	October 14, 2024
Licensure Status:	Active
Expiration Date:	October 31, 2026
Type of Pharmacy:	Community Sterile Compounding
Prior Disciplinary Orders:	No

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Adelia Compounding, LLC (Texas Pharmacy License #35502) has not been subject to disciplinary action by the Texas State Board of Pharmacy.

Form Completed by:

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy

November 26, 2024
Date

The Texas Department of State Health Services, Drugs and Medical Devices Division, Wholesaler Registration, 1100 W. 49th Street, Austin, TX 78756, is responsible for issuing registrations to wholesale drug distributors and drug manufacturers in Texas.

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
(512) 305-8000

License Number: 35502

(Date PDF Version Generated: 10/24/2024)

HELPFUL PHARMACY INFORMATION

- Pharmacies are required to notify TSBP within 10 days of a discontinuance of service, change of location or closure. See the TSBP website here Pharmacy - Renew & Update (texas.gov) for changes.
- Renewals open about 60 days prior to your expiration date, renewal information can be found here Renew | Pharmacy (texas.gov).
- Change of Employment or Change of PIC information can be found here Update | Employment (texas.gov).
- Change of Ownership – Call (512) 305-8021 or see Apply | Change of Ownership (texas.gov).
- For questions or assistance regarding rules, contact TSBP Rules Queue line at (512) 305-8070 see www.pharmacy.texas.gov.
- Non-Resident Pharmacy questions call (512) 305-9127 or email NonResPhcy@pharmacy.texas.gov.

An up-to-date License Verification is always available on the Board's website: http://www.pharmacy.texas.gov/

CERTIFICATE
OF
BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **AS** pharmacy.

License No. **35502** Expiration Date: **10/31/2026**

Balances: **1**

ADELIA COMPOUNDING, LLC
1801 ROYAL LN STE 500
FARMERS BRANCH, TX 75229

Daniel R. Carroll, Pharm.D.,
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 35502

ADELIA COMPOUNDING, LLC

License Information

License Status Active
License # 35502
Expiration Date 10/31/2026
Date License Issued 10/14/2024

Address

1801 ROYAL LN STE 500
FARMERS BRANCH, TX 75229
County DALLAS
Phone (866) 596-9595

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy
Community Sterile Compounding
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
STEPHENS, TANYA J

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	No

Translating services (Listed Below If Available)

Other

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3371205 35502 ADELIACOMPOUNDINGLLC 2024-10 10-2029.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	No
Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	Yes

Compounding Sterile-Risk Level Med	Yes
Compounding Sterile-Risk Level High	Yes
Compounding Non-Sterile	No
24 Hour Service	No
Closed Door	Yes
Compounding, Office Use	No
Home Delivery	No
Infusion	Yes
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
STEPHENS, TANYA J	39669	11/17/2000	10/31/2026	PIC	Active
TSAO, ALLAN CHEEHAO	34897	08/01/1994	08/31/2025	Staff	Active

Page 1 of 1 20 View 1 - 2 of 2

Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
ABDULLAH, TARIQ A	207869	04/30/2012	04/30/2026	Staff	Active

Page 1 of 0 20 View 1 - 1 of 1

Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
ADELIA COMPOUNDING, LLC	OWNER	,			
FOREMAN, JEFFREY DAVID	OFFICER	,			

Page 1 of 1 20 View 1 - 2 of 2

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-15-2024

ADELIA COMPOUNDING, LLC
1801 ROYAL LN STE 500
FARMERS BRANCH, TX 752297509

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D C 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-15-2024

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1801 ROYAL LN STE 500
FARMERS BRANCH, TX 752297509

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Form DEA-223 (9/2016)

4GGG

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FR2926434
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ROMAT VENTURES,INC dba: Alchemist Pharma

Physical Address: 11301 N. US HWY 301 SUITE 106

City: Thonotosassa State: FL Zip: 33592

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 813-252-4443 Toll Free # (NAC 639.708, NRS 639.23286): 833-916-9104

Fax: 813-252-4652 Contact Email: PHARMAALCHEMIST@GMAIL.COM

Website: https://alchemistpharmarx.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): AHMAD ZAITER

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24328

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: MAGDI SALHAB	NV Pharmacist Registration #:
Name: AHMAD ZAITER	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NR5.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: FLORIDA

Parent Company (if any): ROMAT VENTURES,INC

Corporation/Organization Name: ROMAT VENTURES,INC

Mailing Address: 11301 N. US HWY 301 SUITE 106

City: Thonotosassa State: FL Zip: 33592

Telephone: 813-252-4443 Email: PHARMAALCHEMIST@GMAIL.COM

Contact Person Name: MAGDI SALHAB

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the PRESIDENT (title) for ALCHEMIST PHARMACY (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

MAGDI SALHAB

Print Name of Authorized Person

Magdi Salhab

Original signature of Authorized Person (copies or stamps not accepted)

04/25/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Magdi Salhab

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Magdi Salhab

Original signature of Authorized Person (copies or stamps not accepted)

4/26/24

Date

Board Use Only	Date Received: 5/9/24	Amount: $500-check 1057

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: ROMAT VENTURES, INC dba ALCHEMIST PHARMA

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 11301 N US HWY 301 STE 106

City: THONOTOSASSA State: FL Zip: 33592

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 813-252-4443 Toll Free # (NAC 639.708, NRS 639.23286): 833-916-9104

Fax: 813-252-4652 Contact Email: PHARMAALCHEMIST@GMAIL.COM

Website: ALCHEMISTPHARMARX.COM

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): AHMAD ZAITER

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24328

Name of Designated Person(s) as defined by revised USP-797 guidelines: AHMAD ZAITER

Email of Designated Person(s): [redacted]

Telephone of Designated Person(s): [redacted]

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? Sept 2024

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? every month

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

BREMELANOTIDE ACETATE (PT-141)/CYANOCOBALAMIN INJECTABLE 20MG/1000MCG
GLUTATHIONE SOLUTION 10ML VIAL INJECTABLE 200MG/ML
NAD+ (NICODTINAMIDE ADENINE DINUCLEOTIDE) 5ML SOLUTION INJECTABLE 200MG/ML
TESTOSTERONE CYPIONATE IN MCT OIL 5ML INJECTABLE 200MG/ML

12. What laboratory performs your sterility or endotoxin testing?

Name: Pharmetric

Address: 11880 28th St #210

City: St. Petersburg State: FL Zip: 33716

Telephone: 727-209-5778

13. What is your procedure for visual inspection of compounded sterile products?

every unit compounded sterile product must be visually inspected. Please see attached SOP 520.1 Visual Inspection, Particulate Testing, and Reconciliation of Sterile Preparations

14. How often do you perform glove fingertip and medial fill testing?

every six months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Please find the attached SOP 109.1 Personnel Training

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please find the attached SOP 210.1 Cleaning and Disinfecting of Clean Room Compounding Areas

17. Who performs the sterile compounding process at your facility?

Pharmacist Ahmad Zaiter

18. Who is responsible and accountable for the sterile compounding process at your facility?

Pharmacist Ahmad Zaiter

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Please find the attached SOP 540.1 Packaging, Storage and Shipping of Refrigerated and Room Temperature Drug Products

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? LABCULTURE Class II Type A2 Biological Safety Cabinets Airstream® Gen 3 Vertical Laminar Flow Cabinet		
2. Are you complying with all USP 800 guidelines?	■ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

A leaflet printed by pharmacy software for the proper handling and disposal of hazardous drugs every time HD drug is dispensed to the patient

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Please find the attached
SOP 109.1Personnel Training and
SOP 515.1 Compounded Sterile Preparations Competency Testing in Aseptic Manipulation

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐Yes	☐No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐Yes	☐No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

AHMAD ZAITER

Name of Person who Completed the Form

PHARMACIST MANAGER

Title

Signature (copies or stamps not accepted)

10-18-2024

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

ALCHEMIST
PHARMA

STANDARD OPERATING PROCEDURE NO: 515.1

Title: Compounded Sterile Preparations Competency Testing in Aseptic Manipulation		
Effective Date:	**Supersedes** None	**Page:** Page **1** of **6**
Author: Ahmad Zaiter Pharmacist	**Revised by:** ----------	**Approved by:** Ahmad Zaiter Pharmacist

PURPOSE:

To ensure personnel competency in aseptic manipulation when compounding Compounded Sterile Preparations (CSPs)

EQUIPMENT/SUPPLIES:

- Sterile glass vials made of Type 1 glass or better.
- Sterile bromobutyl Stoppers round
- Aluminum caps
- Crimper
- ISO 5 Laminar Flow Hood or classified area with HEPA filtered air or Biological Safety Cabinet in ISO 7Clean room.
- Autoclave
- Depyrogenating Oven
- Syringes
- Filters

- Baxter Pump with sterile tubing
- 0.2-micron filter
- Tryptic Soy powder
- Sterile water

PROCEDURE:

1) Media Fill Test

The drugs and hold times listed in Table 1 are worse case scenarios for each of the aseptic processes performed at Alchemist Pharma and defined in the Definition section of this SOP.

Table 1

Process	Package	Quantity Distributed per Unit	Maximum Time Compounder will Spend Dosing Drug	Number of Units Produced
Media fill #1	10 mL clear glass vials, 250 vials with round stoppers 2 Controls	10 mL	4 hours	2.5 Liter Batch (yield approx. 250 units)

a) Preparation:

i) Compound the drug according to this SOP. Prior to starting compound, obtain a media fill form.

ii) Each person completing a media fill must notify management and ensure a pharmacist or designated technician is available for direct observation.

iii) Record all lot numbers, expiration dates, manufacturers and quantity used for each item in this media fill on the form.

iv) Alchemist Pharma technicians do not take breaks during a compounding run; however, there may be a need to change gloves.

v) The media fill shall be performed for the specified duration of time or until the given number of units is obtained to represent worst case scenario.

vi) Cleaning and disinfecting observation record must accompany each media fill form.

b) Media Fill with Post-GFT and Surface Sampling:

Surface sampling in the DCA must be conducted in conjunction with media-fill testing to assess aseptic manipulation competency. surface sampling should be performed at the end of a compounding activity but before the area has been cleaned and disinfected.

i) Procedures

(1) Take contact plate samples of the ISO 5 hood working surface at the completion of the media fill with a TSA+ and MEA+ contact plate.

(2) Contact plates shall be taken in the DCA for all personnel dependent media fills.

(3) Take TSA+ contact plate samples of compounders both right and left gloves at the end of media fill.

(4) Incubate TSA+ for 3-5 days at 30° – 35°C.Incubate MEA+ plates for 5-7 days at 20° - 25°C.

ii) Interpretation

(1) The action level for gloved fingertip and thumb sampling after media-fill testing is more than 3 CFU total count from both hands.

(2) Successful completion of the gloved fingertip and thumb sampling after media-fill testing is defined as ≤3 cfu as a total from both hands.

(3) Successful completion of DCA sampling after media-fill testing is defined as ≤3 cfu per media device.

c) Media Fill Details:

i) Procedures

(1) Weigh out required Soybean Casein Digest powder.

(2) In a 5 Liter beaker with a spin bar, add powder and sterile water geometrically.

(3) Mix well and let Soybean Casein powder completely dissolve into sterile water.

(4) Set up a Baxter repeater pump with sterile tubing.

(5) Dispense 2 control vials with no filtration as a control vial to confirm growth of media.

(6) Attach appropriate size 0.2-micron filter and filter remaining TSB broth into sterile bag.

(7) Set up Baxter pump and dose total desired volume amount of TSB bag into sterile 10mL clear vials.

(8) Dose 10mL into 250 clear sterile depyrogenated vials.

(9) During the filling process, a pharmacist will do in process volume check to make sure proper volume is dosed.

(10) Use tweezers to stopper the vials.

(11) Cap all 250 vials.

ii) Microbial Analysis:

(1) Incubate samples at 20°C to 25° for seven days, observe and document any growth.

(2) Transfer samples to 30° to 35°C and incubate for seven days.

(3) Failure is indicated by visible turbidity in the medium on or before the total 14 days.

iii) Interpretation:

(1) All units must be sterile.

(2) If any unit has growth, compounder must repeat media fill and cannot sterile compound until a passed media fill is achieved.

(3) Take appropriate corrective and preventive action.

d) Frequency:

i) CSP Category 1 and Category 2:

Media fill test will be done every 6 months.

ii) For category 3 CSP:

Media fill test will be done every 3 months.

RESPONSIBILITIES:

Any compounding pharmacist or technician who will compound and package drug product in the media fill listed must successfully perform this media fill.

The pharmacist must assign compounding responsibilities only to those pharmacy technicians who have passed the requisite media fill.

It is the responsibility of the compounding technician to follow this procedure.

REFERENCE:

USP <797> Pharmaceutical Compounding – Sterile Preparations

USP <71> Sterility Test

CHANGE SUMMARY:

Original SOP

DOCUMENT DESIGNATION:

500 series

ALCHEMIST PHARMA

STANDARD OPERATING PROCEDURE NO: 540.1

Title: Packaging, Storage and Shipping of Refrigerated and Room Temperature Drug Products		
Effective Date:	**Supersedes** None	**Page:** Page 1 of 4
Author: Ahmad Zaiter Pharmacist	**Revised by:** ----------	**Approved by:** Ahmad Zaiter Pharmacist

PURPOSE:

This procedure outlines the process of packaging and shipping of temperature sensitive and controlled room temperature drug product.

DEFINITIONS

N/A

EQUIPMENT/SUPPLIES:

- Insulated mailers
- Coolers
- Bubble wrap.
- Packaging tape
- Uline Cold bricks
- Shock Watch Ascending Temperature Monitor
- Plastic bags
- Shipping labels
- Drug product.

STORAGE OF DRUG PRODUCT INVENTORY

1. After completion of compounding, preparation will be placed into specified quarantine area until all test results have been received and approved.
2. Inventory will be released in inventory software and placed in appropriate storage location in pharmacy.

PROCEDURE FOR PACKAGING FINISHED DRUG PRODUCTS FOR SHIPMENT:

1. CSP packaging: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption.
2. and prevent inadvertent exposure to transport personnel.
3. The outside of each shipping container will bear the name of the intended patient. Patient confidential and private health information should not be disclosed. Items being shipped via common carrier will be labeled with a system-generated shipping label.
4. Refrigerated items should be shipped after achieving refrigerated temperature (36°-46° F).
5. Refrigerated items will be shipped via a Cooler or Insulated mailer along with Shock Watch Ascending Temperature Monitor
6. Heat sensitive item that are not refrigerated will be delivered in Insulated mailer or cooler with 4 Uline Cold bricks 7.5 oz during the months (May-August) and 2 Uline 7.5 oz gel packs during the months (September-April).
7. Uline Cold bricks will be used to help assure maintenance of refrigerated temperatures during delivery. The following are minimum recommended ice packs for various size mailers:

a. 9 x 11 Insulated mailer - 2 x 7.5 oz Uline Cold bricks
b. 12 x 14 Insulated mailer – 3x 7.5 oz. Uline Cold bricks
c. 14 x 18 Insulated mailer- 4x 7.5oz. Uline Cold bricks

8. Insulated mailers will be inflated to prevent unwanted movement of items. Bubble wrap will be used inside packages to avoid movement in package.
9. All medications will be shipped with a plastic over wrap. Light sensitive preparations will be dispensed in light protective over wrap. Re-sealable plastic bags may be used as an over wrap.
10. Loose supplies should be placed in a zip-lock bag for ease of handling.
11. Non-refrigerated items will be shipped via courier service like UPS or Fedex.
12. All refrigerated items will be shipped overnight ship by courier service, UPS or Fedex. Courier service will carry a cooler to maintain refrigerated temperatures.
13. The outside of the container box containing refrigerated items will be labeled "REFRIGERATE UPON ARRIVAL".
14. Follow procedures as per Shipping Validation protocol.

RESPONSIBILITIES:

All Alchemist Pharma employees involved in the shipment of medications shall be responsible for complying with this procedure.

REFERENCE:

USP < 795> Pharmaceutical Compounding – Sterile Preparations

USP <797> Pharmaceutical Compounding – Non-sterile Preparations

CHANGE SUMMARY:

Original SOP

DOCUMENT DESIGNATION:

500 series

ALCHEMIST PHARMA

STANDARD OPERATING PROCEDURE NO: 210.1

Title: Cleaning and Disinfecting of Clean Room Compounding Areas		
Effective Date:	**Supersedes**	**Page:** Page **1** of **5**
Author: Ahmad Zaiter Pharmacist	**Revised by:** ----------	**Approved by:** Ahmad Zaiter Pharmacist

PURPOSE:

The purpose of this standard operating procedure is to establish appropriate procedure for cleaning and disinfecting sterile compounding areas.

EQUIPMENT AND SUPPLIES

A. Quick Clean Mopping System
B. Disposable mop heads and covers.
C. Lint free wipes (single use)
D. Sticky Mop Roller
E. Sterile 70% IPA
F. Sterile Peridox RTU or sporicidal equivalent

PROCEDURE:

1. **Clean Room Start Up and Cleaning**

   a. Generously spray all horizontal work surfaces in all sterile compounding rooms with sterile 70% IPA. Spray all surfaces and sterile lint free wipe, wipe in a top to bottom, side to side motion. Do not overlap strokes. Allow 30 seconds to dry.

b. Generously spray working surface of cleanroom. Allow 30 seconds to pass and wipe from the back to front in a side-to-side motion with a lint free wipe. Do not overlap strokes.

2. **In Process Cleaning:**

a. At the conclusion of each drug compounding, clear the hood of all previous product and packaging components.

b. Generously spray the work surface area with sterile 70% IPA and allow contact time for at least 60 seconds.

c. Wipe with a lint free wipe top/ceiling from the back of the hood towards the front in a straight parallel motion without overlapping strokes. Then clean the sides followed by countertop of hood in same motion.

d. Spray work surfaces with IPA during production any time a spill has occurred or frequently during the compounding process.

e. When compounding hazardous in BSC-1 and/or powder hood at the conclusion of each drug compounding, clear hood of all previous product and packaging components then cleans with Peridox RTU or sporicidal equivalent (contact time based on respective manufacturer guidelines), if using Peridox RTU the contact time is 10 minutes before following up with sterile 70% IPA (60 seconds contact time) wipe down.

f. Turn the Laminar Flow Hood Workbench (LFHW) on for 30 minutes prior to compounding. Begin cleaning by using a sterile lint free wipe saturated with sterile 70% isopropyl alcohol. Start back in long horizontal strokes beginning at the top to bottom without overlapping, then sides vertically from back to front of the hood. Cleaning the roof the HEPA filter should never be sprayed directly; use a sterile lint free wipe saturated with sterile 70% isopropyl alcohol and lightly wipe over the HEPA filter in long horizontal strokes from the back to the front

without overlapping. Clean the rod and hooks, then bench long horizontal strokes from back to the front. Use a new Sterile 70% alcohol saturated wipe for each wall of the LFHW.

g. When working in between compounds clean the Laminar Flow Hood Workbench (LFHW) of all items with Sterile Peridox RTU (10 minutes contact time) to wipe stainless steel surfaces followed by sterile 70% IPA for 60 seconds. Use Peridox RTU followed by sterile 70% IPA between compounds when working in Hazardous clean room to prevent cross contamination.

3. **End of Day Cleaning ISO 5, ISO 7, ISO8 and Prep Room:**

a. Remove all trash from clean room (last step)

b. Sterile Peridox RTU (ready to use) to wipe stainless steel surfaces (10 Minutes kill time) followed by sterile 70% IPA. Use Sterile Peridox RTU or sporicidal equivalent daily on floors.

c. When disinfecting the cleanroom always work cleanest to dirtiest, top to bottom, and back to front of the room or hood; this includes walls and ceilings. Always begin in the critical compounding sites first and workout outward toward the dirty areas of the room. Do not overlap strokes. Use new sterile lint free wipe any time one moves from clean to dirty area.

d. Wipe down the tops of all work surfaces with lint free wipe moistened with sterile Peridox RTU. When applicable, saturating a surface by spraying will supersede using a moistened wipe. Include any touch pads for scales and pumps and other hand contact surfaces such as doorknobs and pass through handles. Spray buckets and totes with alcohol daily.

e. Once sterile Peridox RTU solution has had a minimum of 10 minutes of contact time (or other specified by manufacturer) on the surfaces, change sterile gloves and disinfect with sterile 70% IPA wipe. Using the same procedures as described in 3.d.

f. Using sticky floor roller, start from back of room to front using a rolling motion to pick up any loose debris.

g. Starting from the back of the clean room (the spot furthest from the door), mop in a back-and-forth motion without overlapping strokes. Continue until reaching the exit door.

h. Allow the Peridox RTU to air dry on the floor (10 minutes Contact time).

i. This procedure, as applicable, shall be repeated in the anteroom.

j. After mopping replace mop head and cover. Reusable cleaning tools (e.g., mop frames) are cleaned and disinfected before and after each use. Reusable mops are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas.

4. **Monthly Cleaning**

a. Use Peridox RTU or sporicidal equivalent.

b. Monthly undertray cleaning: Area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned monthly.

c. Same as daily cleaning but including a wipe down ceiling from back of room to door. Then work way down the walls from back of room to door from top to bottom. Do not allow mop head to touch floor. Make sure to change gloves prior to cleaning rest of room.

d. Clean tops of hoods, chairs, tables, bins, legs and lower shelves of tables and other equipment in the clean room with Sterile Peridox RTU (ready to use) to wipe stainless steel surfaces (10 mins kill time) followed by sterile 70% IPA.

e. Document cleaning on "Clean Rooms Monthly Cleaning and Disinfecting Log".

RESPONSIBILITIES

1. Compounding personnel are responsible for performing daily, weekly, and monthly cleaning.
2. Designated Pharmacist will assure proper documentation of cleaning and disinfection.

REFERENCE:

21CFR 210, 211: Good Manufacturing Practices

CDC Guideline for Disinfection and Sterilization in Healthcare Facilities, 2008

CHANGE SUMMARY:

Original SOP

DOCUMENT DESIGNATION:

200 series

ALCHEMIST PHARMA

STANDARD OPERATING PROCEDURE NO: 109.1

Title: Personnel Training		
Effective Date:	**Supersedes** ----------	**Page:** Page **1** of **6**
Author: Ahmad Zaiter Pharmacist	**Revised by:** ----------	**Approved by:** Ahmad Zaiter Pharmacist

PURPOSE:

The purpose of this standard operating procedure is to establish appropriate guidelines and documentation for all personnel involved in the compounding, evaluation, packaging, and dispensing of compounded preparations.

DEFINITIONS

Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

GFT: Gloved fingertip and thumb sampling.

EQUIPMENT/SUPPLIES:

- Training programs
- Job Descriptions
- Training Forms

RESPONSIBILITIES:

It is the responsibility of all employees to follow this procedure and ask for additional training if they feel necessary. Additional training shall be provided to any employee that requests for it.

It is the responsibility of the Supervising Pharmacist to ensure that a training program has been implemented, is documented and that it is ongoing. The Pharmacist will not assign an employee to a task until the training requirements are met.

PROCEDURE:

1) All employees involved in pharmaceutical compounding must read and become familiar with Chapter <795> "Pharmacy Compounding: Nonsterile Preparations" and Chapter <797> "Pharmacy Compounding: Sterile Preparations" of the United States Pharmacopeia-National Formulary. Familiarity will be documented by means of pharmacist verbal or written assessment, followed by employee and pharmacist's signature and date.
2) All employees will read and become familiar with each of the standard operating procedures (SOPs) related to their job description.
   a) Job descriptions include but are not limited to:
      i) Non-Sterile Technician
      ii) Sterile Technician
      iii) Compounding Pharmacist
   b) Each job description will have a check list of training requirements, including but not limited to:

i) Non-Sterile Technician Training Checklist

ii) Sterile Technician Training Checklist

iii) Compounding Pharmacist Training Checklist

3) All employees who enter the sterile compounding area must have sterile gowning training. Efficacy of training will be documented by a gowning qualification test including contact plates.

4) Compounding Techniques:

a) All compounders will be trained and visually observed on proper compounding and/or aseptic techniques.

b) A media fill validation for compounded sterile preparations will be performed by a compounding technician who intends to compound such products.

i) Category 1 and Category 2: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months.

ii) For Category 3 CSP: visual observation, media-fill testing, followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area will be performed at least one time every 3 months.

c) When the pharmacist is confident that the employee has demonstrated an oral and functional knowledge of the procedure, then and only then will the employee be permitted to perform the procedure without supervision.

d) When the pharmacist is satisfied with the employee's knowledge and proficiency, the pharmacist will sign the training documentation form to show that both the employee and the pharmacist agree.

5) The pharmacist will continually monitor the work of the employee and will answer the employee's questions about SOPs.

6) Training is an ongoing exercise. Training opportunities often exist at staff meetings, as a result of Quality Related Events (QRE) investigations, or during audits. These training opportunities should be captured on Training Session form.

7) Lectures, videos, and webinars are good training opportunities.

a) Confirm that the presenter is competent in the procedure or the topic of the training, or the media content is of an appropriate level and content.

b) Confirm the availability of appropriate equipment and supplies for the training session.

c) Allow sufficient time for the presenter and trainee to satisfactorily complete the training program, preferably without interruption.

d) Observe the trainee as they perform the procedure and/ or review the evaluation instrument/ examination for the satisfactory performance.

e) Place documentation or the evaluation instrument in the employee's training file.

8) Off-site seminars represent good training opportunities.

   a) Review the seminar announcement for appropriateness and application to the employee's job function.

   b) Discuss the expenses involved and how much funding is available.

   c) Assist the employee in making the necessary arrangements.

   d) Return all receipts to the pharmacist-in-charge after the seminar.

   e) Provide the pharmacist-in-charge and other appropriate personnel with a summary of the program and its value to the enhancement of job performance.

   f) Document training in employee's training records.

9) All employees will be trained in relevant safety procedures.

10) If, at any time, a pharmacist or technician is disqualified from a certain task, the disqualification shall be noted on the training log, a letter describing the circumstances leading to the disqualification shall be attached and the employee shall be retrained.

RESPONSIBILITIES:

All Alchemist Pharma employees involved in the dispensing, distribution, and compounding shall be responsible for complying with this procedure.

REFERENCE:

USP <795> Pharmacy Compounding: Non-sterile Preparations

USP <797> Pharmacy Compounding: Sterile Preparations

CHANGE SUMMARY:

NA Original SOP

DOCUMENT DESIGNATION:

100 series

ALCHEMIST
PHARMA

STANDARD OPERATING PROCEDURE NO: 520.1

Title: Visual Inspection, Particulate Testing, and Reconciliation of Sterile Preparations		
Effective Date:	**Supersedes**	**Page:** Page **1** of **4**
Author: Ahmad Zaiter Pharmacist	**Revised by:** ----------	**Approved by:** Ahmad Zaiter Pharmacist

PURPOSE:

The purpose of this standard operating procedure is to specify the process used to visually inspect compounded sterile drug preparations for the presence of particulates and other defects.

DEFINITIONS:

A. Particles: visible, insoluble extraneous substances, other than gas bubbles Common sources of particulates include chemicals (undissolved substances, trace contaminants), solvent impurities, packaging components (glass, plastic, rubber, intravenous administration sets), environmental contaminants (air, surfaces, insect parts), processing equipment (glass, stainless steel, rubber, rust), fibers, and people (skin, hair).

EQUIPMENT/SUPPLIES:

- Light Box, White/Black background (well-illuminated) with magnifying glass.
- Non-linting wipes
- Powder free gloves

PROCEDURE:

1. Clear area of all items and ensure previously inspected compound has been completely cleared from visual inspection area.
2. Observations generally include checks for precipitation, cloudiness, leakage, and gas formation, as indicated by a stopper's bulging outward, cracks in the container, and particulates, as described above.
3. Inspect the preparation immediately after preparation and before labeling. If the preparation is not dispensed immediately, also inspect it just before it leaves the pharmacy.
4. Inspect the contents, container, and closure during this procedure. *Note: The container should be free of labels or attachments.*
5. Use a dampened, non-linting wipe to remove any external particles.
6. Put on powder free gloves
7. Hold the container by its top and carefully swirl the contents by rotating the wrist in a circular motion. *Note: Avoid vigorous swirling. Air bubbles will rise to the top and can be discounted.*
8. Hold the container horizontally about four inches above the light source against the white/black background and move the container slowly back and forth between the white and the black backgrounds.
9. Slowly invert the container, even if you observe no particles, and watch for heavy particles that may be on the bottom of the container and that may slide down the container walls.
10. Visually inspect the vials to ensure the following:
    I. Proper fill volume

II. physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects

III. Container closure integrity is intact. (e.g., checking for leakage, cracks in the container, or improper seals)

IV. Correct, pharmaceutically elegant crimp.

11. Record the results of the observation on the quarantine Sheet for review by the pharmacist. Clearly flag the rejected vials and place all vials with defects in a bag clearly marked as defective and segregated from active stock.
12. Ensure all vials of batch are accounted for and match quarantine sheet. Report any discrepancies to the pharmacist.
13. Clear the area of all compounded sterile products from the visually inspected batch.

RESPONSIBILITIES:

Sterile Compounding technician performs this test.

Supervising Pharmacist confirms that the test is properly performed and reviewed.

REFERENCE:

US Pharmacopeial Convention, Inc. *United States Pharmacopeia 23-National Formulary 18.* Rockville, MD: US Pharmacopeial Convention, Inc.; 1995: 1813, 1963–1973.

Akers MJ. *Parenteral Quality Control.* New York, NY: Marcel Dekker, Inc.; 1994: 175–246.

CHANGE SUMMARY:

Original SOP

DOCUMENT DESIGNATION:

500 Series

State of Florida
Department of State

I certify from the records of this office that ROMAT VENTURES, INC. is a corporation organized under the laws of the State of Florida, filed on September 14, 2006, effective September 13, 2006.

The document number of this corporation is P06000118316.

I further certify that said corporation has paid all fees due this office through December 31, 2024, that its most recent annual report/uniform business report was filed on April 6, 2024, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Second day of May, 2024

Secretary of State

Tracking Number: 8943917533CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV797 USP Sterile Compounding

www.FloridaHealth.gov

File # 29877
Insp # 197892

NAME	PERMIT NUMBER	DATE OF INSPECTION
ROMAT VENTURES, INC		04/22/2024
DOING BUSINESS AS		
ALCHEMIST PHARMA		
STREET ADDRESS	**TELEPHONE #**	**EXT**
11301 N. US HWY 301 SUITE 106	813-252-4443	
CITY	**COUNTY**	**STATE/ZIP**
THONOTOSASSA	HILLSBOROUGH	FL/33592

Additional Information

Business Operation Hours

Registered Pharmacist / Intern / Tech

License # PS58257	Licensee Name Ahmad Zaiter
License Type Registered Pharmacists	
License # RPT77720	Licensee Name Joy Sipple
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FR2926434	

License Relations

Pharmacy Affiliate

SALHAB, MAGDI ABDELMOTI	License #

RX DPT MGR/COR/POR

ZAITER, AHMAD	License # 58257

Special Sterile Compounding

ROMAT VENTURES, INC	License # 25731

INV797 - USP Sterile Compounding

A. INTRODUCTION & SCOPE – ALL CATEGORIES

DESIGNATED PERSON: A designated person(s) is identified who is responsible and accountable for the performance and operation of the facility and personnel involved in the preparation of CSPs. [USP 797 Section 1.1.3] *Designated Person: Ahmad Zaiter*	Yes
IMMEDIATE USE COMPOUNDING: When preparing immediate use preparations, written SOPs are in place for all requirements and all criteria are met including 1. aseptic technique, processes, and procedures; and, 2. personnel are trained and demonstrate competency in aseptic processes as they relate to assigned tasks and SOP's, 3. the preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs, 4. the preparation involves not more than 3 different sterile products, 5. Any unused starting component from a single-dose container is discarded, 6. Administration begins within 4 hours following the start of preparation and, 7. Unless directly administered by the preparer or administration is witnessed by the preparer, the CSP is labeled with the names and amounts of all active ingredients, the name or initials of the preparer and the 4 hour period within which administration must begin. [USP 797 Section 1.3]	N/A
BAG & VIAL SYSTEM: Docking of vial and bag systems for future activation and administration is performed in an ISO 5 environment and BUDs are not longer than those specified in the manufacturer's labeling. [USP 797 Section 1.4]	N/A
REPACKAGING: Repackaging of sterile products or preparations from its original container into another container are prepared according to all applicable USP 797 requirements. [USP 797 Section 1.1.2]	N/A

BLOOD-DERIVED OR BIOLOGICAL MATERIAL MANIPULATIONS: Compounding activities that require the manipulation of a patient's blood-derived or other biological material (e.g., autologous serum), are clearly separated from other compounding activities and equipment used in CSP preparation activities and controlled by specific SOPs to avoid cross-contamination. [USP 797 Section 1.1.2]	N/A

B. COMPONENT BUDs (Single and Multi-dose Containers) – ALL CATEGORIES

SINGLE DOSE CONTAINERS (SDCs): SDCs are entered or punctured only in an ISO Class 5 or cleaner air and are used up to 12 hours after initial entry or puncture if the labeled storage requirements during that 12-hour period are maintained. [USP 797 Section 15.1]	N/A
AMPULES: Opened SINGLE DOSE AMPULES are used immediately and not stored for any time period. [USP 797 Section 15.1]	N/A
MULTIDOSE CONTAINERS (MDCs): Upon initially entering or puncturing a conventionally manufactured MDC, the MDC is not used for more than 28 days unless otherwise specified by the manufacturer on the labeling. [USP 797 Section 15.2]	N/A
PHARMACY BULK PACKAGES: Conventionally manufactured pharmacy bulk packages are entered or punctured only in an ISO Class 5 PEC and must be used according to the manufacturer's labeling. [USP 797 Section 15.3] *Pharmacy will be a non-sterile Cat 2 compounder*	N/A
SINGLE DOSE COMPONENT CSPs & STOCK SOLUTIONS: When single-dose CSPs or CSP stock solutions are used as a component to compound additional CSPs, the original compounded single-dose component CSP or CSP stock solution is entered or punctured in ISO Class 5 or cleaner air and is stored under the conditions upon which its BUD is based (e.g., refrigerator or controlled room temperature). Once punctured, the component CSP is used for sterile compounding for up to 12 hours or its assigned BUD, whichever is shorter, and any remainder is discarded. [USP 797 Section 16.2]	N/A
MULTI-DOSE CSPs USED AS A COMPONENT: Meet the criteria for anti-microbial effectiveness testing (see <51>) if aqueous, are stored under the conditions upon which the BUD is based, Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Sections 14.5 & 16.1]	N/A

C. CSP LABELING – ALL CATEGORIES

IMMEDIATE CONTAINER LABEL REQUIREMENTS: Immediate label of CSPs prominently and legibly display 1) assigned internal identification number; 2) active ingredient(s) and their amount(s), or concentration(s); 3) storage conditions if other than controlled room temperature; 4) BUD; 5) dosage form; 6) total amount or volume; 7) statement if CSP is a single dose container or multi-dose container. [USP 797 Section 13]	Yes
ADDITIONAL REQUIREMENTS FOR A CLASS II OR III FACILITY: 1) identification of responsible compounding personnel and/or dispensing pharmacist;2) labels for batch-prepared CSPs must also include: Control or lot number, auxiliary labeling (including precautions); and device-specific instructions. Patient specific medications must also include patient's name, location the medication is to be delivered to and directions for use. [USP 797 Section 13] [F.A.C.64B16-28.108(10)]	N/A
LABELING REQUIREMENTS: Labeling of CSP displays 1) route of administration, 2) special handling instructions, 3) warning statements, and the compounding facility name and contact information if the CSP is sent outside of the facility in which it was compounded. [USP 797 Section 13] *Noted Glutamine/Arginine/Carnitine 25mg/100mg/200mg/ml Inj LG12345 sample label*	Yes
LABELING SOPs: Labeling procedures, as described in facility SOPs, are followed to prevent labeling errors and CSP mix-ups. [USP 797 Section 13] *New Business SOP reference: 527.1 "Labeling of Compounded Sterile Preparations"*	N/A
LABEL VERIFICATION: CSP labels are verified to ensure that they conform with the prescription or medication order, MFR (if required), and the CR. [USP 797 Section 13] *Per SOP as noted on PK batch label*	N/A

D. PERSONNEL PREPARATION & OBSERVATION – ALL CATEGORIES

CONTROLLED ACCESS: Access to the SEC is restricted to authorized personnel and required materials. [USP 797 Section 4.2.1]	Yes
UNNECESSARY ITEMS: Items not necessary for compounding (e.g., food, drinks, mints, gum, earbuds, headphones) are not introduced into the compounding environment. Accommodations are documented. [USP 797 Section 3.1]	Yes
UNNECESSARY PERSONAL ITEMS: Personnel remove outer garments (e.g., bandanas, coats, hats, jackets, sweaters, vests); cosmetics, and all hand, wrist, and other exposed jewelry, including piercings that may interfere with effectiveness of garbing. [USP 797 Section 3.1]	Yes
NAILS: Nails are clean and trimmed. Nail products (e.g., polish, artificial nails, and extenders) are not worn. [USP 797 Section 3.1]	Yes
REQUIRED PPE & GARBING ORDER: Personnel garb (don and doff) in an order that reduces risk of contamination per SOP. Required garb, manner of storage, and order or garbing is documented in SOP's. The minimum required PPE when preparing CSPs includes a garment with sleeves that fit around wrists and enclosed neck, shoe covers, head/facial hair cover, face mask, and sterile powder-free gloves. All PPE is low lint for Category 1 & 2 compounding or sterile if Category 3. [USP 797 Section 3.3]	Yes
NAIL PICK USE: Personnel clean under nails under warm running water with a disposable nail cleaner. Hands and forearms are washed with soap and water for at least 30 seconds prior to entering a compounding area. [USP 797 Section 3.2]	Yes
INAPPROPRIATE HAND HYGIENE PRACTICES: Brushes and hand dryers are not used, and soap containers are not refilled or topped off. [USP 797 Section 3.2]	Yes
ALCOHOL-BASED HAND RUB: Hands are sanitized with alcohol-based hand rub prior to donning gloves. Handrub is used prior to donning garb when hand hygiene is done outside of a classified area. [USP 797 Section 3.3] *Avagard*	Yes
STERILE GLOVES USED: Sterile gloves are donned in classified room or SCA. Skin is not exposed inside ISO 5 PEC (e.g., gloves are not donned or doffed). [USP 797 Section 3.3] *Nitriderm ASTM 6978 gloves and Kimtech sterile gloves*	Yes
GARB STORAGE: Gowns and other garb are stored in a manner that minimizes contamination (e.g., away from sinks) and within a classified area or SCA. [USP 797 Section 3.3] *SOP 501.1 "Clean Room Gowning"*	Yes
SANITIZATION OF STERILE GLOVES: Sterile 70% IPA is applied to gloves prior to compounding and regularly throughout the compounding process. [USP 797 Section 3.3]	Yes
SANITIZATION OF ITEMS INTRODUCED INTO PEC: Items are wiped with sterile 70% IPA and sterile low-lint wipers just prior to being introduced into the PEC and allowed to dry before use. [USP 797 Section 8.2] *As observed*	Yes
CRITICAL SITES (e.g., vial stoppers, ampule necks, and intravenous bag septum's) are wiped with sterile 70% IPA in the PEC to provide both chemical and mechanical actions to remove contaminants. The sterile 70% IPA is allowed to dry before personnel enter or puncture stoppers and septum's or break the necks of ampules. [USP 797 Section 8.3] *TruCare SIPA wipes if needed*	N/A

EQUIPMENT DISINFECTION PRIOR TO ENTRY: Equipment brought into classified areas is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers. [USP 797 Section 9.1]	Yes

E. EQUIPMENT, SUPPLIES, & COMPONENTS – ALL CATEGORIES

DAILY ACD ACCURACY ASSESSMENT: An accuracy assessment is conducted for Automated Compounding Devices (ACDs) or similar equipment before the first use and again each day the equipment is used to compound CSPs. A daily record of accuracy measurements is maintained. Corrective actions are implemented if accuracy measurements are outside of manufacturer's specifications. [USP 797 Section 9.1] *Noted on sample batch record under Baxa Pump calibration*	Yes
EQUIPMENT SOPs: Written SOPs for the calibration, maintenance, cleaning, and use of equipment are established and are based on the manufacturer's recommendations. Procedures are followed and records are maintained. [USP 797 Section 9.1]	Yes
COMPOUNDING EQUIPMENT & SUPPLIES: Equipment and supplies used in compounding (e.g., needles, syringes, filters, tubing sets, beakers, utensils) are of suitable composition that surfaces in direct contact with components are not reactive or sorptive and surfaces in direct contact with CSPs are sterile and depyrogenated. [USP 797 Section 9.2]	Yes
COMPONENT STORAGE: Components are handled and stored in a manner that prevents contamination, mix-ups, and deterioration and under temperature, humidity, and lighting conditions consistent with those indicated in official monographs or specified by the suppliers and/or manufacturers. [USP 797 Section 9.3.4] *Area for component storage noted*	N/A

F. SEGREGATED COMPOUNDING AREA: Category 1

CATEGORY 1 MAXIMUM BUDs & COMPOUNDING AREA REQUIREMENTS: Only Category 1 CSPs are compounded in an ISO class 5 PEC located within a SCA and are assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less when refrigerated. [USP 797 Section 1.5, 4.2.1]	
DEDICATED AREA FOR SCA: The SCA is separated from areas not directly related to compounding, and all surfaces (walls, floors, counters, and equipment) are clean, uncluttered, and dedicated to compounding. [USP 797 Section 4.2.1]	
SCA LOCATION: The SCA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow, all of which may adversely affect the air quality in the PEC. SCA is not located where environmental control challenges (e.g., restrooms, warehouses, or food preparation areas) could negatively affect the air quality of the PEC within the SCA. A sink is not located within 1 meter of PEC. [USP 797 Section 4.2.1]	
ITEMS WITHIN SCA: Only furniture, equipment, and other materials necessary for performing compounding activities are located within the SCA. [USP 797 Section 4.2.1]	

G. FACILITIES & SECONDARY ENGINEERING CONTROLS – Categories 2 and 3

STERILE SUITE CONSTRUCTION: The ISO-classified anteroom and buffer room are separated from the surrounding unclassified areas of the facility by fixed walls and doors, and controls are in place. [USP 797 Section 4.2.1]	Yes
HEPA FILTERED AIR: Air supplied to the cleanroom suite is introducod through HEPA filters located in the ceiling of the buffer room and anteroom. [USP 797 Section 4.2.1]	Yes
AIR RETURNS: Air returns in the cleanroom suite are low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow. [USP 797 Section 4.2.1] *Low wall Vent returns*	Yes
LINE OF DEMARCATION: The anteroom has a line of demarcation to separate the clean side from the dirty side. [USP 797 Section 4.2.1] *Special cleanroom tape*	Yes
SURFACES & WALLS: The surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area are smooth, impervious, free from cracks and crevices, and non-shedding. Walls are constructed of/or covered with durable material. [USP 797 Section 4.3.1] *DeGard material for walls, ceilings*	Yes
CEILINGS & FLOORS: Inlaid panels of ceilings are caulked around each panel to seal them to the support frame. Junctures between the ceiling and the walls and between the walls and the floor are sealed to eliminate cracks and crevices where dirt can accumulate. Floors include coving to the sidewall, or the juncture between the floor and the wall are caulked. [USP 797 Section 4.3.1] *Vinyl floors, hospital grade*	Yes
LEDGES & OVERHANGS: Overhangs and ledges are easily cleanable, and the exterior lens surface of ceiling light fixtures are smooth, mounted flush, and sealed. [USP 797 Sections 4.3.1]	Yes
FURNITURE, EQUIPMENT, & MATERIALS: Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area or SCA. Tacky mats are not placed within ISO-classified areas. [USP 797 Sections 4.2.1 & 4.5]	Yes
CARTS: Carts used to transport components or equipment into classified areas are constructed from nonporous materials with cleanable casters and wheels. [USP 797 Section 4.5] *Steel carts*	Yes
TEMPERATURE & HUMIDITY MONITORING: Temperature and humidity in the cleanroom suite are controlled through a heating, ventilation, and air conditioning (HVAC) system. The temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed, either manually or by a continuous recording device. They are documented at least once daily or stored in the continuous recording device and are retrievable and are reviewed as described in the facility's SOP. [USP 797 Section 4.2] *per TMI*	Yes
PRESSURE DIFFERENTIATION MONITORING & DOCUMENTATION: Facility maintains a minimum differential positive pressure of 0.020-inch water column between the buffer room and anteroom and anteroom and unclassified area. A pressure differential monitoring device is used to continuously monitor the pressure differentials. Quantitative results from the pressure monitoring device are reviewed and documented at least daily on the days when compounding is occurring. [USP 797 Sections 4.2.5] *Magnahelix gauges*	Yes
PEC LOCATION: PECs are located in a buffer room in a manner that minimizes conditions that could increase the risk of microbial contamination (strong air currents, personnel traffic, or air streams from HVAC system(s)) and allows for cleaning around the PEC. [USP 797 Sections 4.2.2 & 4.2.3] *Esco PEC located in ISO 5 non-HD buffer room*	Yes
INTEGRATED VERTICAL LAMINAR FLOW ZONES: IVLFZ is separated from ISO Class 7 area with a physical barrier and there is full coverage of HEPA filters above the work surface. [USP 797 Section 4.2.3]	N/A

H. CERTIFICATION AND RECERTIFICATION – ALL CATEGORIES

INV797 USP Sterile Compounding

Insp # 197892 | ROMAT VENTURES, INC | File # 29877

PEC CERTIFICATION: The PEC is certified initially and every 6 months to meet ISO Class 5 or better conditions, during dynamic operating conditions. [USP 797 Sections 4.1 & 5.0] *Medrep initial certification Dec 11,12, 2023 and subsequently Jan 22, 23, 2024 and Feb 20, 2024.* *Sterile Non-HD buffer room Esco Vertical flow hood LVG-6AG-F9 SN 2022-184389 (ISO 5), Sterile HD room Vertical flow Esco Class II A2 LA2-5A2-E-PORT SN 2022-184390 (ISO 5).*	Yes
SEC CERTIFICATION: SECs are certified initially and every 6 months to meet ISO Class 7 or 8 or better conditions, during dynamic operating conditions (including presterilization activities if applicable). Anterooms providing access to positive-pressure buffer rooms are at least ISO 8 and at least ISO 7 for anterooms providing access to negative-pressure buffer rooms. Classified areas are recertified when changes occur that could affect airflow or air quality [USP 797 Sections 4.1, 4.2.6, & 5.0] *Medrep Initial certification Dec 11,12, 2023 and subsequently Jan 22, 23, 2024 and Feb 20, 2024 under as built conditions.* *Prep room (ISO 8), Sterile Positive pressure Anteroom (ISO 7), Positive pressure Sterile room (ISO 5 and unidirectional); Sterile HD Ante room (ISO 7), Sterile negative pressure HD room (ISO 7), PT#1 and PT#2 (ISO 7), PT#3 (noted by certifier as ISO 8-particle count was 907) page 77 of report med rep will fix to ISO 7 (this typo as clarified on day of inspection), leading into an ISO 5 non-HD sterile buffer room*	Yes
ISO CLASS 7 & 8 REQUIREMENTS: ISO Class 7 rooms maintain a minimum of 30 total HEPA-filtered ACPH during dynamic operating conditions, at least 15 ACPH come from the HVAC through HEPA filters located in the ceiling. ISO Class 8 rooms maintain a minimum of 20 total HEPA-filtered ACPH during dynamic operating conditions; 15 ACPH must come from the SEC. The ACPH from HVAC, ACPH contributed from the PEC, and the total ACPH are documented on the certification report. [UPS 797 Section 4.2.4] *ACPH: Sterile Ante room (84.21), Sterile non-HD buffer room (383.86), Sterile HD Ante room (110.66), HD buffer room (52.02)*	Yes
DOCUMENTATION OF PERSONNEL PRESENT DURING CERTIFICATION: The number of personnel present in each PEC and SEC during total particle counts and dynamic airflow smoke-pattern tests is documented on the certification report. [USP 797 Section 5.0] *Medrep documented 2 personnel from pharmacy and 2 from Medrep*	Yes
PEC DYNAMIC SMOKE PATTERN TEST: Smoke pattern tests are performed under dynamic conditions initially to demonstrate minimal disruption in airflow and repeated if equipment is placed in a different location. Smoke pattern tests are performed under dynamic conditions every 6 months to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s). [USP 797 Section 5.0] *Recorded dynamic smoke study on Jan 23, 2024*	Yes
ROBOTICS / ROBOTIC ENCLOSURES: Robotic enclosures used as a PEC or placed within a PEC have a dynamic airflow smoke pattern test is performed initially and at least every 6 months that confirms 1) the robotic device is properly integrated into the facility, 2) there is no turbulence or refluxing at any critical site(s), 3) room air does not enter the PEC where sterile products and/or preparations may be exposed, and 4) all processes can be performed without introducing contamination to the DCA(s). [USP 797 Section 4.2.3]	N/A
HEPA FILTER INTEGRITY TESTING: HEPA filter integrity testing for both SECs & PECs is conducted initially and every 6 months as part of total particle testing. [USP 797 Section 5.0] *Jan 22, 2024 by Medrep*	Yes
MONITORING DEVICE CERTIFICATION: Temperature and humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. [USP 797 Section 4.2] *Dec 2023*	Yes
CONTAINMENT DEVICES USED FOR PRESTERILIZATION PROCEDURES: CVEs, BSCs, or CACIs used for presterilization procedures are certified at least once every 6 months. [USP 797 Section 4.2.6] *CVE -initial certification Dec 2023*	Yes
CERTIFICATION REPORT REVIEW BY DESIGNATED PERSON: All certification and recertification records are reviewed by the designated person(s). A corrective action plan is implemented and documented in response to any out-of-range results on certification report and data reviewed to confirm that the actions taken have been effective. [UPS 797 Section 5.0] *Reviewed and documented on Feb 28, 2024 by Designated Person on Medrep book*	Yes

I. RABS

LOCATION: If used to prepare Category 2 or Category 3 CSP's RABS are located in a cleanroom suite with an ISO Class 7 or better buffer room with an ISO Class 8 or better anteroom. [USP 797 Section 4.2.3]	
RECOVERY TIME: When a RABS is used, the recovery time after opening the transfer chamber to achieve ISO Class 5 air is documented and internal procedures are developed to ensure that adequate recovery time is allowed after opening and closing the RABS. [USP 797 Section 4.2.3]	
STERILE GLOVES: are worn over gloves attached to RABS sleeves. [USP 797 Section 3.3]	

J. CATEGORY 2 CSPs WITHOUT STERILITY TESTING

CATEGORY 2 COMPOUNDING ENVIRONMENT: Category 2 CSPs are compounded in an ISO class 5 PEC located within an ISO classified anteroom and buffer room. [USP 797 Sections 4.1 & 14.3]	
CATEGORY 2 BUDs FROM STERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from all sterile starting components and in the absence of sterility testing do not exceed the following BUDs: 4 days room temperature, 10 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	
CATEGORY 2 BUDs FROM NONSTERILE COMPONENTS WITHOUT STERILITY TESTING: Category 2 CSPs compounded aseptically from one or more nonsterile starting components and in the absence of sterility testing do not exceed the following BUDs: 1 day room temperature, 4 days refrigerated, or 45 days frozen. [USP 797 Section 14.3]	

K. CATEGORY 2 EXTENDED BUD REQUIREMENTS

CATEGORY 2 BUDs FOR ASEPTICALLY PROCESSED CSPs WITH STERILITY TESTING: Category 2 CSPs compounded aseptically, and which have passed sterility testing do not exceed the following BUDs: 30 days room temperature, 45 days refrigerated, or 60 days frozen. [USP 797 Section 14.3] *New Business, based on SOP 590.1 pharmacy plans on assigning 30 days RT, 45 days refrigerated.*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITHOUT STERILITY TESTING: Category 2 CSPs terminally sterilized and in the absence of sterility testing do not exceed the following BUDs: 14 days room temperature, 28 days refrigerated, or 45 days frozen. [USP 797 Section 14.3] *No plans to terminally sterilize*	N/A
CATEGORY 2 BUDs FOR TERMINALLY STERILIZED CSPs WITH STERILITY TESTING: Category 2 CSPs terminally sterilized, and which have passed sterility testing do not exceed the following BUDs: 45 days room temperature, 60 days refrigerated, or 90 days frozen. [USP 797 Section 14.3]	N/A
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmics) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1] *New Business, per 590.1 "Beyond Use Dating" per v) plan to outsource to Pharmetric the USP <51> test.*	N/A

CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved CSPs), container integrity testing is performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5] *New Business. per 590.1 "Beyond Use Dating" per vi)*	N/A
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are assigned are prepared as a Category 2 CSP, for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5] *No plans on compounding non-preserved solutions*	N/A
OUTSOURCED STERILITY TESTING: Sterility testing is performed for all Category 2 CSPs assigned a BUD requiring sterility testing according to USP <71> or a validated alternative and noninferior method. Membrane Filtration as described in USP <71> is the preferred method when the formulation allows. [USP 797 Section 12.2] *Plan is to use Pharmetric*	N/A
INHOUSE STERILITY TESTING: Sterility testing is according to USP <71> or a validated alternative and noninferior method. Membrane filtration is used if appropriate and filters are rinsed according to USP <71>. Direct inoculation is done only when membrane filtration cannot be carried out. Volume inoculated does not exceed 10% of the culture media volume. Growth promotion test has been done on the media with the 5 specified organisms (not more than 100 CFU) according to USP <71>. TSB or SCD is incubated at 20-25C for 14 days; FTM is incubated at 30-35C for 14 days. (2 incubators present).	N/A
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method. [USP 797 Section 12.2] *Plan is to use pharmetric*	N/A
MAXIMUM BATCH SIZE: The maximum batch size for all CSPs requiring sterility testing is 250 final yield units. [USP 797 Section 12.2] *per SOP 590.1 "Beyond Use Dating" will be 250 as represented by media fill testing*	Yes
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2] *New Business will be per SOP 525.1 "Quarantine Testing and Releasing of Compounded Preparations"*	N/A
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may hava contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2] *New Business. See Out of Specification Investigation Form*	N/A
ENDOTOXIN TESTING: Category 2 Injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing are tested for bacterial endotoxins. [USP 797 Section 12.3] *New Business will be per SOP 525.1 "Quarantine Testing and Releasing of Compounded Preparations"*	N/A
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3] *Routes plan is IV, IM or SQ (GAC L)*	N/A

L. CATEGORY 3 CSPs, BUDs, & RELATED REQUIREMENTS

CATEGORY 3 REQUIREMENTS: All requirements associated with Category 3 compounding (e.g., garbing, cleaning, environmental monitoring) apply to all personnel entering the buffer room where Category 3 CSPs are compounded and always apply regardless of whether Category 3 CSPs are compounded on a given day. [USP 797 Section 14.4.2]	
STERILE/SINGLE USE GARB: When compounding Category 3 CSPs, skin is not exposed in buffer room (i.e., face and neck are covered) and all low lint outer garb is sterile, including sterile sleeves over RABS gauntlet sleeves. Disposable garb items are not reused. [USP 797 Section 3.3]	
STERILIZED/REUSABLE GARB: Non-disposable garb is not reused without being laundered and resterilized with a validated cycle. Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment. [USP 797 Section 3.3]	
CATEGORY 3 BUDs FOR ASEPTICALLY PROCESSED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 60 days room temperature, 90 days refrigerated, or 120 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for aseptically processed CSPs. [USP 797 Section 14.4.3]	
CATEGORY 3 BUDs FOR TERMINALLY STERILIZED CSPs: Category 3 CSPs aseptically processed, sterility tested, and passing all applicable tests (including stability indicating assay, endotoxin, and other dosage form appropriate tests) do not exceed the following BUDs: 90 days room temperature, 120 days refrigerated, or 180 days frozen. Shorter BUDs are assigned when physical or chemical stability of the CSP is less than the maximum allowable Category 3 BUDs for terminally sterilized CSPs. [USP 797 Section 14.4.3]	
MAXIMUM BATCH SIZE: Category 3 CSP batch sizes do not exceed 250 final yield units. [USP 797 Section 12.2]	
STABILITY INDICATING ASSAYS: All Category 3 CSP formulations are supported by data obtained using a validated stability-indicating analytical method that can distinguish active ingredients from degradants and impurities and quantify the amount of active ingredient. CSPs are prepared according to the exact formulation, components, and packaged in a container closure system of the same materials of composition. Facilities have documentation of the stability study, its results, and the method validation available for review. [USP 797 Section 14.3.3]	
STERILITY TESTING: All category 3 CSPs and batches undergo sterility testing performed according to USP <71> or a validated alternative and noninferior method. [USP 797 Sections 12.2 & 14.4.4]	
METHOD SUITABILITY TEST: A Method Suitability Test (or equivalent validation for alternative testing methods) is performed to validate suitability of the sterility testing method for each formulation. [USP 797 Section 12.2]	
STERILITY TESTING QUANTITY & VOLUME DETERMINATION: The minimum quantity of each container tested for sterility is per USP <71> Table 2 and the number of containers tested in relation to the batch size is per USP <71> Table 3. For 1-39 CSPs compounded as single batch, sterility testing is performed on a number of containers or units equal to 10% of the number of CSPs prepared rounded to the next whole number. [USP 797 Section 12.2]	
INVESTIGATION OF STERILITY TEST FAILURES: Sterility tests resulting in failure undergo prompt investigation into possible causes and requires identification of the microorganism(s) as well as evaluation of sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. Impact to other CSPs is assessed. Investigation and resulting corrective actions are documented. [USP 797 Section 12.2]	
ENDOTOXIN TESTING: Category 3 Injectable CSPs compounded from one or more nonsterile component(s) are tested for bacterial endotoxins. [USP 797 Section 12.3]	
ENDOTOXIN LIMITS: In the absence of a bacterial endotoxin limit in an official USP–NF monograph or other CSP formula or scientifically supported source, the CSP does not exceed the endotoxin limit calculated as described in USP <85> for the appropriate route of administration for humans or largest recommend dose per weight for nonhuman species. [USP 797 Section 12.3]	

PARTICULATE MATTER TESTING: Category 3 injectable CSPs undergo USP <788> (Particulate Matter in Injections) and ophthalmic solutions undergo USP <789> (Particulate Matter in Ophthalmic Solutions) test once per formulation with acceptable results. [USP 797 Section 14.3.3]	
ANTIMICROBIAL EFFECTIVENESS TESTING FOR MULTI-DOSE CSPs: Aqueous multiple-dose CSPs (e.g., injectables and ophthalmic) pass USP <51> compliant antimicrobial effectiveness testing once for each unique formulation and each container closure system in which it is packaged. Bracketing studies are allowed. [USP 797 Section 14.5 & 16.1]	
CONTAINER CLOSURE TESTING: Container closure integrity testing is performed once for each unique CSP formulation and container closure system in which it is packaged. For multi-dose (i.e., preserved multi-dose CSPs), container closure integrity testing is also performed per fill volume for each unique CSP formulation and container closure system. [USP 797 Sections 14.3.3 & 14.5]	
MULTI-DOSE, NON-PRESERVED AQUEOUS CSPs: Multi-dose, non-preserved aqueous CSPs (i.e., topical, or ophthalmic solutions) are prepared for use by a single patient, and labeled to indicate that once opened, the CSP must be discard after 24 hours if stored at controlled room temperature or 72 hours when stored under refrigeration. [USP 797 14.5]	
MULTI-DOSE COMPONENT CSPs: Multiple-dose CSP after initially entered or punctured, are not used for longer than the assigned BUD or 28 days, whichever is shorter. [USP 797 Section 16.1]	

M. PERSONNEL TRAINING & COMPETENCIES - ALL CATEGORIES

TRAINING PROGRAM & SOP: Facility maintains a written training program and corresponding SOP which defines required trainings, frequency of training and the process for evaluating the performance of individuals who compound, have direct oversight of compounding personnel, perform in-process checks, final verification and dispensing of CSP's. [USP 797 Section 2] *SOP 515.1 "Compounding Sterile Preparations Competency Testing in Aseptic Manipulation" frequency is every 6 months*	Yes
INITIAL CORE SKILLS KNOWLEDGE & COMPETENCY ASSESSMENT: Before beginning to compound CSPs independently or have direct oversight of compounding personnel, personnel complete training and can demonstrate knowledge of principles and competency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions as applicable to their assigned job functions. [USP 797 Section 2.1]	Yes
INITIAL GLOVED FINGERTIP & HAND HYGIENE/GARBING COMPETENCY: Before beginning to compound independently or have direct oversight of compounding personnel, personnel successfully complete an initial gloved fingertip (GFT) competency no fewer than 3 separate times, with a documented visual audit while performing hand hygiene and garbing procedures. GFT samples are collected before applying sterile 70% IPA to gloves. [USP 797 Section 2.2] *AZ (2-13-24), JS (2-13-24) completed using Hardy TSA with L&T plates P34*	Yes
GLOVED FINGERTIP INCUBATION: Documentation includes the name of the person evaluated; evaluation date and time; media and components used to include manufacturer, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; results and identification of the observer and personnel reading and documenting the results. USP 797 Section 2.2] *per written documentation. Pharmacy has 3 incubators*	Yes
INITIAL MEDIA FILL & ASEPTIC TECHNIQUE ASSESSMENT: Before beginning to compound independently or have direct oversight of compounding personnel, personnel who compound or have direct oversight of compounding successfully complete an initial aseptic manipulation competency evaluation which consists of a visual observation, media-fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area. [USP 797 Section 2.3] *2/9/24 for both compounding personnel*	Yes
MEDIA INCUBATION: Documentation includes the name of the person evaluated, evaluation date and time, media and components used to include their manufacturer or supplier, expiration dates and lot numbers, starting temperature for each interval of incubation, dates of incubation, the results, and the names or other identification of the observer and the person who reads and documents the results. [USP 797 Section 2.3] *7 days at different temperatures*	Yes
CATEGORY 1 AND 2-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency evaluation and GFT every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2] *Feb 9, 2023*	Yes
CATEGORY 1 AND 2-ONGOING MEDIA FILL & ASSESSMENT: After initial aseptic manipulations competency evaluations, compounding personnel complete aseptic technique competency, media fill, GFTs, and surface sampling of DCA every 6 months for Category 1 and Category 2 CSP's. Direct oversight personnel who do not compound complete media fill every 12 months. GFTs and surface samples are appropriately incubated. [USP 797 Section 2.3] *Initial completed Feb 9, 2023*	Yes
ONGOING KNOWLEDGE & COMPENTENCY OF CORE SKILLS: Training and knowledge assessment of sterile compounding principles or core skills is completed at least every 12 months. [USP 797 Section 2.1] *Dec 2023 through Feb 2024 using Critical Point*	Yes
FAILED COMPETENCY INVESTIGATION: Initial and ongoing competency assessment failures are investigated, remediated, and documented in a Corrective Action Plan. [USP 797 Sections 2.2 & 2.3]	N/A
STAFF TRAINING IN VIABLE AIR AND SURFACE SAMPLING: Personnel are trained and competent in air and surface sampling procedures to ensure accurate and reproducible sampling. [USP 797 Section 6.1] *Critical Point*	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-ONGOING GFT & GARBING ASSESSMENT: After initial garbing competency evaluations, compounding personnel complete garbing competency and GFT every 3 months for Category 3 CSP's. Direct oversight personnel who do not compound complete garbing competency and GFT every 12 months. GFTs are appropriately incubated. [USP 797 Section 2.2]	
CATEGORY 3-ONGOING ASEPTIC PROCESSING COMPETENCY: Aseptic competency is repeated at least one time every 3 months for personnel compounding Category 3 CSPs. The simulation must capture elements that could potentially affect the sterility of the CSP. Immediately following the media-fill test, gloved fingertip and thumb sampling is performed on both hands and surface sampling of the direct compounding area. Direct oversight personnel who do not compound must complete media fill every 12 months. [USP 797 Section 2.3]	

N. MICROBIOLOGICAL AIR AND SURFACE MONITORING: ALL CATEGORIES

ENVIRONMENTAL MONITORING PROGRAM & SOPs: The microbiological air and surface monitoring program is clearly described in the facility's SOPs, which includes a diagram of the sampling locations, procedures for collecting samples, frequency of sampling, size of samples (e.g., surface area, volume of air), time of day of sampling in relation to activities in the compounding area, and action levels that trigger corrective action. [USP 797 Section 6] *SOP 212.1 "Active Air Sampling of Clean room Compounding Areas"*	Yes
VIABLE AIR SAMPLING: Volumetric active air sampling using an impaction air sampler collecting at least 1000L of air is conducted in each classified area [e.g., ISO Class 5 PEC and ISO Class 7 and 8 room(s)] during dynamic operating conditions and is completed at least every 6 months. [USP 797 Section 6.2] *per Medrep*	Yes

AIR IMPACTION DEVICE: Device is serviced and calibrated according to the manufacturer's recommendations. [USP 797 Section 6.1] *per Med rep*	Yes
SURFACE SAMPLING: Microbiological surface sampling is conducted in all classified areas and pass-through chambers under dynamic operating conditions and performed at least once monthly. [USP 797 Section 6.3] *SOP 213.1 "Surface Sampling of Cleanroom Compounding Areas"* *Surface sampling is being completed monthly*	Yes
GROWTH MEDIA: A general microbiological growth media that supports the growth of bacteria and fungi is used and a COA from the manufacturer is available. Growth media used for surface sampling contains neutralizing agents (e.g., lecithin and polysorbate 80). [USP 797 Sections 6.2 & 6.3]	Yes
INCUBATION: Samples are incubated at 30°C - 35°C for 48 hours and 20°C - 25°C for an additional 5 days; if dual growth media are used, incubate one media device at 30°C - 35°C for 48 hours and the second media device at 20°C - 25°C for 5 days. The incubator temperature is monitored during incubation, either manually or by a continuous recording device, and results are reviewed and documented as described in the facility's SOPs. Incubators are placed in a location outside of the sterile compounding area. [USP Sections 6.2.2 (Box 5) & 6.3.2 (Box 6)] *Dual plate method*	Yes
ENVIRONMENTAL MONITORING TREND ANALYSIS: Regular review of sampling data is performed to detect trends and review of trending data is documented. [USP 797 Section 6.1]	Yes
CORRECTIVE ACTION: When microbial growth exceeds action levels, the cause is investigated, and corrective action is taken; corrective actions taken are reviewed for effectiveness. An attempt to identify microorganisms at the genus level is made. [USP Sections 6.2.3 & USP 6.3.3] *No growth*	N/A

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-VIABLE AIR SAMPLING: Volumetric air sampling is completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.Air sampling sites are selected in all classified areas. [USP 797 6.2.1]	
CATEGORY 3-SURFACE SAMPLING: Surface sampling for any Category 3 CSPs, is completed in all classified areas, and pass-through chambers connecting to classified areas, prior to assigning a BUD longer than BUD limits for Category 2 CSPs (defined in Table 13 of USP 797) and at least weekly on a regularly scheduled basis regardless of the frequency of compounding Category 3 CSPs. [USP 797 6.2.2]	
CATEGORY 3-BATCH SURFACE SAMPLING: Surface sampling is conducted within the PEC used to prepare Category 3 CSPs, at the end of each batch before cleaning and disinfection occurs, unless a self-enclosed robotic device is used. When a self-enclosed robotic device is used as the PEC, surface sampling is conducted at least once daily at the end of compounding operations before cleaning and disinfection occurs. [USP 797 Section 6.3.2]	

O. CLEANING AND DISINFECTING: ALL CATEGORIES

CLEANING SOPS: The frequency, method(s), documentation requirements, and location(s) of cleaning, disinfecting, and applying sporicidal disinfectants are described in written SOPs; use of agents is in accordance with manufacturer's instructions, procedures, and in adherence with minimum wet contact times. [USP 797 Section 7] *SOP 210.1 "Cleaning"*	Yes
CLEANING PERSONNEL: Cleaning and disinfecting activities are performed by trained and appropriately garbed personnel using facility-approved agents and procedures. Cleaning personnel demonstrate knowledge and competency of core skills related to cleaning, disinfection, and maintenance of environmental conditions initially and at least once every 12 months. [USP 797 Sections 7 & 2.1] *3/11/24*	Yes
REUSABLE GARB: Disinfection procedures described in facility SOPs are followed before reusing goggles, respirators, and other equipment used. [USP 797 Section 3.3] *Goggles are only item that is reused and autoclaved*	Yes
DAILY PEC CLEANING & DISINFECTION: Equipment and all interior surfaces of the PEC are cleaned and disinfected daily on days when compounding occurs and when surface contamination is known or suspected. [USP 797 Section 7] *Peridox followed by SIPA-please name PEC's*	Yes
CATEGORY 1 AND 2-MONTHLY PEC SPORICIDAL DISINFECTION: Equipment and all interior surfaces of the PEC, including underneath of removable work trays, are cleaned with a sporicidal agent monthly. [USP 797 Section 7]	Yes
DAILY SEC & SCA CLEANING & DISINFECTION: Work surfaces, floors, sink surfaces, and pass-through chambers are cleaned and disinfected daily on days when compounding occurs. [USP 797 Section 7]	Yes
CATEGORY 1 AND 2 -MONTHLY SEC & SCA SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings*, walls, doors, and doors frames at least once monthly. *SCA ceilings are only cleaned, disinfected, and have sporicidal agents applied when visibly soiled and when surface contamination is known or suspected. [USP 797 Section 7]	Yes
CLEANING & DISINFECTING AGENTS: Cleaning and disinfecting agents are EPA-registered. If a one-step disinfectant cleaner is not used, surfaces are cleaned prior to being disinfected. [USP 797 Section 7] *Peridox and SIPA*	Yes
STERILE AGENTS USED INSIDE PECs: Cleaning, disinfecting and sporicidal agents used within PECs are sterile. Written SOPs describe the time period during which, once opened, sterile cleaning and disinfecting agents, supplies, and sterile 70% IPA may be reused sterile water is used to dilute concentrated cleaning agents used inside of PECs (if applicable). [USP 797 Section 7.1.1]	Yes
CLEANING AGENT RESIDUE REMOVAL IN PECs: In a PEC, sterile 70% IPA is applied after cleaning, disinfecting, or after one-step disinfectant cleaner or sporicidal agent application to remove residue. [USP 797 Section 7].	Yes
PEC SANITIZATION WITH STERILE 70% IPA: Sterile 70% IPA is applied to the horizontal work surface, including removable trays, immediately before initiating compounding and at least every 30 minutes. If a compounding process takes more than 30 minutes, the work surface is disinfected immediately after the end of the compounding process. Sterile 70% IPA is allowed to dry. [USP 797 Section 7] *Can spray and wipes*	Yes
CLEANING SUPPLIES & TOOLS: All cleaning and disinfecting supplies (e.g., wipers, sponges, pads, and mop heads), except for tool handles and holders, are low lint. Supplies used inside PECs are sterile. [USP 797 Section 7.1.2]	Yes
REUSABLE CLEANING TOOLS: Reusable cleaning tools (e.g., mop frames) are made of cleanable materials and are cleaned and disinfected before and after each use. Reusable tools are dedicated for use in the classified areas or SCA and are not removed. Mops used in HD compounding areas, are dedicated for use only in those areas. [USP 797 Section 7.1.2] *Poles are reusable*	Yes
MATERIALS MOVEMENT INTO CLASSIFIED AREAS: Before any item is introduced into the clean side of anteroom(s), placed into pass-through chamber(s), or brought into the SCA, it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA using low-lint wipers by personnel wearing gloves. Dwell time is followed. [USP 797 Section 8.1]	Yes

FACILITY COMPOUNDS CATEGORY 3

CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF PECs: Weekly cleaning using a sporicidal agent is performed on all internal surfaces of PEC and equipment in PEC's. [USP 797 Section 7]	
CATEGORY 3-WEEKLY SPORICIDAL CLEANING OF SECs: Weekly cleaning using a sporicidal agent includes application on work surfaces outside the PEC, pass-through chambers, and floors. [USP 797 Section 7]	
CATEGORY 3 -MONTHLY SEC SPORICIDAL DISINFECTION: A sporicidal disinfectant is applied to work surfaces, pass-through chambers, storage shelving and bins, equipment outside of PEC's, sink surfaces, floors, ceilings, walls, doors, and doors frames at least once monthly. [USP 797 Section 7]	

P. COMPOUNDING CSPs FROM NONSTERILE COMPONENTS OR SUPPLIES – CATEGORY 2 & 3

PRESTERILIZATION ACTIVITY CONTAINMENT ENCLOSURES: Pre-sterilization procedures, such as weighing and mixing of nonsterile components, occur in ISO Class 8 or better environment (e.g., anteroom or buffer room) and are performed in single-use containment glove bags, CVEs, BSCs, or CACIs. [USP 797 Section 4.2.6]	Yes
LOCATION OF STERILE & NONSTERILE PECs: PECs used for sterile and nonsterile compounding (e.g., pre-sterilization procedures) are placed in separate rooms unless the buffer room can maintain an ISO Class 7 classification during particulate generating activities. Co-located PECs are at least 1 meter apart and particle-generating activities are not performed during sterile compounding processes [USP 797 Section 4.2.1; USP 800 Section 5.3]	Yes
COMPONENT SOPs: Written SOPs address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components including ingredients and container closures. [USP 797 Section 9.3] *SOP 450.1 "Receipt, Storage and Handling of Bulk Chemicals and Finished Drug Preparation"* *Pharmacy has a Vendor Audit Questionairee*	Yes
COMPONENT QUALITY & COA: APIs and components comply with the criteria in the USP-NF (if one exists for inactive components) and have a COA including specifications and test results showing the API or component meets expected quality. APIs and other components labeled "not for pharmaceutical use", "not for injectable use", "not for human use", or equivalent are not used in CSPs. [USP 7 Section 9.3.1]	Yes
API MANUFACTURERS: APIs are manufactured by an FDA-registered facility in the U.S. or comply with the laws and regulations of the applicable regulatory jurisdictions outside of the U.S. [USP 797 Section 9.3.1] *Examples of API Manufacturers: PCCA, Biopeptek, Spectrum, Fagron, Letco, Humco, Medisca (repackager)*	Yes
STERILE, DEPYROGENATED SUPPLIES: Supplies in direct contact with CSPs are sterile and depyrogenated. A COA or similar conformance documentation is reviewed. [USP 797 Section 9.3.1]	Yes
COMPONENT RECEIPT: Upon receipt, the external packaging of components is examined and components of unacceptable quality or showing deterioration are promptly labeled as rejected and segregated from active stock. [USP 797 Section 9.3.2] *Locked quarantine cabinet observed during walk through.* *SOP 450.1 and SOP 452.1*	Yes
COMPONENT EXPIRATION DATING: Upon receipt, APIs and components are inspected for a visible manufacturer expiration date. Components lacking expiration dates are assigned an expiration date no more than 1 year after receipt and both the date of receipt and facility assigned expiration date is clearly marked on the component packaging. [USP 797 Section 9.3.2]	Yes
COMPONENT EVALUATION BEFORE USE: All components are reinspected before use to ensure correct identify, appropriate quality, within expiry date, have been stored under appropriate conditions. [USP 797 Section 9.3.3] *per SOP 450.1*	Yes

Q. STERILIZATION OF CSPs - CATEGORY 2 & 3

CSP Sterilization Overview	No
STERILIZATION METHOD(S) APPROPRIATENESS: Sterilization method(s) used do not degrade CSP physical and chemical stability (e.g., affecting its strength, purity, or quality) or packaging integrity. [USP 797 Section 10] *New Business -using filtration as sterilization method*	N/A
STERILITY ASSURANCE LEVEL (SAL) FOR TERMINAL STERILIZATION METHODS: Terminal sterilization method(s) (e.g., steam, dry heat, or irradiation) achieve a SAL or PNSU (probability of a nonsterile unit) of (0.000001) [USP 797 Section 10]	N/A
STERILIZATION OF INJECTABLES WITHIN 6 HOURS OF COMPLETION: Injectable CSPs containing nonsterile components or that come into contact with nonsterile devices (e.g., containers, tubing) during compounding are sterilized within 6 hours of completion. [USP 797 Section 10] *New Business*	N/A
STERILIZATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, pressure (if applicable), duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10]	Yes
CSP Sterilization by Filtration	Yes
STERILIZING FILTERS: Sterilizing filters used are sterile, depyrogenated, have a nominal pore size of 0.22 µm or smaller, and are appropriate for pharmaceutical use. Sterilizing filters are certified by the manufacturer to retain at least 10,000,000 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area. Filters are chemically and physically compatible with all ingredients in the CSP (e.g., water-miscible alcohols may damage filter integrity); chemically stable at the pressure and temperature conditions that will be used; and have enough capacity to filter the required volumes. [USP 797 Section 10.2] *Plan to use MDI Asepticap filters*	N/A
BUBBLE POINT TESTING: Sterilizing filters are subjected to the manufacturers' recommended integrity testing, such as a post-use bubble point test. If multiple filters are required for the compounding process, each of the filters passes a filter-integrity test. [USP 797 Section 10.2] For failed BP testing, CSP is discarded or, after investigating, refiltered not more than one time. [USP 797 Section 10.2] *Demonstrated in media fill*	Yes
CSP PREFILTRATION: When CSPs are known to contain excessive particulate matter, prefiltration is performed using a filter of larger nominal pore size (e.g., 1.2 µm) or a separate filter of larger nominal pore size placed upstream of (i.e., prior to) the sterilizing filter. [USP 797 Section 10.2] *Not terminally sterilizing*	N/A
CSP Sterilization by Steam	No
STEAM STERILIZATION CYCLES: Sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of the CSP to reach and remain at the sterilizing temperature during the duration of the sterilization period. Items are placed in the autoclave to allow steam to reach CSPs without entrapment of air. [USP 797 Section 10.3] *Not currently terminally sterilizing.* *274 degrees for 20 minutes, per SOP 331.1 "Operation and Maintenance of Tuttnauer 3870 EA Autoclave" Validation Dec 6, 2023*	N/A

BIOLOGICAL INDICATOR USE: The effectiveness of steam sterilization is verified and documented with each sterilization run or load by using appropriate biological indicators (e.g., spores of Geobacillus stearothermophilus) and other confirmation methods. [USP 797 Section 10.3] *Sporview used, but not terminally sterilizing*	N/A
CSP PREFILTRATION: Immediately before filling containers that will be sterilized via steam, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.3]	N/A
AUTOCLAVE WATER SOURCE: The steam supplied in the autoclave is generated using water per the manufacturer's recommendation. [USP 797 Section 10.3] *Distilled water, but not terminally sterilizing*	Yes
CALIBRATED DATA RECORDER: A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (e.g., deviations in temperature or pressure). [USP 797 Section 10.3] *Not currently terminally sterilizing*	N/A
CSP Sterilization by Dry Heat	No
DRY HEAT STERILIZATION CYCLES: Dry heat sterilization cycles allow for an exposure duration that includes sufficient time for the entire contents of CSPs and other items to reach and remain at the sterilizing temperature for the duration of the sterilization period. [USP 797 Section 10.4] *Memert Dry Heat Oven SN B5220016*	N/A
CSP PREFILTRATION: Immediately before filling ampules and vials that will be sterilized by dry heat, CSP solutions are passed through a filter with a nominal pore size of not larger than 1.2 µm for removal of particulate matter. [USP 797 Section 10.4]	N/A
CALIBRATED DATA RECORDER: The calibrated oven is equipped with temperature controls and a timer. A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (e.g., deviations in temperature or exposure time). [USP 797 Section 10.4] *Not currently terminally sterilizing. See graph in Validation Procedure Protocol with accomplished temp of 260C for 1 hour*	N/A
BIOLOGICAL INDICATOR USE: The effectiveness of the dry heat sterilization method is verified and documented with each sterilization run or load using appropriate biological indicators (e.g., spores of Bacillus atrophaeus) and other confirmation methods (e.g., temperature-sensing devices). [USP 797 Section 10.4] *Not terminally sterilizing, uses Mesa labs lot 221001 cat #CIDHI*	N/A

R. DEPYROGENATION OF EQUIPMENT - CATEGORY 2 & 3

DEPYROGENATION SOPs include: 1) A description of terminal sterilization and depyrogenation process(es) used in the preparation of CSPs and/or compounding equipment, including the temperature, duration, permissible load conditions for each cycle, and the use of biological indicators and endotoxin challenge vials (ECVs). 2) Personnel training and competency assessment on sterilization and depyrogenation methods and equipment used by the facility. 3) Schedule and method for establishing and verifying the effectiveness of methods selected. 4) Methods for maintaining and cleaning the sterilizing and depyrogenation equipment. [USP 797 Section 10] *Memert Dry Heat Oven SN B5220016*	Yes
DEPYROGENATION CYCLE: Dry heat depyrogenation is used to render glassware, metal, and other thermostable containers and components pyrogen free. The exposure period includes sufficient time for items to reach the depyrogenation temperature; items remain at the depyrogenation temperature for the duration of the depyrogenation period. [USP 797 Section 10.1]	Yes
DEPYROGENERATION VIA RINSING: Non-thermostable items are depyrogenated by multiple rinses with sterile, nonpyrogenic water (e.g., Sterile Water for Injection or Sterile Water for Irrigation) and then thoroughly drained or dried immediately before use in compounding. [USP 797 Section10.1]	Yes
ENDOTOXIN CHALLENGE VIAL (ECV) USE: The effectiveness of the dry heat depyrogenation cycle(s) is established initially and verified annually using ECVs to demonstrate the cycle achieves a greater than or equal to 3-log endotoxin reduction. The effectiveness of the depyrogenation cycle is re-established if there are changes to the depyrogenation cycle. Cycle verifications are documented. [USP 797 Section 10.1] *Validation date Dec 15, 2023 demonstrating a 6 log reduction by Focus labs*	Yes

S. MASTER FORMULATION AND COMPOUNDING RECORDS – ALL CATEGORIES

MASTER FORMULATION RECORD (MFR): A MFR is created for all CSPs prepared from nonsterile ingredient(s) or CSPs prepared for more than one patient. [USP 797 Section 11.1] *In process-example for GAC-I provided*	Yes
MFR MODIFICATIONS: Any changes or alterations to an MFR are approved and documented per facility's SOPs. [USP 797 Section 11.1] *DP in charge*	Yes
MFR DOCUMENTATION: An MFR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Identities, amounts of all ingredients, and, if applicable, relevant characteristics of components; 3) Type and size of container closure system(s); 4) Complete instructions for preparing the CSP including equipment, supplies, a description of the compounding steps, and any special precautions; 5) Physical description of the of the final CSP; 6) BUD and storage requirements; 6) Stability reference; 7) Quality control procedures; 8) other information as needed to describe the compounding process and ensure repeatability. [USP 797 Section 11.1 (Box 9)] *New Business, first batch will be sent for MS and Stability.*	N/A
COMPOUNDING RECORD (CR): A CR is created for all Category 1, Category 2, and Category 3 CSPs. A CR is created for immediate-use CSPs prepared for more than one patient. [USP 797 Section 11.2] *In PK software-ex GAC-I*	Yes
CR DOCUMENTATION: A CR includes at least the following: 1) Name, strength or activity, and dosage form of the CSP; 2) Date and time of preparation of the CSP; 3) Assigned internal identification number (e.g., prescription, order, or lot number); 4) A method to identify the individuals involved in the compounding process and individuals verifying the final CSP; 5) Name of each component; 6) Vendor, lot number, and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s); 7) Weight or volume of each component; 8) Strength or activity of each component; 9) Total quantity compounded; 10) Final yield; 11) Assigned BUD and storage requirements; 12) Results of QC procedures. And, if applicable, 13) MFR reference for the CSP; and 14) Calculations made to determine and verify quantities and/or concentrations of components. [USP 797 Section 11.2 (Box 10)] *For QA -see sheet Quality Control form* *As noted in Media fill solution form*	Yes
STERILIZATION CYCLE DOCUMENTATION: The date, run, and load numbers of the steam or dry heat sterilizer used to sterilize a CSP are documented on the CR if applicable. [USP 797 Sections 10.3 & 10.4] *New Business -documented on media fill*	Yes

T. RELEASE INSPECTION AND TESTING – ALL CATEGORIES

RELEASE TESTING PROCEDURES: All release testing procedures (e.g., visual inspections and testing) are included in facility documentation such as MFRs and SOPs. [USP 797 Section 12] *See post clearance qualification*	Yes

VISUAL INSPECTION: CSPs are visually inspected before release and dispensing to determine whether the 1) physical appearance of the CSP is as expected (e.g., free of inappropriate visible particulates or other foreign matter, discoloration, or other defects), 2) container closure integrity is intact (e.g., checking for leakage, cracks in the container, or improper seals), 3) CSP and its labeling match the prescription or medication order. [USP 797 Section 12.1] *Not compounding yet, will be per SOP 520.1 "Visual Inspection"*	N/A
DELAYED DISPENSING VISUAL INSPECTION: When CSPs are not released or dispensed on the day of preparation, a visual inspection is conducted immediately before its release to ensure the CSP is free from any defects such as precipitation, cloudiness, or leakage, which could develop during storage. [USP 797 Section 12.1] *New Business -stated to be understood as Light box*	N/A
CSP REJECTION & QUARANTINE: CSPs found to be of unacceptable quality (e.g., observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock. [USP 797 Section 12.1] *Noted as pass/fail on Post Clearance qualification form*	N/A
INVESTIGATION OF OOS RESULTS: Out-of-specifications results and defects indicating sterility or stability problems are investigated to determine the root cause and a corrective action plan is implemented and documented per facility SOPs. [USP 797 Section 12 & 12.1] *Out of Specification Investigation form.*	N/A

U. CSP HANDLING, STORAGE, PACKAGING, SHIPPING, & TRANSPORT – ALL CATEGORIES

STORAGE AREA TEMPERATURE MONITORING: Temperature in CSP & component storage areas is monitored at least once daily and recorded on a log on days when the facility is open or by a continuous temperature recording device; temperature data is readily retrievable. Monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer or every 12 months. [USP 797 Sections 9.3 & 19.1]	Yes
TEMPERATURE EXCURSIONS: When CSPs have been exposed to temperature excursions above or below storage temperature limits for the CSP, a Designated Person determines whether the CSP has retained its integrity or quality. CSPs are discarded if the impact of the excursion cannot be determined. [USP 797 19.1] *New Business-has not begun compounding*	N/A
CSP PACKAGING: CSP packaging and shipping materials are selected to protect CSPs from damage, leakage, contamination, degradation, adsorption and prevent inadvertent exposure to transport personnel. [USP 797 Section 19.2] *per SOP 540.1 "Packaging, Storage and Shipping of Refrigerated and Room Temp Drug Products"*	Yes
SHIPPING & TRANSPORTING: Modes of transport are selected that are expected to deliver properly packaged CSPs in an undamaged, sterile, and stable condition. Special handing instructions are provided and/or affixed to the exterior of the container when applicable. [USP 797 Section 19.2] *New Business-will use UPS and other Couriers*	N/A

V. STERILE QUALITY PROGRAM, SOP's & DOCUMENTATION- ALL CATEGORIES

QA/QC PROGRAM & SOPs: A Quality Assurance (QA) and Quality Control (QC) program is documented in facility SOPs and formally establishes a system of 1) adherence to procedures, 2) prevention and detection of errors and other quality problems, 3) evaluation of complaints and adverse events, and 4) appropriate investigations and corrective actions. The QA/QC SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program. [USP 797 Section 18] *SOP 110.1 "Quality Control and Quality Assurance"*	Yes
INVESTIGATIONS & CAPAs: A designated person(s) follows up to ensure investigations are conducted and corrective actions are taken if problems, deviations, failures, or errors are identified or when complaints or adverse reactions are reported. A complete record of each reported complaint and adverse reaction is created and retained. Investigations and corrective actions are documented. [USP 797 Sections 17, 18.2, & 18.3] *SOP 108.1 "Patient Complaints and Adverse Event Reporting"*	Yes
ADR & COMPLAINT DOCUMENTATION: A complete record of each reported complaint and adverse reaction is created and retained per USP 797. [USP 797 Section 18.1] *New business-Manual form*	N/A
RECALL PROCEDURES & SOP: If CSPs are dispensed or administered before the results of release testing are known, procedures are in place to immediately notify the prescriber of a failure of specifications with a potential to cause patients harm; determine the severity of the problem and urgency for implementation/completion of recall; identify patients (or other points of distribution) who have received affected CSP; recall any unused dispensed CSPs; quarantine remaining stock in the pharmacy; investigate if other lots are affected and recalled if needed; conduct investigation and document reason for the failure. [USP 797 Section 18] *SOP 221.1 "Recall Procedure"*	Yes
RECALL REPORTING: Recalls are reported to the appropriate regulatory body as required by the laws and regulations of the applicable regulatory jurisdiction. [USP 797 Section 18.1] *No recalls has not started compounding*	N/A
ANNUAL QA/QC REVIEW: The overall QA/QC Program is reviewed at least once every 12 months by the Designated Person(s); the review is documented, and corrective actions are taken if needed. [USP 797 Section 18]	Yes
ANNUAL SOP REVIEW: Facility sterile compounding SOPs are reviewed every 12 months by the Designated Person(s); the review is documented. Changes to SOP are made only by the Designated Person and documented. Acknowledgement of revisions to SOP's are communicated to all personnel. [USP 797 Section 17] *Dec 2023*	Yes
STERILE SOPs: Facility maintains SOPs covering all aspects of the sterile compounding process and other support activities. [USP 797 Section 17]	Yes
STERILE COMPLIANCE DOCUMENTATION: Facility has and maintains written or electronic documentation to demonstrate compliance with requirements in this chapter. [USP 797 Section 20] *Manual documentation*	Yes
DOCUMENTATION RETENTION: Documentation complies with all laws and regulations of the applicable regulatory jurisdiction. Records are legible and stored in a manner that prevents their deterioration and/or loss. All required documentation for a particular CSP is readily retrievable for at least 4 years after preparation. [USP 797 Section 20] *New Business*	N/A

W. HAZARDOUS DRUG HANDLING & COMPOUNDING – ALL CATEGORIES

DESIGNATED PERSON: The entity has a Designated Person who is qualified and trained to be responsible for implementing appropriate HD procedures, overseeing compliance with USP 800 requirements, ensuring environmental control of the storage and compounding areas, monitoring HD facility operations, testing, and acting on results. [USP 800 Section 4] *Ahmad Zaiter*	Yes

HAZARD COMMUNICATION PROGRAM (HCP): Facility has SOPs to ensure effective training regarding proper labeling, transport, storage, and disposal of HDs and use of Safety Data Sheets. The HCP and HD SOPs include a written plan describing 1) how USP 800 requirements are implemented, 2) HD chemical container labeling with the identity of the material and appropriate hazard warnings, 3) readily accessible location of HD chemical SDSs known and accessible by all personnel, 4) HD risk training and information provided to all personnel with HD exposure risk before initial HD handling work assignment and whenever hazard changes, 5) personnel of reproductive capability written acknowledgement of understanding of HD handling risks. [USP 800 Section 8] *Black bin to be picked up by Trilogy Med waste*	Yes
ASSESSMENT OF RISK: All HD drugs follow the requirements of USP 800 unless an assessment of risk (AOR) is performed. If an assessment of risk approach is taken, the entity must document what alternative containment strategies and/or work practices are being employed for specific dosage forms to minimize occupational exposure. The AOR is reviewed at least every 12 months and minimally contains the type of HD, dosage form, risk of exposure, packaging, and manipulation. [USP 800 Section 2] *New Business see mock study*	N/A
LIST OF HAZARDOUS DRUGS: Facility maintains a list of HDs that includes any items on the current NIOSH that the entity handles. The list is reviewed every 12 months and whenever a new agent or dosage form is used. [USP 800 Section 2] *2/5/24 list reviewed of HD API's, has not started compounded*	Yes
CONTAINMENT REQUIREMENTS: All antineoplastic HDs requiring manipulation and HD active pharmaceutical ingredients (APIs) on the NIOSH list follow all the requirements of USP 800. [USP 800 Section 2, Box 1] *No product, New business*	N/A
HD HANDLING SOPs: SOPs are created and maintained for the safe handling of HDs used by the facility. SOPs are reviewed annually; review is documented, and any revisions are communicated to personnel handling HDs. [USP 800 Section 17] *702.1 "Gowning for Hazardous Compounding"*	Yes
HD HANDLING AREAS, SIGNAGE, & ACCESS: Signage designating HD handling areas are prominently displayed and access to HD handling areas is restricted to authorized personnel. Designated areas are available for receipt, unpacking, and storage of HDs; and sterile HD compounding. [USP 800 Section 5] *703.1 "Handling of Hazardous Drugs"*	Yes
HD RECEIPT: There is a designated area for the receipt of antineoplastic HDs or API's that is neutral/normal or negative pressure relative to surrounding areas. HDs are not unpacked from external shipping containers in sterile compounding areas or in positive pressure areas. HDs are delivered immediately after unpacking to HD storage area. [USP 800 Section 5.1] *HD receiving area is a traditional designated area*	Yes
HD RECEIVING SOPs: Facility SOPs for receiving HDs that include required PPE during HD receiving and handling, a tiered approach to assessing HD packaging and shipping containers for signs of damage or breakage (e.g., visible signs of leakage, sounds of broken glass), management of known or suspected damaged HD containers, and transport to HD storage location(s) for nondamaged containers. [USP 800 Section 10] *Receiving, Storage and Transport SOP 703.1*	Yes
HD STORAGE: HDs are stored to prevent spillage or breakage, off floors, and in areas appropriate for natural disasters. Antineoplastic HDs and HD API are stored separately from non-HDs to prevent contamination and personnel exposure. HD storage areas are externally ventilated and negative-pressure rooms with at least 12 ACPH. [USP 800 Section 5.2] *Sterile HD Ante room (110.66), HD buffer room (52.02) has a designated storage area for HD's.* *Non-sterile HD room ACPH 88.22 from Dec 2023 Medrep report.*	Yes
HD REFRIGERATED STORAGE: Refrigerated antineoplastic HDs are stored in a dedicated refrigerator, in a negative pressure area with at least 12 ACPH. Pass through refrigerators are not used. [USP 800 Section 5.2] *New business-plan is to place a refrigerator in a HD suite*	N/A
STERILE HDs COMPOUNDED IN A C-SCA: C-SCA maintains a minimum of 12 ACPH of HEPA- filtered air and has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800, sections 5.3.2 Table 3]	N/A
C-SEC DESIGN AND ENGINEERING CONTROLS: The C-SEC has fixed walls physically separated from other preparation areas, is externally ventilated , and has 30 ACPH. [USP 800 Section 5.3.2 Table 3]	Yes
C-SEC DESIGN AND PRESSURE DIFFERENTIALS: The C-SEC has negative pressure to adjacent areas of -0.01" w.c. to -0.03" w.c. [USP 800 Sections 5.3.2 Table 3] *As documented on manual log and per Medrep*	Yes
C-SEC ACCESS VIA ANTE ROOM: The classified area used for entry into the negative pressure buffer room has fixed walls and maintains a minimum of 30 ACPH of HEPA-filtered air, positive pressure of +0.02" w.c. to all adjacent unclassified areas, and ISO7 or better classification. [USP 800 Section 5.3.2] *HD ante room*	Yes
C-SEC ACCESS VIA NON-HD BUFFER: A negative-pressure HD buffer entered exclusively through a non-HD buffer room contains a line of demarcation (LOD) within the negative-pressure buffer room for donning/doffing HD PPE and a method a transport of HDs, HD CSPs, and HD waste into and out of the HD buffer (e.g., pass-through chamber). Pass through chambers are included in semi-annual facility certification. [USP 800 Section 5.3.2] *Non-sterile HD room leading into HD ante which leads into HD buffer (ISO 7)*	N/A
C-SEC SINK & SAFETY EQUIPMENT: A sink is available for hand washing and an eyewash station and/or other emergency safety precautions meeting applicable laws and regulations are readily available and located where operation does not interfere with ISO classifications. Sinks are located at least 1 meter from the entrance into the buffer room (or at least 1 meter from the C-PEC in a C-SCA). [USP 800 Sections 5.3 & 5.3.2] *HD ante and Non-sterile HD prep has a sink.*	Yes
C-PEC LOCATION AND VENTING: All C-PECs used for sterile HD compounding (e.g., CACIs or BSCs), are located within a C-SEC or C-SCA, externally vented, and maintain an ISO 5 or better air quality. [USP 800 Section 5.3.2] *Sterile HD room LA2-5A2-E-PORT (ISO 5) vented to outside air*	Yes
C-PEC OPERATION & OUTAGES: C-PECs operate continuously if supplying some or all the negative pressure in the C- SEC or if used for sterile compounding. During power outages, repairs, or relocation, C-PEC use is suspended immediately. Once C-PEC power is restored, all PEC surfaces are decontaminated, cleaned, and disinfected, and compounding is not resumed until the manufacturer's specified recovery time has elapsed. [USP 800 Section 5.3] *Pharmacy has a generator*	Yes
REQUIRED HD PPE: When compounding HDs, gowns, head, hair, shoe covers, and two pairs of chemotherapy gloves are donned per facility SOPs. For all other HD handling activities, including HD receipt, storage, transport, cleaning activities, spill control, and waste disposal, facility SOPs define the required PPE based on the OSP and AOR. Disposable PPE is not reused; reusable PPE is decontaminated and cleaned after each use. [USP 800 Section 7] *Sterile PPE, including sterile masks and coveralls and sterile shoe cover.*	Yes
GLOVES: Chemotherapy gloves are tested to ASTM standard D6978 (or its successor) and are powder free. Gloves are inspected for physical defects. Gloves are changed when torn, punctured, or contaminated. Personnel wash hands with soap and water after removing gloves. [USP 800 Section 7.1] *Kimtech and Nitriderm COA reviewed*	Yes
GOWNS: HD gowns are disposable, resistant to permeability by HDs, close in back, are long sleeved, closed cuff, and seamless. Gowns are changed per manufacturer's permeation information; if no data is available, HD gowns are change every 2-3 hours or immediately after a spill or splash. Gowns are limited to HD handling areas and are donned over the sterile compounding frock. [USP 800 Section 7.2, USP 797 Section 3.3]	Yes

SHOE COVERS: When compounding, a second pair of shoe covers is donned before entering the C-SEC and doffed when exiting the C-SEC. [USP 800 Section 7.3]	Yes
EYE AND FACE PROTECTION: Appropriate eye (goggles) and face protection (face shield) are worn when there is a risk for spills or splashes or when working outside of a C-PEC. Surgical masks are not used when respiratory protection is required per SOP and/or AOR as protection from HD exposure. [USP 800 Section 7.4]	Yes
PPE DISPOSAL: HD PPE is disposed of appropriately prior to exiting the C-SEC. Chemotherapy gloves and sleeve covers (if used during compounding) are carefully removed and discarded immediately into an appropriate waste container inside of the C-PEC or contained in a sealable bag for discarding outside of the C-PEC. [USP 800 Section 7.6]	Yes
INITIAL HD TRAINING & COMPETENCY: Personnel who handle HDs are trained and demonstrate competency per their job function before independently handling HDs and when a new HD medication, process, SOP, or equipment is introduced. Training minimally includes an overview of the entity's HD list and their risks; review of HD SOPs; proper use of PPE, equipment, and devices; prevention of HD exposures and spills; HD exposure and spill response; use of a spill kit, PPE, and NIOSH-certified respirators; and HD disposal. Based on job duties, personnel receive additional HD training in HD acquisition and receipt, preparation, compounding, dispensing, labeling, storage, and transport. Training and competency assessments are documented. [USP 800 Sections 8, 9, 11.1, 16, & 17] *3/11/24 for both compounding personnel*	Yes
ONGOING HD COMPETENCY ASSESSMENT: HD handling competencies are reassessed and documented at least every 12 months. [USP 800 Section 9] *New Business 3/11/24*	Yes
HD ATTESTATION: Personnel of reproductive capability have a written acknowledgement attesting to their understanding of HD handling risks. [USP 800 Section 8]	Yes
BUDs OF STERILE HDs COMPOUNDED IN A C-SCA: BUDs and storage conditions are in accordance with USP 797 requirements for Category 1. HD CSPs compounded in a C-SCA are prepared from only sterile starting components. [USP 800 Section 5.3.2] CSTDs are used as a supplemental engineering control only. [USP 800 Section 5.3 and Table 3]	N/A
BUDs OF STERILE HDs COMPOUNDED IN A C-SEC: BUDs and storage conditions in accordance with USP 797 requirements for Category 2, or Category 3 CSPs. [USP 800 Section 5.3.2] *per SOP BUD of ex Testosterone will be 30 days RT based on Cat 2 compounding*	N/A
NONSTERILE-TO-STERILE HD COMPOUNDING: HD CSPs compounded from nonsterile starting components are compounded inside a sterile suite. [USP 800 Section 5.3.2]	Yes
DEDICATED HD EQUIPMENT: Disposable or cleanable equipment for compounding (e.g., mortar and pestle, graduated cylinder, spatulas) is dedicated for use with HDs. [USP 800 Section 13]	Yes
NON-HD COMPOUNDING IN A C-PEC: Non-HDs compounded in a HD C-PEC are placed in protective outer wrapping, labeled for PPE handling precautions, and treated as an HD. [USP 800 Section 5.3.2 and Table 3] *Totally dedicated HD suite*	N/A
D/D/C/D SOPs: Written procedures for decontamination, deactivation, cleaning, and disinfection are available and followed. Cleaning of sterile compounding areas also complies with USP 797 requirements. Procedures include agents used, dilutions (if used), frequency, and documentation requirements. [USP 800 Section 15] *SOP 210.1 lists Peridox with 10 min contact time and SOP 703.1 "Handling of HD's" states the DDCD protocol. Procedures include lot # and manufacturer name*	Yes
DEACTIVATION, DECONTAMINATION, CLEANING & DISINFECTION (D/D/C/D): All areas where HDs are handled (receiving, compounding, transport, administering, disposal) and all reusable equipment and devices are deactivated/decontaminated, cleaned, and then disinfected. [USP 800 Section 15]	Yes
TRAINING OF D/D/C/D: Personnel are trained in deactivation/decontamination, cleaning, and disinfection to protect themselves and the environment from contamination. [USP 800 Section 15] *Training form in folder reviewed for both compounding personnel as 3-11-24*	Yes
PPE DONNED DURING D/D/C/D: Personnel wear appropriate PPE resistant to cleaning agents used, including 2 pairs of ASTM-tested chemotherapy gloves and impermeable disposable gowns. Eye protection and face shields are worn if splashing may occur. Respiratory protection is used if warranted. [USP 800 Section 15]	Yes
D/D/C/D AGENTS USED: Agents selected are appropriate for the type of HD contamination(s), location, and surface materials. Sterile 70% IPA is used to remove residue left on sterile surfaces and compounding areas by decontaminating agents. [USP 800 Section 15 & 15.4]	Yes
DECONTAMINATION DURING COMPOUNDING: C-PEC is decontaminated at least daily (when used), after as spill, before and after certification, voluntary interruption, or if ventilation tool is removed. The C-PEC worksurface is decontaminated between compounding of different HDs. [USP 800 Section 15.2]	Yes
MONTHLY UNDERTRAY CLEANING: Area under the work tray of a C-PEC is deactivated, decontaminated, and cleaned at least monthly. [USP 800 Section 15.2] *ESCO has no under tray*	N/A
DISPOSAL OF D/D/C/D CLEANING SUPPLIES: Disposable cleaning supplies are discarded per EPA regulations and facility SOPs. [USP 800 Section 15] *Trilogy*	Yes
LABELING, PACKAGING, TRANSPORT SOP: Facility has SOP for the labeling, handling, packaging, and transport of HDs addressing the prevention of spills/exposures, training for exposure, and spill kit use. The SOP describes appropriate shipping containers and insulating materials for transport based on product specifications (e.g., required storage conditions), transport vendors, and mode of transport. [USP 800 Section 11 & 11.2] *Yellow bag with triangles*	Yes
HD LABELING: HD CSPs are identified as hazardous and labeled with special handling precautions. Labeling process for compounded HD products does not introduce contaminated materials into non-HD areas. [USP 800 Sections 11.1 & 13]	Yes
PACKAGING: Packaging materials and containers that maintain the physical integrity, stability, and sterility of HDs during transport. Packaging protects HDs from damage, leakage, contamination, and degradation, while protecting healthcare workers who transport HDs. [USP 800 Section 11.2]	Yes
TRANSPORT: HDs that are transported are labeled, stored, and handled according to regulations, facility SOPs, and in containers that minimize risk of breakage or leakage. Pneumatic tubes are not used to transport liquid or antineoplastic HDs. [USP 800 Section 11.3]	Yes
HD SPILL SOP: Facility has an SOP to prevent spills. The SOP directs the management and cleanup of suspected or known damage to or spills of HDs upon receipt, storage, handling, compounding, packaging, and transport. SOP addresses appropriate response based on factors such as the size, scope, and who is responsible for cleanup. SOP states the location and capacity of kits and immediate steps that should be taken to evaluate and address personnel exposure, secure spill area, and minimize exposure risk to other personnel. [USP 800 Section 16] *per SOP 703.1 "Handling of Hazardous Drugs"*	Yes
SPILL KITS, & SINGAGE: Spill kits are readily available with appropriate supplies, PPE, and signs to restrict access to affected areas. restriction posted, and documentation of spills occur when needed. [USP 800 Section 16]	Yes

SPILL CLEAN UP & DOCUMENTATION: Spills are contained and cleaned immediately only by qualified personnel with appropriate PPE. After cleanup is complete, spill circumstances and management are documented. Qualified personnel are available at all times while HDs are being handled. [USP 800 Section 16] *No spills but reviewed SOP*	N/A
DISPOSAL REGULATION COMPLIANCE: Disposal of HD waste, including unused HDs and trace-contaminated PPE and materials, is performed by trained and appropriately garbed personnel and complies with federal, state, and local regulations. [USP 800 Sections 11.4 & 17]	Yes

X. LYOPHILIZATION

Sterile preparations prepared for lyophilization are maintained in ISO 5 unidirectional laminar flow air throughout sterilization, filling, and transport to the lyophilizer. [64B16-27.797(5) F.A.C.]	
A recorded smoke study is available and demonstrates that transport from the PEC to the lyophilizer is accomplished in ISO 5 laminar flow air at all times. [64B16-27.797(5) F.A.C.]	
The pharmacy has established and follows policies and procedures for the high-level disinfection of the lyophilizer chamber, piping, and all other areas of the unit which pose a potential risk for contamination of the product. [64B16-27.797(5) F.A.C.]	
The pharmacy validated the high-level disinfection procedure initially, and after changes to the cleaning process or agents. Documentation of studies is available for inspection. [64B16-27.797(5) F.A.C.]	
Validation studies for high level disinfection are performed with the 5-aerobic bacterial and fungal ATCC organisms referenced in USP<71> are conducted by an external vendor unless the firm has an internal laboratory capable of performing the studies. An internal laboratory is separate from the compounding and work areas of the pharmacy to prevent contamination in the pharmacy. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established and followed for cleaning the lyophilizer prior to disinfection and include cleaning agents and schedules. Documentation of cleaning is maintained and available for inspection. [64B16-27.797(5) F.A.C.]	
Policies and procedures are established for the maintenance of the lyophilizer and at a minimum include the manufacturers recommendations. [64B16-27.797(5) F.A.C.]	
The maintenance schedule includes provisions for periodic testing of the chamber for leaks and all other recommended procedures described by the equipment manufacturer. Documentation of routine maintenance is available for inspection. [64B16-27.797(5) F.A.C.]	
SOPs and quality assurance program established to include validation of the filling process, container closure integrity, frequent monitoring of fill volumes, identification of over fills and underfills, assessment of personnel involved in compounding for lyophilization, equipment qualification, formula verification, and evaluation of finished product for conformance to specifications. [64B16-27.797(5) F.A.C.]	
The pharmacy has provisions for sterilizing, with filters, the inert gas or air used for backfilling during the vacuum release phase. These Sterilizing filters undergo the manufacturers recommended integrity test. [64B16-27.797(5) F.A.C.]	
Media fills are conducted every six months using the maximum batch size and demonstrate the filling, transport to the lyophilizer, loading and stoppering operations. Media is NOT frozen during the media fill operation. [64B16-27.797(5) F.A.C.]	
Personnel preparing sterile compounds for lyophilization wear sterile Personal Protective Equipment that covers all exposed skin. [64B16- 27.797(5) F.A.C.]	
Glove Fingertip Sampling is performed with every batch after fill and transport into the lyophilizer on all personnel compounding for lyophilization. The results are incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
In-process acceptance criteria such as color, moisture limits and visual appearance are established for each lyophilized product. [64B16- 27.797(5) F.A.C.]	
A 100% visual examination of the finished product is conducted to determine that the product conforms to the established visual criteria and is incorporated into the batch record. [64B16-27.797(5) F.A.C.]	
Finished product testing is conducted on all batches. Procedures have been established for selecting test samples from the batch and are written and followed. Such procedures may include location of vials in the lyophilizer and positions in the fill line. [64B16-27.797(5) F.A.C.]	
Finished product testing includes sterility testing using a USP<71> method unless an alternative test method has been validated and shown to be equivalent or better. Diluents used to reconstitute the sample vials for testing are preservative free. [64B16-27.797(5) F.A.C.]	
Each batch of lyophilized product with a beyond use date that falls within the USP<797> guidelines and is not tested for sterility, has viable air and surface sampling that is collected in critical areas of ISO 5 locations as well as sampling of the gloves and sleeves of personnel documented in the batch record. [64B16-27.797(5) F.A.C.]	
Every lyophilized product has established endotoxin levels Each batch of lyophilized product is tested for endotoxin in accordance with USP<85> and confirmed to fall within the set limits and documented in the batch record. [64B16-27.797(5) F.A.C.]	
Potency, radiochemical purity, or applicable test to assure label claim is conducted on every batch and documented in the batch record. In lieu of potency testing, weight-based verification may occur based on formula verification. Potency testing shall be based on the USP monograph if one is available. [64B16-27.797(5) F.A.C.]	

Y. SPECIAL PARENTERAL ENTERAL & EXTENDED SCOPE

Technicians properly identified. [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16- 27.420 F.A.C.].	
Medication is properly labeled for dispensing to patient. [64B16-28.108(2) F.A.C.]	
Outdated medications removed from active stock. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality Related Events are available for inspection. [64B 16 27.300 F.A.C.]; [766.101 (1) (a)(l) F.S.]	
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B16-27.800, F.A.C.]	
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05]	
Prescriptions for controlled substances are on counterfeit-proof prescription pads or blanks purchased from a department-approved vendor and the quantity and date meet the requirements of [456.42(2), F.S.].	
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a), F.S.] [21CFR1304.11] [21CFR1304.04]	
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)]	
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [21CFR1304.04]; [465.022(12)(a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	

Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) F.A.C]	
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.]	
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.]	
A special sterile products and parenteral/enteral compounding pharmacy provides telephone accessibility to its pharmacist(s) for its patients at all hours. [64B16-28.820(3)(b)]	
A special sterile products and parenteral/enteral compounding pharmacy provides special handling and packaging of compounded parenteral and enteral preparations when delivering from the pharmacy to the patient or institution as required to maintain stability of the preparations. [64B16-28.820(3)(b)]	

Remarks:

Inspection completed with Hector Medrano and Majed Fackih and Designated Person and PDM Ahmad Zaiter.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

CULLIPHER, MALA

Date:4/22/2024

Representative:

Ahmad Zaiter

Date:4/22/2024

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ROMAT VENTURES,INC dba ALCHEMIST PHARMA

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 11301 N US HWY 301

City THONOTOSASSA State FL Zip 33592

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email PHARMAALCHEMIST@GMAIL.COM

Section 2: Personal Information

First AHMAD Middle _____ Last ZAITER

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City THONOTOSASSA State FL Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.420)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 9: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
IIUM			
Address	**City**	**State**	**Zip**
MALAYSIA	KUANTAN	PAHANG	
Diploma/Degree obtained, if any			
MASTER DEGREE IN PHARMACEUTICAL TECHNOLOGY			
School Name		**From - To (MM/YY – MM/YY)**	
Philadelphia University			
Address	**City**	**State**	**Zip**
AMMAN	JORDAN		
Diploma/Degree obtained, if any			
Bachelor of Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 10: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2/20 - current	[redacted]	Thonotosassa	FL	[redacted]
01/17 02/20		Temple Terrace	FL	
06/16 - 01/17		Plantation	FL	
01/16 06/16		Gainesville	FL	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
ROMAT VENTURES, INC dba ALCHEMIST PHARMA			01/2022	
Business Address		**City**	**State**	**Zip**
11301 n us hwy 301 ste 106		thonotosassa	FL	33592
Phone	**Title**		**Number of Employed Hours**	
813-252-4443	PHARMACIST MANAGER		2945	
Description of Duties				
RESPOPNSIBLE FOR DAILY OPERATION OF THE PHARMACY, COMPOUNDING AND RETAIL DEPARTMENTS				

Business Name			From - To (MM/YY – MM/YY)	
American Affordable Drugs Pharmacy				
Business Address		**City**	**State**	**Zip**
32866 US Hwy 19 N		Palm Harbor	FL	34684
Phone	**Title**		**Number of Employed Hours**	
727-202-2217	PHARMACIST MANAGER		2500	
Description of Duties				
RESPOPNSIBLE FOR DAILY OPERATION OF THE PHARMACY, COMPOUNDING AND RETAIL DEPARTMENTS				

Business Name			From - To (MM/YY – MM/YY)	
Absolute Pharmacy				
Business Address		**City**	**State**	**Zip**
16011 N Nebraska Ave #103, Lutz, FL 33549		LUTZ	FL	33549
Phone	**Title**		**Number of Employed Hours**	
813-999-2700	PHARMACIST SUPERVISOR		4320	
Description of Duties				
RESPOPNSIBLE FOR DAILY OPERATION OF THE COMPOUNDING DEPARTMENT.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, AHMAD ZAITER, **certify that as the designated representative for**

ROMAT VENTURES, INC dba ALCHEMIST PHARMA,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. YES I am at least 21 years of age;
3. YES I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. YES I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. YES I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. YES I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. YES I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

AHMAD ZAITER
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

10/30/2024
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Ahmad Zaiter

Print Name (First, last)

Original Signature (electronic, copies or stamps not accepted)

10/30/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, Ahmad Zaiter, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

10/30/2024

Date

Subscribed and Sworn to before me this 30th day of October

Andrea Fuentes

Notary Public Signature

ANDREA FUENTES
Commission # HH 258606
Expires April 28, 2026

(Seal)

Romat Ventures, INC

List of owners/ officers

Magdi Salhab President

Phone: 813-252-4443

Address: 11301 N. US HWY 301 SUITE 106

Thonotosassa FL 33592

Ownership: 100%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site ROMAT VENTURES ,INC DBA ALCHEMIST PHARMA

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 11301 N US HWY 301 STE 106

City THONOTOSASSA State FL Zip 33592

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 813-252-4443 Website https://alchemistpharmarx.com/

Licensing Company Email PHARMAALCHEMIST@GMAIL.COM

Section 2: Personal Information

First MAGDI Middle _____ Last SALHAB

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City TEMPLE TERRACE State FL Zip [redacted]

Telephone 813-252-4443 Email PHARMAALCHEMIST@GMAIL.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	NA	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF FLORIDA		08/04-5/08	
Address	City	State	Zip
DISTANCE CAMPUS			
Diploma/Degree obtained, if any			
PHARM D (DOCTOR OF PHARMACY)			
School Name		From - To (MM/YY – MM/YY)	
EMORY UNIVERSITY		08/1998-6/2002	
Address	City	State	Zip
201 Dowman Dr	ATLANTA	GA	30322
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
BERKELEY PREP			
Address	City	State	Zip
4811 Kelly Rd	tampa	fl	33615
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/01-01/25	[redacted]	Tampa	FL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
ROMAT VENTURES,INC			01/22- CURRENT
Business Address	**City**	**State**	**Zip**
11301 N US HWY 301	THONOTOSASSA	FL	33592
Phone	**Title**		
813-252-4443	PRESIDENT		

Description of Duties

Setting Vision and Direction: Establish and communicate the long-term vision and strategic direction of the pharmacy.

Business Name			From - To (MM/YY – MM/YY)
SALHAB PHARMACY			
Business Address	**City**	**State**	**Zip**
12643 N 56th St.	Temple Terrace	FL	33617
Phone	**Title**		
813-515-7918	PHARMACIST		

Description of Duties

DAY TO DAY OPERATION OF CHECKING PERSCRIPTION and managing the retail prescription department

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	City		State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

02/04/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Magdi Salhab
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/04/2025
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pasco

I, MAGDI SALHAB, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/04/2025
Date

Subscribed and Sworn to before me this 4th day of February, 2025

Notary Public Signature

ANDREA FUENTES
Commission # HH 258606
Expires April 28, 2026

(Seal)

Department of Health

ROMAT VENTURES, INC Alchemist Pharma

License Number: PH35098

Data As Of 4/24/2024

Profession	Pharmacy
License	PH35098
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2025
License Original Issue Date	04/23/2024
Address of Record	11301 N. US HWY 301 SUITE 106 THONOTOSASSA, FL 33592
Discipline on File	No
Public Complaint	No

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

Department of Health

ROMAT VENTURES, INC

Alchemist Pharma

License Number: PH35098

Data As Of 2/18/2025

Profession	Pharmacy
License	PH35098
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2027
License Original Issue Date	04/23/2024
Address of Record	11301 N. US HWY 301 SUITE 106 THONOTOSASSA, FL 33592
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

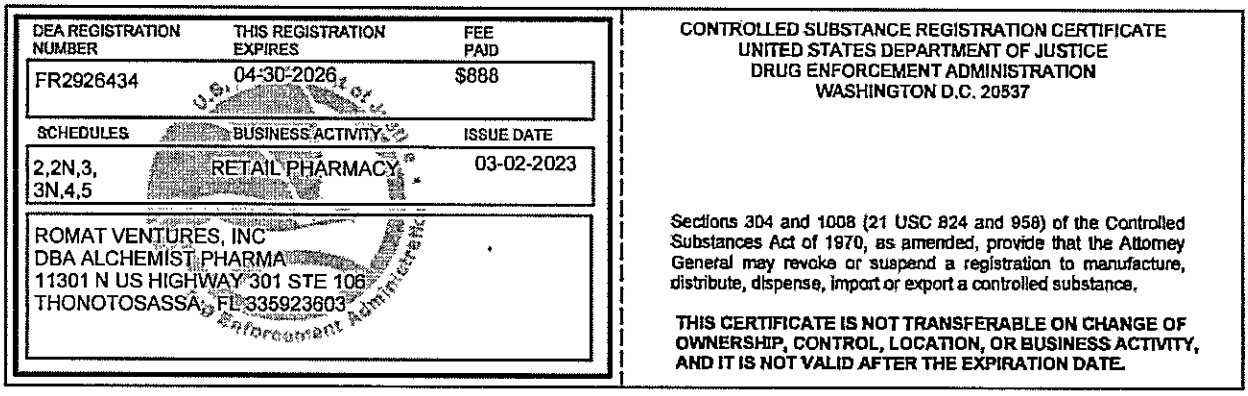
Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
SALHAB, MAGDI ABDELMOTI	PHARMACY AFFILIATE	PHARMACY AFFILIATE		04/23/2024
ZAITER, AHMAD	RX DPT MGR/COR/POR	PHARMACIST	58257	04/23/2024

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FR2926434	04-30-2026	$888

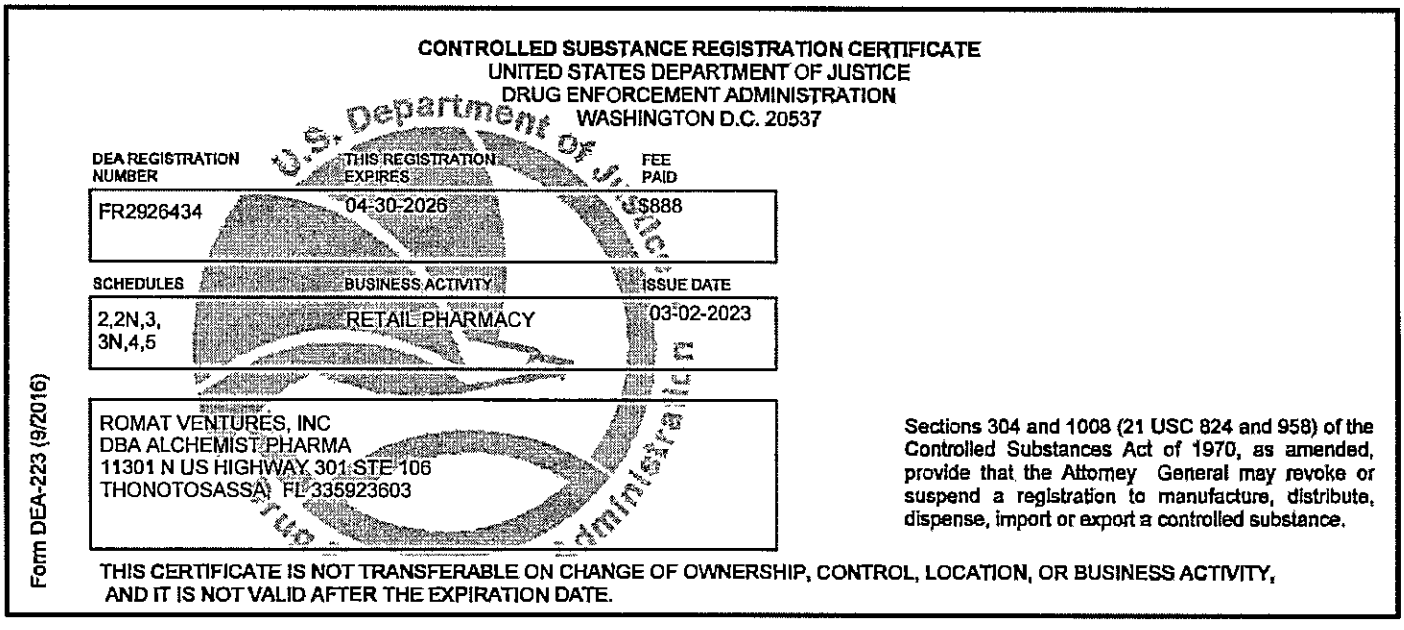
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-02-2023

ROMAT VENTURES, INC
DBA ALCHEMIST PHARMA
11301 N US HIGHWAY 301 STE 106
THONOTOSASSA, FL 335923603

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FR2926434	04-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-02-2023

ROMAT VENTURES, INC
DBA ALCHEMIST PHARMA
11301 N US HIGHWAY 301 STE 106
THONOTOSASSA, FL 335923603

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FR2926434	04-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-02-2023

ROMAT VENTURES, INC
DBA ALCHEMIST PHARMA
11301 N US HIGHWAY 301 STE 106
THONOTOSASSA, FL 335923603

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

U.S. Department of Justice
REPORT
CHANGES
PROMPTLY
Drug Enforcement Administration

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:
   Drug Enforcement Administration
   P.O. Box 2639
   Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

4HHH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FC1747887 ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Castleton Pharmacy Corp

Physical Address: 252B Port Richmond Ave

City: Staten Island State: NY Zip: 10302

Mailing Address (if different from physical address): 826 Forest Ave

City: Staten Island State: NY Zip: 10310

Telephone: 718-556-0942 Toll Free # (NAC 639.708, NRS 639.23286): 1-866-9-enexia

Fax: 718-360-9655 Contact Email: admin@enexiaspecialty.com

Website: www.enexiaspecialty.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Yakov Ratner

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): Yakov Ratner /24450

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Yakov Ratner	NV Pharmacist Registration #: 24450
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): _____

Corporation/Organization Name: Castleton Pharmacy Corp / Enexia specialty

Mailing Address: 826 Forest Ave

City: Staten Island State: NY Zip: 10310

Telephone: 7118-720-3710 Email: admin@enexiaspecialty.com

Contact Person Name: Boris Natenzon

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility – MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for Castleton Pharmacy Corp (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Boris Natenzon

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/3/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Boris Natenzon

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/3/25

Date

Board Use Only	Date Received: 3/4/25	Amount: $500 - ck 103419

Castleton Pharmacy Corp Owners Information

Name : Boris Natenzon- CEO

Home Address: [redacted]

Office Address :826 Forest Ave , SI, NY 10310

Phone no [redacted] Business : 718-720-3710

DOB : [redacted]

Percentage owned :83%

Email: bnate@enexiaspecialty.com

Name : Bernard Glezerman - COO

Home Address: 2[redacted]

Office Address :252B Port Richmond Ave , SI, NY 10302

Phone no [redacted] usiness : 718-556-0942 Xt 1220

DOB : [redacted]

Percentage owned :17%

Email: bglezerman@enexiaspecialty.com

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	CASTLETON PHARMACY CORP.
DOS ID Number:	3533135
Entity Type:	DOMESTIC BUSINESS CORPORATION
Entity Status:	EXISTING
Date of Initial Filing with DOS:	06/19/2007
Statement Status:	CURRENT
Statement Due Date:	06/30/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on January 30, 2025 at 02:39 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

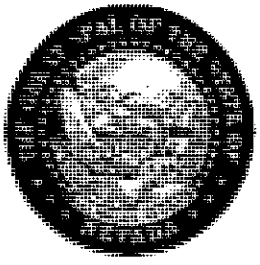
Authentication Number: 100007382155 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

SECRETARY OF STATE

STATE OF NEVADA

FOREIGN CORPORATION (80) QUALIFICATION

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **CASTLETON PHARMACY CORP.** did on **08/22/2024** file in this office its Qualification to do Business in this State and is now on file and of record in the office of the Nevada Secretary of State, and further, that said corporation is at the date of this Certificate duly qualified to exercise therein all the powers recited in its Articles and to transact business in the State of Nevada in accordance with the laws of said State.



IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 08/22/2024.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202408224898917
You may verify this certificate
online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

DEPUTY BAKKEDAHL
Deputy Secretary for Commercial Recordings

STATE OF NEVADA

OFFICE OF THE SECRETARY OF STATE

Commercial Recordings Division
401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7141

North Las Vegas City Hall
2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2888

Business Entity - Filing Acknowledgement

08/22/2024

Work Order Item Number:	W2024082201668 - 3883342
Filing Number:	20244272766
Filing Type:	Foreign Qualification
Filing Date/Time:	08/22/2024 15:28:55 PM
Filing Page(s):	6

Indexed Entity Information:

Entity ID: E42727672024-3

Entity Name: CASTLETON PHARMACY CORP.

Entity Status: Active

Expiration Date: None

Commercial Registered Agent
INCORP SERVICES, INC.*
9107 West Russell Road Suite 100, Las Vegas, NV 89148, USA

The attached document(s) were filed with the Nevada Secretary of State, Commercial Recording Division. The filing date and time have been affixed to each document, indicating the date and time of filing. A filing number is also affixed and can be used to reference this document in the future.

Respectfully,

FRANCISCO V. AGUILAR
Secretary of State

CASTLETON PHARMACY CORP. X

GENERAL INFO

ENFORCEMENT ACTIONS

Type	Pharmacy
Legal Name	CASTLETON PHARMACY CORP.
Trade Name	ENEXIA SPECIALTY
Street Address	252B PORT RICHMOND AVE STATEN ISLAND NY 10302
Registration No	029846
Date First Registered	November 23, 2009
Registration Begins	November 01, 2024
Registered Through	October 31, 2027
Supervisor	061549 - RATNER YAKOV
Establishment Status	Active
Successor	NONE

March 4, 2025 02:19 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=029846&professionCode=020

CASTLETON PHARMACY CORP. X

GENERAL INFO

ENFORCEMENT ACTIONS

Registration No: 029846

No Enforcement Actions Found

March 4, 2025 02:19 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=029846&professionCode=020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CASTLETON PHARMACY CORP

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 252B PORT RICHMOND AVE

City STATEN ISLAND State NY Zip 10302

Mailing Address (if different from physical address) 826 FOREST AVE

City STATEN ISLAND State NY Zip 10310

Telephone 718-720-3710 Website WWW.ENEXIASPECIALTY.COM

Licensing Company Email ADMIN@ENEXIASPECIALTY.COM

Section 2: Personal Information

First YAKOV Middle _____ Last RATNER

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Bellmore State NY Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University Of Buffalo School Of Pharmacy			
Address	**City**	**State**	**Zip**
285 Pharmacy Bldg	Buffalo	NY	14214
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/2015-02/2018	[redacted]	Staten Island	NY	[redacted]
0/2018-0/2022		Howard Beach.	NY	
06/2022-Present		Bellmore	NY	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
CASTLETON PHARMACY CORP			10/2016-Present	
Business Address		**City**	**State**	**Zip**
252B PORT RICHMOND AVE		STATEN ISLAND	NY	10302
Phone	**Title**		**Number of Employed Hours**	
201-916-4239	PIC		23000	
Description of Duties				
Pharmacist in Charge: Manages the pharmacy staff, ensures compliance with regulations, and oversees medication dispensing.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Yakov Ratner, **certify that as the designated representative for** Castleton Pharmacy Corp., **that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):**

1. (YR) I am at least 21 years of age;
3. (YR) I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. (YR) I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. (YR) I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. (YR) I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. (YR) I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

YAKOV RATNER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/3/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Yakov Rotner

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/3/25

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Richmond

I, Yakov Rotner, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/3/25

Date

Subscribed and Sworn to before me this 3rd day of February 2025

Notary Public Signature

JEREMY P MINORE
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01MI6416172
Qualified in RICHMOND County
Commission Expires 01 [illegible] 25
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CASTLETON PHARMACY CORP

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 252B PORT RICHMOND AVE

City STATEN ISLAND State NY Zip 10302

Mailing Address (if different from physical address) 826 FOREST AVE

City STATEN ISLAND State NY Zip 10310

Telephone 718-556-0942 Website WWW.ENEXIASPECIALTY.COM

Licensing Company Email ADMIN@ENEXIASPECIALTY.COM

Section 2: Personal Information

First BERNARD Middle _____ Last GLEZERMAN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City STATEN ISLAND State NY Zip [redacted]

Telephone 718-556-0942 XT 1220 Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LONG ISLAND UNIVERSITY		09/1993-01/1998	
Address	**City**	**State**	**Zip**
University Plz,	Brooklyn	NY	11201
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2014-02/2021	[redacted]	Englewood Cliffs	NJ	[redacted]
02/2021 Present	[redacted]	Englewood	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
CASTLETON PHARMACY CORP			06/2007-Present	
Business Address		**City**	**State**	**Zip**
252B PORT RICHMOND AVE		STATEN ISLAND	NY	10302
Phone	**Title**			
718-556-0942	COO			
Description of Duties				
Manage day-to-day operations, including human resources, IT, and facilities management				

Business Name			From - To (MM/YY – MM/YY)	
BB MYRTLE PHARMACY CORP			06/2008-Present	
Business Address		**City**	**State**	**Zip**
141 CHARLES AVE		STATEN ISLAND	NY	10302
Phone	**Title**			
718-20-5604	COO			
Description of Duties				
Manage day-to-day operations, including human resources, IT, and facilities management				

Business Name			From - To (MM/YY – MM/YY)	
NATES PHARMACY CORP			07/2012-Present	
Business Address		**City**	**State**	**Zip**
100 JERICHO TURNPIKE		FLORAL PARK	NY	11001
Phone	**Title**			
212-995-9400	COO			
Description of Duties				
Manage day-to-day operations, including human resources, IT, and facilities management				

Business Name			From - To (MM/YY – MM/YY)	
RED HOOK PHARMACY CORP			08/2003-Present	
Business Address		**City**	**State**	**Zip**
376 VAN BRUNT STREET		BROOKLYN	NY	11231
Phone	**Title**			
718-797-0200	COO			
Description of Duties				
Manage day-to-day operations, including human resources, IT, and facilities management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/3/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BERNARD GLEZERMAN

Print Name (First, Last)

Bernard Glezerman — 2/3/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Richmond

I, Bernard Glezerman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Bernard Glezerman — 2/3/25

Original Signature — **Date**

Subscribed and Sworn to before me this 3rd day of February 2025

Notary Public Signature

JEREMY P MINORE
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01MI6416172
Qualified in: RICHMOND County
Commission Expires 04/05/2025

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site CASTLETON PHARMACY CORP

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 252B PORT RICHMOND AVE

City STATEN ISLAND State NY Zip 10302

Mailing Address (if different from physical address) 826 FOREST AVE

City STATEN ISLAND State NY Zip 10310

Telephone 718-556-0942 Website WWW.ENEXIASPECIALTY.COM

Licensing Company Email ADMIN@ENEXIASPECIALTY.COM

Section 2: Personal Information

First BORIS Middle _____ Last NATENZON

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City STATEN ISLAND State NY Zip [redacted]

Telephone 718-720-3710 XT 1006 Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120):	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
LONG ISLAND UNIVERSITY		09/1994-01/1999	
Address: University Plz,	City: Brooklyn	State: NY	Zip: 11201
Diploma/Degree obtained, if any: PHARMACIST			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2013-present	[redacted]	COLTS NECK	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
CASTLETON PHARMACY CORP			06/2007-Present	
Business Address		**City**	**State**	**Zip**
252B PORT RICHMOND AVE		STATEN ISLAND	NY	10302
Phone	**Title**			
718-556-0942	CEO			
Description of Duties				
Oversee the day-to-day operations of the company, including human resources, finances, sales, and production.				

Business Name			From - To (MM/YY – MM/YY)	
BB MYRTLE PHARMACY CORP			06/2008-Present	
Business Address		**City**	**State**	**Zip**
141 CHARLES AVE		STATEN ISLAND	NY	10302
Phone	**Title**			
718-20-5604	CEO			
Description of Duties				
Oversee the day-to-day operations of the company, including human resources, finances, sales, and production.				

Business Name			From - To (MM/YY – MM/YY)	
NATES PHARMACY CORP			07/2012-Present	
Business Address		**City**	**State**	**Zip**
100 JERICHO TURNPIKE		FLORAL PARK	NY	11001
Phone	**Title**			
212-995-9400	CEO			
Description of Duties				
Oversee the day-to-day operations of the company, including human resources, finances, sales, and production.				

Business Name			From - To (MM/YY – MM/YY)	
RED HOOK PHARMACY CORP			08/2003-Present	
Business Address		**City**	**State**	**Zip**
376 VAN BRUNT STREET		BROOKLYN	NY	11231
Phone	**Title**			
718-797-0200	CEO			
Description of Duties				
Oversee the day-to-day operations of the company, including human resources, finances, sales, and production.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

2/3/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BORIS NATENZON

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/3/25

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Richmond

I, Boris Natenzon, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/3/25

Date

Subscribed and Sworn to before me this 3rd day of February 2025

Notary Public Signature

JEREMY P MINORE
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01MI6416172
Qualified in RICHMOND County
Commission Expires 04/05/2025

JEREMY P MINORE
NOTARY PUBLIC, STATE OF NEW YORK
[illegible] 01MI6416172
[illegible] Richmond County
Commission [illegible]
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: CASTLETON PHARMACY CORP

NV Pharmacy or Outsourcing facility license # (if applicable):

Physical Address: 252B PORT RICHMOND AVE

City: STATEN ISLAND State: NY Zip: 10302

Mailing Address (if different from physical address): 826 FOREST AVE

City: STATEN ISLAND State: NY Zip: 10310

Telephone: 718-556-0942 Toll Free # (NAC 639.708, NRS 639.23286): 1-866-9-ENEXIA

Fax: 718-360-9655 Contact Email: [redacted]

Website: WWW.ENEXIASPECIALTY.COM

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): YAKOV RATNER

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24450

Name of Designated Person(s) as defined by revised USP-797 guidelines: YAKOV RATNER

Email of Designated Person(s): [redacted]

Telephone of Designated Person(s): 718-556-0942 EXT.1280

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? August 2024

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly surface sampling

10. Will you be performing sterile hazardous drug compounding? Yes ■ No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

- Hydromorphone 10mg/ml IV solution
- Hydromorphone 1mg/ml IV solution
- Morphine 10mg/ml IV solution
- Morphine 1mg/ml IV solution
- Dobutamine 5mg/ml IV solution
- Dobutamine 2000mcg/ml IV solution
- Milrinone 0.8mg/ml IV solution
- Milrinone 0.2mg/ml IV solution
- Morphine 10mg/ml IV solution
- Morphine 1mg/ml IV solution
- Semaglutide/Methylcobalamine 2.5mg/0.5mg/ml injection
- Tirzepatide/Methylcobalamine 15mg/0.5mg/ml injection
- Atropine 0.01%
- Atropine 0.05%
- Atropine 0.02%
- Atropine 0.025%
- Fentanyl 200mcg/ml IV solution
- Fentanyl 50mcg/ml IV solution
- Methadone 10mg/ml IV solution
- Methadone 1mg/ml IV solution

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Biopharma

Address: 840 Research Parkway, Suie 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 800-393-1595

13. What is your procedure for visual inspection of compounded sterile products?
All preps are visually checked on a black and white background using an LED light to check for particulates. All filters used are immediately checked for bubble point, and the bubble point is documented on the formula work sheet. If the filter fails bubble point, the prep is re-filtered using a new filter. All products are checked for proper color, consistency, container, quality, elegance, labeling and BUD dating. A sample of all sterile products are sent for sterility, potency, and endotoxin testing prior to dispensing to a patient.

14. How often do you perform glove fingertip and medial fill testing?
We perform glove fingertip and media fill testing every 6 months.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
All sterile compounding employees are trained and must complete competencies which include: Aseptic Technique and Conduct in Controlled Environment, Baxter Repeater Pump. Bubble Point Testing Technique, Cleaning and Disinfecting of Sterile Compounding Areas, Cleaning and Disinfecting of Sterile Compounding PEC, and Hand Hygiene and Garbing. Employees are tested initially and then every 6 months. All employees must pass initial media fill and finger tip testing. They are then tested every 6 months thereafter. All sterile employees are also required to complete CEs pertaining to sterile compounding on Pharmcon Free CE website initially and then yearly thereafter.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
All floors are wiped daily using sterile SEC specific floor mop with floor pads wet with PREempt Plus. Once per week, all ceilings and walls are cleaned using the designated SEC ceiling and wall mop wet with Peridox RTU starting with the cleanest area and cleaning into the dirtiest area. Once per week the SEC floors are cleaned using the designated SEC floor mop wet with Peridox RTU starting with cleanest area and working way toward the dirtiest area. All surfaces of pass-through, outer surfaces of the PEC, and all vertical surfaces, sink surface, all storage shelving, garbage bins, tables, chairs, doors, handles and vents are cleaned with low lint wipes wet with Peridox RTU and then 70% isopropyl alcohol. All three PECs are cleaned daily and with each shift change. They are cleaned clean to dirty. We first use a sterile Easy reach pad wet with Sterile TB1 3300. Irregular surfaces are wiped first. Pre-saturated Sterile 70% IPA is used to wipe down all equipment. Sterile Easy Reach Pads soaked with TB1 3300 are used to clean the PEC ceiling, the n back, then walls, then front face, then the deck. All sections are wiped using horizontal passes cleaning from clean to dirty. The same sequence is followed using pre-saturated Sterile 70% wipes for irregular surfaces, and Sterile Easy Reach pads wet with Sterile 70% IPA for the ceiling, back, walls, front face, and deck. Between compounds the PEC is wiped down with pre-saturated sterile 70% IPA.

17. Who performs the sterile compounding process at your facility?

Pharmacists and Pharmacy Interns

18. Who is responsible and accountable for the sterile compounding process at your facility?
Yakov Ratner, PIC

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
All products that require refrigeration are send in a styrofoam shipping box located inside a cardboard shipping box. Pre-frozen ice packs are shipped with the product inside the styroform. We use plastic bubble to protect the product.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.) N/A		
1. What type of primary engineering controls will you be using in your facility?		
2. Are you complying with all USP 800 guidelines?	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	Yes	No
5. Do you have a negative pressure buffer room at your facility?	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

YAKOV RATNER

Name of Person who Completed the Form

PIC

Title

Signature (copies or stamps not accepted)

2/3/25

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

THE UNIVERSITY OF THE STATE OF NEW YORK
THE STATE EDUCATION DEPARTMENT
OFFICE OF PROFESSIONAL DISCIPLINE

R6764

PHARMACY INSPECTION REPORT ☒ Pharmacy ☐ M/W

Inspection # _____ conducted by
Investigator Mohammed Islam
Date 03/12/24 Time In/Out 11 / _____

1. Routine
2. New Registration
3. Transfer Ownership
4. Discontinuance
5. Change of Name/Address
6. Medication Recall
7. Complaint Related
8. Follow-up to Previous Inspection
9. Special Project of Renovation (Sterile Compd.)

Reg. name Castleton Pharmacy Corp
Trade name Enexia Specialty
No. and Street 2528 Port Richmond Avenue
City Staten Island County Richmond Zip 10302
Reg. # 29846 Telephone 718 556 0942
Hours open per week 59 # RXs daily 500

Pharmacists' Names	Hrs. Per Week	License Number	License Date	License Displayed	Registration Displayed
S.P. Yakov Ratner	40	61549	4/7/16	(Y) N	(Y) N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Pharm.				Y N	Y N
Intern				Y N	Y N

Circle "S" if item is Satisfactory. Circle "N" if item is Not Satisfactory, and explain in Details of Inspection section below. Be sure to include item number in explanation.

1. Registration name on exterior ..... (S) N
2. Licenses/current reg. displayed ..... (S) N
3. Registered pharmacist on duty ..... (S) N
4. Equip., facilities, and ref. items ..... (S) N
5. Price list available/current ..... (S) N
6. Drug stock current ..... (S) N
7. Stock properly branded ..... (S) N
8. Daily RX record ..... (S) N
9. Required RX filings ..... (S) N
10. DEA records complete/available ..... (S) N
11. Safety/approp. closures/containers ..... (S) N
12. RX labels required information ..... S N
13. Valid RX formats ..... (S) N
14. Substitution law compliance ..... (S) N
15. Required information on RXs ..... (S) N
16. Refill authorization/fill ..... (S) N
17. Refills in daily record ..... (S) N
18. Controlled substance compliance ..... (S) N
19. General sanitation ..... (S) N
20. Intern/unlicensed supervision ..... (S) N
21. Counseling offered/given/refusals documented ..... (S) N
22. Types of pharmacy (circle those applicable): retail, hospital, skilled nursing, assisted living, (compounding) sterile preparation, internet, home delivery, ~~mail delivery~~, nuclear, veterinary

Details of Inspection on 3/12/24; Inspection conducted in the presence of owner & SP (Yakov Ratner); Renovated space + Pharmacy operators Board compliant

Recommendation (completed in office)
Investigator _____
Supervisor _____

I have received a copy of this inspection report.
Signature _____
Print name Yakov Ratner
Title Pharmacist in Charge Date 03/12/2024

OPD 234 (6/2011) 11-005 CDC

ORIGINAL - TO CENTRAL OFFICE

This is page _____ of _____ page(s)

NABP ACCREDITED
COMPOUNDING PHARMACY

Castleton Pharmacy Corp dba Enexia Specialty

located at

252 B Port Richmond Ave, Staten Island, NY 10302

This business has met all the compounding pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the compounding pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/compounding.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/03/2024 - 04/02/2027
Period of Accreditation

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Pharmacy e-Profile ID:	793515		Inspection Information
Legal Business Name:	Castleton Pharmacy Corp	Conference Call Date:	5/30/2023
Doing Business As (DBA):	Enexia Specialty	Start Time: 24-hour format (13:00)	1:00
Address:	252 B Port Richmond Ave	End Time: 24-hour format (13:00)	1:50
City:	Staten Island	Onsite Inspection Date:	5/31/2023
State:	NY	Start Time: 24-hour format (13:00)	10:00
Zip Code:	10302	End Time: 24-hour format (13:00)	19:00
Telephone number:	718/556-0942	Inspector Name:	Tony H. Qi, PharmD, BS, RP
Toll free number:	866/936-3942	Inspection Performed by (NABP, State, etc):	NABP
Fax number:	718/360-9655	Observer Name/Affiliation (if applicable):	N/A
Website:	www.enexiaspecialty.com	Observer Name/Affiliation (if applicable):	N/A

Pharmacy Hours of Operation	Check if 24/7: ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			x
Monday	9:00	19:00	
Tuesday	9:00	19:00	
Wednesday	9:00	19:00	
Thursday	9:00	19:00	
Friday	9:00	19:00	
Saturday	9:00	15:00	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist In Charge	Yakov Ratner	compounding@enexiaspecialty.com	592331
Nonsterile Compounding Supervisor	Yakov Ratner	compounding@enexiaspecialty.com	592331
Sterile Compounding Supervisor	Yakov Ratner	compounding@enexiaspecialty.com	592331
Hazardous Compounding Supervisor	Yakov Ratner	compounding@enexiaspecialty.com	592331

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Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Lilly Rose Ahmed	Pharmacy Tech	NA
2	Joseph Attia	Pharmacist	Y
3	Iryna Bazhankova	Pharmacy Tech	NA
4	Engy Botros	Pharmacy Tech	NA
5	Olga Buldakova	Pharmacist	Y
6	Samml Cheung	Pharmacy Tech	NA
7	Nicole Dimicelli	Pharmacist	Y
8	Hanan Farraj	Pharmacy Tech	NA
9	Dawn Fazio	Pharmacy Tech	NA
10	Karina Nguyen	Pharmacist	Y

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present. During the inspection, a total of 8 Pharmacists, 15 pharmacy technicians, 3 supportive, and 3 interns were present

Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
New York State Board of Pharmacy	Castleton Pharmacy Corp	Pharmacy/029846	10/31/2024
US-DOJ	Castleton Pharmacy Corp dba Enexia Specialty	Controlled Substance/FC1747887	8/31/2024

Inspector Notes: List states in which Non-Resident licenses are held: AZ, CO, CT, DE, FL, NJ, PA and RI

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Attachments
(NO PHI, including prescription numbers)

Attachment Name	Description
Photo01_NS38.00_EnexiaSpecialty_StatenIsland_NY	One of the Non-Sterile Compounding Room and Hood, A total of 4 units and 8 hoods
Doc01_HD1.01_EnexiaSpecialty_StatenIsland_NY	List of all HD compounds provided by the Pharmacy
Doc02_N16.01_EnexiaSpecialty_StatenIsland_NY	COA sample for every vendor used in the past 12 months

Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail		Telepharmacy	
Open to the Public		Central Fill/Processing/Shared Services	
Closed Door	X	Specialty Pharmacy	
Drive-through window		Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy	X	Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)		Sterile Compounding	X
Internet Pharmacy (Refill Rx)		Sterile Hazardous Drug Compounding	

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	2,500	Total Pharmacists:	8
Nonsterile Compounding Room size:	400 (4 rooms, total)	Number of Compounding Pharmacists	4
Nonsterile Compounding powder hoods number:	8	Total Graduate Students or Residents:	2
Nonsterile Hazardous Drugs (HD) Compounding Room size:	200	Total Student Interns:	2
Nonsterile HD Compounding BSC/CACI hoods number:	4	Total Technicians:	14 full time, 5 part time
Sterile Compounding Ante Room size:	64	Number of Compounding Technicians	8
Sterile Compounding Clean/Buffer Room size:	80	Of technicians, how many are certified?	0
Sterile Compounding Number LAFW hoods/areas:	0	Of technicians, how many are techs-in-training?	1
Sterile Compounding Number BSC hoods:	0	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	2	Total Other Unlicensed Personnel:	6
Negative Pressure Sterile HD Room size:	0	Ratio #tech:#RPh present at time of inspection:	7 RP: 14 Techs
Sterile HD Compounding Number of BSC hoods:	0	Total Pharmacist Hours Per Week:	320
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	660

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	150	Total Orders Distributed/day:	0
% Veterinary Prescriptions	15-20%	% Veterinary Orders	0
% Controlled Substance Prescriptions	5-10%	% Controlled Substance Orders	0
% Nonsterile Compounded Prescriptions	70%	% Nonsterile Compounded Orders	0
% Sterile Compounded Prescriptions	28%	% Sterile Compounded Orders	0
% Hazardous Drugs (HD) Prescriptions	20%	% Hazardous Drugs (HD) Orders	0

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Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: If not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)	62	0	last 30 days
Arkansas (AR)			
California (CA)			
Colorado (CO)	41	0	last 30 days
Connecticut (CT)	249	0	last 30 days
Delaware (DE)	13	0	last 30 days
District of Columbia (DC)			
Florida (FL)	365	0	last 30 days
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy mails/delivers prescription products and volume dispensed, and volume distributed per day (or week or month):
Note: If not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)	1246	0	last 30 days
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)	221	0	last 30 days
Rhode Island (RI)	17	0	last 30 days
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)			
Wyoming (WY)			
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	minimum of 40 hours
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	Yes	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel interviewed as part of the inspection, including name and title:	[redacted]	Boris Natenzon, President/CEO Enexia Pharmacy Group; Nicole DiMicelli, PharmD

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e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
Types of Practice Additional Questions	**If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	3/16/2018; NY BOP does not have a set schedule for inspections.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	Intern/Unlicensed Supervision; The PIC stated that this was corrected.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	Yes	The PIC stated that for unknown time period, the pharmacy had a PCAB accreditation and for unknown reason, it was not renewed.
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	All records are kept onsite, including limited hard copies, for 10 years and then shred after.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically

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National Association of Boards of Pharmacy®
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General Pharmacy Inspection

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronically records have backup copies in the server.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	No	The pharmacy personnel acknowledged and will implement this.
Personnel	**If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	HR at the corporate main office keeps results in an electronic file.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	HR at the corporate office, 826 Forest Ave, Staten Island, checks OIG exclusion list and NY state website and keeps search results in each personnel file.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	On the date of the inspection, the pharmacy has the RP to Tech ratio counting the CEO, who is also a RP. The pharmacy maintains ratio of 1:2 at the intake area. The PIC stated that a RP must be physically present in the sterile compounding buffer room. RP is also in the general 795 area. The pharmacy has four 795 compounding rooms within the general 795 area.

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		Finding	Notes
	Facility and Security — If any part of a question is no, enter "No" and explain the observation.		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Alarmingly Affordable is the security monitoring company. Internal and external cameras were visible.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	The firm CEO/President, Boris Natenzon, stated that the pharmacy would have personnel stay onsite and if needed, products can be moved to other Enexia pharmacy locations.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	No destruction onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Return Solutions
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Bridging Access to Care is the company handling HD Waste.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	N/A	

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		Finding	Notes
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The pharmacy uses a traditional ThermPro unit to measure the drug storage temperature. It was 70F at the time of the inspection.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	No	Temperature is not monitored 24/7. The pharmacy acknowledged and stated that it would implement changes.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	No	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	No	3 refrigerators were located in the compounding area. The pharmacy uses a traditional temperature meters. USP range is used. Records are maintained per PnP.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	No	The three refrigerators initially had readouts as following: 42F, 49F and 40F. The one reading 49F later on had a second read and it was 45F.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No pharmaceuticals were in the freezer.
42.01	Is the temperature in the freezer within the USP range (between -25° to -10°C or -13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	The PIC stated that the first step was to contact the repair personnel and move products to other functional units.

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		Finding	Notes
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	The PIC stated that the process was to contact the contracted repair person.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	1 repeater pump
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	Repeater pump was used to compound sterile compounds and the pharmacy does not compound sterile HD products.
Product Receipt and Inventory	**If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	The PIC stated that he requests a copy of wholesale state registration and copy of the FDA wholesale license and keeps the records.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	McKesson, Kinray
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	No	

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		Finding	Notes
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	Note the volume of traditional pharmacy dispensing is less than 2%. The pharmacy personnel checks the products and notifies the RP on-duty and the wholesalers.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	No	
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	Yes	PIC only and Bernard Glezerman, Minority owner

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		Finding	Notes
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory in computer
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	The PIC and the owner stated that there had been no diversion and qualified events would be reported to the DEA and the BOP.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	The PIC stated that CII inventory for APIs are perpetual in PK software per dispensing. Biennial inventory counts all manufactured dosage forms and API quantities.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	May 1, 2023 was the last inventory date and the pharmacy conducts this biennially.

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		Finding	Notes
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	The pharmacy checks outdates monthly, including OTC if any.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	Selected inventory, including APIs, were reviewed.
60.02	How often is active-stock examined for drugs past the expiration date?		Monthly
61.00	Does the pharmacy prepackage bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	

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		Finding	Notes
62.00	Does the pharmacy prepack multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
Prescription Processing	**If any part of a question is no, enter "No" and explain the observation.**		
64.00	Patient Profile: Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	The pharmacy technicians typically enters and updates when the prescription and patient information change.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Species followed by the first name of pet, and the owner's last name
65.00	Prescription: Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	The PIC stated that for unknown prescribers, the pharmacy would verify the orders by directly contacting the facilities.

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		Finding	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	The PIC and the owner stated that the pharmacy does not use tele platforms to fill compounding orders. All prescribers have established accounts with the pharmacy.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both controls and non-controls
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	Accuracy: Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Accuracy of data entry is verified by a RP and documented on the compounding records in PK and IPS.
67.00	DUR: Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	No	For compounds, the pharmacy does not collect a complete drug profile to conduct DUR. Three sampled patient profiles did not have recorded allergy information.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	N/A	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	N/A	
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	

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		Finding	Notes
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	The pharmacy applies NDC number for compounded controls and reports to the PDMP.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	N/A	
67.07	Is the DUR process performed electronically by the computer system? *Identify integrated drug database used.*	N/A	
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	N/A	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	Yes	Veterinary drug handbook 9th edition
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	The compounding orders and calculations are reviewed by a RP and recorded in the PK software. PV1 is recorded in IPS.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Labels are compliant to the NY state regulations.
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	IPS is used for overall record keeping and PK is used for compounding records.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	

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		Finding	Notes
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	

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74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
Patient Counseling and Communication	**If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	This is a closed door pharmacy.
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	
76.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
77.00	Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	
77.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	N/A	
78.00	Is patient counseling provided for <u>delivered</u> prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	toll free number is provided. The PIC stated that all delivered prescriptions are counseled prior to delivery.

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General Pharmacy Inspection

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		Finding	Notes
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	toll free number is provided. The PIC stated that all mailed prescriptions are counseled prior to shipping.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	No	The pharmacy does not provide additional patient education information related to a compound after phone counseling.
81.00	Are Med Guides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	No	
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for Isotretinoin, or Tikosyn).*	N/A	The PIC stated that there is no REMs drugs onsite.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Counseling notes can be included in the IPS notes section.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	24/7 emergency calls are for hospice patients. Non hospice patients can leave messages for the next day call back.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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		Finding	Notes
Quality Assurance/Quality Improvement Program	**If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	The PIC oversees this program. Since the pharmacy conducts approximately 98% compounding, trending of CQI program is based upon compounding quality assurances (garbing, gowning, testing and environmental monitoring trending). The pharmacy uses a hard copy form to record different variances and documents are scanned and consolidated to the corporate office in Staten Island.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronic
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	Documentation of QREs starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronic
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	

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88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation includes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	QRE data collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	Analysis is performed based upon each event.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	Quality meetings are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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		Finding	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Unknown	Unknown whether incidents have been reported to the BOP or other agencies after being consolidated back to the corporate office.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	N/A	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	No	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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		Finding	Notes
General Operations and Information			
1.00	Does the pharmacy dispense nonsterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	No	Reviewed a few patient profiles which missed patient allergy.
1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	Yes	
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?	No	
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?	Yes	
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?	Yes	
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?	No	
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?	No	

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		Finding	Notes
2.00	Does the pharmacy distribute nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	N/A	
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	N/A	
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*	No	
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided.*	No	
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds provided.*	N/A	
2.06	If yes, are any of these controlled substances? *List compounds provided.*	N/A	
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?	No	The PIC and the owner confirmed this that the pharmacy does not send compounds to other sister locations for dispensing purpose.
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*	N/A	
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.*	Yes	Capsules, liquids, lozenges

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		Finding	Notes
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.*	Yes	Gels, creams, ointments, rectal suppositories, nasal spray
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List.*	Yes	Thiamine riboflavin suspension
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list.*	No	
8.00	Does the pharmacy compound investigational drugs? *Provide List.*	No	
9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*	Yes	The pharmacy compounds Acetaminophen 32mg/ml when the product is not available.
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	Unknown	Compounding of acetaminophen suspension is based upon the drug shortage, however, the shortage time period and review date were not documented.
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	Unknown	
10.00	Does the pharmacy perform compounding identified as simple? *Indicate percentage of simple compounding.* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*	Yes	80%

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		Finding	Notes
11.00	Does the pharmacy perform compounding identified as **moderate**? *Indicate percentage of moderate compounding.* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*	Yes	15%
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding.* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*	Yes	5%
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs.* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.	Yes	0.2
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?	Yes	
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding.*	Yes	1%; Hydromorphone solution, Ketamine nasal spray. Testosterone cream
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	

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		Finding	Notes
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs.*	Yes	PCCA, Medisca, Letco, DarMerica (see attached for all COA samples)
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*	Yes	The PIC contacts the API company and obtains a copy of the FDA registration.
16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate sources.*	No	
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.*	Yes	
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	Yes	PH testing for selected liquids
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*	No	
19.00	Does the pharmacy use scales/balances for nonsterile compounding?	Yes	
19.01	If so, what type of scale/balanced is used? *List manufacturer and model number*	[redacted]	Eight Ohaus Model 423
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency*	No	The PIC stated that the pharmacy uses weight calibrate daily.
19.03	Describe the pharmacist checks for the measurement of each ingredient	[redacted]	The pharmacist checks the compound record before and after the finish. The PIC stated that the weight is set to be within 3%.

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		Finding	Notes
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**	Yes	This section is based upon the review of the P&P provided. The PIC stated that all QREs are recorded on hard copies, scanned and consolidated to the central office located in Staten Island.
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?	No	The pharmacy currently does not conduct potency testing for extended BUD products.
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?	Yes	
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?	Yes	
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?	Unknown	QREs are consolidated to the corporate central office.

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		Finding	Notes
Component Selection and Use			
	Total Non-Compliant (Includes Unknowns)	0	
21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.	Compliant	
21.02	USP- or NF-grade substances used, if available	Compliant	
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	Compliant	
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*	Compliant	
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding	Compliant	

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		Finding	Notes
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*	N/A	The PIC stated that all APIs have expiration date.
21.08	All APIs and components received without an expiration date are labeled with the date they were received.	N/A	
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	N/A	
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	
22.00	Where water is an ingredient, purified or distilled water is used.	Compliant	
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	Compliant	

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24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	
25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	
26.00	For animal compounding: The compounding meets the same standards as compounding for human patients.	Compliant	
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	Compliant	
26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	N/A	The PIC stated that the pharmacy only compounds for pet animals.
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	The PIC confirmed that the pharmacy does not compound for performance animals or food-producing animals.

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Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
Beyond Use Dating (BUD)			
	Total Non-Compliant (Includes Unknowns)	4	
27.00	BUDs are assigned from the day of preparation.	Compliant	
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	Compliant	
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*	Non-Compliant	The pharmacy currently applies reference data from Trissels, PCCA, ASHP etc.
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*	Non-Compliant	
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	Compliant	
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	Non-Compliant	
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.	Non-Compliant	Sampled suspensions are assigned BUDs ranging from 35 days to 90 days. No potency testing has been performed independently. All data is from references.

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	Environment	Finding	Notes
	Total Non-Compliant (Includes Unknowns)	7	
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	Compliant	
34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	Compliant	
35.00	Only one preparation compounded at a time.	Compliant	
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	Compliant	
37.00	The compounding area is well lit.	Compliant	
38.00	The pharmacy performs hazardous non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*	Unknown	Attached photograph indicates one of the eight compound hoods. The PIC stated that the filter is behind the white board, leading to a central filter through duct work. The room is in negative pressure which was indicated via the pressure meter (see attached). Four rooms and the hoods are not certified annually.
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.	Non-Compliant	Eights hoods are not certified.

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		Finding*	Notes
38.02	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.	N/A	
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.	Compliant	
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).	Compliant	
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.	Compliant	
41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is recommended - not required)*	Compliant	
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.	Compliant	
43.00	Temperature in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Non-Compliant	Temperature in the general compounding room was monitored by a traditional ThermaPro unit and it is not 24/7.
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Non-Compliant	

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		Finding	Notes
43.03	Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	N/A	The drug storage area is the compounding area.
43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	N/A	
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	N/A	
44.00	Humidity in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.	Non-Compliant	Humidity in the general compounding area was at 49%
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Non-Compliant	Humidity monitoring was not 24/7 by continuous monitoring or retroactive detection using min/max
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Non-Compliant	The range of humidity was not set to detect the 49% reading at the time of the inspection.
44.03	Humidity monitoring is also performed in drug storage areas (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.	N/A	The drug storage area is the compounding area.
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	N/A	

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		Finding	Notes
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	N/A	
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.	Compliant	
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	Compliant	
47.00	All components and packaging containers and closures are properly rotated to use oldest first.	Compliant	
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)	Compliant	
49.00	Trash is disposed of in a safe, sanitary, and timely manner.	Compliant	
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.	Compliant	
Training - *Verify records of all compounding personnel (up to 10)*			
	Total Non-Compliant (Includes Unknowns)	0	
50.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.	Compliant	Every 6 months, suspension, gel, capsules
51.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.	Compliant	

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e-Profile ID: 793515
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		Finding	Notes
52.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.	Compliant	
53.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*	Compliant	six months training
54.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.	Compliant	
54.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.	Compliant	
55.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.	N/A	No relief pharmacist
Compounding Equipment			
	Total Non-Compliant (includes Unknowns)	3	
56.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*	Compliant	
57.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.*	Non-Compliant	The PIC stated daily before compounding, all eight Ohaus balances are calibrated manually by weights. During the inspection, the general compounding room pressure gauge indicated the negative reading to the ambient area outside of the compounding room. The owner checked with the contractor and the situation was rectified and the gauge reading turned positive.
58.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.	Non-Compliant	The hoods are not certified periodically.
58.01	Hood filters are checked regularly and replaced when necessary.	Unknown	The central filter replacement record was not accessible during the inspection.

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		Finding	Notes
59.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed. **Recommended** rinsed with purified water.*	Compliant	
60.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	Compliant	
Documentation			
	Total Non-Compliant (Includes Unknowns)	0	
61.00	The pharmacy creates a master formulation record the first time before compounding a new preparation	Compliant	
61.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	Compliant	
61.02	The master formulation record includes:		
61.03	Official or assigned name, strength, and dosage form	Compliant	
61.04	All necessary calculations	Compliant	
61.05	Description of all ingredients and their quantities	Compliant	
61.06	Compatibility and stability information including references (when available)	Compliant	
61.07	Equipment used for the preparation	Compliant	

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		Finding	Notes
61.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)	Compliant	
61.09	Container used and packaging requirements	Compliant	
61.10	Assigned BUD information	Compliant	
61.11	Labeling information including the name of and quantity or concentration of each active ingredient	Compliant	
61.12	Description of the finished preparation	Compliant	
61.13	Storage requirements	Compliant	
61.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).	Compliant	
62.00	The pharmacy creates a compounding record for each compound prepared	Compliant	
62.01	The compounding record includes:		
62.02	Official or assigned name, strength and dosage of the preparation	Compliant	
62.03	Master Formulation Record reference	Compliant	
62.04	Sources, lot numbers, and expiration dates of all components	Compliant	
62.05	Total quantity or number of dosage units compounded	Compliant	

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		Finding	Notes
62.06	Person compounding the preparation	Compliant	
62.07	Person performing the quality control procedures	Compliant	
62.08	Person who approved the preparation	Compliant	
62.09	Date of compounding	Compliant	
62.10	Assigned internal identification number or prescription number	Compliant	
62.11	Description of the final preparation	Compliant	
62.12	Assigned BUD	Compliant	
62.13	Duplicate label	N/A	
62.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?	Compliant	
62.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Compliant	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
Compounding Procedures			
	Total Non-Compliant (includes Unknowns)	1	
63.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	Compliant	
64.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	Non-Compliant	The pharmacy currently does not have a weight analysis for tablets.
65.00	The containers and closures selected meet USP standards (from container supplier).	Compliant	
66.00	Container selection determined by physical and chemical properties of the preparation.	Compliant	
67.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	Compliant	
68.00	Personnel don appropriate protective garb when performing compounding.	Compliant	
68.01	If hazardous compounding, personnel don appropriate protective garb when compounding.	Compliant	
69.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*	Compliant	

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e-Profile ID: 793515
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		Finding	Notes
70.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage. **Recommended:** compounding accuracy checked by a person other than the compounder.*	Compliant	
71.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.	Compliant	
72.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*	Compliant	
73.00	Personnel are appropriately garbed for protection when cleaning.	Compliant	
74.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. **Compounding MUST be observed**, if compounding is not being performed at the time of survey, mark as "Non-Compliant".*	Compliant	
74.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "**Denial of Authorization**" form. List individual who signs the Denial of Authorization*	[redacted]	

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		Finding:	Notes
Finished Preparation Release Checks and Tests			
	Total Non-Compliant (Includes Unknowns)	3	
75.00	The finished preparation is observed to appear as expected in the master formulation record and documented.	Compliant	
76.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.	Non-Compliant	
77.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.	Non-Compliant	
78.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.	Non-Compliant	
78.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient	N/A	
78.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.	N/A	
79.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*	Compliant	
80.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.	Compliant	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
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		Finding	Notes
80.01	Labeling contains generic name and quantity or concentration of each active ingredient.	Compliant	
80.02	Labeling contains assigned BUD.	Compliant	
80.03	Labeling contains storage and handling information.	Compliant	
80.04	If hazardous, labeling contains storage and handling information.	Compliant	
80.05	Labeling contains prescription or control number, whichever is applicable.	Compliant	
81.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	Compliant	
82.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
83.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.	Compliant	
84.00	Preparations are examined immediately after preparation AND again immediately prior to dispensing for any signs of instability.	Compliant	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
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Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
Patient Counseling and Communication			
	Total Non-Compliant (includes Unknowns)	1	
85.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?	Compliant	Currently the pharmacy provides an orange label indicating HD caution of handling and disposal.
86.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?	Non-Compliant	No additional drug information material sheets are provided for the compounded products.
87.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
88.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.	Compliant	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
	Indicate the drug name, dosage or strength, and the size of the sample obtained for testing. *(NA if no sample)*		N/A
	Indicate the areas/rooms of the pharmacy entered to perform the inspection. *If the inspector did not fully garb and enter buffer room(s), indicate reason.*		The inspector garbed and entered the non-sterile compounding room and observed sterile compounding processes through an un-obstructed observation window directly to the buffer room.
	General Operations Information		
1.00	Does the pharmacy **dispense** sterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	No	Sampled patient profile did not list patient allergy information.
1.02	Are sterile compounded prescriptions picked up at the pharmacy?	No	
1.03	Are sterile compounded prescriptions delivered/mailed to patients in their homes or residential facilities?	Yes	
1.04	Are sterile compounded prescriptions delivered/mailed to the practitioner for administration to the patient in the office, clinic, or facility?	No	
2.00	Does the pharmacy **distribute** sterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	
2.01	Does the pharmacy distribute sterile compounded preparations to practitioners for office use?	No	
2.02	Does the pharmacy distribute sterile compounded preparations to hospitals, clinics, or surgery centers?	No	

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		Finding	Notes
2.03	Is the pharmacy registered with the FDA as an Outsourcing Facility?	No	
2.04	Does the pharmacy have a sales force that distributes samples containing active ingredients? *List samples provided.*	No	
3.00	Does the pharmacy provide sterile compounded preparations to other pharmacies for dispensing?	No	
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations?	N/A	
4.00	Which of the following sterile compounds are prepared?		
4.01	Allergen extracts	No	
4.02	Parenteral solutions	Yes	
4.03	Parenteral *suspensions*	No	
4.04	Preservative-free parenterals	Yes	
4.05	Ophthalmic preparations	Yes	
4.06	Oral or nasal *inhalation* preparations (not topical sprays)	No	
4.07	Baths and soaks for live organs and tissues	No	
4.08	Irrigations for wounds and body cavities	No	

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		Finding	Notes
4.09	Any other sterile preparations (implants, pellets, etc.). *Provide list.*	No	
5.00	Does the pharmacy compound investigational drugs? *Provide list.*	No	
6.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate name and volume/percent compounded currently.*	Yes	The pharmacy compounds semaglutide with B12; volume is approximately two dozen per day; The PIC and the owner stated that they check daily in the morning. When it is unavailable, the pharmacy then compounds based upon patient needs. The compound is for weight loss and cash based.
6.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	Unknown	The drug shortage, however, was not documented.
6.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	Unknown	
7.00	Does the pharmacy perform low-risk compounding? *Indicate percentage of low-risk sterile compounding.*	Yes	48%
7.01	Are all low-risk compounds assigned BUDs within USP guidelines (48 hours at controlled room temperature, 14 days refrigerated, 45 days frozen)?	No	Dobutamine and Milrinone-sterile to sterile-no extended BUDs
7.02	If low risk, are the compounds located in segregated area are BUD 12 hours or less?	N/A	
7.03	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		Atropine 0.05% solution-60days; Atropine 0.025% solution-60day
7.04	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*	Yes	sterility testing per USP 71 for every lot (no skipping)

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		Finding	Notes
8.00	Does the pharmacy perform medium-risk compounding? *Indicate percentage of medium-risk sterile compounding.*	Yes	1-2%; hospice antibiotics; reconstitute then inject into an IV bag
8.01	Are all medium-risk compounds assigned BUDs within USP guidelines (30 hours at controlled room temperature, 9 days refrigerated, 45 days frozen)?	Yes	
8.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		
8.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*	Yes	The PIC stated that sterility testing per USP 71 for every lot (no skipping) is performed.
9.00	Does the pharmacy perform high-risk compounding? *Indicate percentage of high-risk sterile compounding.*	Yes	50%; 1% infusion MDV
9.01	Are all high-risk compounds assigned BUDs within USP guidelines (24 hours at controlled room temperature, 3 days refrigerated, 45 days frozen)?	N/A	
9.02	If extended BUDs are used, list products with Extended BUDs and maximum BUD in notes.		Fentanyl 0.9% 50mcg/ml IV-90 days; Hydromorphone 10mg/ml IV-90 days; Morphine Sulfate 10mg/ml IV-90 days;
9.03	If extended BUDs are used, is further testing being performed to justify the use of extended BUDs? *List the types of testing performed (potency, sterility, stability, etc).*	Yes	sterility testing per USP 71 for every lot (no skipping), Time point potency testing. The PIC stated that the pharmacy holds for 14 days until sterility testing data is cleared.
10.00	Does the pharmacy provide sterile compounded preparations to be administered via an implantable infusion pump?	Yes	
11.00	Does the pharmacy perform compounding for immediate use? *Indicate percentage of immediate use sterile compounding.*	No	0%

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		Finding	Notes
12.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of hazardous sterile compounding.* *NIOSH list of hazardous drugs including chemotherapy, hormones, etc.*	No	0%
12.01	Does pharmacy have a plan to comply with USP Chapter <800> by the implementation date? Describe plan.	N/A	
12.02	Are hazardous drugs segregated and stored in a room that is negative pressure (at least -0.01" wc) to adjacent areas and with at least 12 ACPH?	N/A	
12.03	Is hazardous drug waste quarantined in a designated area and disposed of in compliance with local, state, and federal regulations?	N/A	
13.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
14.00	Does the pharmacy perform compounding using **blood products** (or other biological materials)? Such as wound care, autologous eye drops, etc. *Describe.*	No	
15.00	Does the pharmacy compound using any **Federally controlled substances** I-V? *Indicate controlled substances used and percentage of controlled substance sterile compounding.*	Yes	Fentanyl 0.9% 50mcg/ml IV; Hydromorphone 10mg/ml IV; Morphine Sulfate 10mg/ml IV - small percentages of these but exact number was not shared.
16.00	**APIs:** Does the pharmacy make any sterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *If not, Indicate the source of APIs*	Yes	PCCA, Medisca, Letco, DarMerica
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified*	Yes	The PIC stated that he obtains a copy of the FDA registration directly from the facility.

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		Finding	Notes
16.03	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*	No	
16.04	Does the computer track on-hand quantities of APIs used for compounding?	Yes	
17.00	Does the pharmacy use scales/balances for sterile compounding?	Yes	
17.01	If so, what type of scale/balanced is used? *List manufacturer and model number.*	[redacted]	Ohaus Model 423
17.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency.*	Yes	The PIC stated that before each day's compounding, the compounding personnel calibrates the balance utilizing weights.
18.00	Does the pharmacy have a lyophilizer?	No	
18.01	Where is the lyophilizer located? *Indicate location and ISO class of room.*	[redacted]	N/A
18.02	Note the products lyophilized, and the volume or percent of products per week produced using the lyophilizer.	[redacted]	N/A
18.03	Is the lyophilizer part of the viable air and surface sampling, media fill testing procedures, and cleaning schedules and procedures?	N/A	
19.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	Yes	Bubble point testing
20.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed*	Yes	ARL does 14 day sterility testing and potency testing

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		Finding	Notes
21.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include sterile compounding measures? ***Note: If the facility indicates "yes", please ask each question below to verify.***	Yes	
21.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
21.02	Does the pharmacy continuous quality improvement program include nonviable environmental monitoring and testing?	Yes	
21.03	Does the pharmacy continuous quality improvement program include viable environmental testing?	Yes	
21.04	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
21.05	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
21.06	Does the pharmacy continuous quality improvement program include sterilization method testing and validation?	Yes	
21.07	Does the pharmacy continuous quality improvement program include end product testing (such as: potency, particulates, sterility, endotoxin, etc.)?	Yes	
21.08	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding CSPs?	Yes	

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		Finding	Notes
21.09	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
21.10	Does the recall system include communication with both the patient and the physician/prescriber regarding the potentially contaminated CSP administered and the potential risks?	Yes	
21.11	Are QREs involving CSPs that may have been contaminated or are recalled reported to the appropriate agency such as the Board of Pharmacy and/or FDA.	Yes	
21.12	Are all CFUs detected by any personnel, environmental, or product testing; or any other checks or tests including endotoxin, purity, potency, etc. remediated, appropriately investigated, cause determined, and processes implemented to prevent in the future, where applicable? *Review QA trends.*	No	Currently CFUs identified through gloved fingertip sampling are not tested to the genus level.
	Component Selection and Use		
	Total Non-Compliant (includes Unknowns)	0	
22.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	
22.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before being used for compounding.	Compliant	
22.02	USP- or NF-grade substances used, if available.	Compliant	

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		Finding	Notes
22.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	Compliant	
22.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels*	Compliant	
22.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding.	Compliant	
22.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
22.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned is not greater than one (1) year, unless it is supported with data and/or testing. *Note: purity and quality testing may be performed to extend.*	N/A	
22.08	All APIs are labeled with the date they were received.	Compliant	
22.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	N/A	

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		Finding	Notes
22.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	
23.00	There are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	
24.00	When manufactured products are used for compounding, all the other excipients (in addition to the active ingredient) in the manufactured product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	
25.00	For animal compounding, does the compounding meet the same standards as compounding for human patients?	N/A	No sterile compounds are for animals.
25.01	The pharmacist is knowledgeable or has the most up-to-date references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	N/A	
25.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	N/A	
25.03	The pharmacist familiar with, or has the most up-to-date reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
25.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
25.05	The pharmacist is familiar with, or has the most up-to-date reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	

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		Finding	Notes
26.00	If the pharmacy compounds stock solutions or components (that are then used to compound a finished product) using APIs, these stock solutions are categorized as high-risk compounding.	N/A	The PIC stated that the pharmacy does not compound stock solution.
26.01	The stock solutions are assigned BUD based on the USP<797> high-risk compound BUD, OR are assigned on the basis of direct testing or extrapolation from reliable literature sources to support an extended BUD.	N/A	
26.02	Compounded preparations using the stock solution are classified as high-risk compounds with appropriate handling with regard to BUD and testing requirements.	N/A	

Environment

	Total Non-Compliant (Includes Unknowns)	6	
27.00	If the facility performs both sterile and nonsterile compounding, the areas are separated and distinct.	Compliant	
28.00	If the facility performs compounding using blood products (or other biological materials), this compounding area is separate and distinct from the general compounding areas.	N/A	
28.01	Are components used in compounding with blood products restricted to the blood compounding area (not used in other compounding areas)?	N/A	
29.00	Entry into the sterile compounding areas is limited to task critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel).	Compliant	

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		Finding	Notes
30.00	The anteroom has a line of demarcation or other separation of the dirty to the clean side. Note: the line of demarcation may NOT be the doorway between the anteroom and the clean/buffer room.	Compliant	
30.01	Carts used to bring supplies from the storeroom are kept on the outside of the line of demarcation.	Compliant	
30.02	Carts used in the clean/buffer room are kept on the clean side of the line of demarcation.	Compliant	
31.00	All surfaces of the sterile product compounding area carts, shelves, stools, chairs, and other items are resistant to disinfectants, non-permeable, non-carpeted or upholstered, and low particulate generating.	Compliant	
32.00	Walls are constructed of durable material, which is cleanable, such as epoxy-coated or heavy-gauge polymer material. *If panels are used, they are locked together and sealed.*	Compliant	
33.00	The ceiling surface shall be impervious and hydrophobic. *If tiles are used, they shall be locked and the seams between the tiles and where they meet the walls shall be caulked and sealed.*	Compliant	
34.00	The floor overlaid with wide sheet flooring and seamless or with heat welded seams, with coving to the sidewall, and a sealed seam where the coving meets the wall.	Compliant	
35.00	The clean/buffer room or anteroom does not have dust collecting overhangs.	Compliant	
36.00	The exposed surfaces of:		

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		Finding	Notes
36.01	PEC are free of dirt, rust, chips and particulate matter.	Compliant	
36.02	Light fixtures are smooth, mounted flush, and sealed.	Compliant	
37.00	A working sink, located on the clean side of the line of demarcation, is available that enables pharmacy personnel to wash hands and enter the sterile compounding area without contaminating his/her hands and is away from/not adjacent to any PEC(s).	Compliant	
38.00	There is no sink or drain in the clean/buffer room.	Compliant	
39.00	Hand drying is with lint-free disposable towels, or an electronic or HEPA filtered hand dryer.	Compliant	
39.01	If using a hand dryer, particle count and smoke testing validation is performed while dryer is in use (while someone is actively using to dry their hands) at certification, and the immediate area around the dryer is part of the viable air and surface testing program performed. *(N/A if only using towels)*	Compliant	
40.00	All air ducts controlling air flow into the sterile compounding clean/buffer room and anteroom are equipped with High Efficiency Particulate Air filtered air that maintains the cleanroom with an ISO Class 7 environment and the anteroom with an ISO Class 7 (when adjacent to HD cleanroom) or ISO Class 8 environment.	Compliant	
41.00	Incoming air ducts through HEPA filters are on or near the ceiling and air return ducts are low on the walls in the anteroom and clean/buffer room.	Compliant	
42.00	If there are particle generating equipment/appliances in the clean/buffer room or anteroom (e.g. computers, printers, refrigerators, dishwashers, etc), they are located by an air return so air flows over and out of the room taking particles with it, and this air flow has been confirmed by smoke testing while in use.	N/A	

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Sterile Compounding Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Findings	Notes
43.00	Beverages including drinking water, chewing gum, candy, or food items are prohibited from the clean/buffer room or anteroom.	Compliant	
44.00	If compounding occurs using nonsterile ingredients, products, components, or devices (for example compounding with non-sterile APIs or using nonsterile vials and closures), the pharmacy has appropriate equipment to sterilize the finished product.	Compliant	
* 44.01	Pre-sterilization procedures for high risk level CSPs (such as weighing and mixing) are performed in no worse than an ISO Class 8 environment.	Non-Compliant	Currently the API used for sterile compounding is weighed in one of the four non-sterile room and brought into the cleanroom traversing the non-ISO classified area.
45.00 *	Completely enclosed anteroom and clean/buffer room (with a door) are equipped with monitors or gauges to measure differential pressure.	Compliant	
45.01	Anteroom is at least 0.02" wc positive pressure to general pharmacy areas.	Compliant	
45.02	Clean/buffer room is at least 0.02" wc positive pressure to Anteroom.	Compliant	
45.03	Hazardous compounding room and drug storage area is at least 0.01" wc negative pressure to ISO Class 7 anteroom.	N/A	
45.04	Pressures are reviewed and documented on a log at least every work shift (minimum of once daily) or monitored by a continuous recording device. *View logs*	Compliant	
45.05	Written plan in place to detect and react to pressure differentials outside of limits.	Compliant	
46.00	If the clean/buffer room and anteroom are not fully enclosed (open or with plastic strips - no door that closes), the air flow is measured across the openings.	N/A	

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		Finding	Notes
46.01	The air flow is at least 40 feet per minute across the entire opening.	N/A	
46.02	Airflow is read and recorded each shift (minimum of once daily) or continuously recorded. *View logs.*	N/A	
46.03	Written plan in place to detect and react to air flow measurements outside of limits	N/A	
46.04	This area is used only for low- and medium-risk compounding (HD and high-risk not allowed).	N/A	
47.00	**Temperature:** The temperature of all compounding and drug storage areas shall be maintained in accordance with standards, and a written plan shall be in place and followed to address any excursions.	Compliant	
47.01	Temperature in the compounding area is maintained to provide comfortable working conditions for compounding personnel of 20° C or cooler (68° F or cooler); Temperature can be more restrictive if warranted by specific drug product storage requirements. *Temperature records are maintained.*	Compliant	
47.02	If drugs are stored in the compounding area, temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. *Temperature records are maintained.*	Non-Compliant	
47.03	Temperature monitoring is also performed in drug storage areas (if separate from the compounding areas). Temperature is maintained at controlled room temperature of 20° - 25° C (68° - 77° F) or as specified by FDA approved labeling for drug product storage.	Compliant	
47.04	Temperature monitoring in the drug storage area is performed at least once daily and documented. *Temperature records are maintained.*	Compliant	

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		Finding	Notes
47.05	Temperature in the refrigerator or cooler is maintained to provide controlled cold temperature of 2° to 8°C (36° to 46°F) or as specified by FDA approved labeling for drug product storage.	Compliant	
47.06	Temperature monitoring in the refrigerator is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. Alternatively, continuous monitoring or retroactive detection using min/max may be used. *Temperature records are maintained.*	Compliant	
47.07	Temperature in the freezer is maintained to provide controlled frozen temperature of -25° to -10°C (-13° to 14°F) or as specified by FDA approved labeling for drug product storage.	N/A	
47.08	Temperature monitoring in the freezer is performed at least once daily and documented. Additionally, compounding personnel shall note the storage temperature when placing the product into or removing the product from the storage unit in order to monitor any temperature aberration. *Temperature records are maintained.*	N/A	
47.09	Action plan in place for any temperature excursions including evaluating excursion effects on drug product integrity for all temperature monitored areas.	N/A	
48.00	**Humidity:** If warranted by specific drug products, humidity in the compounding area is maintained to provide humidity within the specified ranges. If drug products require storage in a "dry place", humidity is not to exceed 40%. (*Generally recommended range is 35-60% for performing sterile compounding.*)	Non-Compliant	buffer room humidity was showing 45%
48.01	If applicable, humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Non-Compliant	

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		Finding	Notes
48.02	If applicable, excursion action plan in place including evaluating excursion effects on drug product integrity.	Non-Compliant	
48.03	If applicable, humidity monitoring is also performed in drug storage areas (if separate from the compounding areas).	Non-Compliant	
49.00	Blowers on ISO 5 PECs are operated continuously during compounding activity, including during interruptions of less than eight hours.	Compliant	
50.00	When the ISO 5 PEC blower is turned off, and before other personnel enter to perform compounding activities, only one garbed person is allowed to enter the buffer area for the purposes of turning on the blower (for at least 30 minutes) and of sanitizing the work surfaces	N/A	
51.00	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	Compliant	
52.00	The inside and outside doors of a pass-through are prevented from both being open at the same time. *By interlocking, training of personnel, or signage.*	Compliant	
53.00	**If the PEC is a BSC or LAFW that is NOT located in an ISO Class 7 clean/buffer room:** BSC or LAFW has been certified to maintain ISO Class 5 during compounding activities.	N/A	
53.01	Used only for low-risk compounded preparations with a 12-hour or less BUD assigned. *If yes, list percentage.*	N/A	
53.02	All garbing requirements are adhered to.	N/A	
53.03	Located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	N/A	

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		Finding	Notes
53.04	Location does not contain any unsealed windows or doors that connect to the outdoors or areas of high traffic flow, and is not adjacent to construction sites, warehouses, or food preparation areas?	N/A	
53.05	The sink is separated from the immediate area of the ISO Class 5 BSC or LAFW (not adjacent).	N/A	
54.00	**If the PEC is a CAI/CACI that is NOT located in an ISO Class 7 clean/buffer room:** CAI/CACI has been certified to maintain ISO Class 5 under dynamic conditions including transferring of ingredients, components and devices, and during preparation of CSP.	N/A	2 CAI, 6 feet, are located within ISO 7 buffer room.
54.01	The pharmacy has documentation from the manufacturer that the CAI or CACI will meet this standard when located in worse than ISO Class 7 environments.	N/A	
54.02	The CAI or CACI is located in an area that is maintained under sanitary conditions and only traveled by persons engaging in the compounding of sterile preparations.	N/A	
54.03	The sink is separated from the immediate area of the CAI or CACI (not adjacent).	N/A	
54.04	For NIOSH hazardous compounding in a CACI that is NOT located in a clean/buffer room, the CACI is located in a physically separated area that maintains a negative pressure of 0.01" water column pressure to adjacent areas and a minimum of 12 ACPH.	N/A	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
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		Finding	Notes
Cleaning and Disinfection			
	Total Non-Compliant (includes Unknowns)	0	
55.00	Are all personnel performing cleaning appropriately garbed?	Compliant	
56.00	Is the sterile compounding area equipped with appropriate nonshedding cleaning equipment and supplies? *All cleaning tools, such as wipers, sponges, and mops, must be nonshedding, dedicated to and labeled for use in either the buffer or clean area (no wooden handles are allowed).*	Compliant	
57.00	If cleaning tools are reused, is there a procedure to rinse and sanitize the tools and an appropriate clean storage area?	N/A	
58.00	Are reusable tools appropriately labeled to prevent them from being used inappropriately?	N/A	mop heads are disposable and used for different purposes.
59.00	For cleaning and sanitizing agents that are not "ready-to-use" formulations, are there formulas and instructions for mixing or diluting the agents prior to use and is the preparation documented?	N/A	All ready-to-use formulations
60.00	Are cleaning and sanitizing agents appropriately labeled including expiration dates? *Verify no expired agents present.*	Compliant	Wolf Medical sterile IPA; and Peridox RTU
61.00	Are appropriate cleaning agents used that are effective for bacteria, viruses, fungi, and spores?	Compliant	
62.00	Is the ISO 5 PEC cleaned at the beginning of each shift, between compounding activities, at least every 30 minutes while compounding and after spills or suspected surface contamination?	Compliant	

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		Finding	Notes
62.01	If heavily soiled, cleaning includes the appropriate agent. *List agent(s) used.*	Compliant	Peridox RTU, sterile IPA and sterile water for irrigation
63.00	Does sanitizing of the ISO 5 PEC include sanitizing with sterile 70% IPA using a nonlinting wipe?	Compliant	
64.00	Does daily cleaning and sanitizing include counters and easily cleanable work surfaces?	Compliant	
65.00	Does daily cleaning include the floors starting from the clean/buffer room and working outwards? Floor cleaning is not to occur during compounding.	compliant	
66.00	If fatigue mats are used, are they cleaned daily and let dry on both sides?	N/A	
67.00	Is a tacky mat used and if so, is there a procedure in place regarding replacement?	Compliant	daily or visibly soiled
68.00	Are the ceilings, walls, all shelving, bins, carts, chairs, and the tops and sides of the primary engineering controls (PECs) thoroughly cleaned monthly? (*This includes removing everything from shelves and bins before cleaning, cleaning the undersides of cart surfaces and stools, wheels, etc.) Check inside bins and shelving for dust if you are garbed.*	Compliant	
69.00	Is enough time allocated for cleaning activities, including contact/dwell times for the cleaning/disinfection agents?	Compliant	

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		Finding	Notes
Training *Verify records of all compounding personnel (up to 10).*			
	Total Non-Compliant (includes Unknowns)	2	
70.00	There is documentation that compounding personnel are appropriately trained including policies and procedures, documentation, hazardous drug handling, cleaning/disinfection/spills, garbing/gowning/hand hygiene, and aseptic technique. *Note that "compounding personnel" includes personnel performing compounding, supervising compounding, and performing verification of compounding. List number of personnel training files viewed.*	Compliant	2 training records were reviewed.
70.01	All personnel performing compounding are not allowed to compound until training and initial testing is successfully completed.	Compliant	
70.02	All personnel that SUPERVISE compounding and/or perform verifications of other's compounding are not allowed to supervise or verify compounding until training and initial testing is successfully completed.	Compliant	
71.00	All personnel of reproductive capability who handle or compound hazardous drugs or chemicals have confirmed in writing that they understand the risks of handling hazardous drugs. *Teratogenicity, carcinogenicity, reproductive issues.*	N/A	
72.00	There is documentation, such as an observational checklist, that all personnel (including housekeeping or other outside personnel) that perform cleaning activities in the compounding areas including hazardous compounding areas are appropriately trained in garbing, cleaning and disinfection.	Compliant	
73.00	There is documentation of training on the operation of any equipment that may be used when preparing compounded sterile products. *Documentation needs to include training on operation, and troubleshooting*	Compliant	

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		Findings	Notes
74.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, training and certifications are verified. *View documentation.*	N/A	
75.00	There is documentation that all compounding personnel (including those supervising or performing verifications) have passed an initial written exam, and subsequent annual written exams for the appropriate compounding risk levels and NIOSH hazardous drugs when applicable. *Indicate frequency, if testing more than annually*	Compliant	Competency testing is done every 6 months.
76.00	There is documentation that all compounding personnel have passed an initial and subsequent annual competency assessments of aseptic compounding skills using observational audit tools including handling NIOSH hazardous drugs when applicable. Compounding skills evaluation to include use of equipment. *Indicate frequency, if testing more than annually.*	Compliant	Competency testing is done every 6 months.
77.00	There is documentation that new compounding personnel have passed an initial observed gowning procedure and three gloved fingertip sampling tests? *Personnel must pass the tests upon initial validation before being allowed to compound . Action required if the tests yield any garbing deficiencies, or if the sampling results are >0 colony-forming units (CFU)/plate on the three initial validations. Indicate frequency, if testing more than annually.*	Compliant	Initial gowning and initial 3 sets of gloved fingertip sampling are performed once before starting to compound
78.00	There is documentation that compounding personnel preparing low or medium risk-level products have passed an annual observed gowning procedure and gloved fingertip sampling test. *Action required if the tests yield any garbing deficiencies, or if the fingertip sampling results are >3 CFU (total both hands, all 10 fingers). Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than annually.*	Compliant	The pharmacy conducts aseptic competency testing following high risk compounding process every 6 months.
79.00	There is documentation that a media fill test procedure is performed for each compounding employee at least annually for individuals that prepare low or medium risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are incubated and failure is indicated by visible turbidity in the medium on or before 14 days. Indicate frequency, if testing more than annually.*	Non-Compliant	The pharmacy conducts aseptic competency testing following high risk compounding process every 6 months. Repeater pump was not incorporated.

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		Finding*	Notes
80.00	The media-fill testing procedures include:		
80.01	Media selection (including obtaining COAs or growth promotion certificates from suppliers)	Compliant	
80.02	Fill Volume	Compliant	
80.03	Incubation time and temperature (Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.)	Compliant	
80.04	Inspection of filled units	Compliant	
80.05	Documentation	Compliant	
80.06	Interpretation of results	Compliant	
80.07	Action levels set with the corrective actions required	Compliant	
81.00	**High-Risk Sterile Compounding:** There is documentation that compounding personnel have passed an observed gowning procedure and gloved fingertip sampling test every six (6) months. *Action required if the tests yield any garbing deficiencies, or if the sampling results are >3 CFU on both hands upon revalidation. Documentation to include type of media used, COA on media, incubation time and temperature and interpretation of results. Indicate frequency, if testing more than every 6 months.*	Compliant	

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		Finding	Notes
82.00	**High-Risk Sterile Compounding:** There is documentation that a media fill test procedure is performed for each compounding employee at least every six (6) months for individuals that prepare high risk-level products. *The test conditions must closely simulate the most challenging or stressful conditions encountered during compounding of the highest risk level product and include any automation used in compounding. Media-filled vials are generally incubated at 20° to 25° or at 30° to 35° for a minimum of 14 days. If two temperatures are used for incubation of media-filled samples, then these filled containers should be incubated for at least 7 days at each temperature.*	Compliant	
83.00	**Failed testing:** Employees who have failed any testing are prohibited from compounding until training is performed/reviewed and subsequent testing is performed successfully.	Compliant	
83.01	Gloved fingertip tests that have failed have the organisms identified down to the genus to determine the most likely source of the contamination. This data is used to develop plans to prevent contamination.	Non-Compliant	
83.02	There is a plan to evaluate the sterile compounds prepared by an employee with failed gloved fingertip tests or media fills to detect potential contamination of the sterile preparations compounded.	Compliant	
	Garbing		
	Total Non-Compliant (Includes Unknowns)	0	
84.00	Personnel are prohibited from compounding, or entering the clean/buffer room or anteroom if they have a rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection.	Compliant	
85.00	Personnel are required to remove all personal outer garments such as hats, scarves, sweaters, vests, coats, or jackets and any makeup or cosmetics before entering compounding areas. *Include observations in the comments.*	Compliant	Personnel first is to enter the prep area for non-sterile compounding, garb and gown and then enter the ISO 7 anteroom for garbing and gowning ready for sterile compounding.
86.00	Personnel are required to remove all hand and wrist jewelry, and all visible jewelry or piercings such as earrings, lip or eyebrow piercings, etc. before entering clean/buffer room.	Compliant	

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		Finding*	Notes
87.00	Personnel are prohibited from wearing artificial nails or extenders, and required to keep natural nails neat and trimmed.	Compliant	
88.00	Garbing with dedicated shoes or shoe covers that are donned as the line of demarcation is crossed (with the dedicated or covered shoe never touching the same side of the line of demarcation as the dirty shoe).	Compliant	
89.00	Garbing includes head and facial hair covers and masks. *Note that facial hair requires both a facial hair cover AND a mask. Eye shields are optional unless using cleaning agents or preparing hazardous drugs. There is a method available to assure that all hair is covered.*	Compliant	
90.00	Hand cleaning is performed in the anteroom and includes removing debris from under the nails with a nail cleaner followed by a vigorous washing of the hands and forearms with soap for at least 30 seconds with hands and arms then dried with a non-linting disposable towel or a hand dryer. *Scrub brushes are NOT recommended as they cause skin irritation and damage.*	Compliant	
91.00	The gown is nonshedding with sleeves that fit snugly around the wrists and enclosed at the neck.	Compliant	
92.00	All bare skin is covered on the arms and the legs (no bare ankles, wrists, etc.).	Compliant	
93.00	Prior to donning sterile gloves, a waterless alcohol based surgical hand scrub with persistent activity is used and hands allowed to dry. *Note: regular Purell Hand Sanitizer is NOT appropriate. Purell or other brand surgical hand scrub is appropriate - must have residual activity.*	Compliant	
94.00	Upon leaving the sterile product compounding area, gowns are taken off and disposed of, or if used for nonhazardous compounding they are left in the anteroom and not reused for longer than one shift.	Compliant	

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		Finding	Notes
95.00	Pharmacists or other personnel do NOT enter the anteroom and cross the line of demarcation without donning shoe covers or dedicated shoes. *Watch for personnel traversing back and forth across the line of demarcation without doffing and donning new shoe covers or dedicated shoes.*	Compliant	
96.00	Pharmacists or other personnel do NOT enter the clean/buffer room without fully washing and garbing (wearing just a mask to check technician's work, for example)	Compliant	
Environmental Monitoring			
	Total Non-Compliant (Includes Unknowns)	**2**	
97.00	The most recent PEC and room certification report is available.	Compliant	
97.01	All ISO Class 7 and 8 SECs (clean/buffer rooms and anterooms) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	compliant	
97.02	All ISO Class 5 PECs (laminar airflow workbenches or areas, BSCs, CAIs, CACIs, and barrier isolators) have been certified within the last 6 months. *If non-compliant, record the date of the last certification.*	Compliant	
97.03	Certification is performed at least every six months (view date of previous certification) and whenever a device or room is relocated or altered, or major service to the facility is performed. *If non-compliant, record the date of the previous certification.*	Compliant	
97.04	Certification is performed to the Controlled Environment Testing Association (CETA) guide (USP: CETA CAG-003-2006 Certification Guide for Sterile Compounding Facilities) and is noted on the report.	Compliant	

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Sterile Compounding Inspection

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Findings	Notes
97.05	If the certification standard used and noted on the report is NOT CETA CAG-003-2006, the facility has performed a comparison and determined the standard used is the same or better than the CETA CAG-003-2006 guide.	N/A	
97.06	The PIC/compounding supervisor is familiar with what testing is required and interpretation of results, ensures all testing is performed appropriately (under dynamic conditions where appropriate), has action levels identified, evaluates results to detect issues or trends, and action levels are further customized based on trended data of performance.	Compliant	
98.00	The certification report includes information about the equipment used for performing each test including: identification of the equipment used by model, serial number, last calibration date (or date when next calibration is due).	Compliant	
98.01	The equipment used had not exceeded its calibration date at the time of certification.	Compliant	
99.00	The HEPA filtered air changes per hour (ACPH) were measured for the compounding rooms.	Compliant	
99.01	ISO Class 7 sterile compounding room is certified as having a minimum of 30 ACPH with at least 15 ACPH from outside air sources. *Recirculated air from the PECs may account for up to 15 ACPH in nonhazardous classified rooms only.*	Compliant	
99.02	ISO class 7 anteroom is certified as having a minimum of 30 ACPH. *Anteroom must be ISO class 7 if connected to a NIOSH hazardous compounding clean/buffer room.*	Compliant	The pharmacy has a negative pressure room ISO 7 currently being decommissioned. Hoods were not on. Anteroom was certified as ISO 7.
99.03	ISO class 7 hazardous sterile compounding room is certified as having a minimum of 30 ACPH. *Typically all of the air will be from outside.*	N/A	The pharmacy does not compound HD sterile compound.

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		Finding	Notes
99.04	If a CACI is used in a non-HEPA filtered room, the room is certified to maintain a minimum of 12 ACPH.	N/A	2 CAIs are located with positive pressure buffer room
100.00	Air pattern analysis using smoke testing was performed under dynamic conditions (people working in the PECs and rooms). The smoke flow is described in the report for the various tests such as turbulent, sluggish, smooth, etc.	Non-Compliant	No personnel were working in the room other than the certifier.
100.01	Air pattern analysis was conducted at the critical area (direct compounding area inside the ISO Class 5 PEC) to demonstrate unidirectional airflow and sweeping action over and away from the product under dynamic conditions (personnel compounding or simulating compounding in PEC).	N/A	CAIs were used for compounding.
100.02	Air pattern analysis was conducted to confirm positive pressure (and negative pressure into hazardous compounding rooms) at all points around all openings, doorways, and pass-throughs	Compliant	
100.03	Air pattern analysis conducted around particle generating equipment *while the equipment was in operation* to confirm air flow.	Non-Compliant	
101.00	Differential air pressure between rooms was measured.	Compliant	
101.01	The differential pressure measured was at least 0.02" water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed.	Compliant	
101.02	The differential pressure measured was at least 0.01" water column negative from the hazardous clean/buffer room to the anteroom with the doors closed.	N/A	

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		Finding	Notes
102.00	Displacement airflow between rooms or areas was measured. This is for a clean/buffer room without a door that closes to the anteroom - may be an open space or may have plastic strips in doorways.	N/A	
102.01	Displacement airflow (for low and medium-risk non-hazardous rooms only) was measured at a minimum differential velocity of 40 feet per minute from the cleanroom to the anteroom. *Note that it is very important to maintain this velocity across the entire opening and the report should indicate multiple points of measure across all openings.*	Compliant	
103.00	Particle counts of particles 0.5um and larger were measured under dynamic conditions.	Compliant	
103.01	ISO Class 5 areas and PECs are certified as having less than 3,520 particles per cubic meter of air (100 particles per cubic foot).	Compliant	
103.02	ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air (10,000 particles per cubic foot).	Compliant	
103.03	ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air (100,000 particles per cubic foot).	N/A	
104.00	HEPA filter tests were performed.	Compliant	
104.01	All room HEPA filters were leak tested and if leaks found, they were fixed	Compliant	
104.02	All PEC HEPA filters were leak tested and if leaks found, they were fixed	Compliant	
105.00	PECs with failed tests are not used for compounding until the conditions are corrected and verified by subsequent testing.	Compliant	

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		Finding	Notes
106.00	Viable air (every six months) and surface sampling (periodically) tests have been conducted as required. *Document frequency.*	Compliant	
106.01	Appropriate growth media used (containing tryptic soy agar medium with polysorbate and lecithin (TSApl) added to neutralize cleaning agents for surface sampling) with appropriate corresponding incubation time and temperature used. *Required to use media that supports both bacterial and fungal growth for high risk compounding.*	Compliant	
106.02	Viable air sampling by active impaction using a volumetric air sampling device. *NOTE: Passive air sampling or settling plates are not compliant with USP Chapter <797>.*	Compliant	
106.03	Air samples were taken in each ISO Class 5 PEC, and in each sterile compounding room and anteroom and volume sufficient volume of air (400-1000L) was collected? *Note: 1000L must be collected in ISO Class 5 PECs to be able to detect the action level. Room samples can be 400-1000L.*	Compliant	
106.04	Surface samples performed on all direct compounding areas inside of each ISO 5 PEC, in each ISO classified room, inside any pass-throughs, and on surfaces likely to be contaminated due to position relative to doorways, etc.	Compliant	
106.05	Viable air and surface samples did not exceed USP action levels (or internal action levels if more restrictive). Classification — Air Sample — Surface Sample ISO Class 5 — >1 CFU/m3 — >3 CFU/plate ISO Class 7 — >10 CFU/m3 — >5 CFU/plate ISO Class 8 — >100 CFU/m3 — >100 CFU/plate *CFUs are TOTAL of bacterial plus fungal/mold plates. If air sampling volume is less than 1000 liters (one cubic meter), the raw total microbial count must be multiplied by the appropriate factor to determine the number of CFU/cubic meter.*	Compliant	

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		Finding	Notes
106.06	CFUs detected by any means (viable air or surface sampling, gloved fingertip testing, failed sterility tests, etc.) are identified to the genus level. *All CFUs detected must be identified even if the number of CFUs does not exceed an action level.*	Compliant	
106.07	If the number of CFUs detected in the rooms exceeds action levels, begin immediate remediation (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
106.08	If the number of CFUs detected in the PECs exceeds action levels, begin immediate remediation, (e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
106.09	If any highly pathogenic microbes (e.g. mold, yeast, coagulase positive staphylococcus, or gram negative rods) were detected (whether or not the number of CFUs exceeds action levels), begin immediate remediation(e.g. recleaning and retesting); and conduct investigation into the source(s) of the contamination.	Compliant	
107.00	Facilities performing routine air or surface sampling with internal qualified personnel routinely verify sampling procedures. *Indicate the outside vendor used to verify procedures and frequency of verifications.*	Compliant	RC testing certifies the room every 6 months.
Equipment			
	Total Non-Compliant (Includes Unknowns)	2	
108.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (autoclaves, ovens, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines.*	Compliant	
109.00	All environmental monitoring equipment and gauges (differential pressure gauges or probes, air flow and velocity measuring equipment for rooms not fully enclosed, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented.	Compliant	

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#		Finding	Notes
110.00	All temperature and humidity (where applicable) monitoring devices (thermometers, hygrometers, probes, etc.) are periodically inspected, and calibrated yearly or in accordance with the equipment manufacturer guidelines. Calibration is documented	Non-Compliant	Calibration needs to be documented. The pharmacy stated that they would implement 24/7 temp humidity monitoring in all compounding rooms.
111.00	Automated Compounding Devices (ACDs) are used for sterile compounding (such as repeater pumps) and there is a P&P for the use and calibration.	Compliant	
111.01	There is documentation of the ACD tubing being changed or discarded every 24 hours	Compliant	
111.02	The ACD is used when performing media fill testing.	Non-Compliant	

Compounding Procedures

#	Total Non-Compliant (Includes Unknowns)	Finding	Notes
		1	
112.00	Gloves are disinfected with adequate frequency with an approved disinfectant, such as sterile 70% isopropyl alcohol (IPA).	Compliant	
113.00	Nonessential objects that shed particles are prohibited in the buffer or clean area, including pencils, cardboard cartons, paper towels, reading material, and cotton items (e.g., gauze pads)?	Compliant	
114.00	Essential paper related products (syringe overwraps, work records contained in a protective plastic sleeve) are wiped down with sterile 70% IPA before being brought into the buffer or clean area.	Compliant	
115.00	Supplies required for the scheduled operations of the shift are prepared by wiping the outer surface with sterile 70% IPA (or removing the outer wrap as the item is introduced into the aseptic work area) and brought into the buffer or clean area in a bin or on a movable cart.	Compliant	

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		Finding	Notes
116.00	Compounding employees are using appropriate aseptic technique. *May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). Compounding MUST be observed, if compounding is not being performed at the time of survey mark item as "Non-Compliant".*	Compliant	
116.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "Denial of Authorization" form. List individual who signs the Denial of Authorization*		
117.00	Compounding personnel ascertain that ingredients for CSPs are of the correct identity and appropriate quality by reading vendors' labels, and a unit-by-unit physical inspection of the product before use.	Compliant	
118.00	All rubber stoppers, of vials and bottles and the necks of ampules are disinfected with sterile 70% IPA waiting for at least 10 seconds before they are used to prepare CSPs.	Compliant	
119.00	Single-dose vials exposed to ISO Class 5 or cleaner air are used within six (6) hours of the initial puncture and any remaining contents discarded. *If exposed to less than ISO Class 5 air, used within 1 hour and discarded.*	Compliant	
120.00	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *May not be stored for any time period.*	Compliant	
121.00	Multiple-dose vials formulated for removal of portions on multiple occasions are used within 28 days (or the manufacturer's specific BUD if less) after the initial entry or puncture and any remaining contents discarded.	Compliant	

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		Finding	Notes
122.00	The compounding record is complete. *View several completed compounding records and answer each of the following questions. List records reviewed.*	Compliant	
122.01	Official or assigned name, strength and dosage of the preparation	Compliant	
122.02	Names, lot numbers and expiration dates of all components	Compliant	
122.03	Total quantity or number of units compounded	Compliant	
122.04	Person compounding the preparation	Compliant	
122.05	Person performing the quality control procedures	Compliant	
122.06	Person who approved the preparation	Compliant	
122.07	Date of compounding	Compliant	
122.08	Assigned internal identification number or prescription number	Compliant	
122.09	Assigned BUD and reference if extended beyond USP guidelines	N/A	
122.10	Duplicate label	Compliant	
122.11	Sterilization method (if applicable)	Compliant	
122.12	Indication of the quality control procedures to perform (testing, filter integrity, etc.) and results of the testing, quality control issues, and investigation/recall if applicable	Compliant	

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		Finding	Notes
123.00	Procedure for in-process checks is followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper measurement, reconstitution, and component usage.*	Compliant	
124.00	Labels on BATCH preparations include the name and quantity of all contents, date, and time of preparation (or internal code indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	The PIC stated that anticipatory compounding is 10 days.
125.00	Labels on PATIENT-SPECIFIC containers, in addition to standard label requirements, also include names and quantity or concentration of active ingredients, BUD, total volume, route of administration, storage conditions and other information for safe use.	Compliant	
126.00	Inspect several different finished products and look for any particulates. Do any of the finished products inspected show any evidence of particulates? *If so, list the products including lot and expiration date and obtain photos (if possible).* **REQUEST THE PRODUCT BE QUARANTINED AND NOTIFY NABP IMMEDIATELY.**	Compliant	
127.00	Preparations without additional stability testing or supported by data are assigned BUDs within USP<797> guidelines. **Low Risk:** 48 hours room temp, 14 days refrigerated, 45 days frozen **Medium Risk:** 30 hours room temp, 9 days refrigerated, 45 days frozen **High Risk:** 24 hours room temp, 3 days refrigerated, 45 days frozen	Compliant	
128.00	If extended BUDs are assigned, are they assigned on the basis of stability data extrapolated from reliable literature sources? *View records, preparation must exactly match the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*	Compliant	

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		Finding	Notes
129.00	If extended BUDs are assigned, has the facility performed its own stability testing? *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc. If so, view records for at least three products and list the products reviewed below. List the products reviewed.*	Unknown	Currently the pharmacy performs time point potency testing not stability testing. For Semaglutide API compound, since it does not have USP monograph, the pharmacy assigns 30 day BUD based upon commercial product dating. The PIC confirmed that the pharmacy holds the product for 14 days until sterility testing is cleared.
130.00	Compounded multiple-dose vials with extended BUDs assigned have additional instruction provided that indicates remainder must be discarded 28 days after first puncture or use.	Compliant	
131.00	**Filter sterilization** in an ISO 5 environment and documentation includes:	[redacted]	
131.01	If the compounded preparation contains large particles, a prefilter is placed upstream from the sterilizing filter.	Compliant	
131.02	The 0.2 micron sterile microporous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP; and the filter is intended for human-use applications for sterilizing CSPs (labeling on the filter does not indicate "research only" or "laboratory only", for example).	Compliant	
131.03	Is the appropriate capacity filter being used for the volume being filtered.	Compliant	
131.04	Filtering is completed rapidly without filter replacement.	Compliant	
131.05	Confirmation of filter integrity/bubble testing is performed and value documented for each filter used with each batch sterilized by filtration. View documentation on compounding records of items sterilized by filtration to confirm.	Compliant	
132.00	**Steam sterilization** documentation includes:	[redacted]	

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		Finding	Notes
132.01	The autoclave has been verified for the exposure time and mass of the items to be sterilized	N/A	The PIC stated that the pharmacy purchases sterile vials and syringes.
132.02	Ensures live steam contacts all ingredients and surfaces to be sterilized, effectiveness verified with biological indicators and temperature sensing devices	N/A	
132.03	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization	N/A	
132.04	That the CSP will not be adversely affected by the steam and heat	N/A	
132.05	The description of steam sterilization includes conditions and duration for specific CSPs	N/A	
132.06	That the effectiveness of steam sterilization is verified each time using appropriate biological indicators of Bacillus stearothermophilus and other confirmation methods such as temperature-sensing devices.	N/A	
133.00	Dry heat sterilization documentation includes:		
133.01	Dry heat is only used for those items that cannot be sterilized by steam or would be damaged by moisture	N/A	
133.02	Sufficient space is left between materials to allow for air circulation	N/A	
133.03	The description of dry heat sterilization includes conditions and duration for specific CSPs	N/A	
133.04	That the effectiveness of dry heat sterilization is verified each time using appropriate biological indicators of Bacillus subtilis and other confirmation methods such as temperature-sensing devices.	N/A	

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		Finding	Notes
133.05	Heated filtered air is evenly distributed throughout the chamber with a blower and the oven is equipped with a system for controlling and recording temperature and exposure period.	N/A	
134.00	**Depyrogenation by dry heat** documentation includes:		
134.01	Dry heat depyrogenation is used to render glassware and containers (such as vials) free from pyrogens as well as viable microbes	N/A	
134.02	The description of the cycle and duration for specific load items	N/A	
134.03	The effectiveness of the cycle is verified using endotoxin challenge vials (ECVs)	N/A	
134.04	Bacterial endotoxin testing is performed on the ECVs to verify the cycle is capable of achieving a 3-log reduction in endotoxins	N/A	
135.00	Other methods of sterilization are used with documented procedures and validation performed. *Indicate method.*	N/A	
Finished Preparation Release Checks and Tests			
	Total Non-Compliant (Includes Unknowns)	1	
136.00	Are products visually checked for particulates or other foreign matter against both a light and a dark colored background as a condition of release?	Non-Compliant	
137.00	Are there checks for container, closure integrity and any other apparent visual defects?	Compliant	
138.00	Is compounding accuracy documented by verification of steps?	Compliant	

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		Finding	Notes
139.00	Is verification of ingredient identity and quantity verified? *Is there a reconciliation of components?*	Compliant	
140.00	Are labels verified as being correct and is a copy of the label included in the record? *Complies to regulation, contains the correct names and amounts or concentrations of ingredients, total volumes, BUDs, storage conditions, and route of administration.*	Compliant	
141.00	**Sterility testing (USP <71>).** *If testing is performed to a higher standard than the minimums below, describe.*		
141.01	Sterility testing includes both bacterial and fungal testing.	Compliant	
141.02	Sterility testing is performed for all CSPs that have extended BUDS.	Compliant	
141.03	Sterility testing is performed for high-risk CSPs prepared in batches of more than 25 identical containers	Compliant	
141.04	Sterility testing is performed for CSPs exposed longer than 12 hours at 2°C-8°C or longer than six hours at warmer than 8°C before being sterilized	Compliant	
141.05	The appropriate quantities of units are sterility tested. Parenterals, number of units in the batch is: 1. Not more than 100, test 10% or four units, whichever is greater 2. More than 100 but more than 500, test 10 units 3. More than 500, test 2% or 20 units, whichever is less For large volume parenterals: 2% or 10 containers, whichever is less. For non-parenterals (eye drops, inhalation, etc.): 1. Not more than 200 containers, test 5% or 2 containers, whichever is greater 2. More than 200, test 10 containers 3. If the product is packaged in unit doses, use the parenteral testing above.	Compliant	
141.06	For products failing testing, product is quarantined, and an investigation is performed including microbial identification and action taken. *View testing records and note any products with failed results and actions taken.*	Compliant	

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Sterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
141.07	If items are dispensed or distributed prior to sterility testing completion, there is a written procedure requiring daily observation of the incubated media. If there is any evidence of microbial growth, there is an immediate recall and both the patient and the physician/prescriber of the patient to whom a potentially contaminated CSP was administered are notified of the potential risk. *View testing records and note any products with failed results and actions taken.*	Compliant	
142.00	**Endotoxin testing (USP <85>).** *If testing is performed to a higher standard than the minimums below, describe.*		
142.01	Is endotoxin testing performed for all high-risk level CSPs for administration by injection prepared in groups of more than 25 single-dose packages (such as ampules, bags, syringes, vials)	Compliant	
142.02	High-risk CSPs prepared in multiple dose vials for administration to multiple patients	Compliant	
142.03	High-risk CSPs exposed longer than 12 hours at 2°C-8°C (25°F-46°F) or longer than six (6) hours at warmer than 8°C (46°F) before they are sterilized	Compliant	
142.04	For products failing testing, product is quarantined, and an investigation is performed and action taken. *View testing records and note any products with failed results and actions taken.*	Compliant	

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e-Profile ID: 793515
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		Finding	Notes
Patient Counseling and Communication			
	Total Non-Compliant (includes Unknowns)	**2**	
143.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of hazardous products such as chemotherapy medications?	Compliant	
144.00	Are the above required printed drug information materials (drug information, PPI, MedGuides, etc.) provided for the compounded products?	Non-Compliant	
145.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Non-Compliant	
146.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated CSP was administered are notified of the potential risk.	Compliant	

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Hazardous Drugs - Handling in Health Care Settings

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e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
	General Information and Scope:		
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that require all the containment requirements of USP <800>?	Yes	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	Testosterone, Progesterone, Methimazole, Estradiol are the most compounded. The complete list is attached.
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	No	
2.00	Does the pharmacy handle any drugs on the NIOSH list that do not require all containment requirements of <800>?	No	The general HD policy is to treat all non-sterile compounding process per USP 800. This process includes the receipt of APIs, opening of boxes, taking to the negative pressure hoods for further examination. If the APIs are HD, they are moved to a negative pressure venting cabinet. All four non-sterile compounding rooms are in negative pressure. Each room is dedicated to specific dosage forms. Both rooms and hoods can be used for both HD and non-HD compounds. The PIC stated that the cleaning process is in compliance to USP 800. Cleaning uses PeridoxRTU followed by dwell time. Garbing gowning is the only area that differentiates. If compound API is deemed as HD on the list, extra pair of ASTM chemo grade glove and extra layer of chemo impermeable gown are applied. Doffing process was also reviewed.
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	No	
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	Yes	See the list from 1.01
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	No	

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		Finding	Notes
List of Hazardous Drugs			
	Total Non-Compliant (Includes Unknowns)	0	
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Compliant	The list refers the one from 1.01.
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Compliant	Every year, the PIC prints out an updated list that is applicable to the practice.
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Compliant	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Compliant	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Compliant	
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Compliant	

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		Finding	Notes
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	N/A	The pharmacy has a specific methodology applied in handling all APIs and compounds APIs. (see 2.00)
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	N/A	No specific assessment has been performed. The pharmacy treats all APIs the same per 2.00.
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	N/A	
8.02	Dosage form;	N/A	
8.03	Risk of exposure;	N/A	
8.04	Packaging;	N/A	
8.05	Manipulation; and	N/A	
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	N/A	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	N/A	

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
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		Finding	Notes
Personnel Responsibilities			
	Total Non-Compliant (Includes Unknowns)	0	
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Compliant	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Compliant	
Documentation and Standard Operating Procedures (SOPs)			
	Total Non-Compliant (Includes Unknowns)	8	
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:	[redacted]	Page 321 of the SOP addresses the assessment SOP " an assessment of risk is not performed, all HDs must be handled with all containment strategies defined in USP <800>." The PIC states that all APIs are handled with containment strategies in handling and compounding processes, except the garbing gowning differentiation.
10.01	**Receiving:** Contacting HD residues on packaging, work surfaces, floors	Unknown	
10.02	**Dispensing:** Counting or packaging tablets and capsules	Unknown	

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		Finding	Notes
10.03	**Compounding/other manipulations:** Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Unknown	
10.04	**Administration and other patient care activities** (if applicable).	Unknown	
10.05	**Spills:** Spill generation, management, and disposal.	Unknown	
10.06	**Transport**	Unknown	
10.07	**Waste:** Collection and disposal of HD waste and trace contaminated waste	Unknown	Waste spill SOP was reviewed. No assessment was performed for each API that is being handled.
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Compliant	
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Compliant	Electronically available. The inspector reviewed SOP included the application.
13.00	SOPs address at a minimum:		
13.01	Hazard communication program plan	Compliant	
13.02	Competent personnel	Compliant	

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Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
13.03	Occupational safety program	Compliant	
13.04	Designation of HD areas	Compliant	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Compliant	
13.06	A list of HDs	Compliant	
13.07	Storage of HDs	Compliant	
13.08	Compounding of HDs	Compliant	
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C-PECs], containment secondary engineering control [C-SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Compliant	
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Compliant	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents used	Compliant	
13.11.02	Dilutions, if used	Compliant	

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Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
13.11.03	Frequency	Compliant	
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Compliant	
13.11.05	Documentation requirements	Compliant	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Compliant	
13.13	If a shipping container appears damaged and **does not need to be opened:**		
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Compliant	
13.13.02	Labeled as "hazardous"; and	Compliant	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Compliant	
13.14	If a damaged shipping container **must be opened:**		
13.14.01	Container is sealed in plastic or an impervious container;	Compliant	

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		Finding	Notes
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Compliant	
13.14.03	container is placed on a plastic-backed preparation mat;	Compliant	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Compliant	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Compliant	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Compliant	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Compliant	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	Compliant	
13.15	Safe work Practices SOPs	Compliant	
13.16	Dispensing SOPs	Compliant	
13.17	Packaging and labeling SOPs	compliant	
13.18	Transport SOPs	Compliant	

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e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
13.19	Administering SOPs, if applicable	Compliant	
13.20	Environmental monitoring (eg, wipe sampling) SOPs	Compliant	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Compliant	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		
13.22.01	Size and scope of spill;	Compliant	
13.22.02	Responsible person for handling spills;	Compliant	
13.22.03	Location of spill kits and clean-up materials;	Compliant	
13.22.04	Capacity of the spill kits;	Compliant	
13.22.05	PPE to be worn during spills;	Compliant	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Compliant	

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		Finding	Notes
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Compliant	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Compliant	
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	No	The SOP Additional Document XI 4-14. The PIC stated that the pharmacy currently does not have this program implemented.
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Compliant	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		IV 04-01 is in the SOP. The personnel stated that the pharmacy currently does not have an implemented program.
15.01	A written plan that describes how the standard will be implemented;	Non-Compliant	

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		Finding	Notes
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Compliant	
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Compliant	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Compliant	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Compliant	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Compliant	
Personnel Training - *Check four employee files for documentation*			
	Total Non-Compliant (Includes Unknowns)	0	
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Compliant	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Compliant	

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		Finding	Notes
18.00	For non-sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Compliant	
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	N/A	
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Compliant	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Compliant	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Compliant	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Compliant	

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Hazardous Drugs - Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
23.02	Review of the SOPs related to HDs;	Compliant	
23.03	Proper use of PPE;	Compliant	
23.04	Proper use of equipment and devices (eg, engineering controls);	Compliant	
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Compliant	
23.06	Response to known or suspected HD exposure;	Compliant	
23.07	Spill management;	Compliant	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Compliant	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Compliant	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	N/A	The pharmacy did not conduct fit test, nor did HD risk assessment. The PIC stated that all personnel wear N-95 masks in the compounding room regardless of the nature of APIs being HD or non-HD.

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		Finding	Notes
Personal Protective Equipment			
	Total Non-Compliant (Includes Unknowns)	1	
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Compliant	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Compliant	
26.02	Storage;	Compliant	
26.03	Transport;	Compliant	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Compliant	
26.05	Sterile Compounding (if performed by the pharmacy);	N/A	
26.06	Administration, if applicable;	N/A	

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		Finding	Notes
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Compliant	
26.08	Spill control;	Compliant	
26.09	Waste disposal; and	Compliant	
26.10	If administering injectable antineoplastic, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	
27.00	Disposable PPE is not reused.	Compliant	
28.00	Reusable PPE is decontaminated and cleaned after each use.	Compliant	
29.00	**Gloves:** The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Compliant	
29.01	**Recommendation:** Are *chemotherapy gloves worn for handling all HDs including non-antineoplastic and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder-free.	Compliant	

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		Finding	Notes
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Compliant	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	N/A	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Compliant	
29.06	**Recommendation:** Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	No	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Compliant	
30.00	**Gowns:** The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Compliant	
30.01	Gowns are disposable.	Compliant	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Compliant	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Compliant	

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		Finding	Notes
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Compliant	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Compliant	
30.06	Gowns worn in HD areas are not worn to other areas.	Compliant	
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Compliant	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C-SEC and doffed when exiting the C-SEC.	Non-Compliant	The pharmacy personnel currently are not donning a second pair of shoe cover while HD and non-HD nonsterile compounds can occur in the same room during the shift.
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	N/A	
32.00	**Eye and Face Protection:** The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C-PEC), if required.	Compliant	

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		Finding	Notes
32.01	If a risk to eyes, goggles (or a full-face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Compliant	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn.	N/A	
33.00	**Respiratory Protection:** The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Compliant	Anyone entering compounding room must wear N-95 masks.
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
33.03	Full-face piece, chemical cartridge-type respirator;	No	
33.04	PAPR; and/or	No	
33.05	Other (describe in notes).	No	

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		Finding	Notes
34.00	Surgical masks are not used as PPE when respiratory protection is needed.	Compliant	
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Compliant	Prep room-booty, lab coat, hair net, eye protection, N-95 (same for the day). HD impermeable gown; gloves ASTM.
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	No	
35.03	Full-face piece, chemical cartridge-type respirator;	No	
35.04	PAPR; and/or	No	
35.05	Other (describe in notes).	No	

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		Finding	Notes
36.00	Surgical masks are not used as PPE when respiratory protection is needed.	Compliant	
37.00	**Disposal of Used PPE:** Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Compliant	
37.01	Worn PPE is placed in an appropriate HD waste container.	Compliant	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Compliant	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	Compliant	

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		Finding	Notes
Facilities and Engineering Controls			
	Total Non-Compliant (Includes Unknowns)	4	
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	N/A	Per 2.0
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	N/A	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	N/A	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	N/A	

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		Finding	Notes
40.00	***Recommendation :*** *If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilotion systems in order to maintain negative pressure in the cose of power loss?*	Unknown	
41.00	**Receipt:** Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Compliant	all products after receipt are taken to a designated room and open in a designated hood and if they are deemed HD and then move to a vented cabinet in the same room.
41.01	Antineoplastic and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Compliant	
41.01.01	Neutral	N/A	
41.01.02	Negative	Yes	
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C-SEC).	Compliant	
43.00	**Storage:** Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Compliant	HDs are moved to a vented cabinet in the same room where the HDs are opened.

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		Finding	Notes
43.01	HDs are not stored on the floor.	Compliant	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Compliant	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	N/A	
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non-HDs.	N/A	No antineoplastic HDs are located onsite.
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Compliant	
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Unknown	ACPH is unknown. The rooms and hoods are not certified.
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C-SCA]).	N/A	
44.04	**Recommendation:** *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	N/A	

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		Finding	Notes
45.00	If non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastic are stored with other non-HD inventory, there is a written policy/SOP addressing it.	N/A	They are stored separately.
46.00	**Compounding:** There are appropriate engineering controls to protect the HD preparation from cross-contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	N/A	No sterile HD compounding. The pharmacy's methodology handling HDs are listed in 2.0
47.00	All HD compounding are performed within a C-PEC located in a C-SEC room.	Compliant	
47.01	The C-SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Compliant	
47.01.02	Is externally vented;	Compliant	
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Unknown	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Compliant	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Compliant	

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		Finding	Notes
48.00	The C-PEC operates continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.	Compliant	
49.00	There is a sink readily available for handwashing on the hazardous side.	Compliant	
49.01	There is an eyewash station readily available.	Compliant	
49.02	Water sources and drains are a minimum of 1 meter away from the C-PEC.	Compliant	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01-54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	N/A	The pharmacy has a negative pressure sterile buffer room but it is not in use.
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N/A	
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding**:		
50.02.01	Class I biological safety cabinet (BSC)	No	

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		Finding	Notes
50.02.02	Class II BSC	No	
50.02.03	Containment ventilated enclosure (CVE)	Yes	
50.02.04	Compounding aseptic containment isolator (CACI)	No	
50.02.05	Other, describe	No	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; and/or	Compliant	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	N/A	
52.00	Does the pharmacy use the same C-PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	No	
52.01	Is **nonsterile HD compounding** only "occasional"? *If yes, please describe frequency and quantity.*	N/A	

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		Finding	Notes
52.02	Is the nonsterile HD compounding activity only occurring when sterile HD compounding is not being performed?	N/A	
52.03	Is the C-PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C-SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Unknown	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding. *If non-compliant describe.*	Compliant	
55.00	Does the pharmacy engage in sterile HD compounding? If yes, complete 55.01-61.02.03. If no, skip to 62.	No	
55.01	Select the type(s) of containment primary engineering control(s) used for sterile HD compounding:		
55.01.01	CACI	N/A	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	N/A	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	N/A	

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Hazardous Drugs - Handling in Health Care Settings

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
55.01.04	Class II BSC, Type B1	N/A	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	N/A	
55.01.06	Class III BSC	N/A	
55.01.07	LAFW (not for antineoplastic)	N/A	
55.01.08	CAI (not for antineoplastic)	N/A	
56.00	The C-PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	N/A	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	N/A	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non-HD preparations, is the non-HD preparation placed into a protective outer wrapper during removal from the C-PEC?	N/A	
58.01	If used for both, is the non-HD preparation labeled to require PPE handling precautions?	N/A	

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		Finding	Notes
59.00	If the C-SEC is an unclassified containment segregated HD compounding area (C-SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C-SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	N/A	
59.02	A handwashing sink is at least one meter or more away from the C-PEC	N/A	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C-SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	N/A	
60.01	The buffer room has fixed walls.	N/A	
60.02	The buffer room is externally vented.	N/A	
60.03	The buffer room has HEPA-filtered supply air.	N/A	
60.04	The buffer room has at least 30 ACPH.	N/A	

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Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	N/A	
60.06	The anteroom has fixed walls.	N/A	
60.07	The ante room has a minimum of 30 ACPH of HEPA-filtered supply air.	N/A	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	N/A	
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	N/A	
61.00	If the negative-pressure HD buffer room is entered through a positive-pressure non-HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	N/A	
61.01	There is a design and method to contain and minimize HD contamination when transporting HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	N/A	
61.02	Indicate how HD contamination is minimized:		

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		Finding	Notes
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	N/A	
61.02.02	Use of sealed containers	N/A	
61.02.03	Other, *describe*	N/A	
Environmental Quality and Control - Surface wipe sampling			
62.00	**Recommendation: Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	No	The PIC stated that the pharmacy currently does not have an implemented process for surface wipe sampling.
62.01	Interior of C-PEC and equipment within the C-PEC	No	
62.02	Pass-through chambers	N/A	

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Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
62.03	Surfaces in staging or work areas near the C-PEC	No	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	No	
62.05	Areas immediately outside the HD buffer room or the C-SCA	No	
Receiving			
	Total Non-Compliant (Includes Unknowns)	0	
63.00	**Recommendation:** HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Compliant	
65.00	A spill kit is readily accessible in the receiving area.	Compliant	

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e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Compliant	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Compliant	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C- PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C-PEC.\	Compliant	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	N/A	The PIC stated that the pharmacy has not had any damaged package receipt.

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Facility Name: Castleton Pharmacy Corp dba Enexia Specialty
e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
Labeling, Packaging, Transport, and Disposal			
	Total Non-Compliant (Includes Unknowns)	2	
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Compliant	
70.00	Labeling processes do not introduce contamination into non-HD handling areas.	Compliant	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Unknown	There is no differentiation between HD and Non-HD shipping processes. Risk assessment is not performed.
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	N/A	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		

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Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
73.01	Labeling specified in SDS for transport;	Compliant	
73.02	Storage and disposal instructions; and	Compliant	
73.03	Labeled with HD category.	Non-Compliant	
Dispensing, Packaging, and Compounding Processes			
	Total Non-Compliant (Includes Unknowns)	1	
74.00	Counting of antineoplastic is done by hand (eg, not placed into automated counting devices).	N/A	
75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Non-Compliant	The CVEs are not dedicated just for HD compounding. The pharmacy applies HD cleaning process to address this instead.

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		Finding	Notes
75.01	**Recommendation:** Equipment is decontaminated after every use.	Yes	
75.02	**Recommendation:** When compounding, a plastic-backed preparation mat is placed on the C-PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	Yes	
75.02.01	Immediately if a spill occurs	Yes	
75.02.02	Regularly during use	Yes	
75.02.03	At the end of a shift	Yes	
76.00	APIs or other powdered HDs are handled in a C-PEC during particle-generating activities, such as crushing, opening capsules, and weighing powders.	Compliant	

3000

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e-Profile ID: 793515
Inspection Date: 05/30/2023 - 05/31/2023

		Finding	Notes
Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)			
	Total Non-Compliant (Includes Unknowns)	**0**	
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Compliant	
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Compliant	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	Compliant	
79.01	Between compounding of different HDs	Compliant	
79.02	At least daily when used	Compliant	
79.03	Any time a spill occurs	Compliant	
79.04	Before and after certification	Compliant	

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		Finding	Notes
79.05	Any time voluntary interruption occurs	Compliant	
79.06	If the ventilation tool is moved	Compliant	
80.00	HD containers are wiped down prior to placing them in the C-PEC and the solution used does not alter the product label.	Compliant	
81.00	Areas, other than the work surface of the C-PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Compliant	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Compliant	
Spill Control			
	Total Non-Compliant (Includes Unknowns)	0	
83.00	Spills are contained and cleaned immediately.	Compliant	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Compliant	

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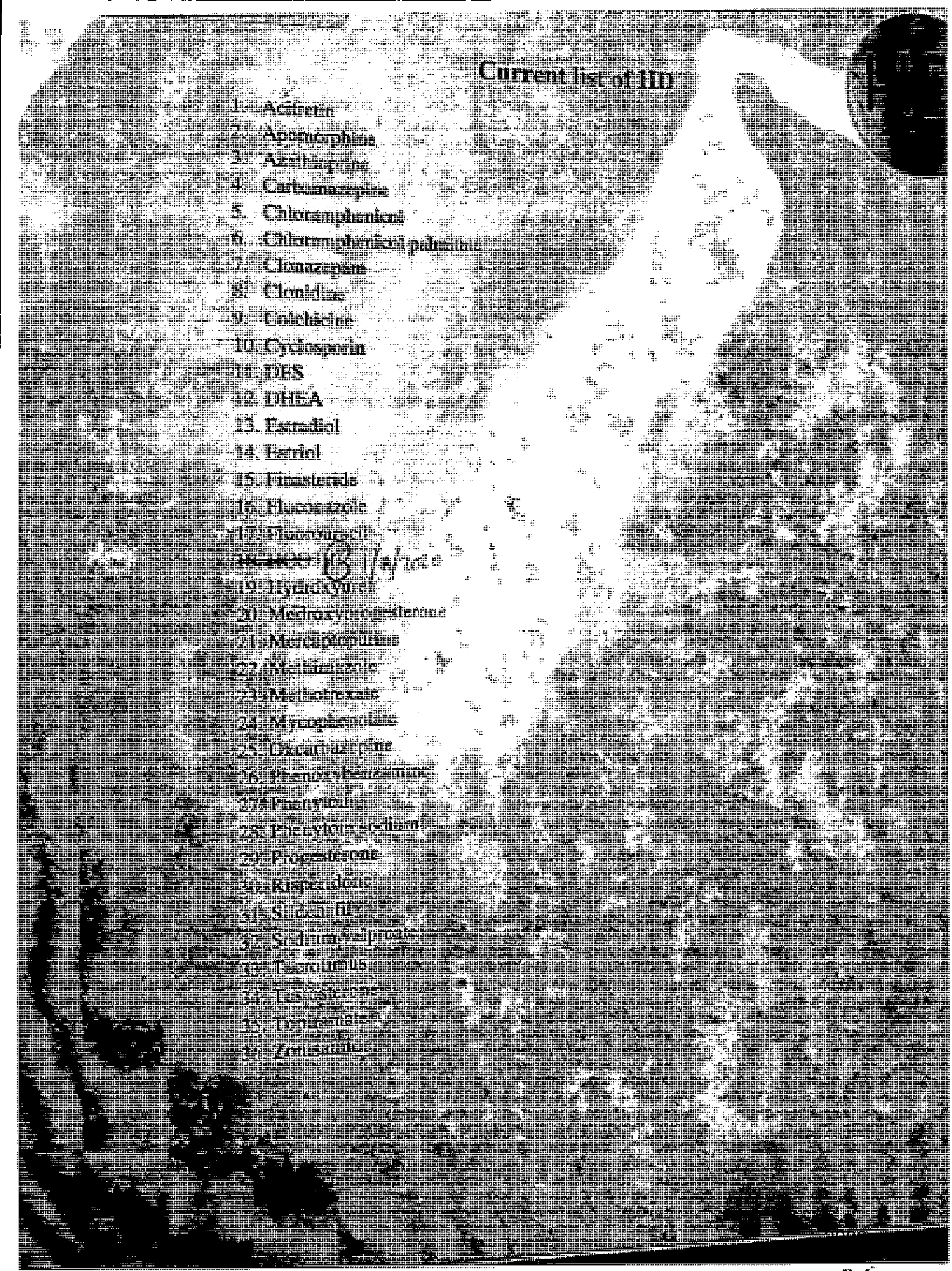
		Finding	Notes
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Compliant	
86.00	There are signs available to restrict access to spill areas.	Compliant	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Compliant	
88.00	Spill materials are disposed of as hazardous waste.	Compliant	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	N/A	No spill incidents were identified.

Acronym	Definition
ACD	Automated Compounding Device
ACOEM	American College of Occupational and Environmental Medicine
ACPH	Air Changes Per Hour
ADA	Americans with Disabilities Act
ADR	Adverse Drug Reaction
ALARA	As Low As Reasonably Achievable
API	Active Pharmaceutical Ingredient
ASHP	American Society of Health-System Pharmacists
ASTM	American Society for Testing and Materials
AU	Authorized User
BOP	Board of Pharmacy
BSC	Biological Safety Cabinet
BUD	Beyond Use Date
CACI	Compounding Aseptic Containment Isolator
CAI	Compounding Aseptic Isolator
CDC	Center for Disease Control and Prevention
CETA	Controlled Environment Testing Association
CFR	Code of Federal Regulations
CFU	Colony-forming unit
CLIA	Clinical Laboratory Improvement Amendment
COA	Certificate of Analysis
C-PEC	Containment Primary Engineering Control
CQI	Continuous Quality Improvement
CS	Controlled substance
C-SCA	Containment Segregated Compounding Area
C-SEC	Containment Secondary Engineering Control
CSOS	Controlled Substance Ordering System
CSP	Compounded Sterile Preparation
CSTD	Closed-System drug-Transfer Device
CVE	Containment Ventilated Enclosure
DBA	Doing business as
DCA	Direct Compounding Area
DEA	Drug Enforcement Administration
DME	Durable medical equipment
DOT	Department of Transportation
DUR	Drug Utilization Review
EMT	Emergency medical technician
EPA	Environmental Protection Agency

FCC	Food Chemicals Codex
FDA	Food and Drug Administration
GHS	Globally Harmonized System (of classification and labeling of chemicals)
HazMat	Hazardous Materials
HCS	Hazardous Communication Standard
HD	Hazardous Drug
HEPA	High Efficiency Particulate Air (filter)
HIPAA	Health Insurance Portability and Accountability Act
HMO	Health maintenance organization
IPA	Isopropyl Alcohol
IV	Intravenous
LAFW	Laminar Air Flow Workbench
LOD	Line of Demarcation
MSDS	Material Safety Data Sheet
MTM	Medication Therapy Management
NF	National Formulary
NIOSH	National Institute for Occupational Safety and Health
NRC	Nuclear Regulatory Commission
NSAID	Non-steroidal anti-inflammatory drug
NVLAP	National Voluntary Laboratory Accreditation Program
OIG	Office of the Inspector General
ONS	Oncology Nursing Society
OSHA	Occupational Safety and Health Administration
OTC	Over-the-Counter
P&P	Policies and Procedures
PBM	Pharmacy benefits manager
PDMP	Prescription drug monitoring program
PEC	Primary Engineering Control
PHI	Protected Health Information
PIC	Pharmacist-in-charge
PMP	Prescription Monitoring Program
PPE	Personal Protective Equipment
PPI	Patient Package Insert
QA	Quality Assurance
QI	Quality Improvement
QRE	Quality Related Event
RAM	Radioactive Material
RCRA	Resource Conservation and Recovery Act
REMS	Risk evaluation mitigation strategy

RSO	Radiation Safety Officer
Rx	Prescription
SDS	Safety Data Sheet (formerly MSDS – Material Safety Data Sheet)
SOP	Standard Operating Procedure
ULPA	Ultra Low Particulate Air (filter)
USP	United States Pharmacopeia
VAERS	Vaccine Adverse Event Reporting System
VFC	Vaccines for Children Program
WD	Wholesale distributor

Term	Definition
Dispense/dispensing	Pursuant to a patient specific prescription, labeled with patient name at the pharmacy
Distribute/distributing	Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy.
Type of Practice: Central Fill/Processing/ Shared Services	Where part of the prescription processing and dispensing process occurs at another location
Type of Practice: Closed Door	Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent
Type of Practice: HMO/PBM only	Limited to only the beneficiaries of the specific insurance program - no cash patients
Type of Practice: Institutional	Such as a hospital or jail
Type of Practice: Internet Pharmacy	Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line.
Type of Practice: Investigational Drugs, Clinical Trials or Research	Approved to handle investigational drugs
Type of Practice: Long Term Care	Nursing Home pharmacy
Type of Practice: Manufacturer	Registered with the FDA as a manufacturer
Type of Practice: Open to the Public	Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist
Type of Practice: Outsourcing Facility	Registered with the FDA as an Outsourcing Facility
Type of Practice: Provides Office Use	Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy.
Type of Practice: Specialty Pharmacy	Business is primarily with specialty drugs and works with specific disease states
Type of Practice: Telepharmacy	Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility.
Type of Practice: Traditional retail	Also known as Community Pharmacy.
Type of Practice: Veterinary Pharmacy	Pharmacy business is primarily or exclusively for animals.
Type of Practice: Wholesale Distributor	Pharmacy is licensed or registered as a wholesale distributor



Current list of HD

1. Acitretin
2. Apomorphine
3. Azathioprine
4. Carbamazepine
5. Chloramphenicol
6. Chloramphenicol palmitate
7. Clonazepam
8. Clonidine
9. Colchicine
10. Cyclosporin
11. DES
12. DHEA
13. Estradiol
14. Estriol
15. Finasteride
16. Fluconazole
17. Flunarizine
18. HCT
19. Hydroxyurea
20. Medroxyprogesterone
21. Mercaptopurine
22. Metimazole
23. Methotrexate
24. Mycophenolate
25. Oxcarbazepine
26. Phenoxybenzamine
27. Phenytoin
28. Phenytoin sodium
29. Progesterone
30. Risperidone
31. Sildenafil
32. Sodium valproate
33. Tacrolimus
34. Testosterone
35. Topiramate
36. Zonisamide

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CERTIFICATE OF ANALYSIS

PRODUCT: CALCIUM GLUBIONATE
ITEM NUMBER: 30-4832
LOT NUMBER: C202806
MFG DATE: 10/01/2022
EXPIRATION: 09/30/2025

CAS: 12569-38-9
MW: 610.5000000000
FORMULA: C18H32CaO19-H2O

MANUFACTURER TESTS

TEST	SPECIFICATIONS	RESULTS
ARSENIC	<=0.0002 %	0.0000017 %
ASSAY-AS CA CONTENT	6.10-7.10 %	6.77 %
CHLORIDE	<=0.05 %	<0.05 %
DESCRIPTION	WHITE GRANULAR POWDER	PASS
HEAVY METALS	<=0.002 %	<0.002 %
IDENTIFICATION A-CALCIUM	POSITIVE	PASS
IDENTIFICATION B-TLC	MEETS TEST	PASS
IRON	<=0.004 %	<0.004 %
LOSS ON DRYING	<=5.0 %	1.75 %
PH	6.0-9.5 5% W/V SOLUTION	6.68
SOLUBILITY	SOLUBLE IN WATER, FREELY SOLUBLE IN BOILING WATER	PASS
SULFATE	<=0.03 %	<0.03 %

Tested By: Ahmed Amin
Reviewed By: Rachel Buckner

QC APPROVED: 2022.11.23
PRINT DATE: 2023.05.27

The above test results have been obtained by our supplier or in our quality control laboratory.
This analysis is not to be construed as a warranty, expressed or implied.

3009

PCCA USA
9901 South Wilcrest Drive
Houston, TX 77099
Tel:281.933.6948
Fax: 281.933.6627

PCCA Canada
744 Baransway Drive
London, ON N5V 5J2
Tel: 800.668.9453
Fax: 519.455.0690

PCCA Australia
Unit 1. 73 Beauchamp Road
Matraville, NSW 2036
Tel: 02.9316.1500
Fax: 02.9316.7422

CERTIFICATE OF ANALYSIS

PRODUCT: CALCIUM GLUBIONATE
ITEM NUMBER: 30-4832
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CAS: 12569-38-9
MW: 610.5000000000
FORMULA: C18H32CaO19-H2O

PCCA TESTS

TEST	SPECIFICATIONS	RESULTS
CALCIUM TEST	MEETS THE REQUIREMENTS	PASS
DESCRIPTION	CREAM TO WHITE CRYSTALLINE OR GRANULAR POWDER	WHITE GRANULAR POWDER
PH	6.0-9.5 5% SOLUTION	6.4
SOLUBILITY	SOLUBLE IN WATER; FREELY SOLUBLE IN BOILING WATER	PASS

End of Report

Tested By: Ahmed Amin
Reviewed By: Rachel Buckner

QC APPROVED: 2022.11.23
PRINT DATE: 2023.05.27

The above test results have been obtained by our supplier or in our quality control laboratory.
This analysis is not to be construed as a warranty, expressed or implied.

3010

Medisca

CERTIFICATE OF ANALYSIS

ACETAMINOPHEN, USP

Batch/Lot Number :	194178	
Manufacturing Date :	09/25/2022	
Expiration Date :	08/31/2026	
CAS:	103-90-2	

This lot was manufactured by:

ANQIU LU'AN PHARMACEUTICAL CO. LTD.
NO.35 WEIXU NORTH ROAD
ANQIU CITY, SHANDONG, 262100
CN

TESTS	SPECIFICATIONS	RESULTS
ASSAY ON DRIED BASIS	98.0 - 102.0 %	99.6 %
DESCRIPTION	White, odorless, crystalline powder.	CONFORMS
IDENTIFICATION A <197A>*	IR: Reference to standard spectrum.	POSITIVE
IDENTIFICATION B*	Reference to standard chromatogram.	POSITIVE
RESIDUE ON IGNITION <281>	<= 0.1 %	0.04 %
ELEMENTAL IMPURITIES <232>	Meets the requirements.	CONFORMS
LIMIT OF FREE 4-AMINOPHENOL	<= 0.005 %	NOT DETECTED
ORGANIC IMPURITIES	<= 0.05 % (Related compound B)	0.006 %
	<= 0.05 % (Related compound C)	NOT DETECTED
	<= 0.05 % (Related compound D)	NOT DETECTED
	<= 0.001 % (Related compound J)	NOT DETECTED
	<= 0.05 % (Individual unspecified impurity)	0.005 %
	<= 0.1 % (Total impurities)	0.014 %
LOSS ON DRYING <731>	<= 0.5 %	0.09 %
RESIDUAL SOLVENTS<467>	Meets the requirements	CONFORMS
SOLUBILITY	Freely soluble in alcohol; soluble in boiling water and in 1 N sodium hydroxide.	
PACKAGING AND STORAGE	Preserve in tight, light-resistant containers, and store at room temperature. Protect from moisture and heat.	

LOT TESTED BY:

CED Analytical Laboratory Inc.
6641 N Beltline Rd Unit 130
Irving, TX 75063

PUBLISHED BY:

PUBLISHED DATE:

12/14/2022

ISSUE DATE:

12/14/2022

The above mentioned product conforms to the specifications of USP

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk. This lot was manufactured by M-ZZ1032.

All dates in this document are in format mm/dd/yyyy unless otherwise specified

This document has been electronically approved through MEDISCA's Quality Management System.

Medisca

CERTIFICATE OF ANALYSIS

ACETAMINOPHEN, USP

Batch/Lot Number :	194178
Manufacturing Date :	09/25/2022
Expiration Date :	08/31/2026
CAS:	103-90-2

This lot was manufactured by:

ANQIU LU'AN PHARMACEUTICAL CO. LTD.
NO.35 WEIXU NORTH ROAD
ANQIU CITY, SHANDONG, 262100
CN

TESTS	SPECIFICATIONS	RESULTS
*TESTED ON 12/14/2022		
Lot number has been changed from 2211006 to 194178.		

LOT TESTED BY:

CED Analytical Laboratory Inc.
6641 N Beltline Rd Unit 130
Irving, TX 75063

PUBLISHED BY:

PUBLISHED DATE:

12/14/2022

ISSUE DATE:

12/14/2022

The above mentioned product conforms to the specifications of USP

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk. This lot was manufactured by M-ZZ1032.

All dates in this document are in format mm/dd/yyyy unless otherwise specified.

This document has been electronically approved through MEDISCA's Quality Management System.

Letco MED

Letco Medical, LLC.

DATE CREATED	REVISION	PAGE
November 28, 2022	00	1 of 1

CERTIFICATE OF ANALYSIS

Letco Item	685558	685559	685560	691042
Letco Lot	2301050003	2301050004	2301050005	2301050006

DESCRIPTION	SOURCE LOT	DATE OF MANUFACTURE	EXPIRATION DATE
Hypromellose USP Methocel E4M Premium	2464220704	July 9, 2022	July 8, 2027

TEST	SPECIFICATION	RESULT	METHOD
Apparent Viscosity[1]	2663 - 4970 mPa sec	4246 mPa sec	USP/EP/JP/ChP
Loss on drying	≤ 5.0%	1.3%	USP/EP/JP/ChP
Residue on ignition	≤ 1.5%	0.3%	USP/JP/ChP
Sulfated ash	≤ 1.5%	0.3%	Current USP/EP/JP
pH[2]	5.0 - 8.0	7.8	USP/EP/JP/ChP
Methoxyl content	28.0 - 30.0%	28.9%	USP/EP/JP/ChP
Hydroxypropoxyl content	7.0 - 12.0%	8.8%	USP/EP/JP/ChP
Opalescence	Passes test	Passes test	Current EP
Color Evaluation[3]	Passes test	Passes test	Current EP

ADDITIONAL INFORMATION

The material property data reported in this CoA are representative values obtained in laboratory tests conducted on a product sample taken from the batch produced. The manufacturer certifies, that at the time of issuance of this CoA, that the material property data reported are the results of the tests conducted. It is the recipient's sole responsibility to determine the suitability and legality of its proposed use of the Products.

If provided in any language other than English, the original English version will control, and the manufacturer hereby disclaims responsibility for any errors caused by translation.

It is hereby certified by the manufacturer that the material indicated above has been manufactured in accordance with excipient and food additive GMPs, was inspected and tested in accordance with current USP/Ph.Eur./JP/ChP/E464/JECFA/FCC for Hypromellose/Hydroxypropyl Methylcellulose and, unless agreed otherwise, conforms in all respects to the specification relevant thereto.

This batch, based on audit testing and process control, is certified by the manufacturer to be NMT 10mg/kg heavy metals (as Pb) and also meets all specification requirements for harmonized identification tests, residual solvents and microbiological limits.

1) Measurement conditions: 2% in water @ 20°C
2) Measurement conditions: 2% in water
3) Measurement conditions: Solution Color

LETCO QA REVIEW: Stacie Baker

Digitally signed by Stacie Baker
DN: cn=Stacie Baker, o=Fagron, ou=Quality Assurance, email=Stacie.Baker@Fagronus.c=US
Date: 2023.04.10 16:40:14 -05'00'

Letco Medical certifies that this is a true duplication of the manufacturer's original certificate of analysis

Darmerica
198 Wilshire Boulevard
Casselberry, FL 32707
www.darmerica.com

Certificate of Analysis

Tylosin Tartrate USP

Product Name : Tylosin Tartrate
Mfg. Date : Aug 19, 2022
CAS No. : 1405-54-5

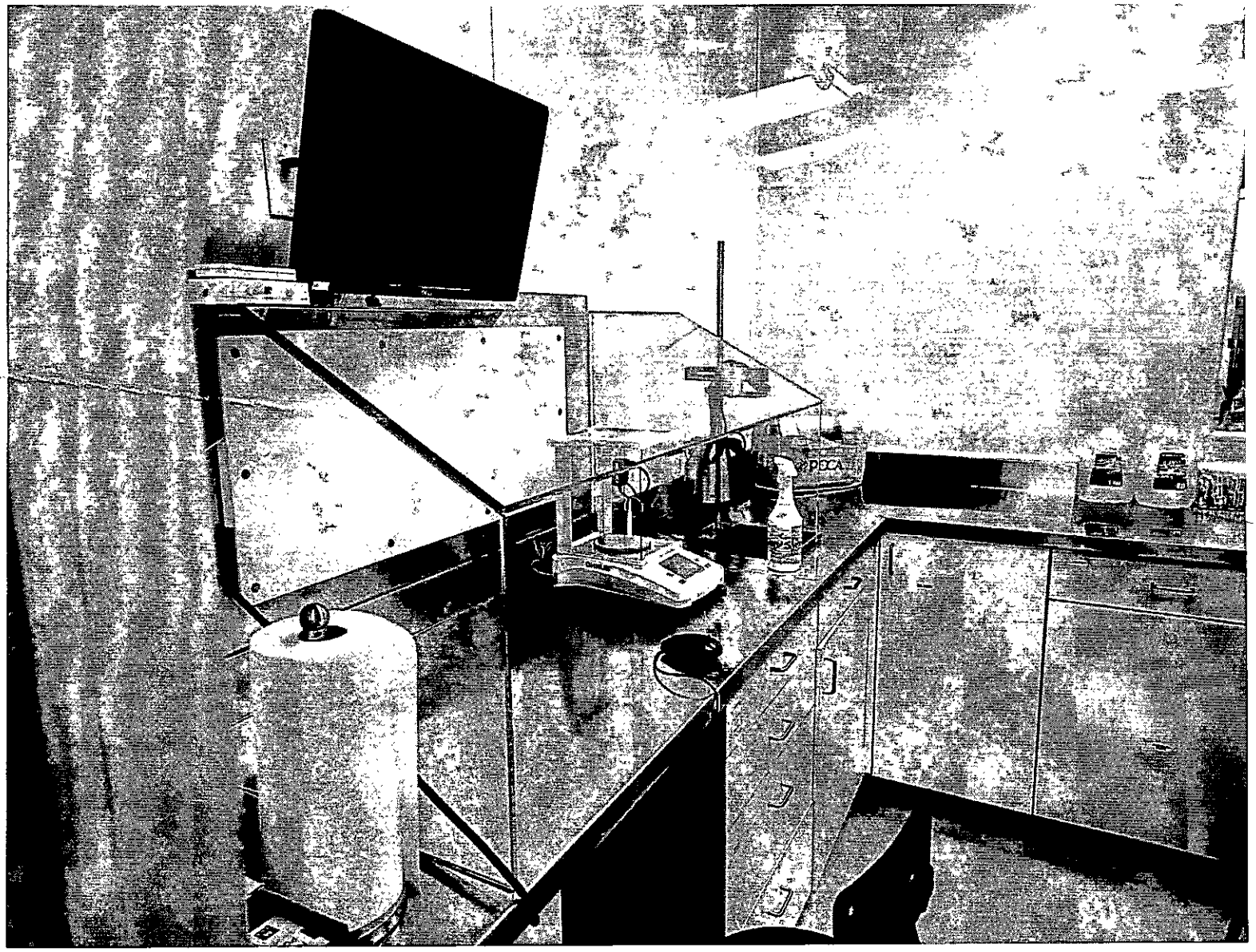
Lot No. : DS7217
Exp. Date : Aug 18, 2025
Batch Qty : 1200 kg

TESTS	SPECIFICATIONS		RESULTS
Appearance	Almost white or slightly yellow, hygroscopic powder		Slightly yellow, hygroscopic powder
Solubility	Freely soluble in water and in dichloromethane; slightly soluble in alcohol. It dissolves in dilute solutions of mineral acids.		Complies
Identification	Positive reaction of Tartrate <191>		Complies
	HPLC as obtained in the assay		
	IR <197K>		
Residue on ignition <281>	≤ 2.5%		0.13%
Tyramine (UV)	Absorption of sample solution is not more than the control solution (≤ 0.35%)		0.06%
Loss on drying <731>	≤ 4.5%		2.36%
pH <791>	5.0 – 7.2		5.5
Tylosin Compositions (HPLC) <621>	Tylosin A	≥ 80.0%	90.2%
	A + B + C + D	≥ 95.0%	97.0%
Assay (Antibiotics Microbial Assay) <81>	≥ 800 u/mg		901 u/mg (Wet)
			920 u/mg (Dry)
Conclusion: The product meets the USP Monograph specifications. Long Term Storage: Store in a sealed container at room temperature. Special Labeling Requirement: FOR VETERINARY USE ONLY. ID Test was confirmed by FT-IR on-site. Distributed by Darmerica.			

Note: Analytical results transcribed from the original COA provided by Hubei YaoChi Pharmaceutical and Chemical Co., Ltd. (China); Lot No. YC-TLST20220819.

Based on the review of the above information, the lot stands released.

	Name	Title	Signature	Date
Prepared by	Kamlesh Mistry	Quality Manager		12/02/2022
Released by	Brandon Manansingh	Quality Assistant		01/18/2023



THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2024-27

SUPERVISING PHARMACIST
YAKOV RATNER

THIS IS TO CERTIFY

CASTLETON PHARMACY CORP.
252B PORT RICHMOND AVE
STATEN ISLAND, NY 10302

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF NOVEMBER, 2024.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF OCTOBER, 2027.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
029846

EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FC1747887	08-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-10-2024

CASTLETON PHARMACY CORP.
DBA: ENEXIA SPECIALTY
252 PORT RICHMOND AVE
STATEN ISLAND, NY 103021749

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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WASHINGTON D.C. 20537

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DBA: ENEXIA SPECIALTY
252 PORT RICHMOND AVE
STATEN ISLAND, NY 103021749

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Form DEA-223 (9/2016)

4III

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☑ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 02736	☑ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☑ Retail/Community ☑ Dangerous drugs ☑ Controlled substances DEA #: FD5023988 ☑ Non-sterile Compounding ☑ Sterile Compounding ☑ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: DCA Pharmacy

Physical Address: 233 Bedford Way

City: Franklin State: TN Zip: 37064

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 615-832-7232 Toll Free # (NAC 639.708, NRS 639.23286): 833-876-0550

Fax: 615-331-6673 Contact Email: bmyatt@diabcorp.com

Website: www.dcapharmacy.com

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Benjamin Myatt

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20143

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Benjamin Myatt	NV Pharmacist Registration #: 20143
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Tennessee

Parent Company (if any): _____

Corporation/Organization Name: Joycrafters, LLC

Mailing Address: 233 Bedford Way

City: Franklin State: TN Zip: 37064

Telephone: 615-832-7232 Email: bmyatt@diabcorp.com

Contact Person Name: Benjamin Myatt

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Owner (title) for DCA Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Benjamin Myatt

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/15/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Benjamin Myatt hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Owner (title) for DCA Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 21 day of Jan., 20 25

Bridget Fields Hatchett
Notary Public

BRIDGET FIELDS HATCHETT
STATE OF TENNESSEE NOTARY PUBLIC
WILLIAMSON COUNTY
MY COMMISSION EXPIRES FEBRUARY 16, 2027

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Myatt

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/15/2025

Date

Board Use Only	Date Received: 2/4/25	Amount: $500 ck 1009

Dear members of the Board,

I am writing to explain the situation involving the disciplinary action I have received during my pharmacy career. My records indicate that the Kentucky Board of Pharmacy issued a fine in 2015, because I attempted to renew my license before completing the required CE. I did, however, complete the CE necessary to renew in my home state (which is Tennessee). The requirements are different, the renewal periods are different, and I did not perform the due diligence to verify I had met the requirements before renewing. My intent was not out of maliciousness or lack of caring. Later on, in 2016 when I was renewing my Louisiana and Maryland licenses, I neglected to note on my renewals for those permits that I had been reprimanded by another State Board, which resulted in reprimands by those state boards. Specifically, in my Maryland renewal, I detailed the Kentucky reprimand, but not the Louisiana reprimand. It was an oversight, and not my intent to hide punishment. I know that punishments are published to NABP, so I know that attempting to misrepresent myself is futile and unprofessional. I have been forthright with other boards of pharmacy. I have since paid my fines and have been allowed to renew my license in each state. I have no restrictions in any state that I am licensed in. I did not try to appeal to the boards of pharmacy to lessen or remove punishment because the fault was mine, but I believe that issues in my personal life had led to oversights in my professional life. During this period, I experienced the rigors of divorce, which unfortunately dominated the focus of every aspect of my life. Since resolving that issue, my personal and professional life has been in balance. Thank you for considering me for licensure in your state. I welcome the opportunity to provide exceptional service and care to patients in your state.

Professionally yours,

Dr. Benjamin Myatt, PharmD, BCSCP

RECD KYBOP JUL 15'15

COMMONWEALTH OF KENTUCKY
KENTUCKY BOARD OF PHARMACY
Case No. 15-0209

IN RE: PHARMACIST LICENSE NO. 016242 HELD BY BENJAMIN MICHAEL MYATT

Agreed Order

Come the parties, the Kentucky Board of Pharmacy ("Board") and Benjamin Michael Myatt ("Respondent"), and both having been fully informed regarding the matter set forth herein, state as follows:

(1) Pursuant to Chapter 315 of the Kentucky Revised Statutes, the Board is authorized to regulate and control all matters related to pharmacists and pharmacies not delegated to another agency of the Commonwealth. The matter herein has not been delegated to another agency of the Commonwealth.

(2) Respondent is a pharmacist in the Commonwealth of Kentucky, having been assigned pharmacist license no. 016242.

(3)(a) Respondent completed 7 hours of 15 required continuing education hours before January 1, 2015, in violation of 201 KAR 2:015, Section 5.

(b) The above actions subject Respondent to discipline pursuant to KRS 315.121(1)(b).

(4) The Board and Respondent have agreed to address this matter by entering into this Agreed Order, in lieu of the filing of a formal Complaint.

WHEREFORE, IT IS HEREBY AGREED AND ORDERED THAT:

(A) Respondent shall be fined $500, payable on or before August 6, 2015. Respondent's check shall be made payable to the Kentucky State Treasurer and sent to the Kentucky Board of Pharmacy, State Office Bldg., Annex, Ste. 300, 125 Holmes St., Frankfort, Kentucky 40601.

(B) Respondent shall submit to the Board office within six months of the Board's entry of this Agreed Order proof of no less than sixteen (16) continuing education hours, which programs shall not be used in any way to satisfy Respondent's continuing education requirements for renewal.

(C) By entering into this Agreed Order, Respondent expressly acknowledges that the Respondent was fully and completely informed of Respondent's right to due process, that the Respondent fully understands those rights, and that the Respondent knowingly, voluntarily, and willingly agrees to waive those rights and to enter into this Agreed Order.

(D) The above information shall be reported to the National Association of Boards of Pharmacy ("NABP") and is subject to disclosure under the Kentucky Open Records Act.

Joel Thornbury, President
Kentucky Board of Pharmacy — Date 9/11/15

Benjamin Michael Myatt, Respondent — Date 7/12/2015

THIS COPY IS FOR YOUR RECORDS

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: CONSENT ORDER

BENJAMIN MICHAEL MYATT

PHARMACIST LICENSE NO. 20062 Case No. 15-0432

****

CONSENT AGREEMENT

WHEREAS, **BENJAMIN MICHAEL MYATT** (hereinafter referred to as "Respondent"), holder of PHARMACIST LICENSE NO. 20062, was sanctioned by the Kentucky Board of Pharmacy by Board Order effective September 11, 2015. Such action is considered disciplinary action and was reported to the National Association of Boards of Pharmacy as such.

WHEREAS, information received and/or gathered by the Board produced evidence indicating that Respondent violated the following laws and regulations:

La. R.S. 37:1241(A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1241(A)(2): Has attempted to or obtained a license by misrepresentation.

LA. R.S. 37:1241(A)(6) Has had his license, permit, certification, registration or any other designations deemed necessary to engage in the practice of pharmacy revoked or suspended, or has had other disciplinary action taken, or has had his application for licensure refused, revoked, or suspended by the proper authorities of another state, territory, or country based upon conduct by the licensee similar to conduct that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(7): Has failed to report to the board any adverse action taken by another government agency, law enforcement agency, or court that would constitute grounds for action as defined in this Section.

La. R.S. 37:1241(A)(22): Has failed to furnish to the board or representatives any information legally requested by the board.

To facilitate the submission of this Consent Agreement, Respondent does not offer any defense to the allegations of violations cited above and further agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

THIS COPY IS FOR
YOUR RECORDS

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

1. **PHARMACIST LICENSE NO. 20062 belonging to BENJAMIN MICHAEL MYATT is hereby issued a LETTER OF REPRIMAND.**

2. **BENJAMIN MICHAEL MYATT is ordered to pay a fine of $1,000.00 and reimburse the Board $250.00 for administrative costs for a total of $1,250.00 due by *certified check or money order* at the signing of this agreement.**

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing, and to judicial review of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting.

However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon his signing said Order.

I, **BENJAMIN MICHAEL MYATT**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of my case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

Respondent agrees that Respondent's execution of this Consent Agreement grants the Board the authority to collect any monies owed pursuant to this Consent Agreement and not paid to the Board notwithstanding the Board's acceptance of this Consent Agreement.

THIS COPY IS FOR
YOUR RECORDS

Respondent agrees to provide the Board with the following for reporting purposes to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB):

Respondent's National Provider Identifier (NPI) Number: [redacted]

Medicare Provider Number (if in the possession of one): _____

SIGNED, AGREED TO AND ENTERED ON 22 DAY OF February, 2016.

BENJAMIN MICHAEL MYATT
PHARMACIST LICENSE NO. 20062

HILARY E. [illegible]
NOTARY PUBLIC
TENNESSEE
COUNTY OF WILLIAMSON
My Commission Expires

My Commission expires May 27, 2019

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
3388 Brentwood Drive
Baton Rouge, LA 70808
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 4, 2016, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Carl W. Aron, President and Hearing Officer for the Board

THIS COPY IS FOR YOUR RECORDS

MARYLAND
Department of Health

Larry Hogan, Governor • Boyd Rutherford, Lt. Governor • Robert R. Neall, Secretary

MARYLAND BOARD OF PHARMACY
4201 Patterson Avenue, Baltimore, Maryland 21215-2299
Mitra Gavgani, Board President • Deena Speights-Napata, Executive Director

26 February 2018

Benjamin Myatt, R.Ph.
[redacted]
Franklin, Tennessee [redacted]

RE: Consent Order, License No. 22267

Dear Mr. Myatt:

Please find enclosed the fully executed Consent Order regarding your license to practice as a pharmacist in the state of Maryland.

If you have any questions regarding this matter please give me a call at (410) 764-4152 between 7:30 am and 4:00 pm.

Sincerely,

Heather McLaughlin

Heather McLaughlin, M.A., CFE
Compliance Coordinator

Enclosure

Cc: Linda M. Bethman, Assistant Attorney General, Board Counsel
Brett E. Felter, Assistant Attorney General, Board Counsel
Deena Speights-Napata, Executive Director
Thomas P. Evans, R.Ph., Compliance Director
Lisa S. Sanderoff, R.Ph., Pharmacist Investigator Supervisor

IN THE MATTER OF	*	**BEFORE THE**
BENJAMIN MYATT, R.Ph.	*	**MARYLAND STATE**
LICENSE NO. 22267	*	**BOARD OF PHARMACY**
	*	**Case No. 18-022**

* * * * * * * * * * * *

CONSENT ORDER

Background

The Maryland Board of Pharmacy (the "Board") received credible information indicating that Benjamin Myatt, R.Ph. (the "Respondent"), License Number 22267, had been disciplined by the Kentucky and Louisiana Boards of Pharmacy, based on failure to complete continuing education credits and failure to report disciplinary action, respectively. In addition, the Respondent failed to report the Louisiana disciplinary action to the Board.

In lieu of instituting formal proceedings against the Respondent, in accordance with the Maryland Pharmacy Act, Md. Code Ann., Health Occ. § 12-101 *et seq.*, the Board and Respondent, have agreed to resolve this matter as set forth in this Consent Order.

FINDINGS OF FACT

1. On or about March 19, 2014, the Respondent was issued a license to practice pharmacy in Maryland. The Respondent's license is active and will expire on September 30, 2019.
2. The Respondent is the designated Maryland licensed pharmacist for a non-resident pharmacy permit holder located in Tennessee in accordance with Md. Code Ann., Health Occ. Art. § 12-403(e).

3. On or about September 11, 2015, the Kentucky Board of Pharmacy entered into an Agreed Order with the Respondent in which he agreed to pay a fine of $500. The Agreed Order was based on the Respondent's failure to complete the required continuing education credits for renewal.
4. On or about May 4, 2016, the Louisiana Board of Pharmacy entered into a Consent Agreement with the Respondent in which he was reprimanded and ordered to pay a fine of $1,000 and reimburse the board $250 for administrative costs. The Consent Order was based on the Respondent's failure to report the Kentucky Board disciplinary action as required.
5. On the Respondent's August 23, 2017 renewal application to the Board, he answered the question, "Has any state licensing or disciplinary board (including Maryland) or any similar agency in the Armed Forces, denied your application for registration, reinstatement or renewal, or taken any action against any registration or licensed held by you? Such actions include, but are not limited to, limitations on the registration, additional education, admonishment, reprimand, suspension or revocation," by reporting the Kentucky Board disciplinary action, but failed to report the disciplinary action imposed by the Louisiana Board.

CONCLUSIONS OF LAW

Based on the foregoing Findings of Fact, the Board concludes that Benjamin Myatt, R.Ph., License Number 22267, is subject to discipline in accordance with Md. Code Ann., Health Occ. § 12-313(b)(1) and (24).

ORDER

Based upon an affirmative vote of the Board under the authority of Md. Code Ann., Health Occ. Art. § 12-313, it this 26th day of February, 2018, hereby,

ORDERED that Respondent, License No. 22267, shall pay a FINE in the amount of $250, within sixty (60) days of the date of the effective date of this Order, payable to the Maryland Board of Pharmacy and mailed to P.O. Box 2051, Baltimore, MD 21203-2051, with a reference to Case No. 18-022; and be it further,

ORDERED that in the event that Respondent violates any of the terms above, the Board, after notice and an opportunity for a hearing, and a determination of a violation, may impose any further disciplinary sanction it deems appropriate, including probation, suspension and revocation, or the imposition of a civil fine, said violation being proven by a preponderance of the evidence; and be it further,

ORDERED that this is a formal order and as such is a public document pursuant to Md. Code Ann., General Provisions Article § 4-333.

2-26-18
Date

Deena Speights-Napata,
Executive Director for:

Mitra Gavgani, Pharm.D.
Board President

CONSENT

1. By signing this Consent, Respondent submits to the foregoing Consent Order as a resolution of this matter and agrees to be bound by its terms and conditions.

2. Respondent acknowledges the validity of this Consent Order as if it were made after a hearing in which Respondent would have had the right to counsel, to confront witnesses, and to all other substantial procedural protections provided by law.

3. Respondent acknowledges that, by entering into this Consent Order, Respondent is waiving his right to appeal any adverse ruling of the Board that might have followed such an evidentiary hearing.

4. Respondent acknowledges the legal authority and the jurisdiction of the Board to enter and enforce this Consent Order.

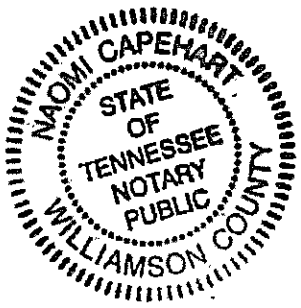
5. Respondent signs this Consent Order freely and voluntarily, after having had the opportunity to consult with counsel. Respondent fully understands the language, meaning, and effect of this Consent Order.

2/13/18
Date

Benjamin Myatt

STATE OF Tennessee
COUNTY/CITY OF Williamson

I hereby certify that on this 13th day of Feburary, 2018, before me, a Notary Public of the State of Tennessee and County/City aforesaid, personally appeared BENJAMIN MYATT, and made an oath in due form that the foregoing Consent was his voluntary act and deed.



Naomi Capehart
Notary Public
My commission expires: April 6 2021

Joycrafters, LLC (dba DCA Pharmacy)

List of Owners/Officers

Name	Address	Phone	Title	Owner
Benjamin Myatt	[redacted]	[redacted]	CEO	100 %
Pharmacist License: 35575 (Tennessee)				
Hilary Tutt-Myatt	[redacted]	[redacted]	Secretary	0 %

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

BENJAMIN MYATT
1187 GLENBROOK DRIVE
FRANKLIN, TN 37064

January 17, 2025

Request Type: Certificate of Existence/Authorization
Request #: 0620728

Issuance Date: 01/17/2025
Copies Requested: 1

Document Receipt

Receipt # : 009459640 — Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3890149702 — $20.00

Regarding: **Joycrafters, LLC**

Filing Type:	Limited Liability Company - Domestic	Control # :	1352820
Formation/Qualification Date:	09/19/2022	Date Formed:	09/19/2022
Status:	Active	Formation Locale:	TENNESSEE
Duration Term:	Perpetual	Inactive Date:	
Business County:	WILLIAMSON COUNTY		

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

Joycrafters, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 072235116

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: DCA Pharmacy

NV Pharmacy or Outsourcing facility license # (if applicable): PH 02736

Physical Address: 233 Bedford Way

City: Franklin State: TN Zip: 37064

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 615-832-7232 Toll Free # (NAC 639.708, NRS 639.23286): 833-876-0550

Fax: 615-331-6673 Contact Email: bmyatt@diabcorp.com

Website: www.dcapharmacy.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Benjamin Myatt

Supervising/Managing Pharmacist NV Pharmacist Registration #: 20143

Name of Designated Person(s) as defined by revised USP-797 guidelines: Benjamin Myatt

Email of Designated Person(s): bmyatt@diabcorp.com

Telephone of Designated Person(s): 615-832-7232

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☑ Category 1 ☑ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ✓ Yes | No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☑ Aseptic ☑ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ✓ Yes — No

5. When was the most recent certification for the ISO classified areas? Dec-19-2024

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☑ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ✓ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? monthly

10. Will you be performing sterile hazardous drug compounding? (Yes) No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

1) Methylcobalamin 1mg/mL and 10mg/mL injection.
2) MC-B complex injection (Multivitamin).
3) Glutathione 200mg/mL injection.
4) IV Bags (Sterile Water and/or Normal Saline) if on backorder.
5) Semaglutide injection if on FDA Drug Shortage List.

12. What laboratory performs your sterility or endotoxin testing?

Name: Eagle Analytical Services
Address: 11111 S. Wilcrest Dr, Suite S1000
City: Houston State: TX Zip: 77099
Telephone: 800-745-8916

13. What is your procedure for visual inspection of compounded sterile products?
Examine finished product against a lit white and black background for particulates and clarity. Check container closure for integrity and seal. If entire batch isn't dispensed the same day, repeat these visual inspections at time of dispensing.

14. How often do you perform glove fingertip and medial fill testing?
Every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
Initial: 3 passing Gloved fingertip/Thumb samples + Gowning competency + Media fill + cleaning competency + didactic training + surface sample after Media fill
Ongoing: Every 6 months, repeat initial competencies (Except only need 1 Gloved Fingertip/Thumb sample for each hand)

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
See attached SOP

17. Who performs the sterile compounding process at your facility? Pharmacists only.
West Conner and Benjamin Myatt

18. Who is responsible and accountable for the sterile compounding process at your facility?
Benjamin Myatt

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
FedEx 2 day for room temperature products. fedex Priority Overnight for cold-chain products (Plus ice pack in a padded "Kangaroo" insulated envelope with a "Warm Mark" temperature excursion indicator).

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Class 2 A2 Biological Safety Cabinet		
2. Are you complying with all USP 800 guidelines?	(Yes)	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	(Yes)	No
4. Is your BSC or CACI vented 100% to the outside?	(Yes)	No
5. Do you have a negative pressure buffer room at your facility?	(Yes)	No
6. Will you be compounding with antineoplastic HDs or HD API?	(Yes)	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	(Yes)	No
8. Will you be utilizing a closed system transfer device?	Yes	(No)
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

HDs are placed inside a sealed bag that is labeled "Hazardous". Disposal steps are described on the bag labeling and refers patients of local drug take-back programs as a disposal option as well.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Same initial competencies are required as for non-hazardous sterile compounding.
In addition, personnel are trained on Receiving, Storing, Handling, Disposal of HD waste, Spills, Garbing, Reviewing Safety Data Sheets, and Reviewing the NIOSH List. Employees sign an acknowledgement form indicating they understand the inherent risks of HD exposure.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.) Not Applicable

1. List the specific Category 3 sterile products that your facility compounds:

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? Yes No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Myatt

Name of Person who Completed the Form

Pharmacist & Owner

Title

Signature (copies or stamps not accepted)

1/15/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

TITLE: CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY		
SOP NUMBER: 3.020	**VERSION NUMBER: 2.0**	
Written By: Megan Jeffrey Liotta	Date: 10-21-14	Dept: Compounding
Revised By: Ben Myatt	Date: 6-5-23	
Reviewed By: Ben Myatt	Date: 3-1-24	
Date Effective: 11-1-23		

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements and documentation for cleaning and maintenance of the clean room facility.

2.0 SCOPE

2.1 This procedure applies to DCA Pharmacy facility under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <797>. This policy must be followed to reduce the amount of particulate matter and airborne microbial contamination.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge or supervisor shall supervise this procedure and document that all personnel responsible for cleaning and maintenance of the clean room facility shall comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations"

4.2 SOP 1.060 "General Aseptic Technique"

4.3 SOP 3.030 "Environmental Monitoring of the Clean Room Facility"

4.4 SOP 9.100 "Required Garb for Clean Room Facility Access"

5.0 DEFINITIONS

5.1 Clean Room-Includes the buffer room and any items in the buffer room.

6.0 FREQUENCY

6.1 Daily (before initiating compounding and when sterile compounding activities are completed)

6.1.1 Clean and sanitize (using sterile IPA 70%) all horizontal work surfaces and floors, including passthroughs. If performing HD compounding activities, 1st Deactivate and Decontaminate then Clean and sanitize all horizontal surfaces and floors.

6.1.2 Clean and sanitize all in-use hoods. If performing HD compounding activities, 1st Deactivate and Decontaminate then Clean and sanitize all in-use hoods.

6.1.3 Clean and sanitize removable work tray and under removable work tray in hazardous ISO 7 room.

6.1.4 Clean and sanitize all in-use equipment. If performing HD compounding activities, 1st Deactivate and Decontaminate then Clean and sanitize all in-use equipment.

6.1.5 Clean and sanitize the sink.

6.1.6 Remove and discard trash as needed.

6.1.7 Record the temperature and humidity.

6.1.8 Record pressure differential.

6.2 Monthly

6.2.1 Perform daily requirements listed in section 6.1. Choose an agent that contains sporicidal activity (Steri-Perox or Spor-Klenz).

6.2.2 Clean and sanitize with sporicidal disinfectant all equipment stored in the clean room facility including chair and Baxa repeater pump.

6.2.3 Clean and sanitize with sporicidal disinfectant all items in the controlled buffer environments including ISO 7 shelves, ISO 7 cart, and waste can.

6.2.4 Clean and sanitize with sporicidal disinfectant the work surface of the removable tray in the PEC and area underneath the removable work tray.

6.2.5 Clean and sanitize with sporicidal disinfectant passthrough and all walls and ceilings.

6.2.6 Clean and sanitize with sporicidal disinfectant hand hygiene sink.

6.2.7 Clean and sanitize with sporicidal disinfectant all doors and door frames.

6.2.8 Clean and sanitize with sporicidal disinfectant anteroom shelves.

6.2.9 Clean and sanitize with sporicidal disinfectant all other equipment outside PEC.

7.0 EQUIPMENT & SUPPLIES

7.1 Mop with disposable cleaning pads labeled for use on the floors of the cleanroom facility only

7.2 Hazardous Room mop with disposable cleaning pads labeled for Hazardous Room only.

7.3 Tacky mat

7.4 Lint-free towels or wipes

7.5 An appropriate deactivating agent, decontaminating agent, cleaning agent and sanitizing (disinfecting) agent.

7.6 Waste container liners

7.7 Step stool if needed

7.8 Room thermometer and hygrometer

7.13 Isolator/LAFW/BSC pressure monitors

8.0 GENERAL INFORMATION

8.1 An appropriate cleaner.

8.2 A minimum contact time per manufacturer's recommendation is recommended for maximum disinfection efficacy when using bleach or other appropriate cleaner.

8.3 Document the disinfectant in use.

9.0 PROCEDURE

9.1 Personnel must remove all makeup and jewelry prior to entering the clean room facility.

9.2 Personnel must gown appropriately for the areas to be cleaned following the cleanroom gowning procedure.

9.3 The necessary cleaning materials are dedicated solely to cleaning the clean room facility. These materials shall be stored in the ante room of the cleanroom facility and shall be kept separate from other cleaning materials.

9.4 Cleaning solutions shall be prepared as needed.

9.4.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs or manufacturers' recommendations.

9.5 Cleaning shall be performed using a detergent followed by sanitization if there is any visible particulate. A damp, non-shedding material shall be used for cleaning.

9.6 Except for sanitization of the isolator/LAFW/BSC, cleaning of the sterile compounding area is prohibited during compounding operations.

9.6.1 Ensure all compounding operations are completed and all equipment has been removed from the isolator/LAFW/BSC prior to sanitization.

9.6.2 The operator must clean and sanitize the exposed work surfaces (counters and walls) of the isolator/LAFW/BSC after each workday and the counter between each batch preparation, and immediately should a spill occur.

9.7 The order of cleaning within the clean room facility is as follows (procedure included):

9.7.1 Isolator/LAFW/BSC (ISO 5)

9.7.1.1 Ceiling: start at rear left corner (closest to back wall of hood) and wipe >right> with a horizontal motion maintaining pressure the entire motion across the ceiling. Then pull toward you slightly and wipe <left< across the ceiling (your passes should overlap each other by approximately 1/3rd to ensure that no part of the ceiling is skipped). Continue in this manner working towards you until you have wiped the entire ceiling. Discard the wipe.

9.7.1.2 Rear Wall: start at upper left corner of the wall and wipe and wipe >right> with a horizontal motion maintaining pressure the entire motion across the wall. Then wipe down slightly and wipe <left< across the wall (your passes should overlap each other by approximately 1/3rd to ensure that no part of the wall is skipped). Continue in this manner working downwards you until you have wiped the entire wall. Discard the wipe.

9.7.1.3 Side Walls: start at the rear upper corner of the wall and wipe down in a vertical motion maintaining pressure the entire motion down the wall. Then pull toward you slightly and wipe up the wall (your passes should overlap each other by approximately 1/3rd to ensure that no part of the wall is skipped). Continue in this manner working towards you until you have wiped the entire wall. Discard the wipe. Repeat this procedure for the other wall and discard the wipe.

9.7.1.4 Hood Surface: start at the rear left corner of the surface (closest to back wall of hood) and wipe >right> with a horizontal motion maintaining pressure the entire motion across the surface. Then pull toward you slightly and wipe <left< across the surface (your passes should overlap each other by approximately 1/3rd to ensure that no part of the surface is skipped). Continue in this manner working towards you until you have wiped the entire surface. Discard the wipe.

9.7.2 Buffer room (ISO 7)

9.7.2.1 Ceiling: start at rear left corner (above the hood) and wipe >right> with a horizontal motion maintaining pressure the entire motion across the ceiling. Then pull toward you slightly and wipe <left< across the ceiling (your passes should overlap each other by approximately 1/3rd to ensure

that no part of the ceiling is skipped). Continue in this manner working towards you until you have wiped the entire ceiling. Discard the wipe.

9.7.2.2 Walls (1st: Rear Wall behind hood, 2nd: Side Walls and Outer surface of Passthrough, 3rd: Room Entry Wall): start at the rear upper corner of the wall (closest to hood) and wipe down in a vertical motion maintaining pressure the entire motion down the wall. Then pull toward you slightly and wipe up the wall (your passes should overlap each other by approximately 1/3rd to ensure that no part of the wall is skipped). Continue in this manner working towards you until you have wiped the entire wall. Discard the wipe. Repeat this procedure for the other walls and discard the wipe after each wall.

9.7.2.3 Floor: start at the rear left corner of the floor (closest to back wall behind hood) and wipe >right> with a horizontal motion maintaining pressure the entire motion across the floor. Then pull toward you slightly and wipe <left< across the floor (your passes should overlap each other by approximately 1/3rd to ensure that no part of the floor is skipped). Continue in this manner working towards you until you have wiped the entire floor (you should end at the entry door). Discard the wipe.

9.7.3 Hazardous Buffer room (ISO 7)

9.7.3.1 Includes all requirements and procedures listed in section 9.7.2.

9.7.3.2 For the Hazardous Buffer Room, Deactivation and Decontamination with an appropriate agent must occur before the cleaning and sanitization procedure.

9.7.3.3 Leave the designated hazardous mop in the hazardous buffer room and discard the additional hazardous garb before proceeding to clean the Anteroom.

9.7.4 Anteroom (ISO 8)

9.7.4.1 Ceiling: start at rear left corner (above the sink) and wipe >right> with a horizontal motion maintaining pressure the entire motion across the ceiling. Then pull toward you slightly and wipe <left< across the ceiling (your passes should overlap each other by approximately 1/3rd to ensure that no part of the ceiling is skipped). Continue in this manner working towards you until you have wiped the entire ceiling. Discard the wipe.

9.7.4.2 Walls (1st: Rear Wall behind sink, 2nd: Side Walls and Outer surface of Passthrough, 3rd: Room Entry Wall): start at the rear upper corner of the wall (closest to hood) and wipe down in a vertical motion maintaining pressure the entire motion down the wall. Then pull toward you slightly and wipe up the wall (your passes should overlap each other by approximately 1/3rd to ensure that no part of the wall is skipped). Continue in this manner working towards you until you have wiped the entire wall. Discard the wipe. Repeat this procedure for the other walls and discard the wipe after each wall.

9.7.4.3 Floor: start at the rear left corner of the floor (closest to back wall under sink) and wipe >right> with a horizontal motion maintaining pressure the entire motion across the floor. Then pull toward you slightly and wipe <left< across the floor (your passes should overlap each other by approximately 1/3rd to ensure that no part of the floor is skipped).

Continue in this manner working towards you until you have wiped the entire floor (you should end at the entry door). Discard the wipe.

9.8 Daily Requirements (when sterile compounding has occurred)

9.8.1 Empty all waste receptacles by removing the filled plastic bag. Wipe the receptacle with cleaning solution, let dry and place a clean plastic bag in the receptacle. Use an appropriate bag for the type of waste being removed (e.g. for hazardous waste, use a clearly labeled bag designated for hazardous waste material). **Do not remove or relocate receptacles within the clean room facility.**

9.8.2 Temperature, humidity, and air differential pressure readings shall be taken in all areas of the clean room facility.

9.8.2.1 The temperature and humidity in the clean room facility can be monitored electronically.

9.8.2.2 The humidity should be maintained in the range of 30%–65%.

9.8.2.3 The temperature in the clean room shall be maintained at 20°C (68°F) or cooler. The temperature stability of the APIs shall be determined.

9.8.2.4 Document results on the Temperature and Humidity Monitoring of the Clean Room Facility form (Attachment 2) or other designated form or attach printout and date and initial.

9.8.3 Clean and sanitize the isolator/LAFW/BSC including all equipment.

9.8.4 Clean and sanitize counter tops.

9.8.5 Wipe down equipment and devices.

9.8.6 Peel off soiled tacky mat and replace with a fresh tacky mat.

9.8.7 Mop the floors starting from a far corner and working toward the center of the room from each sidewall toward the door.

9.8.8 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.8.9 Document all activities on the Cleaning and Maintenance of the Clean Room Facility form (Attachment 3) or other designated form. If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.9 Monthly Requirements

9.9.1 Includes all requirements listed in section 9.8.

9.9.1.1 For the Hazardous Buffer Room, Deactivation and Decontamination with an appropriate agent must occur before the cleaning and sanitization procedure.

9.9.2 Clean and sanitize the ceiling first (when scheduled) beginning at the farthest point from the door and working toward the door.

9.9.3 Clean and sanitize the walls next (when scheduled) beginning with the wall farthest from the door and working toward the door.

9.9.4 Remove all supplies from shelving and carts and clean and sanitize the storage units.

9.9.5 Clean and sanitize the floor last beginning at the far corner and working toward the center of the room from each sidewall toward the door.

9.9.6 Allow all rooms and equipment to air dry before sterile compounding resumes.

9.9.7 Document all activities on the Cleaning and Maintenance of the Clean Room Facility form (Attachment 3) or other designated form. If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.10 All cleaning should be performed upon completion of compounding, so the clean room facility is always stored cleaned. Cleaning can be performed as often as needed, but the minimum requirement is at the end of the day after compounding.

9.11 The Pharmacist-in-charge or compliance officer shall ensure the completion of tasks daily and shall review and sign/date Attachment 1 or other designated form at the end of each month. The form shall be retained in a cleaning/maintenance binder.

10.0 ATTACHMENTS

10.1 Attachment 1 – Cleaning and Maintenance of the Clean Room Facility (obsolete)

10.2 Attachment 2 – Temperature, Humidity and Pressure Monitoring of the Clean Room

10.3 Attachment 3 – Cleaning and Maintenance of the Clean Room Facility

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0		New SOP.	n/a
2.0	6-5-23	Adjusted headers and footers	CR23001
	11-1-23	Changed temp/humidity monitoring log format, Added detailed cleaning procedure	CR23004

The remainder of this page was intentionally left blank.

CLEANING AND MAINTENANCE OF THE CLEAN ROOM FACILITY

Month/Year: _____ Cleaning Solution: Sterile IPA, Hypo-Chlor, Steri-Perox

Cleaner _____ Dwell Time_____

Daily with Cleaner and Sterile IPA

Day	Clean		ISO7 Floors	Passthrough	Sink	Work Surfaces
	ISO 5 BSC	ISO 5 LFW	Mopped			
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						
25						
26						
27						
28						
29						
30						
31						

Monthly with Steri-Perox

ISO 7 Shelves	
ISO 7 Cart	
Chair	
Pump	
Waste Can	
Ceiling	
Walls	
Anteroom Shelves	
PEC	
Work Surfaces	
Passthrough	
Sink	
Floors	
Doors	
Door Frames	
HD Removable Tray ISO 5	

As Needed

Trash	Tacky Mat
Discarded	Replaced

Reviewed by: _____ Filter: ____/____/_____

MONITORING OF THE CLEAN ROOM FACILITY

Month/Year _____

Day	Pressure (In of Water) / /	Pressure in Hood	Pressure in Neg Press Room (PSI)	Initials
1				
2				
3				
4				
5				
6				
7				
8				
9				
10				
11				
12				
13				
14				
15				
16				
17				
18				
19				
20				
21				
22				
23				
24				
25				
26				
27				
28				
29				
30				
31				

Reviewed by: _____

Environmental Monitoring Form -- DCA Pharmacy Sterile Compounding

Month/Year _____

Daily Procedure

1. Review sensor data for temperature/humidity/pressure differential
2. Document excursions. What excursion occurred? How long did it occur? What actions were taken? Did compounding take place during excursion?

Date	Reviewed by	Excursion Yes/No	If Yes, Explain (location, time, action taken)
1			
2			
3			
4			
5			
6			
7			
8			
9			
10			
11			
12			
13			
14			
15			
16			
17			
18			
19			
20			
21			
22			
23			
24			
25			
26			
27			
28			
29			
30			
31			

Monthly **Hood Surface, Table, Passthrough** Testing start date and time: NAME:

QI Medical EnviroTest ET1000 Starting Temp:

PEC Clean Room

	Date	Time	Read by	Media Lot#	Exp Date	Incubation Temp	CFUs	Initials	Comments
Day 1						30-35			
Day 2						30-35			
Day 3						20-25			
Day 4						20-25			
Day 5						20-25			
Day 6						20-25			
Day 7						20-25			

PEC Hazardous Room Starting temp

	Date	Time	Read by	Media Lot#	Exp Date	Incubation Temp	CFUs	Initials	Comments
Day 1						30-35			
Day 2						30-35			
Day 3						20-25			
Day 4						20-25			
Day 5						20-25			
Day 6						20-25			
Day 7						20-25			

Table

	Date	Time	Read by	Media Lot#	Exp Date	Incubation Temp	CFUs	Initials	Comments
Day 1						30-35			
Day 2						30-35			
Day 3						20-25			
Day 4						20-25			
Day 5						20-25			
Day 6						20-25			
Day 7						20-25			

Passthrough

	Date	Time	Read by	Media Lot#	Exp Date	Incubation Temp	CFUs	Initials	Comments
Day 1						30-35			
Day 2						30-35			
Day 3						20-25			
Day 4						20-25			
Day 5						20-25			
Day 6						20-25			
Day 7						20-25			

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY		
STREET		
CITY	ZIP	
DATE OPENED	TELEPHONE NO.	
LICENSE NO.	EXPIRY DATE	
DEA NO.	EXPIRY DATE	
PHARMACIST IN CHARGE/Duty	LIC NO.	EXPIRY DATE

Inspected by	Date

This Inspection Satisfactory Yes ☐ No ☐

☐ Opening ☐ Relocation
☐ New Ownership ☐ Follow-up
☐ Counseling Compliance
☐ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
		1. Appropriate identification/Name Tags
		2. D. Ph./Tech ration
		3. Personnel/apparel clean
		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
		5. Certificates Displayed
		6. RX Dept. – Sufficient Space/Counseling
		7. Fully enclosed when applicable
		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
		9. Dispensing area clean, orderly, well lighted
		10. Sink, hot and cold water
		11. Refrigeration
		12. References, periodicals
		13. Vials and closures (child-proof)
		14. Shelves and drug stock clean
		15. Drugs in-date
		16. Labels correct on repackaging
		17. Legend drugs stored in RX Dept.
		18. Syringes/insulin, restricted products non-accessible

Pharmacy Hours

Compliance Yes	Compliance No	
		19. RXs numerically filed
		☐ All C's together ☐ C-11's separate ☐ Multiple file method
		20. Patients identifiable
		21. Prescribers identifiable
		22. New verbal RXs initialed by appropriate personnel
		23. Date of original dispensing
		24. Initials of dispensing D.Ph.
		25. Quantity dispensed indicated
		26. Appropriate Emergency C-11 RXs
		27. Computer labels applied appropriately to RXs
		28. Pharmacist Signature Log
		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
		30. Authorization documented on Rx
		31. Manufacturer indicated on Rx or System
		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
		33. Patient profiles
		34. Drug Utilization Review
		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
		36. Readily retrievable
		37. All C-11 records separate
		38. DEA Form 222 Copy 3 on hand & completed
		39. Drug Receipt date on invoices
		40. Record of drug transfers
		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
		42. Last DEA Inventory (date) _____
		42. Last Theft/loss report (date) _____
		43. Access to Control Substance Monitoring Database

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** **YES ☐** **NO ☐**

Immediately _____
Needs Improvement _____
Within 30 Days _____

Remarks or Recommendations: _____

I _____ hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PH-4031 REV 01/18

RDA SW-30

NABP Inspection

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business or Facility ID:	602265		Inspection Information:
Legal Business Name:	Diabetes Corporation of America	Document Call Date:	9/30/2024
Doing Business As (DBA):	DCA Pharmacy	Start Time: [24-hour format (13:00)]	10:05
Address:	253 Indirect Way	End Time: [24-hour format (13:00)]	11:37
City:	Franklin	Onsite Inspection Date(s):	10/1/2024; 10/2/2024; 10/3/2024
State:	Tennessee	Start Time(s): [24-hour format (13:00)]	12:30; 8:00; 8:15
Zip Code:	37064	End Time(s): [24-hour format (13:00)]	W ek; 17:00; 10:30
Telephone number:	615-832-7252	Inspector Name(s):	Chet Atwood RPh
Toll free number:	833-676-4DCA	Inspection performed by: [NABP, state, etc.]	NABP
Fax number:	615-331-6075	Observer Name/Affiliation: [if applicable]	NA
Website:	www.dcapharmacy.com	Observer Name/Affiliation: [if applicable]	NA

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not listed below to which the facility may want to consider further response.
General Pharmacy: 44 (a), 44 (d), 47 (a, b), 48 (a), 50 (a), 52 (a), 73 (a)
Nonsterile: 44 (a), 44 (d), 47 (a, b), 48 (a), 50 (a), 52 (a), 73 (a)

Additional information is listed in Inspector's narrative.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is submitted directly from NABP to an Interested Recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

Pharmacy Hours of Operation	Closed at 3MT		
	Open Start Time: [24-hour format]	End Time: [24-hour format]	Closed (X)
Sunday			X
Monday	8:00	17:00	
Tuesday	8:00	17:00	
Wednesday	8:00	17:00	
Thursday	8:00	17:00	
Friday	8:00	17:00	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	West Conner	wconner@diabcorp.com	223308
Nonsterile Drug/Hood person(s)	Benjamin Myatt	bmyatt@diabcorp.com	269985
Sterile Designated person(s)	Benjamin Myatt	bmyatt@diabcorp.com	269985
Insurance Designated person(s)	Benjamin Myatt	bmyatt@diabcorp.com	269985

Personnel Present at Time of Inspection	Name	Title	License or Registration available and current (Y/N)
1	Brayden Myatt	Pharm2 Designated Person	Y
2	West Conner	RC	Y
3	Kay Allen	Owner (RT)	Y
4	Joshua Gallardo	Pharmacist	Y
5	Ed Voyer HB	Pharmacy Technician	Y
6	Rebecca Parent	Pharmacist	Y
7	Carissa Broburg	Pharmacy Technician	Y
8	Maryjesus Embrey	Pharmacy Technician	Y
9	David Cubros	Pharmacy Technician	Y
10	Amanda Hufhubbe	Pharmacy Technician	Y

Additional personnel were 2 pharmacy technicians, 2 administrative personnel, 3 shipping clerks and 12 customer service representatives.

Reminder Literature Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

Licensure/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Drug Enforcement Administration	DCA Pharmacy	Pharmacy	BD4990348 & exp - 07/31/2025
Tennessee Department of Health	Diabetes Corporation of America	Pharmacy	3481 & exp - 11/30/2024

Inspector Notes: List states on which Non-Resident licenses are held. Non-Resident Licenses are held in AL, AZ, AR, CO, FL, GA, IL, IN, IA, KS, KY, LA, MD, MI, MN, MO, MT, NC, NV, NJ, NY, NC, OH, OK, PA, SC, TX, VA, WV and WI. Prescriptions are also sent to Massachusetts (no permit required). DCA Pharmacy is a retail pharmacy that performs hazardous and non hazardous, nonsterile and sterile compounding. No ReSA meals was found on site and the pharmacy does not utilize platforms that are a marketplace to obtain drugs. The pharmacy is in the process of adding a new nonsterile hazardous negative room to replace the 2 hazardous nonsterile compounding rooms currently in use.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_19, Doc02_PI	Compounding Record for Terbinafine, Compounding Record for Semaglutide
Doc03_13117.00	Response to the TN Board inspection utilizing the NABP sterile module
Doc04_NS.AL2	CCAs
Doc05_1625.00	List of Hazardous Drugs
Photo01_19	Photo of Semaglutide API label

Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail	X	Central Fill/Processing/Repackaging	
Open to the Public	X	Mail-order Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		Home Infusion/Enteral Nutrition	
Medication order (eg prescriptions) are mailed through USPS or through common carrier) See table below	X	Outsourcing Facility	
Medication order (eg prescriptions) are mailed through USPS or through common carrier) See table below	X	FDA Registered Drug Manufacturer (eg Manufacturer, Repackager, etc/with)	
Local Delivery (if out of state provide in note)		Wholesale Distributor	
Veterinary (Pharmacy occasionally dispenses prescriptions for animals)	X	Nuclear Pharmacy (Provide appropriate license)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long Term Care (nursing home, institutional pharmacy)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials Research	X (1drug)	Nonsterile Hazardous Drug Compounding	X
Long-term care		Sterile Compounding	X
Internet Pharmacy		Sterile Hazardous Drug Compounding	X

Compounded Sterile Preparations (CSPs) Type "X" for all that apply		Outsourced Sterile Preparations (CSPs) Type "X" for all that apply	
CSP's with commercial substance(s)	X	CSP's with commercial substance(s)	X
CSP's with vitamins or nutritional supplements		CSP's with vitamins or nutritional supplements (lecithin and poor/sence in the dose)	X
CSP's sold to other pharmacies (if no, but to whom in-state, out of state, under common ownership/shared services, central fill agreement) and state if patient-specific or distributed		CSP's sold to other pharmacies (if no, but to whom in-state, out of state, under common ownership/shared services - and/or fill agreement) and state if patient-specific or not distributed	
Patient specific (compounded preparation labeled for an individually identified patient)		Patient specific (compounded preparation labeled for an individually identified patient)	
CSP's for animals	X	CSP's for animals	
CSP's for human patients	X	CSP's for human patients	X
Distributed (compounded preparation leaves the pharmacy without a patient-specific label) eg non patient-specific)		Distributed (compounded preparation leaves the pharmacy without a patient-specific label) eg non patient-specific)	
CSP's for animals		CSP's for animals	
CSP's for human patients		CSP's for human patients	
CSP's to practitioners for office use		CSP's to practitioners for office use	
CSP's to hospitals, clinics, or surgery centers		CSP's to hospitals, clinics, or surgery centers	

Types of CSPs		Categories of CSPs	
Aqueous	X	Category 1 CSPs	
Nutrigenomic	X	Category 2 CSPs	X
Hyperbaric bupivacaine		Category 3 CSPs	
Ophthalmic preparations	X	Types of CSPs	
Liquid oral preparations	X	Allergenic extracts	
Otic preparations		Allergenic extracts in addition to penicillin-related pens	
Rectal preparations	X	Immediate Use	
Vaginal preparations	X	Respiratory (eg, mist inhalations)	
Topical preparations	X	Blood derived or other biological materials (eg, platelet gels, sealants)	
Nasal and sinus preparations	X	Sterile, radiological, allergy extracts	X
Other (please list)		Oral solids or dosage forms	X
		Baths and soaks for live organisms and tissues	
		Implant of Portals	X
		Other (please list)	

Sterile Compounding Activity Data for Previous Fiscal Year (approximate)		Personnel	
Total Pharmacy staff	12000	Total Pharmacists	5
Nonsterile Compounding hours per week	1335	Number of Compounding Pharmacists	4 (1 nonsterile 3 sterile)
Nonsterile Compounding powder Rooms	2	Total Technicians	6
Nonsterile Chemotherapy Rooms		Total technicians (technicians actively compounding)	6 technicians (unlicensed & billing only -do not perform technician functions)
Nonsterile HD Compounding CVI ASC (CAG) Rooms	2	Number of Compounding Technicians	4 nonsterile
Sterile Compounding Area Rooms	21	Of technicians, how many are nationally certified?	7
Sterile Compounding Graphite/Ni Rooms	143	Of technicians, how many are techs in training?	0
Sterile Compounding Negative Pressure Rooms	1	Total Other Unlicensed Personnel	17
Sterile Compounding Number BSC hoods	0	Ratio of technician(s) : pharmacist(s) present at time of inspection	9:4
Sterile Compounding Number CAI (CAG) hoods	0	If multiple compounding suites are present under the same roof facility (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs, (eg location name, approximate size of space, and number and type of PEC's	N/A
Nonsterile Chemotherapy Sterile HD Rooms	84		
Sterile HD Compounding Number of CAG hoods	1		
Sterile HD Compounding Number of BSC hoods	0		

Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing, (N/A if no sample)	N/A		
Indicate the observations of the pharmacy noticed by you(s) the CSP inspection, if the responsible and fully gown and sniffer bathed records), indicate issues.	Modular anteroom was a completely viewable from the outside. Hand washing, gowning and compounding were observed through the windows.		
Volume Information		Volume Information	
Total Preparations Dispensed/day	850	Total Orders (Data Boundary)	0
% Veterinary Prescriptions	<1%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	1.7%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	2.1%	% Nonsterile Compounds Orders	0%
% Sterile Compounded Prescriptions	68%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	30%	% Hazardous Drugs (HD) Orders	0%

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: If not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	day, week, month
Alabama (AL)	398	0	week of 9/23/2024 - 9/15/2024
Alaska (AK)			
Arizona (AZ)	58	0	week
Arkansas (AR)	54	0	week
California (CA)			
Colorado (CO)	90	0	week
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)	76	0	week
Georgia (GA)	92	0	week
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)	17	0	week
Indiana (IN)	6	0	week
Iowa (IA)	28	0	week
Kansas (KS)	207	0	week
Kentucky (KY)	64	0	week
Louisiana (LA)	9	0	week
Maine (ME)			
Maryland (MD)	87	0	week
Massachusetts (MA)	3	0	week
Michigan (MI)	6	0	week
Minnesota (MN)	72	0	week
Mississippi (MS)	14	0	week
Missouri (MO)	765	0	week
Montana (MT)	0	0	week

Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: If not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	day, week, month
Nebraska (NE)	52	0	week
Nevada (NV)	2	0	week
New Hampshire (NH)			
New Jersey (NJ)	6	0	week
New Mexico (NM)			
New York (NY)	19	0	week
North Carolina (NC)	3	0	week
North Dakota (ND)			
Ohio (OH)	17	0	week
Oklahoma (OK)	8	0	week
Oregon (OR)			
Pennsylvania (PA)	11	0	week
Rhode Island (RI)			
South Carolina (SC)	3	0	week
South Dakota (SD)			
Tennessee (TN)	1477	0	week
Texas (TX)	94	0	week
Utah (UT)			
Vermont (VT)			
Virginia (VA)	25	0	week
Washington (WA)			
West Virginia (WV)	3	0	week
Wisconsin (WI)	11	0	week
Wyoming (WY)			
Other			

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General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 699286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

	General Pharmacy	Observation	Notes
1.00	Is the PIC (or pharmacy manager/site owner) present for the inspection? If no, is the observation over-ride?	Yes	
2.00	Is the PIC employed full-time at the pharmacy? (List the schedule if it varies or short job notes in note).	Yes	40+
3.00	Are there any other businesses located at this address? If yes, note type of business and name.	Yes	Health Homes is located at the address. Health store is separate locked access from the pharmacy area.
4.00	Does the pharmacy have any other addresses? (Include the address(es).)	No	
4.01	Does the pharmacy hold pharmacy wholesaler(s)?	No	
5.00	Do any other wholesalers link to the pharmacy website (such as a provider, or other affiliated? If yes, list	No	
6.00	Does the pharmacy allow patients to securely interactively provide and medical information through the website (such as through a secure patient portal)?	Yes	Patients may upload their prescription refills through an app provided by Pioneer
7.00	Are patients able to order or refill prescriptions through the website? If yes, describe.	Yes	Refills may be requested through the app
8.00	Are photographs allowed during the inspection (yes/no)?	Yes	
9.00	List of additional personnel interviewed as part of the inspection, including name and title:		Roy Allen, owner; Benjamin Myatt, (Name?) and Designated Person

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 699286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

	Types of Practice Additional Questions	Observation	Notes
10.00	Is the pharmacy majority or primary filled prescriptions (patient specific, labeled with product name when it leaves the pharmacy), and any of the deliveries to a provider or facility for administration to the patient? (Yes, if the majority of prescriptions or deliveries going to a provider or facility or if only a few stated reasons for dispensing to a provider or facility or office visits)	Yes	4% in TN and 4% in other states
11.00	Does the pharmacy provide prescription products to a provider or facility for office use? (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? If yes, explain reasons or circumstances that lead to decision to supply within the state and methods or procedures preferred by a provider or facility in other states	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributor (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.01	If yes, is the percentage of product distributed at wholesale to providers or facilities within the state less than 5%? (address active compliance risk if the percentage is found to exceed 5% - examples of prescriptions, other amounts of the state or other aspects of practice to note)	N/A	5
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? (Include active compliance risk if the percentage is found to exceed 5% - examples of prescriptions, other amounts of the state or other aspects of practice to note)	N/A	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
	General Operations and Licensure		
15.00	Are pharmacy licenses, permits, and registrations (controlled substances, U.S.A., etc.) posted in customers' view and current? *If any permits should be in a board-of-pharmacy approved licensure, etc.*	Yes	The licenses are posted on the wall.
16.00	Is the most recent board of pharmacy inspection report available for review? *Include the date of the most recent inspection and the frequency of a routine inspection by the board.*	Yes	The most recent board of Pharmacy inspection was conducted March 20-21, 2024. The onsite inspection utilized the NABP models.
17.00	Were any deficiencies noted? *Indicate the number and date of the most recent inspection.*	Yes	The deficiencies have been corrected. See Ck#10_6913 as the pharmacy's response to the inspection.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If "Yes," list the date, and the state. If the inspection and frequency of regard both for every state.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If "Yes," list the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (DEA, U.S.A., etc)? *If "Yes," state the agency and additional facts.*	No	

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the frequency and date, and was such a visit announced or unannounced?*	No	DEA came to the facility in 2017-2018 to view the labels prior, but did not perform an inspection.
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the most recent date and was the inspection announced or unannounced, if it was?*	No	FDA has not been in the facility since 2012.
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and when it was received and date, and if applicable, the frequency of a routine inspection by the NCPA.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *If yes, list and indicate when it was.*	Yes	NABP Accreditation was previously held by the pharmacy but the pharmacy did not meet onsite its accreditation in 2022, per VP.
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab device is current (usually the FDA or the lab device warns). If yes, report the Clinical Laboratory Improved Amendments (CLIA) waiver information, and list the name of the device used.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Pharmacy may be audited at any time without notice.*	Yes	Records are maintained on site for 7 years.
29.01	Are written and verbal prescriptions produced in writing kept on site for the entire retention period? *Include how they are kept (electronically, original and wet signatures).*	Yes	
29.02	Are electronic prescriptions (data as fax, e-scripts) kept on site for the entire retention period? *Include how they are kept (electronically, original and wet signatures).*	Yes	Maintained electronically.
30.00	Are all dispensing records (such as refills, modifications, DAW overrides) kept on site for the entire retention period? *Describe how each of the following records is printed and kept in hard copy:*	Yes	Maintained electronically.
30.04	Is there evidence in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Determine how they can and if deletions/edits or deletions are logged (e.g.)*	Yes	May discontinue a dispensed prescription but not delete. Maintained electronically.

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
	NAPLEX results are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
32.00	Is there a statement in the VAF or are other means used to ensure that the most stringent board regulations are followed? *Determine pharmacy status.*	Yes	Licensed in 31 states and also able to Massachusetts. The Designated Person keeps up with the revisions of regulations to that states the pharmacy is licensed
	Personnel *If any part of a question is no, check "No" and explain the circumstances.*		
34.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how. Do not disclose any*	Yes	The licenses are posted on the wall.
35.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	VPAD Pharmacy Services provides DEA check monthly. Licenses are validated at renewal.
36.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *Immunization, CPR, MTM, etc.). Mark N/A if no patient services that require additional training/certification. If you mark certification and it's current.*	N/A	
37.00	Does the pharmacy maintain the proper technician to pharmacist ratio? *Mark N/A if not governed by municipal, state, or federal law. Indicate the ratio of technicians to pharmacists and who must be in the store.*	Yes	The ratio at the time of inspection was 8:4. The technician ratio is 4:1.
	Facility and Security *If any part of a question is no, select "No" and explain the circumstances.*		
38.00	Does the pharmacy have a working security system in place? *If yes, describe.*	Yes	Alarm is monitored by Sys-care which includes video, door and window contacts and motion detectors
39.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If NO, determine how controlled substances are secured in place.*	Yes	Schedule II controlled substances are secured in a locked cabinet in the sterile storage area.
40.00	Are there contingency plans in the event the pharmacy cannot be secured? *Determine how the drugs should be secured and accessed.*	Yes	A pharmacist will stay on site until the drug is secured.

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
41.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter or crowding and how or backlog of prescriptions to be checked. If no, discussed with pic.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document trip hazards.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *Look destruction logs and ask how it is destroyed on site*	N/A	No destruction on site.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Clearcycle
37.05	Does the pharmacy have a hazardous waste handling and collection system? *For example, empty bottles that contained chemotherapy medications or vaccines, or hazardous drug compounding waste. If yes, include how often the bins are collected/picked and the vendor used.*	Yes	Stericycle collects every 2 weeks.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	The facility may be utilized if empty of an adjacent professional room should be utilized.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature (68° to 77°F), or more restrictive if warranted by specific drug product storage requirements? *Describe how and the frequency of the check of equipment.*	Yes	Manual continuously monitors the temperature and humidity. Alert is alerted of an excursion by text/email. The temperature was 72.5 degrees F.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or excursion detection using wireless? *Temperature must be documented. If yes, describe system.*	Yes	Manual continuously monitors the temperature and humidity. Alert is alerted of an excursion by text/email.
39.02	Are excursion action plans in place including re-labeling associated affects on drug product integrity?	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 608286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
44.00	Are the refrigerator and freezer restricted to drug products only and food?	Yes	
41.00	Does the pharmacy have a process for how the refrigerated temperature is monitored for deviations 24/7? If yes, describe the process. Include steps that are performed if a deviation is identified.	Yes	alarmed continuously monitors the temperature and humidity. Staff is alerted of an excursion by email/text. The range is 36-46 degrees F. Records are maintained indefinitely.
41.01	Is the temperature in the fridge/freezer within the USP range (2° 8°C or 36° 46 °F) or as specified by FDA approved labeling for drug product storage? Record the temperature at the time of the audit.	Yes	The refrigerators temperatures were 40.6, 41.6, and 39.42 degrees F.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? If yes, describe the process. Include steps that are performed if a deviation is identified. How long are records maintained?	Yes	alarmed continuously monitors the temperature and humidity. Staff is alerted of an excursion by email/text. The range is -13 to 14 degrees F. Records are maintained indefinitely.
42.01	Is the temperature in the freezer within the USP range (between -25° to -10°C or -13° to 14 °F) or as specified by FDA approved labeling for drug product storage? Record the temperature at the time of the audit.	Yes	One freezer is monitored, but in case of failure, the patient would be moved to another freezer. Freezer temperature was 2.7 degrees F.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? Describe process.	Yes	A generator (the generator has been refurbished since the last NABP inspection) is on site and there are redundant refrigerators and freezers if mechanical failure occurs.
44.00	Are there contingency plans in the event of heating or air conditioning failure? Describe process.	Yes	HVAC contract maintained.
45.00	In twice a year or action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated quantitative for prescription compounding/dispensing (such as robotics, Baker cells, etc)? FAS monitors and tapes.	Yes	2 Kirby Lea/Ao counters
4n.01	If yes, do they have and follow policies and procedures and evening cross-contamination and data alterations of drug products?	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 608286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
	Product Receipt and Inventory		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? Describe.	Yes	All wholesales utilized have attained NABP Drug Distributor Accreditation.
47.01	Does the pharmacy purchase all prescription drugs only from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? If yes, list pharmacy name (business), and attach records relating to the purchase.	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? List non-retail/bulk sources.	Yes	Amerisource/Bergen and Prescription Supply
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? If yes, how is that verified?	Yes	Prescription Supply provides transaction data on the invoice. Amerisource/Bergen states on their invoice that the product came directly from the manufacturer. The pharmacy views transaction data on the Amerisource website.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? If yes, describe the steps the pharmacy takes to determine the chain of custody and ownership of the drugs and/or the source of the product. Are the pharmacy records (pedigree, invoices and/or transactions) of each purchase available for review? Describe. (Example: pharmacy purchases from wholesaler, which in turn purchases from manufacturer.)	No	
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? If yes, describe the process.	Yes	Verify through the Board website
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? If yes, describe the process.	Yes	Verify through the FDA website
47.08	Does the pharmacy have a process to handle suspect and dispensable product investigations? If yes, describe the process.	Yes	Quarantine product and investigate.

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
47.09	Has the pharmacy conducted any recalls or discontinue product investigations of any, describe the process, including the steps taken, decision and classification (Examples: counted qty, etc)?	No	None to date.
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? Describe how the pharmacy ensures this is received and maintained for one for a minimum of 6 years.	Yes	
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA 222 forms to procure Schedule II substances? If yes, how are they received? Who has the authority and/or is allowed to sign the DEA 222 forms?	Yes	The 222 forms would only be utilized if CSOS could not be accessed and are locked in the C-S safes.
49.00	Does the pharmacy utilize CSOS (electronic) to procure Schedule II substances? If yes, who has power-to-act in CSOS?	Yes	PIC, Vivek Doctor
50.00	Is the receipt of Schedule II orders documented appropriately? DEA 222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.	Yes	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open / Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.	Yes	

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e-Profile ID: 608286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? If so, describe which product is and from whom they are purchased, product name, dosage and # of other items.	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? Describe. Are controlled substances counted on a routine basis? Describe frequency of counts and who is responsible for counts.	Yes	Controls are in place throughout the pharmacy and a perpetual inventory is maintained in Pioneer.
54.01	Are incidents of diversion or misappropriation of personnel for cause reported to the Board of Pharmacy, local authorities and DEA? Describe any incidents that have occurred and how they were handled.	Yes	Incidents would be reported to the Board of Pharmacy, local authorities and DEA if a controlled substance was involved.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedules II controlled substances (including APIs, if applicable)?	Yes	An inventory of controlled substance APIs are maintained in the computer system and a manual inventory is maintained, also. All are locked substances and maintained in the Pioneer system. The facility does not compound with Schedule II APIs.
56.00	Is the Schedule II perpetual inventory log reconciled regularly? Describe how often the Schedule II inventory is reconciled. How the pharmacy log and record that reconciliation is performed.	Yes	Controlled substances are reconciled during the controlled substance inventory.
57.00	At the most recent complete controlled substances inventory available for review? Indicate the date of the CS inventory and the inventory taken procedure (only one choice).	Yes	Controlled substance inventory is conducted every 2 years and the most recent was 4/30/2024.
57.01	Does the pharmacy maintain what any brief inventories (such as change in PIC, practices, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine and/or ephedrine products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are there products mixed, sold, or distributed into and stolen? How logs, if yes, if the store does?	N/A	

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
56.00	Does the pharmacy stock and sell other OTC medicated products for which ID is required and a log kept of the sale? *If yes, indicate product type.*	No	
56.01	Are these products stocked, sold, or delivered via any other means? *View logs. If yes, no observations noted.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how does the pharmacy ensure the removal of date products? Does it return to OTC storage?*	Yes	
60.01	Are all drugs within active stock within expiration date? *If no, how often are expirations and checked.*	Yes	
60.02	How often is active stock reviewed for drugs past the expiration date?		Monthly
61.00	Does the pharmacy prepackage bulk containers of prescription medications into smaller containers for ease of use? *How often is this done and by whom? How long are prepackaged materials kept?*	Yes	Varies. Compounded capsules are placed in a smaller container for ease of use and labeled with the BUD assigned.
62.00	Does the pharmacy prepack multiple drugs into a single container for compliance packaging? *What is the process for prepackaging?*	N/A	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with the label removed and BUD adjusted?	Yes	

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
	Prescription Processing		
64.00	Patient Profile: Is patient profile data re-printed and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate any missing patient profile data and the computer system that it is stored in or generated.*	Yes	A pharmacy technician enters the prescription. Customer service contacts the patient to obtain payment method and verification (e-prescribe including medications, OTC medications and herbal supplements). These are updated with each patient contact. A pharmacist performs a prescript and DUR at point-of-sale, if filling, final verification and counseling is offered (via text or phone call at the pharmacist's discretion).
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the owner/operator as required by state law? *Determine how it is established that the person is not the owner? Ask how it is determined that the patient is an animal? Ask how it is determined that the person who presents for pick-up is authorized (pet, relative).*	Yes	There is a dropdown of animal or human and the species and weight are entered in the Pioneer system.
65.00	Prescriptions: Are adequate processes in place to ensure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure in follow when a prescription is suspected of (or actually is) fraudulent? *Describe the input and reported process.*	Yes	Contact the prescriber to verify and contact the Board of Pharmacy if fraudulent.
65.02	Are adequate precautions in place for ensuring that prescription medications are not prescribed or dispensed based on erroneous medical conditions without there being a pre-existing prescriber patient/client relationship? *Describe the process with patients presenting the physical appearance of the patient and procedure.*	Yes	Compare addresses and staff is aware of the procedures that the monitoring staff was alerted. Staff is familiar with the procedures.
65.03	Does the pharmacy have electronic prescription capability? *Include whether it is for non-controlled and controlled substances, or both.*	Yes	Capability for controlled and non-controlled substances.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	Accuracy: Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	A pharmacist verifies each prescription at pre-check and final verification.

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
67.00	DUR: Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process it occurs in the DUR sale path.*	Yes	DUR occurs at pre-check by a pharmacist.
67.01	Does the DUR include: - drug-drug interaction (Prescription and OTC), - drug-allergy interaction, - therapeutic duplication, - under- or over-utilization (including correct dose/refinement), - overuse rate of question contraindication, - incorrect dosage or duration of therapy, and - gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	Some drug interactions are flagged for certain species.
67.02	In addition to the pharmacy DUR systems, does the pharmacy staff obtain other information to use in the DUR process? *Describe*	Yes	Weight may be obtained.
67.03	Does the pharmacy have adequate reference material(s) related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP on the state and the drug dates in which the pharmacy is licensed? *Describe.*	Yes	Actual data to report as required through Pioneer.
67.05	Does the pharmacy access state PMP/CSAP data for specific patients? *Verify there is a policy regarding access and follow up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/approvals documented? *Indicate how the override is documented and how does user log override.*	Yes	Documented electronically by log in credentials of the pharmacist.

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The information and comments obtained on the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Diplomat Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
67.07	Is the DUR process performed solely/mainly by the computer system? *Identify computerized drug database used.*	Yes	Medispan
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed.	Yes	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database and reference used, if any? *Identify what is used for veterinary medical DUR.*	Yes	Medi-Span has flagged some veterinary interactions. Xylitol (for dogs) has been flagged. Plumb's Veterinary Drug Handbook is utilized.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Describe process, as well, and how documented.*	Yes	Verified by a pharmacist at pre-check and final verification.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Follow state and federal regulations.
70.00	Counterfeiting: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access granted as appropriate such as upon termination. Provide a non-technical explanation of the system's controls.*	Yes	Pioneer
70.01	Does the pharmacy destroy RX including all-used prescription vials?	Yes	Iron Mountain shreds.
71.00	Mail Delivery: If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transit?	Yes	
72.00	Off-site Processes: Are any portions of the prescription processing (in the questions below) performed at a different location? *Note: Please ask each question below to verify.*	No	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 899295
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
#2.01	If yes, is the other location under common ownership? *If not answered, select "N/A". If there is a central pharmacy, is each location licensed in which it fills and dispenses outside of its own location.*	N/A	
#2.02	If yes, is that location in a different state than this facility? *If so, complete.*	N/A	
#3.00	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
#3.10	Off-Site Inventory: Does the pharmacy maintain any inventory at its nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note ownership of facilities or vehicles.*	No	
#3.01	Do the emergency kits contain any compounded products? *If so, evaluate whether one or both of remainder and see Sterile Compounding inspection procedure.*	N/A	
#4.00	Off-Site Inventory: Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy (such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc.? *Note types and locations.*	No	
#4.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Review policies.*	N/A	
#4.02	Do the automated dispensing devices contain any compounded products? *If so, evaluate whether certain policies and see Sterile Compounding inspection procedure.*	N/A	

Patient Counseling and Communication

If any part of a question is true, enter "Yes" and explain the circumstances.

#5.00	Does the pharmacist provide counseling on all new prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
#5.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer."*	Yes	A pharmacist has to make the offer
#6.00	Does the pharmacist provide counseling on all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	No	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 899295
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
#6.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	Any employee may make the offer of counseling on meds
#7.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	A pharmacist may refuse a meds that the medication cannot be picked up unless the pharmacist speaks to the patient or patient's representative.
#7.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer."*	N/A	
#8.00	Is patient counseling provided for pharmacy or exceptions? *Patient information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Determine how.*	N/A	No over-the-counter prescriptions.
#9.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Determine how.*	Yes	Printed information and toll-free number are included with the medication
#9.03	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Check the box.*	Yes	Printed and included with medication.
#9.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Check the box.*	Yes	Printed and included with medication.

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 899295
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
#2.00	Are HLMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *(for prescribing such as Isotretinoin, Thalidomide)*	Yes N/A	
#3.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Determine how.*	Yes	
#4.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the applicable state. Determine how (such as a phone number) and how it works (live vs. IVR).*	No	A patient may leave a message that will be returned when the pharmacy opens
#5.00	Are processes in place to handle a drug recall?	Yes	
#6.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
#6.01	Does the take-back program include controlled substances?	N/A	
#6.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 899295
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
	Quality Assurance/Quality Improvement Program *If any part of the question is true, enter "Yes" and explain the circumstances.*		
#7.01	Is there a documented continuous quality improvement (CQI) Program for the purposes of detecting, documenting, evaluating, and preventing quality related events (QREs)? *If not, skip the remainder of the program.*	Yes	Jess Myers
#7.01	Policies and procedures for the program are maintained in the pharmacy in an easily retrievable area. *Confirm if them in use, reviewed, current.*	Yes	Daily reviews and hard copy are maintained
#7.02	"Quality Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient, or inadequate or incorrect packaging, labeling, or drug advice; 2. a failure to identify and manage over utilization or under utilization, therapeutic duplication, drug-disease contraindications, drug-drug interactions, incorrect drug dosage or duration of drug treatment, drug-allergy interactions, or clinical abuse/misuse; 3. packaging or markings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy	Yes	
#7.03	There is documentation of establishing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or mentioned at a yearly meeting.*	Yes	
#8.00	Documentation of QREs starts as soon as possible, but no more than three days after determining they occurred. *Indicate if QREs are entered into a hard copy or computer log.*	Yes	Hard copy and computerized initially and stored electronically. Documentation begins as soon as possible.

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 908288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
89.01	Documentation includes all the pertinent data about the prescription involving including personnel involved at each step.	Yes	
89.02	Documentation includes documenting the type of CAS, details and how who discovered the CAS.	Yes	
89.03	Documentation includes possible contributing factors such as dry and time the CAS occurred, impact of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work flow at the time.	Yes	
89.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.05	CAS data collected is analyzed to assess causes and any contributing factors (root causes) trended with a defined time period and frequency (shift, each event, weekly, monthly, quarterly, etc.)	Yes	Ran shift patterns with each event.
89.06	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop preventive systems and workflow processes designed to prevent CAS's and increase good outcomes for patients.	Yes	
89.07	For pharmacies utilizing e-chop laboratory products, review of each formulary is conducted to ensure that appropriate medications are being offered/included to the best interest of patients.	N/A	
90.00	Quality meetings are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, training, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 908288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
90.02	Improvements or changes made are evaluated for pertinence to measure the effectiveness of the CQI program.	Yes	
91.00	Reporting: Incidents or CAS's are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. Include NAPP organizations and reported activity, if the pharmacy reports CAS's to the board of pharmacy.	No	Board of Pharmacy if required.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, EMS, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	Quality Self-Audits are performed by the pharmacy at least quarterly (and each change in PIC) to determine whether the occurrence of CAS's has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	No	Annually per licensed.
93.00	Consumer Surveys are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
94.00	Patient Complaints are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 908288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		Note: Each NCSP will not have each SOP. Identify the most applicable SOP(s) for each compounded sterile dose (CSD) observed during the inspection.	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? *If yes, document "yes.xyz" in Inspector Notes. If yes, document the name, number, and version of each SOP in the Inspector Notes*	Yes		11
1.1	Buildings and Facilities: The pharmacy has an SOP for the compounding facility. *Inspector note: Per USP <795>, there is a written SOP for "the method of segregation for the area designated specifically for nonsterile compounding and processes for manufacturing, labeling, and servicing the compounding area and equipment."*		3.01, 3.02 3.04, 3.05	4.1 5, 11
1.2	Personnel Training and Evaluation: The pharmacy has an SOP describing the training programs, the frequency of training, and the process for evaluating the competency of personnel. *Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."*		2.01 (Employee Training), 2.03 (Sterile Compounded Dose), 2.04 (Non-Sterile Compounded Dose)	2, 11

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
1.3	Personal Hygiene and Garbing: The pharmacy has an SOP regarding personnel hygiene, gloves, and garbing requirements consistent with compounding activities. *Inspector note: Per USP <795>, "Garbing requirements and frequency of changing gear must be determined by the facility and documented in the facility's SOPs."*		3.06 (Proper Hand Washing), 3.10 (Limit Garb), 3.13 (Nonsterile Lab Garb)	3.3, 11
1.4	Components: The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. *Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."*		6.01 (Product Procurement, Receipt, and Inspection), 7.01 (Receiving, Storage, and Handling of Hazardous Drugs)	6.2, 11
1.5	Temperature Monitoring: The pharmacy has an SOP regarding temperature monitoring and recording of refrigerator. *Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage areas."*		3.03 (Environmental Monitoring) 3.08 (Action Plan for Excursions)	4.2 11
1.6	Equipment: The pharmacy has an SOP for assessment of need for closed systems processing devices based on the types of CNSPs prepared. *Inspector note: Per USP <795>, "Weighing, processing, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], inhaled substances), and nonsterile manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."*		1.03 (General Compounding Techniques)	6.1, 11

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024, 10/2/2024, 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
5.7	Safety Data Sheet (SDS)/Spill Management: The pharmacy has an SOP describing spill management and disposal. (a) *Inspector note: Per USP <795>, "The management and documentation of final assessment component spills and disposal must be described in the facility's SOPs."*		2.1H (Safety Procedures)	9.2 h, 11
5.8	Master Formulation Records (MFR): The pharmacy has an SOP on the process for MFR creation and revision. *Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."*		3.04 (Compute Worksheet)	7.1, 11
5.9	Labeling: The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errant and CNSP mix-ups and required displayed information. *Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."*		5.02 (Product Labeling)	9, 11
5.10	Quality Assurance (QA)/Quality Control (QC) Program: The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), training of compounding personnel, adherence to procedures, and prevention and detection of errors and quality issues. *Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."*		6.01 (The Quality Assurance Program)	11, 12 USP <1163>

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

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Inspection Date: 09/30/2024; 10/1/2024, 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
5.11	CAGO Progress Complaint Handling and Adverse Event Reporting: The pharmacy has an SOP for resolution of complaints and adverse events, including investigations and corrective actions. *Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."*		3.02 (Complaint Handling), 9.05 (Recalls)	9.1, 9.1.1, 12.1, 12.2, 12.3
5.12	Packaging: The pharmacy has an SOP describing packaging CNSPs. *Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."*		5.04 (Billing and Delivery)	11, 13.1
5.13	Transporting: The pharmacy has an SOP describing transporting CNSPs. *Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."* *If the pharmacy does not transport CNSPs, Inspector should answer statement as N/A.*		5.04 (Billing and Delivery)	11, 13.1

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Inspection Date: 09/30/2024, 10/1/2024, 10/2/2024, 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
5.14	Recalls: The pharmacy has an SOP describing minimum requirements for recalls. *Inspector note: Per USP, "The facility must have procedures in place to:* *- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the personnel to cease patient harm (eg, strength, purity, or other quality attributes)* *- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy.* *- Investigate all affected lots are affected and recall if necessary"* *An SOP for recall should address:* *- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall.* *- Procedures to determine the distribution of any affected CNSP, including the date and quantity of distribution.* *- Procedures to identify persons who have received the CNSP.* *- Procedures for disposal and documentation of the recalled CNSP (any)* *- Procedures to investigate and document the reason for recall."*		9.05 (Recalls)	12.1
	Designated Person(s) and Personnel Training Program			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? *Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."* *If no, go to compliance statements*	Yes		11.1.4

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties involved in them.	Yes		11.1.4, 12
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. *Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."*	Yes		11.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure the competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		11.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		11.1.4, 11.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		11.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		11.1.4, 11.

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 806286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and orderly.	Yes		4.1
8.4	The compounding area is orderly (e.g., clutter free, no shipping materials).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix-ups among components, substances, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes sources of contamination from non-compounding areas.	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
9.0	Is the nonsterile compounding area free of carpet?	Yes		4.1
10.0	Does the pharmacy's storage area for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open: *Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."* *If pharmacy does not use a continuous recording system, evaluate the frequency of temperature recording in the notes.*	Yes		4.2
10.2	The pharmacy's temperature-monitoring records are readily retrievable. *Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."*	Yes		4.2
10.3	Temperature-monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. *Inspector note: Per USP, "All temperature-monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.* *Monitoring devices are typically calibrated or replaced.*	Yes		4.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 806286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
10.4	Pharmacy has a process to ensure temperature excursions *Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either lower or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component's integrity or quality has been compromised and if so, the CNSP or component must be discarded."*	Yes		4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment free of dirt, dust, and debris, and waterproof/moisture proof to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the bulk/non-sterile compounding storage area? *Record in the Inspector Notes.*	[redacted]	73.3 degrees F	4.2
12.0	Are plumbing fixtures, water heaters, and cleanliness of sink in compliance with USP <795> standards? *If no, go to compliance statements*	Yes		4.3
12.1	The pharmacy well was easily accessible with valves or nearby the nonsterile compounding area?	Yes		4.3
12.2	There is hot and cold (running water) available at the sink(s) in nearby the nonsterile compounding area.	Yes		4.3

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e-Profile ID: 806286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
12.3	The sink is constructed of SS (stainless) or nonporous material and is free from any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or previous osmosis water used for rinsing equipment and utensils used in nonsterile compounding? *Inspector note: This is a USP recommendation.*	Yes	Sterile water for injection	4.3 USP <1231>
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? *Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and potential potential to cause residues."* *List the agents in the Inspector Notes.*	[redacted]	IPA 70 %, PHE-empt and Sani Cloth wipes	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces of the minimum frequency per Table 1 and documented in a log or other format in compliance with USP <795> standards? *Review compounding cleaning logs* *If no, go to compliance statement*	Yes		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the beginning of each shift on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the end of each shift on days when compounding occurs.	Yes		5 Table 1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808288

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
15.2	All work surfaces are cleaned and sanitized between compounding CNSPs with different components.	Yes		5 Table 1
15.3	Gloves are donned and sanitized each time compounding occurs.	Yes		5 Table 1
15.3.1	Walls and ceilings are cleaned and sanitized when visibly soiled. *Inspector note: No specific frequency is specified by USP. Have compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.*	Yes		5 Table 1
15.3.2	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (e.g. spills/dust) or spills are known or suspected.	Yes		5 Table 1
15.3.3	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
15.5	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? *Inspector note: This is a USP recommendation. Per USP, floors should be resistant to damage by cleaning and sanitizing agents.*	Yes		5

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Nonsterile Compounding Inspection for USP <795>
Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bag)? *Inspector note: Per USP, examples of closed-system processing devices include, containment ventilated enclosure (CVE), biological safety cabinets (BSC's), and single-use contained glove bags.* *If YES, list the type(s) in the inspector notes.*	Yes	(BSCs are utilized)	5.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? *Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or adsorptive, and must not alter the quality of CNSPs."* *Review certification reports, calibration records, and cleaning logs.* *If no, go to compliance statements*	Yes		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs compounded. *Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.*	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.2	Pharmacy has evaluated and documented the risk(s) for compounding pharmacy activities for weighing, measuring, and dispensing the API (assessment of risk). *Inspector note: Per USP, "components, that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."* *If no, inspector should answer observations.*	Yes		6.1
18.3	The equipment and devices used for compounding CNSPs are stored and stored in a manner and frequency that protects the risk of contamination. *Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination on the next preparation." Additionally, per Table 2:* *- CVE/BSC are cleaned and sanitized at the beginning and at each shift when compounding begins, after spills, and when surface contamination (e.g., from spills) is known or suspected;* *- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;* *- Under the work surface of a BSC is cleaned and sanitized at least monthly; and* *- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.* *If no, inspector should describe observations.*	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). *Inspector note: For example, the pharmacy may need to have a scale and/or balance prior to use.*	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.5.1	Equipment and devices are verified for accuracy as recommended by the manufacturer or at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent. *If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as scales needed for weighing or measuring), the inspector should answer this statement as N/A.*	Yes		6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. *If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If no pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.*	Yes		6.1
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for these products.* *If no, go to compliance statements.*	Yes		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. *If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.*	Yes		6.2.1

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		Observation	Inspector Notes	USP Reference(s)
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for purity) and that the test results for the component show the API meets expected quality. *Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay, has been performed and will include water content (so any concentration calculations can be performed).*	Yes	Qual20_20270 2	6.2.1
20.3	All APIs used are manufactured by an FDA registered facility. *Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer to find out the COA to determine if they are registered as an FDA drug establishment listed at https://fdf.accessdata.fda.gov/scripts/cder/drugsatfda/index.cfm*	Yes		6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? *List the type(s) in the inspector notes.*	[redacted]	Sterile Water for Irrigation	6.2.1
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? *If not, go to compliance statements.*	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
23.1	For non-commercially manufactured components, the COA is reviewed upon receipt. *Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in all appropriate USP–NF monographs. If any it does." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify any COA as reviewed.*	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including receipt date, identity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaged system received the date the component must no longer be used by the pharmacy. *Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797, 8.3.2. Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."*	N/A		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or manufacture is/are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
23.5	Any other lots of that (rejected) component have that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		6.2.1, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging systems (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have occurred during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components whose correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or illegible labeling) are immediately rejected and if not, immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and local/applicable of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, then loss and deterioration.	Yes		6.2.4

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		Observation	Inspector Notes	USP Reference(s)
25.0	When components are removed from the original container and not used at compounding (eg, excess after weighing), are they documented and not returned to the original container to minimize risk of contaminating of the original unopened container? *Inspector note: This is a GMP recommendation, not required.*	Yes	Components are never returned to container	6.2.4
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit on the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process in manager who documents any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 800288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
	Multi-Mr Formulation Records (MFR) and Compounding Records (CR)			
	Inspector should review a minimum of five (5) MFRs and five (5) CRs.			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? *Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.* *If no, go to compliance statements.*	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Bullet 2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1
27.3	Does the designated person(s) or employee evaluate CNSP's characteristics when correlating the assigned BUD for all MFRs? *Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders have to consider parameters that may affect quality, including but not limited to the following:* *- Chemical and physical integrity properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparations are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)* *- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, absorption, and storage conditions)* *- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP* *- Potential for microbial proliferation in the CNSP (and)* *- Significant deviations from essential compounding steps and procedures; if omitted, the essential compounding steps may have an impact on the stability of the formulation."*	Yes		7.1, 10.2 Table 4

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		Observation	Inspector Notes	USP Reference(s)
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? *If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.*	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container-closure system(s).	Yes		7.1
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. *Inspector note: Per USP, the MFR will also include, "Other information needed to [describe] the compounding process and ensure reproducibility [(e.g., labeling, temperature)]." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure reproducibility include, but are not limited to: speed of mixing, settings on equipment, and specific order of mixing of ingredients."* *Inspector should review several MFRs for completeness of instructions.*	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
29.0	MFR contains the calculations to support the assigned BUD.	Yes		7.1
29.1	Labeling requirements (eg, those with the generation of the MFR).	Yes		7.1
29.2	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
29.3	An MFR has CR(s) procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
30.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? *If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).*	Yes		7.2, 14
30.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
30.2	The CR includes the name, strength of activity, and dosage form of the CNSP.	Yes		7.2, 14
30.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
30.4	The CR includes the assigned internal identification number (ID), prescription, order, or lot number).	Yes		7.2, 14
30.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
30.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
31.0	The CR includes, name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
31.1	The CR includes the weight or measurement of each component.	Yes		7.2, 14
31.2	The CR identifies the total quantity compounded.	Yes		7.2, 14
31.3	The CR has the assigned BUD and storage requirements.	Yes		7.2, 14
31.4	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.2, 14
31.5	The CR has a physical description of the final CNSP.	Yes		7.2, 14
31.6	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
31.7	The CR includes a MFR reference for the CNSP.	Yes		7.2, 14
31.8	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
31.9	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

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		Observation	Inspector Notes	USP Reference(s)
30 D	Are there procedures for in-process checks performed by a second staff member? *Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks include written procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation.* *Inspector should describe their observations in the Inspector Notes.*	Yes	The components are assessed and the weight is electronically sent to the Compounding Record. Liquid measurements are verified by a pharmacist. A pharmacist performs final verification once compounding is completed.	2, 7.2, 8
Labeling				
31 D	Are the pharmacy's labels for CNSPs in compliance with USP </795> standards? *If no, go to compliance statements.*	Yes		9
31.1	Information on the label is permanently and legibly displayed. *Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper on which the article is enclosed, except for any outer shipping container."*	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1 3, 9
31.3	The label on the immediate container includes an assigned internal identification number (for example, prescription, order, or lot number).	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
31.4	The label on the immediate container includes the active ingredients and their amount(s), potency(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container lists the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container displays the BUD. *If no, please describe whether the pharmacy stated it used the term "expiration date" or similar language or if the information was not included on the label.*	Yes		9
31.7	The label on the immediate container indicates the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not dispensed from the container.	Yes		9
32 D	Does the labeling on the dispensed CNSP include the route of administration? *Inspector note: This is a USP recommendation.*	Yes		9
33 D	Does the labeling contain information identifying the CNSP as a compounded preparation? *Inspector note: Per USP, this is a recommendation.*	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? *Inspector note: This is a USP recommendation.*	Yes		9
35 D	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be used outside of the facility or health care system? *Inspector note: This is a USP recommendation.* *If the pharmacy only compounds CNSPs for patient use inside the, e.g., health care facility, inspector should answer this question as N/A.*	Yes		9

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
Establishing Beyond-Use Dating (BUD)				
36 D	Is each CNSP assigned and labeled with a BUD in compliance with USP </795> standards? *Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date." If no, go to compliance statements.*	Yes		(4) USP </7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and should be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes		10.1
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in light, light resistant containers/overpacks. *Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the safety of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in light, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Compelling BUDs for CNSPs apply."*	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
37.0	Does the pharmacy assign the beyond-use date (BUD) based on stability data or any relevant peer-reviewed literature specific to the drug, dosage form, and storage conditions for the compounded preparation? *Inspector note: Per USP, "For CNSPs prepared from one or more nonsterile components, the BUD should generally not exceed the shortest BUD of any of the individual nonsterile components; however, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the constituted components, the physical, chemical, and microbiological quality of the final CNSP must not be adversely impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see and track: solutions (and other formulas within a formula) such as methocel 10% ointment, which is a combination of two components, including the name of the component whose BUD was shorter was the assigned BUD of the final CSP.*	Yes		10.4
38 D	Does the pharmacy document the calculations used to establish the assigned BUD? *If no, what calculations are missing from the BUD for a MFR?*	Yes		7.1, 10.2, 10.3
39 D	Does the pharmacy compound CNSPs with an USP monograph?	No		10.5
40 D	Does the pharmacy compound CNSPs following the USP monograph precisely? *If no, go to compliance statements.*	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. *If no, inspector to collect a copy of the compounding record, label, and describe what specific steps of the monograph were not followed.*	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.3	Components used by the compounder match those listed in the monograph. *If no, describe the source of the component in the monograph and the source that the pharmacy used.*	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. *If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.*	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD timesaving limits established in Table 4 for CNSPs in compliance with USP <795> standards? *Inspector note: This question is for the CNSPs compounded that are not following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has components or has access to CNSP-Specific Stability References). Per USP, the pharmacy is not required to measure water activity (A$_w$) for a CNSP.* *If no, go to compliance statements.* *If all CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.*	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.1	Non-preserved, Aqueous Dosage Forms: The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. *Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a A$_w$ ≥ 0.8, eg, emulsions, gels, creams, solutions, sprays, or suspensions.* *If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	N/A		10.4 Table 4 USP <795>
42.2	Preserved, Aqueous Dosage Forms: The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. *Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a A$_w$ ≥ 0.8, eg, emulsions, gels, creams, solutions, sprays, or suspensions.* *If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	Yes		10.4 Table 4 USP <795>

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		Observation	Inspector Notes	USP Reference(s)
42.3	Nonaqueous, Oral Liquid Dosage Forms: The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. *Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A$_w$ < 0.8. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspensions.* *If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	Yes		10.4 Table 4 USP <795>
42.4	Nonaqueous Dosage Forms: The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. *Inspector note: Per USP <795>, Nonaqueous (solid) dosage forms are ones that have a A$_w$ < 0.8. Some examples include capsules, tablets, granules, powders, nonaqueous suppositories, suppositories, and troches or lozenges.* *If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.* *If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.*	Yes		10.4 Table 4 USP <795>

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		Observation	Inspector Notes	USP Reference(s)
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the limits in Table 4 (refer to Q42.0)?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? *If no, go to compliance statements.*	N/A		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 100 days. *If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.*	N/A		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 300 days. *If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.*	N/A		10.5
44.3	Pharmacy is following the result of their own stability study (one ... *If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.* *If pharmacy is following a brokered study, inspector may mark this statement as yes if nonconformance of CNSPs are not within the concentrations specified within the study. If pharmacy is following a brokered study and is using a concentration outside the ? study, answer this question as N and describe observations.*	N/A		10.5

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method for extending BUDs. *Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.* *If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another facility) for extending BUDs, inspector should answer this question as N/A.* *If no, please describe the inspector observations.*	N/A		10.5
44.5	The cited stability study (which used a stability-indicating analytical method for extending BUDs) canvasses the API(s), CNSP formulation, and material composition of the container closure used. *If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another facility) for extending BUDs, inspector should answer this question as N/A.* *If no, please describe the inspector observations.*	N/A		10.5
44.6	The cited stability study (which used a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. *If no, describe the concentrations cited in the stability assay and the concentration of the CNSP compounded by the pharmacy.* *If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another facility) for extending BUDs, inspector should answer this question as N/A.*	N/A		10.5

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation on the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation and the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system) *Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information satisfies the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.*	N/A		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM)			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? *If no, go to compliance statements*	Yes		11.3, 12
45.1	The pharmacy has a formal (QA/QC) program with documented activities. *Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."*	Yes		12
45.2	The QA/QC program addresses adherence to procedures.	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
46.1	The QA/QC program has defined prevention and detection of errors and takes quality positions:	Yes		12
46.4	The QA/QC program defines evaluation of complaints and adverse events. *Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.*	Yes		12
46.5	The QA/QC program defines approaches to investigations and corrective actions.	Yes		12
46.6	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. *Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint, in addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up, the name of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."*	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
47.3	Complaints are reviewed to determine whether a deficiency in a potential quality problem with the CNSP	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations include whether the quality problem extends to other CNSPs.	Yes		12.2
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. *Inspector note: Per USP, the pharmacy is to "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."*	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint or questioned until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		11.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? *Inspector note: Per USP <795> registries all recalls to be readily retrievable for two years, including recalls. However, the state/jurisdictional regulatory body requirements may be longer for a longer period of time.* *Review event record recall and determine if the inspector agrees. If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.*	No		12.1, 14
48.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		12.1, 12.2, 12.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808288
Inspection Date: 09/30/2024; 10/01/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
48.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
48.2	The pharmacy demonstrate the implementation of the recall.	Yes		12.1
48.3	If necessary, reports received CNSP's to the appropriate regulatory bodies (as required by law) and inspections of the applicable regulatory jurisdictions.	Yes		1.1.3, 12.1
48.4	Investigational data on adverse events that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
49.0	Does the pharmacy procedures indicate a step to immediately notify the prescriber of a failure of reconstitution with potential to cause harm (eg, strength, purity, or other quality parameter)? Inspector note: This is a USP recommendations.	Yes		12.1
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? *If no, go to compliance statements.*	Yes		13.1
51.1	The packaging materials protect CNSP's from breakage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used provide preservation from exposure (inside the packaged CNSP).	Yes		13.1
52.0	The packaging materials intended by the pharmacy maintain the physical and chemical integrity and stability desired for CNSP's (eg, prevent from light).	Yes		13.1

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personnel Observations *(Inspector note: Observe personnel performing compounding and not their supervisor. The observation should be conducted by observing the work of the individual performing compounding. It is acceptable for the inspector to observe compounding activities with the consent of the individual being observed. The inspector should not interrupt the individual while he/she is performing compounding activities.)*			
53.0	Personal Preparation Observation: Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? *If no, go to compliance statements*	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, handbags, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may wear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1
Note: 53.5	Any accommodations permitted by the designated personnel's health by documented inspector note: *For USP <795>, accommodations may be permitted as long as the quality of the CSP and environment are not affected.*	N/A	None are documented	3.1
54.0	Hand Hygiene Observation: Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? *If no, go to compliance statements*	Yes		3.2, Box 1

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		Observation	Inspector Notes	USP Reference(s)
54.1	All personnel who enter the compounding area to compound participated hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	Garbing Observation: Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOP's).	Yes		3.3 Box 1
55.2	All personnel wear sterile compounding activities sun gloves. *Inspector note: Per USP, "Gloves must be worn for all compounding activities."*	Yes		3.2, 5.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves rebuilt or replaced before beginning compounding a CNSP with a different component or when other physical injury occurs (eg, pens, keyboards) to minimize risk of cross contamination with other CNSP's? *Inspector note: This is a USP recommendation.*	Yes		3.3
57.0	List the name(s) of the CNSP's observed by the inspector as part of the compounding demonstration.		Cutasol 0.5mg/ml eye/ET cream	

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		Observation	Inspector Notes	USP Reference(s)
58.0	Compounding Observations: Are compounding personnel using appropriate nonsterile compounding techniques for CNSP's in compliance with USP <795> standards? *If no, go to compliance statements.*	Yes		2 line 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOP's.	Yes		3.1, 4.1
58.2	The compounding personnel selected the correct area for CNSP's.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct SA of for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. *Inspector note: Per USP <795>, Box 1, personnel are to wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.*	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (API's) and/or components. *Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.*	Yes		6.2 [6.2.1 - 6.2.5]
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR/SOP and is in good working order prior to use for the CNSP. *Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, temperature and/or balances).*	Yes		6.1 Table 2

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		Observation	Inspector Notes	USP Reference(s)
08.6	The compounding personnel have knowledge of and access to the 795	Yes		6.2
08.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1, 1.3
08.10	The compounding personnel compound the CNSP according to the MFR. *If no, inspector needs to describe in detail (not observations in the Inspector Notes) and collect a copy of the MFR and CR (no PHI or ID to be collected).*	Yes		7.1, 7.2 Box 2
08.11	The compounding personnel document any required steps listed in the MFR on the CR. *Inspector note: This would include any weights, volume, and any in-process checks accessed.*	Yes		7.2, 14 Box 3
08.12	Documentation on the CR is legible. *If no, collect copy of record that is illegible. Redact any PHI on record.*	Yes		14
08.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
08.14	The compounding personnel performed any quality control steps specified in the MFR. *Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.* *If no, describe observations in Inspector Notes.*	Yes		7.2, 8, 8.1; 14 Box 3
08.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		6.1 Box 2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
08.16	The compounding personnel labeled the CNSP. *Inspector note: Storage requirements must be included on the label if refrigerated or frozen (no patient-centered info stored - beyond/use requirements).*	Yes		6
08.17	The compounding personnel completed any documentation on the CR. *If no, describe observations of what was missing or omitted in Inspector Notes.*	Yes		7.2, 8, 14 Box 3
08.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
09	Final CNSP check observation: Does the visual inspection of the CNSP by the pharmacist conform all USP <795> requirements? *Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs reviews inspection observed in the Inspector Notes.* *If no, go to competency statements.*	Yes		8, 8.1, 8
09.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, precautions must be shielded for phase separation).	Yes		8, 8.1
09.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
09.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
09.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
09.5	CNSP label was verified against the CR	Yes		8, 8.1, 9

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
09.6	If the CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
09.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14
09.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal.	Yes		8.1
09.9	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? *Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.* *Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, discoloration/suspected mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information, BUD assigned; and collect photographs, copy of MFR, and CR.*	Yes		12

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Nonsterile Compounding Inspection for USP <795>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
01.0	Cleaning and Disinfection Observation: Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standard? *Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.* *If no, go to compliance statements.*	Yes		5
01.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
01.2	Pharmacy staff performs cleaning and sanitizing between compound ng CNSPs with different components. *Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."*	Yes		5 Table 1
01.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross-contamination of the next preparation).	Yes		6.1 Table 2
01.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

Nonsterile <795> Employee File Records Review:

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. Do not record the employee names, but only their title or position.

From the drop-down List, –

"Mark as "Yes" if the document is present in the records and the competency evaluation was completed in compliance with USP <795> requirements.

"Mark as "No" if the document is present in the records but is not in compliance with USP <795>requirements.

"Mark as "Missing" if any part of the record is missing and explain in Notes column.

"Mark as "N/A" if the training does not apply (e.g., for non-pharmacy staff who have some training activities). Document further in the Notes column.

	Employee Title	Designated Person	Pharmacy Technician	Pharmacy Technician	Pharmacy Technician	Pharmacy Technician	Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competences listed below:						
1.1	Compounding personnel are trained on facility SOP's	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for gowning is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting chlorumentol and CNSPs is complete	Yes	Yes	Yes	Yes	Yes	

	Employee Title	Designated Person	Pharmacy Technician	Pharmacy Technician	Pharmacy Technician	Pharmacy Technician	Notes
1.7	The training record for aseptic gowning is complete	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete	Yes	Yes	Yes	Yes	Yes	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete	Yes	Yes	Yes	Yes	Yes	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete	Yes	Yes	Yes	Yes	Yes	
1.12	The training record for spill management is complete	Yes	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following areas:						When the new hire standards were released all training was present. Annual competencies are not yet due
2.1	Compounding personnel are trained on facility SOP's	N/A	N/A	N/A	N/A	N/A	
2.2	Compounding personnel are trained on USP <795> standards	N/A	N/A	N/A	N/A	N/A	
2.3	The annual competency assessment for hand hygiene is complete	N/A	N/A	N/A	N/A	N/A	
2.4	The annual competency assessment for gowning is complete	N/A	N/A	N/A	N/A	N/A	

	Employee Title	Designated Person	Pharmacy Technician	Pharmacy Technician	Pharmacy Technician	Pharmacy Technician	Notes
2.5	The annual competency assessment for cleaning and sanitizing is complete.	N/A	N/A	N/A	N/A	N/A	
2.6	The annual competency assessment for handling and transporting chlorumentol and CNSPs is complete.	N/A	N/A	N/A	N/A	N/A	
2.7	The annual competency assessment for measuring and mixing is complete.	N/A	N/A	N/A	N/A	N/A	
2.8	The annual competency assessment for proper use of equipment is complete.	N/A	N/A	N/A	N/A	N/A	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	N/A	N/A	N/A	N/A	N/A	
2.10	The annual competency assessment for interpreting a COA is complete	N/A	N/A	N/A	N/A	N/A	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	N/A	N/A	N/A	N/A	N/A	
2.12	The annual competency assessment for spill management is complete.	N/A	N/A	N/A	N/A	N/A	
3.0	The designated person(s) has documented a (personal) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note, if there are not observations documented, the inspector should answer this question as N/A.* For DCA, the designated person(s) should monitor and oversee compounding activities and must also incorporate evidence within their daily and practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel.	N/A	N/A	N/A	N/A	N/A	

Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation; thereby becoming the active ingredient in that preparation and exhibiting pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A commercially manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inhaling, applying, or otherwise providing a nonsterile medication in its final form in a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids for facility patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned Period	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Categorical Safety Control (CSC)	A verified control that may be used for compounding. These controls are divided into three general classes: Class I, Class II, and Class III. Class II CSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the methods.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.

Glossary & References	USP <795>
Component	Any ingredient used in the compounding of a preparation, including any API, added substances, or nonmedicinally manufactured product
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, mixing, pooling, incorporating other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designed for nonsterile compounding.
Compounding personnel	Individual (names) is competent at overseeing compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A weight-wise disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, consider, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	That part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.

Glossary & References	USP <795>
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a particular including for its identity, strength, purity, and performance. It also describes the tests to validate that it maintains and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available if and when needed for consultation, even if not physically present (e.g.,
Preservatives	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). The source water may be purified using unit operations that include domestication, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1 [Purified Water].)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that operations have been met for the CNSP.
Reconstitution	(the process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Retrospective inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	(An tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its evaluation or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 838208

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
Standard Operating Procedures (SOPs) for Compounded Sterile Preparations (CSPs)			Please note NABP did not review each SOP for alignment on USP <797>. The SOPs described below require verification of alignment by the pharmacy and be shared with the inspector during the onsite inspection.	
1.0	Does the pharmacy have a designated person(s) who meets the requirements in compliance with USP <797> standards? *Inspector note: Per USP, "The compounding facility must designate one or more individuals (ie, the designated person(s)) to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CSPs and for performing other functions." If no, go to compliance statements.*	Yes		1 1 3 2
1.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		18

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
1.2	The designated person(s) is responsible and accountable for the performance and operation of the facility. *Per USP, "The designated person(s) is responsible for ensuring that each area related to CSP preparation meets the classified air quality standard appropriate for the activities conducted in that area. The designated person(s) must also ensure that the ISO Class 5 areas are located, operated, maintained, monitored, and certified as have appropriate air quality.*	Yes		2, 4.2, 4.5
1.3	The designated person(s) is responsible for personnel performing sterile compounding or other related functions (eg, quality checks and prescription dispensing of compounded preparations).	Yes		2, 17
1.4	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practices and such review is documented.	Yes		2, 17
1.5	The designated person(s) ensures that SOP revisions are implemented.	Yes		2, 17

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 809298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
1.6	The designated person(s) communicates all SOP revisions to all impacted personnel. *Inspector note: USP <797> recommends that personnel should also document acknowledgment and communication of SOP changes and revisions.*	Yes		2, 17
1.7	The designated person(s) ensures that personnel demonstrate competency in performing every procedure that relates to their job function.	Yes		2, 17
1.8	The designated person(s) ensures that corrective actions are taken if problems, deviations, out-of-range results, failures, or errors are identified. *Inspector note: Per USP, "Data collected in response to corrective actions must be reviewed to confirm that the actions taken have been effective."*	Yes		2, 5, 12
2.0	Has the pharmacy developed and implemented SOPs that describe sterile compounding procedures and other support activities in compliance with USP <797> standards? *Inspector note: In order for this to be answered yes, all topics must be addressed if applicable to their business practices.* *If no, document "no/sag" in Inspector Notes* *If yes, document the name, number, and version of each SOP in the Inspector Notes.*	Yes		17

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 809298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
2.1	Scope of Practice: Types of CSPs that are prepared (eg, immediate use, allergenic extracts, Category 1, Category 2, Category 3). Roles and responsibilities of the designated person(s).		1.06 (General Aseptic Technique)	1.6
2.2	Personnel Training and Evaluation: Description of initial and ongoing training and competency for the designated person(s), compounding personnel, personnel with direct oversight of compounding personnel, and personnel who only perform hand washing or cleaning and disinfecting duties outside of the primary engineering control (PEC). Description of media-fill testing procedures, hand hygiene and gloving competency, and aseptic manipulation competency. Training and competency assessment of personnel on all sterilization methods and equipment used by the facility. Frequency of training is defined.		2.03 (Sterile compounding personnel Cont.), 9.11 (Sterile compounding Process Validation)	2, 2.7, 10 Box 1, Box 2 Table 2, Table 3
2.3	Personal Hygiene and Garbing: Description of the required garb, manner of donning, and order of garbing, including disinfection procedures for donning goggles, respirators, and other reusable equipment. *Inspector note: Per USP, the RABS for pharmaceutical isolator) sleeves and glove changes should (not required) be changed per the manufacturer's recommendations and defined in the facility's SOPs.*		9.10 (Required Garb for Clean Room	3, 3.3

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
2.4	Facility Design and Engineering Controls: Description of design requirements to maintain air quality standards and procedures for evaluating, maintaining, and certifying the areas used for compounding.		9.01 (Quality Assurance Program) 3.01 (sterile compounding area requirements)	4, 4.2
2.5	Certification and Recertification: Description of sampling sites and procedures.		3.03 (Environmental monitoring of the Clean Room)	5, 5.1
2.6	Microbiological Air and Surface Monitoring: Description of the pharmacy's microbiological air and surface monitoring program which includes a diagram of the sampling locations; procedures for collecting samples; frequency of sampling; size of samples (eg, surface area, volume of air); time of day of sampling in relation to activities in the compounding area; and action levels that will trigger corrective actions and documentation requirements.		3.03 (Environmental monitoring of the clean Room)	6, 6.1, 6.2, 6.3
2.7	Cleaning, Disinfection, and Application of Sporicidal Disinfectants and Sterile 70% IPA: Description of procedures for cleaning, disinfecting, and applying sporicidal disinfectants and include the frequency, methods, locations of cleaning, and documentation requirements.		3.02 (Cleaning and maintenance of the Clean Room)	7, 7.2 Box 7, Box 8

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 809298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
2.8	Equipment: Description of procedures for the calibration, maintenance, cleaning, use of the equipment, and documentation requirements.		4	9.1, 10, 20
2.9	Components: Description of procedures that address the selection, receipt, evaluation, handling, storage, and documentation of all CSP components, including all ingredients and personnel cleaners.		9.01 (Product Procurement, Receipt, and Inspection)	9.3
2.10	Master Formulation and Compounding Records: Description of procedures for developing and maintaining MFRs and required information, documentation, and record-keeping requirements for MFRs and CFRs.		9.04 (Formula worksheet)	11.1, 11.2, 20
2.11	Release Inspections and Testing: Description of release testing procedures (eg, visual inspections and/or sterility and endotoxin testing), out-of-specifications procedure, corrective action procedures, and documentation requirements.		9.12 (Sterile compounding Finished Preparation Testing)	12, 18, 20
2.12	Labeling: Procedures for labeling and label verification (containing against the prescription or medication order, the MFR, and the CFR) in order to prevent errors, CSP mix-ups, and required displayed information.		9.02 (Product Labeling)	13

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 602206

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
2.13	C&P handling, storage, packaging, shipping, and transport: Processes and techniques for handling, storing, packaging, and transporting CSPs that include temperature monitoring, containers, shipping containers, packaging requirements, and selected transportation modes.	[redacted]	5.04 (Billing and Delivery)	19
2.14	Documentation: Record keeping requirements and procedures for documentation maintenance and storage. *Inspector note: USP requires locally retrievable records for two years; however, it is acknowledged that state or accreditation organizations may require records for a longer period of time.*	[redacted]	9.02 (Good documentation practices)	20
2.15	Sterilization and Depyrogenation: Description of methods used for establishing and verifying the effectiveness of the terminal sterilization and depyrogenation methods selected, as well as the methods for maintaining and cleaning the sterilizing and depyrogenation equipment. *If not applicable to their business practices, inspector should answer statement as N/A.*	[redacted]	5.01 (Sterilization and Depyrogenation)	10

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 602206

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
2.16	Immediate Use CSPs: Description of processes followed to meet all conditions of exemption from the requirements for Category 1, Category 2, and Category 3, CSPs. *If not applicable to their business practices, inspector should answer statement as N/A.*	[redacted]	N/A	1.3
2.17	Blood/Biological Handling: Description of processes used to avoid cross-contamination and meet applicable regulatory requirements. *If not applicable to their business practices, inspector should answer statement as N/A.*	[redacted]	N/A	1 1 2
2.18	Allergenic Extracts: Description of procedures for training, competency assessments, personnel hygiene and gowning, facility requirements, donning and doffening, beyond use dates (BUDs), labeling, storage, shipping and transporting, and documentation. *If applicable to their business practices, please complete the Allergenic Extracts module. If not applicable to their business practices, inspector should answer statement as N/A.*	[redacted]	N/A	21

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 602206

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
	CSPs - Immediate Use, Proprietary Vial/Bag Systems, and Blood Glucose			
3.0	Does the pharmacy prepare and dispense compounded sterile preparations for direct and immediate use? *If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.*	N/A		1.3
4.0	Does the pharmacy meet all conditions specified in USP <797> for CSPs compounded for direct and immediate use? *Inspector note: Per USP <797>, all conditions must be met to qualify for exemptions of the requirements for Category 1, Category 2, and Category 3 CSPs. If no, go to compliance statements. If the pharmacy does not prepare and dispense compounded sterile preparations for direct and immediate use, the inspector should answer question as N/A.*	N/A		1.3
4.1	Aseptic technique, processes, and procedures are followed. *Inspector note: Per USP <797>, facility SOPs must describe procedures followed "to minimize the potential for contact with nonsterile surfaces, introduction of particulate matter or biological fluids, and mix-ups with other conventionally manufactured products or CSPs."*	N/A		1.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 602206

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
4.2	Personnel are trained and demonstrate competency in specific procedures as they relate to assigned tasks and the facility's SOPs. *Review personnel records to verify.*	N/A		1.3
4.3	Preparation is performed in accordance with evidence-based information for physical and chemical compatibility of the drugs. *Inspector note: Examples of this include approved labeling and/or published or unpublished stability and compatibility studies.*	N/A		1.3
4.4	Preparation involves not more than three (3) different sterile products (e.g., ingredients and/or components in a single container).	N/A		1.3
4.5	Unused components from a single-use container are discarded after the preparation for one individual patient is complete (i.e., single-dose containers are not used for more than one patient).	N/A		1.3

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 809286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
4.6	Administration begins within four hours of the start of the preparation, and if not, the preparation is discarded. *If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.*	N/A		1.3
4.7	Unless the person preparing the preparation is administering or witnessing administration, the preparation is labeled with names and amounts of all active ingredients, name or initials of preparer, and exact four-hour time period in which administration must begin. *If administration is not performed within the same facility/campus of the pharmacy and/or is outside the pharmacy's control, inspector should answer statement as N/A.*	N/A		1.3
n	Does the pharmacy prepare proprietary bag and vial systems (ex. addEASE, ADD-Vantage, Mini Bag Plus, Vial2Bag) in compliance with USP <797> standards? *Inspector note: Docking and activation of proprietary bag and vial systems for immediate administration to an individual patient is out of scope of USP <797> and may be performed outside of an ISO Class 5 environment.* *If no, go to compliance statements.* *If the pharmacy does not stock, prepare, and/or dispense any proprietary vial and bag systems, inspector should answer statement as N/A.*	N/A		1.4

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 809286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
5.1	Docking for future activation and backchecking is performed in an ISO Class 5 environment and in accordance with requirements of USP <797>, with the exception of BUD assignment.	N/A		1.4
5.2	BUD assignment is not longer than specified in the manufacturer's labeling.	N/A		1.4
6.0	Does the pharmacy meet the conditions specified in USP <797> for CSPs to be prepared per approved labeling? *Inspector note: Preparing a conventionally manufactured sterile product in accordance with the directions in the manufacturer's approved labeling is considered outside the scope of the USP chapter.* *If no, go to compliance statements.* *If the pharmacy only compounds sterile preparations (eg, does not prepare sterile preparations that strictly adhere to the conventionally manufactured approved labeling for preparation), inspector should answer statement as N/A.*	N/A		1.4
6.1	The product is prepared as a single dose for an individual patient.	N/A		1.4
6.2	The approved labeling includes information for the diluent, the resultant strength, the container closure system, and the storage time.	N/A		1.4

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
7.0	Does the pharmacy perform compounding activities that require the manipulation of a patient's blood-derived or other biological material (eg, autologous serum)?	No		1.1.2
8.0	For compounding activities that require the manipulation of a patient's blood-derived or other biological material, does the pharmacy perform manipulations that are clearly separated from other compounding activities and equipment used in CSP preparation activities and are controlled by specific SOPs to avoid any cross-contamination? *Inspector note: Per USP, a separate cart could be used for blood-derived or other biological materials (a separate area is not required by the chapter). Pharmacy should change garb. Pharmacy to have cleaning processes as part of SOPs to avoid cross-contamination.* *If the pharmacy does not compound with blood products or other biological materials, inspector should answer statement as N/A. If the inspector answers the compliance question as "no", please describe your observations.*	N/A		1.1.2

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e-Profile ID: 809286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
	Facility Design and Engineering Controls			
9.0	Segregated Compounding Area (SCA): Does the pharmacy use an SCA as an SEC in compliance with USP <797> standards for facility design and environmental control? *Inspector note: Per USP, only Category 1 CSPs may be compounded in a SCA.* *If no, go to compliance statements.* *If pharmacy only uses a cleanroom suite for sterile compounding preparations, inspector should answer question as N/A.*	N/A		4.1, 4.1.1, 4.1.2, 4.2.1 Table 5
9.1	The facility is designed to afford a well-lighted and comfortable working environment.	N/A		4.2, 4.2.1
9.2	Only Category 1 CSPs are prepared in a SCA. *If pharmacy is compounding Category 2 or Category 3 CSPs in a SCA, inspector should answer this statement as no and collect photographs and copies of the MFR, CR, and provide a description of their observations in the Inspector Notes.*	N/A		4.2.1, 4.2.3 Table 5

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808206
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
9.3	The SCA is located away from unsealed windows, doors that connect to outdoors, and traffic flow. *Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."*	N/A		4.2.1
9.4	The SCA is located away from environmental control challenges and opposite from areas not rated to compounding (ie, restrooms, kitchenettes, food preparation areas).	N/A		4.2.1
9.5	A visible perimeter establishes the boundaries of the SCA. *Inspector note: Per USP, the SCA is defined as "a designated space, area, or room that is not required to be classified and is defined with a visible perimeter." The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only." USP further defines a perimeter as "a visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA." The perimeter will be defined in the pharmacy's SOPs. Tape or an alternative method may be used to define this visible perimeter, since this is not a classified space.*	N/A		4.2.1 Glossary

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
9.6	Access to the SCA is restricted to authorized personnel. *Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning.*	N/A		4.2.1
9.7	Free-standing humidifiers/dehumidifiers and air conditioners are not located within the perimeter of the SCA.	N/A		4.2
9.8	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in the compounding area. *Inspector note: Per USP, these items should be low-shedding, easily cleaned, and disinfected. This applies to items within the perimeter around the Primary Engineering Control (PEC).*	N/A		4.5
9.9	Shipping cartons or other corrugated or uncoated cardboard are not allowed in the SCA.	N/A		4.5
9.10	The SCA and all surfaces (walls, floors, counters, equipment) are clean, uncluttered, and dedicated to compounding.	N/A		4.2.1, 4.3.2
9.11	The sink is located inside the SCA or in close proximity and is located at least one meter away from the PEC.	N/A		4.4
9.12	The area within one meter of the PEC is dedicated only for sterile compounding (eg, not storage, hand hygiene, donning and doffing gear, or other highly particle-generating activities, such as patient care).	N/A		4, 4.2.1

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		Observation	Inspector Notes	USP Reference(s)
9.13	If overhangs or ledges are present in the SCA, are they easily cleanable? *If no, describe observations in Inspector Notes.*	N/A		4.2.1, 4.3.2
10.0	Are surfaces smooth, impervious, free from cracks and crevices, and non-shedding so they can be cleaned and disinfected? *Inspector note: this is a recommendation by USP.* *If no, describe in comments Inspector Notes (eg, peeling of Formica countertop).*	Yes		4.3.3
11.0	Are surfaces resistant to damage from cleaning, sanitizing, and sporicidal agents used? *Inspector note: this is a recommendation by USP.* *If no, describe in comments inspector observations (ie observed rust on preparation cart or flaking of particle board on shelving).*	Yes		4.2.1, 4.3.2
12.0	Cleanroom Suite: Does the pharmacy use a Cleanroom Suite (ISO-classified anteroom and buffer room) as a SEC in compliance with USP <797> standards for facility design and environmental control? *Inspector note: Per USP <797>, a cleanroom suite is required if compounding any Category 2 and Category 3 CSPs* *If no, go in compliance statements.* *If pharmacy only uses an SCA for Category 1 CSPs, inspector should answer question as N/A.*	Yes		4.1, 4.1.1, 4.1.2, 4.2.1, 4.3.1 Table 5

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e-Profile ID: 808206
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
12.1	Access to the cleanroom suite is restricted to authorized personnel. *Inspector note: Per USP, authorized personnel includes personnel involved in compounding processes, maintenance, and cleaning. Some examples pharmacies may use to demonstrate compliance with the statement (but are not specifically required by the chapter) include: posting a sign or creating a badge access point for authorized personnel to enter the cleanroom suite.*	Yes		4.2.1
12.2	The facility is designed to afford a well-lit environment.	Yes		4.2, 4.2.1
12.3	The facility provides a comfortable working environment (eg, temperature and humidity settings as appropriate garb can be donned).	Yes		4.2.1
12.4	The anteroom and buffer room are separated from surrounding unclassified areas by floor walls and doors.	Yes		4, 4.2.1
12.5	Controls are in place to minimize the flow of lower-quality air into the more-controlled areas. *Inspector note: Per USP, "strong air currents from opened doors, personnel traffic, or air streams from the HVAC system can disrupt the unidirectional airflow of an open-faced PEC."*	Yes		4.2.1

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Sterile Compounding Inspection for USP<797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
12.8	Anteroom providing access to only positive pressure buffer rooms must at least ISO Class 8 specifications. *If the pharmacy has a negative pressure room, inspector should answer statement as N/A.*	N/A		4.1.2, 4.2.1
12.7	The anteroom provides access to a negative pressure room and meets at least ISO Class 7 specifications. *If the pharmacy does not compound hazardous drugs, inspector should answer statement as N/A.*	Yes		4.1.2, 4.2.1
12.8	The buffer room, where the PEC is placed, meets ISO Class 7 or better air quality specifications. *Inspector note: If the PEC is a pharmaceutical isolator, the buffer room must be at least ISO Class 8 air quality or better and an anteroom is not required.* *For USP <797>, a pharmaceutical isolator is defined as an enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. A CAI or CACI is not a pharmaceutical isolator.*	Yes		4.1.2, 4.2.1, 4.2.8

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
12.9	Air supply to the anteroom and buffer room is introduced through HEPA filters in the ceiling.	Yes		4.2.1
12.10	Air returns are located low on the wall. *If the pharmacy has a visual smoke study (as described in the USP chapter and compliance statement below), inspector should answer statement as N/A.*	Yes		4.2.1
12.11	A visual smoke study demonstrates an absence of stagnant air where particles can accumulate and is repeated if any equipment/personnel changes when air returns are not located low on the wall. *Inspector note: Per USP, "the smoke study, along with environmental monitoring, must be repeated whenever a change is made in the placement of equipment within the room or any other alteration is performed within the cleanroom suite that affects the quality of the air (eg, HVAC alterations, change of HEPA filter units)."* *If air returns are low on the wall, inspector should answer statement as N/A.*	N/A		4.2.1

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
12.12	The anteroom has a line of demarcation to separate the dirty side from the clean side or has two separate anterooms, a dirty anteroom and a clean anteroom. *Describe observations for the type of line of demarcation in the Inspector Notes.*	Yes	Vinyl tape designates the clean side from dirty side.	4.2.1
12.13	Personnel enter the dirty side/room first from the unclassified area and the clean side/room is located closest to the buffer room.	Yes		4.2.1
12.14	All surfaces (ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets) are smooth, impervious, free from cracks and crevices, and non-shedding.	Yes		4.2.1, 4.3.1
12.15	Junctures between ceilings and walls and between the walls and floors are sealed.	Yes		4.2.1, 4.3.1
12.16	If the ceiling consists of inlaid panels, the panels are caulked to seal them to the support frame. *If the ceiling does not consist of inlaid panels, inspector should answer statement as N/A.*	N/A		4.2.1, 4.3.1
12.17	Walls are constructed of, or covered with, a durable material (eg, epoxy paint, heavy gauge polyvinyl) and integrity of surfaces maintained.	Yes		4.2.1, 4.3.1

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		Observation	Inspector Notes	USP Reference(s)
12.18	Walls, if paneled, are joined together and sealed to the support structure. *If walls are not paneled, inspector should answer statement as N/A.*	Yes		4.2.1, 4.3.1
12.19	Floors include coving to the sidewall or the junctures between floor and wall is caulked.	Yes		4.2.1, 4.3.1
12.20	If overhangs or ledges are present, they are easily cleanable. *If there are no overhangs, ledges, utility pipes, windowsills, etc, inspector should answer statement as N/A.*	Yes		4.2.1, 4.3.1
12.21	Lighting fixtures outside of the ceiling light fixtures are sealed, recessed flush, and sealed.	Yes		4.2.1, 4.3.1
12.22	All other penetrations through the ceiling or walls (eg, conduit domes) are sealed.	Yes		4.2.1, 4.3.1
12.23	The buffer room does not contain plumbed water sources (eg, sinks, eyewashes, showers, or floor drains).	Yes		4.4
12.24	The anteroom does not contain floor drains.	Yes		4.4

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 802286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
13.0	Are PECs used to prepare CSPs located in the appropriate space (eg, buffer room or SCA) for category types prepared in compliance with USP <797> standards? *Inspector to review certification reports and observe compounding area(s) to evaluate.* *If no, go to compliance statements.*	Yes		4.2.1, 4.2.2, 4.2.3 Table 4, Table 5
13.1	All compounded sterile preparations (that are not for immediate use) are compounded in a PEC.	Yes		1.3, 4, 4.1.2
13.2	PEC is certified to maintain ISO 5 classification or better conditions during dynamic operating conditions. *The inspector should only answer yes if the PEC has been certified within the past six months.*	Yes		4.2.2, 4.2.3, 5
13.3	The PEC is located out of traffic patterns and away from room air currents that could disrupt the intended airflow patterns inside the PEC. *Review certification reports.*	Yes		4, 4.2.2, 4.2.3
13.4	Placement of the PEC allows for cleaning around the PEC.	Yes		4.2.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 802286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
13.5	Category 2 and Category 3 PEC(s) are located in a cleanroom suite. *If pharmacy only compounds Category 1 CSPs, inspector should answer this statement as N/A.*	Yes		4.2.3, Table 5
14.0	Does the pharmacy have any CAIs/CACIs used for sterile compounded preparations? *If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.*	N/A		4.2.3, Table 5
15.0	Are CAIs/CACIs (RABS) used for compounding sterile preparations operated in compliance with manufacturer specifications and USP <797> standards? *If no, go to compliance statements.* *If the pharmacy does not use any CAI/CACIs for compounding CSPs, inspector should answer question as N/A.*	N/A		4.2.3
15.1	The documented recovery time is followed after opening the CAI/CACI transfer chamber to maintain ISO Class 5 air quality. *Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.*	N/A		4.2.3
15.2	Staff ensures that adequate recovery time is allowed after closing the CAI/CACI during compounding operations. *Inspector note: The recovery time should come from the manufacturer of the CAI/CACI.*	N/A		4.2.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 802286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
16.1	Sterile gloves are worn over the gloves attached to the CAI/CACI sleeve. *Inspector note: Per USP, if using a RABS (ie, a CAI or CACI), disposable gloves should be (not required) worn inside the gloves attached to the RABS sleeves.*	N/A		3.3
16.0	Are there controls in place to minimize the influx of contaminants from materials (supplies and equipment) and personnel as they move from areas of lower quality to those of higher quality in compliance with USP <797> standards? *Inspector note: An example of material movement from lower quality air to higher quality air includes movement from a non-classified area to an ISO Class 8 anteroom, ISO Class 8 anteroom to an ISO Class 7 buffer room, or from an ISO Class 7 buffer room to an ISO Class 5 PEC.* *If no, go to compliance statements.*	Yes		4.5
16.1	Before any item is introduced into the SEC, placed into the pass-through chamber, or brought into the SCA (provided that packaging integrity will not be compromised), it is wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% isopropyl alcohol (IPA) using low-lint wipers by personnel wearing gloves.	Yes		4.5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 802286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
16.2	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low-lint wipers and allowed to dry before use.	Yes		4.5
17.0	Does the pharmacy have the appropriate facility design and controls (including the fixtures, types of equipment, materials, and supplies that are stored) in the classified areas in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		4, 4.1, 5.1
17.1	The sink used for hand hygiene, located outside of the anteroom, is placed in an appropriate area and clean space to minimize the risk of bringing contaminants into the anteroom. *Inspector note: Inspector should evaluate the sink location in relation to the activities that occur where the sink is located as well as the distance between the sink and the entrance to the compounding suite/SCA.* *Examples that may not be considered appropriate include but are not limited to: sink is located in the bathroom, an adjacent suite or property, or in an employee breakroom where food is prepared.* *If the sink is located in the anteroom, inspector should answer statement as N/A.*	N/A		4.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
17.2	The sink used for hand hygiene, located inside of the anteroom, is placed in an appropriate area to minimize the risk of bringing contaminants into the buffer room. *Inspector note: Inspector should evaluate the sink location in relation to the doors and compounding activities. For example, the sink is where compounders perform hand hygiene close to where gloves is stored (where it can easily get re-contaminated).* *If the sink is located outside the anteroom, inspector should answer statement as N/A.*	Yes		4.4
17.3	The doors into the anteroom from the general pharmacy area and from the anteroom into the clean/buffer room are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	Signage	4.2.1
17.4	The airlock and outside doors of a pass-through are prevented from both being open at the same time (eg, by interlocking, training of personnel, or signage).	Yes	Interlocking	4.2.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
17.5	Only furniture, equipment, and other materials necessary for performing compounding activities are permitted in a classified area as SCA. *Inspector note: Per USP, items necessary for performing compounding activities are low-shedding and can be easily cleaned and disinfected. If no, describe the types of items that are observed. If appropriate, submit a photograph with inspection report.*	Yes		4.5, 9.9
17.6	Tacky mats are not used in the classified areas. *Inspector note: Per USP <797>, "Tacky mats must not be placed within ISO-classified areas."*	Yes		4.2.1
17.7	Shipping cartons or other corrugated or unsealed cardboard are not permitted in the classified areas.	Yes		4.5
17.8	Carts used to transport components or equipment into classified areas are of a suitable and non-porous material with cleanable casters and wheels.	Yes		4.5
17.9	Carts (including casters) are cleaned and disinfected prior to moving from the dirty side to the clean side of the anteroom.	Yes		4.5

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
18.0	Does the pharmacy's facility design for maintaining (eg, recording, monitoring, and controlling) temperature and humidity (eg, HVAC) comply with USP <797> standards? *Inspector note: Compounded preparations that are finished and stored will be addressed in the general pharmacy module. Inspector should be aware that USP cleanroom temperature recommendations may not be harmonized with USP, FDA, or manufacturer/supplier temperature requirements for drug storage.* *If no, go to compliance statements.*	Yes		4.2, 10.1 USP <659>
18.1	The compounding area temperature and humidity is maintained by a heating, ventilation, and air conditioning (HVAC) system. *If inspector finds a free-standing air conditioner, humidifier, or dehumidifier within the classified area or the SCA, the inspector should answer statement as "No." Additionally, inspector should describe what they observed, where the equipment was located, and collect/submit photographs.*	Yes		4.2, 9.3.4, 10.1
18.2	The pharmacy records the temperature of the cleanroom suite on days when sterile compounding occurs. *If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.*	Yes		4.2, 9.3.4, 10.1

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e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
18.3	The pharmacy records the humidity of the cleanroom suite on days when sterile compounding occurs. *If pharmacy does not use a continuous recording system, describe the frequency of humidity recording in the notes.*	Yes		4.2, 9.3.4, 10.1
18.4	The pharmacy maintains the records of temperature and humidity that are specific to the cleanroom suite. *Temperature and humidity for drug storage areas will be documented in the general pharmacy module.* *If the pharmacy only uses an SCA, inspector should answer statement as N/A.*	Yes		4.2, 9.3.4, 10.1
18.5	The pharmacy can readily retrieve temperature and humidity records. *If the electronic monitoring system is only capable of providing text message alerts for excursions alone (eg, a report cannot be generated for ongoing temperature conditions), inspector should answer statement as "No."*	Yes		4.2, 9.3.4, 10.1

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National Association of Boards of Pharmacy®
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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808288

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
18.5	The pharmacy controls temperature and humidity to maintain appropriate working conditions if no overnight drug storage occurs and/or is following the most restrictive drug label. *Inspector note: Per USP <797>, the cleanroom suite should be maintained at a temperature of 20°C or cooler and a relative humidity of 60% or below to minimize the risk of microbial proliferation and to provide comfortable conditions for compounding personnel attired in the required garb. CRT is defined as 20°C-25°C per USP <659>.*	Yes		4.2, 9.3.4, 19.1
18.7	The placement of the HVAC unit does not cause cross contamination or interfere with the functioning of the classified area. *Inspector note: Air streams from the HVAC system(s) can disrupt the unidirectional airflow of an open faced PEC such as a laminar airflow workbench (LAFW).*	Yes		4, 4.2
18.8	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. *Inspector note: Monitoring devices are typically calibrated or replaced.*	Yes		4.2, 9.3.4

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808288

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
18.9	Humidity monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. *Inspector note: Monitoring devices are typically calibrated or replaced.*	Yes		4.2, 9.3.4
19.0	Does the pharmacy store drugs in the cleanroom suite overnight and/or for long periods of time? *Inspector note: Long periods of time is not defined as pre-compounding preparation right before compounding activities are commenced.*	Yes	APIs are stored in the HD nonsterile and sterile compounding rooms.	4.2, 9.3.4, 19.1
21.0	If the pharmacy is storing drugs inside the cleanroom suite overnight and/or long periods of time, are any of the drugs stored unable to tolerate temperature excursions?	No		4.2, 9.3.4, 19.1
21.5	What is the current temperature of the cleanroom suite/SCA? *Record in the Inspector Notes.*	[redacted]	67.5 degrees F	4.2, 9.3.4, 19.1
22.0	What is the current relative humidity percentage of the cleanroom suite/SCA? *Record in the Inspector Notes.*	[redacted]	44%	4.2, 9.3.4, 19.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808288

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
23.0	Is the humidity maintained at less than 60% relative humidity (RH) in the compounding area to minimize risk of microbial proliferation?	Yes		4.2, 9.3.4, 19.1
24.0	Is differential positive pressure maintained in compliance with USP <797> standards? *Inspector note: Per USP <797>, no pressure differential is required between the SCA and the surrounding area.* *If no, go to compliance statements.* *Inspector should view logs and current status (while observing compounding) to verify.* *If the pharmacy uses an SCA for sterile compounding environment, inspector should answer statement as N/A.*	Yes		4.2.1, 4.2.b, b
24.1	The facility design creates room separation to allow positive pressure differentials between spaces (rooms) for movement of air from higher quality air to lower quality air. *Inspector should review a graphic of the airflow contained in the certification report.*	Yes		4.2.1, 4.2.b, b

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
24.2	The facility has a system in place to continuously monitor pressure differentials (eg, magnehelic gauge). *Per USP, pressure differentials need to be monitored continuously, but personnel are not specifically required to visually monitor pressure during compounding activities.*	Yes		4.2.1, 4.2.b, b
24.3	The facility has a record system to record pressure differentials on days when compounding occurs. *Inspector note: Per USP, the quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurs.*	Yes		4.2.1, 4.2.b, b
24.4	The differential positive pressure between unclassified and the first space in the compounding suite is at least 0.020 inch water column. *Inspector note: Per USP, certifiers should confirm (this is a USP recommendation) positive pressure around doorways, pass-throughs and any opening in the cleanroom suite with smoke testing (to confirm positive pressure is maintained) with initial certification of the cleanroom suite.* *If no, record the observed pressure differential between the two identified spaces (eg, ISO Class 8 anteroom and the general pharmacy area).*	Yes		4.2.1, 4.2.b, b

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 809238
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
24.5	The differential positive pressure between adjacent classified areas is at least 0.020 inch water column. *If no, record the observed pressure differential between the two adjacent spaces (eg, ISO Class 8 anteroom and the ISO Class 7 buffer room).*	Yes		4.2.1, 4.2.5, b
24.6	Pressure differential monitoring and quantitative results are reviewed and documented at least daily on days when compounding occurs.	Yes		4.2.1, 4.2.5, b
25.0	Does the pharmacy have a policy in place to cease compounding when the pharmacy is unable to maintain positive pressure differentials (unaided, unobstructed indications due to opening and closing of doors)?	Yes		4.2.1, 4.2.5, b
26.0	Are pressure differential monitoring procedures in place that provide an alarm or alert when there is an excursion? *Inspector note: USP <797> does not require there to be an alarm or an alert.*	Yes		4.2.5
27.0	Does the facility perform both sterile and nonsterile compounding?	Yes		4.2.1

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 809238
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
28.0	If the pharmacy performs nonsterile compounding and sterile compounding, are the designated areas separate and distinct from each other?	Yes		4.2.1
29.0	If PECs are placed into the same room that are used for both sterile and nonsterile compounding, is the pharmacy in compliance with USP <797> standards? *Inspector note: Per USP <797>, PECs used for both sterile and nonsterile compounding may be placed in the same room only if the PECs are sufficiently effective that the room can continuously maintain ISO Class 7 classification.* *If no, go to compliance statements.* *If the pharmacy does not perform nonsterile compounding in the same room as sterile compounding, inspector should answer this question as N/A.*	N/A		4.2.1, 4.2.6
29.1	PECs used for nonsterile compounding are placed at least one meter away from PECs used for sterile compounding.	N/A		4.2.1
29.2	Particle-generating activity must not be performed while sterile compounding is in process.	N/A		4.2.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 809238
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
29.3	PECs are sufficiently effective that they more than continuously maintain ISO Class 7 clean/inactive air quality during nonsterile compounding.	N/A		4.2.1
30.0	Does the pharmacy prepare Category 2 and Category 3 CSPs from nonsterile components? *Inspector note: Category 1 CSPs can be made from nonsterile components.* *If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.*	Yes		4.2.1, 4.2.6
31.0	Does the pharmacy's preparation procedures comply with USP <797> standards? *If no, go to compliance statements.* *If the pharmacy does not compound using nonsterile components, the inspector should answer question as N/A.*	Yes		4.2.6
31.1	Preparations procedures, such as weighing and mixing, are completed in an ISO Class 8 or better environment (eg, anteroom or buffer room). *Inspector note: This statement only applies for Category 2 and Category 3.*	Yes		4.2.6

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 809238
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
31.2	Preparations procedures, such as weighing and mixing, are performed in a single-use containment glove bag, CVE, BSC, or CAC, to minimize the risk of airborne contamination. *Inspector note: This statement only applies for Category 2 and Category 3. CVEs, BSCs, or CACIs used for preparation procedures must be certified at least every six months.*	Yes		4.2.6
	Certification and Environmental Monitoring			
32.0	Does the pharmacy ensure that each area related to CSP preparation is certified to meet the classified air quality standard appropriate for the activities conducted in that area in compliance with USP <797> standards? *If no, go to compliance statements.* *Inspector is to review current certification reports*	Yes		b
32.1	The most recent PEC and CEC certification reports are available for review.	Yes		4.2, b, 20

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 620288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
32.2	Certification of all classified areas, including PECs, is performed at least every six months.	Yes		4.2.3, 6
32.3	Certification of all classified areas, including PECs, is performed whenever a device is relocated or a major service to the facility is performed. *Inspector note: Cleanrooms and buffer areas must be recertified if there are changes to the area such as redesign, construction, replacement or relocation of any HEPA filters, or alterations to the configuration of the room that could affect airflow or air quality.*	Yes		5
32.4	Certification reports are reviewed by the designated person(s). *Inspector note: If the designated person(s) review is not documented, describe how it is ensured that the review occurred.*	Yes	The report is ensured to the PIC and trained to maintain in a binder. They are reviewed for compliance	4.2, 5
32.5	All ISO Class 5 PECs (laminar airflow workbenches or hoods, BSCs, CAIs, CACIs, pharmaceutical isolators, RABS, and robotic enclosures) have been certified within the last six months. *If no, record the date of the last certification and include a copy of the certification report with the inspection report.*	Yes		4.2.3, 6

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 620288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
32.6	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. *Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.* *If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).*	Yes		4.1.1, 5.1 Table 4
32.7	All ISO Class 7 and 8 SECs (cleanroom rooms and anterooms) have been certified within the last six months. *Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.* *If no, record the date of the last certification and include a copy of the certification report with the inspection report.*	Yes	No ISO 6 SECs are at this location.	4.1.1, 4.1.2, 5.1 Table 4

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 620288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
32.8	All PECs meet ISO Class 5 air quality requirements with (total, nonviable) particle counts documented within the report. *Inspector note: Per ISO definition, ISO Class 5 areas are certified as having less than 3,520 particles per cubic meter of air under dynamic operating conditions.* *If no, describe what occurred and the pharmacy's response to total airborne particle sampling results, data evaluation, and action level (eg, pharmacy took PEC out of service, pharmacy ordered new HEPA filter, PEC was repaired and re-certified).*	Yes		4.1.1, 5.1 Table 4
32.9	All ISO Class 7 and 8 SECs (cleanroom rooms and anterooms) have been certified within the last six months. *Inspector note: Per ISO definition, ISO Class 7 areas are certified as having less than 352,000 particles per cubic meter of air under dynamic operating conditions and ISO Class 8 areas are certified as having less than 3,520,000 particles per cubic meter of air under dynamic operating conditions.* *If no, record the date of the last certification and include a copy of the certification report with the inspection report.*	Yes	No ISO 6 SECs are at this location.	4.1.1, 4.1.2, 5.1 Table 4

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		Observation	Inspector Notes	USP Reference(s)
33.2	All SECs meet ISO Class 7 air quality requirements and ISO Class 8 air quality requirements where permitted, with particle counts documented within the report. *If no, describe what occurred and the pharmacy's response (eg, pharmacy relocated BUD, pharmacy used an alternative facility, pharmacy followed mitigation strategies, and/or disaster planning processes).*	Yes		4.1.1, 5.1 Table 4
33.0	Does the certification report provided by the pharmacy have all required elements documented for the pharmacy's designated person(s) to make an informed decision related to functionality of PEC and SEC environments in compliance with USP <797> standards? *Inspector note: It is recommended that the designated person review the certification report in its entirety.* *If no, go to compliance statement.*	Yes		5, 20
33.1	The certification report includes information about the equipment used for performing each test including last calibration date (or date when next calibration is due). *Inspector note: Per USP, "total particle count testing must be performed under dynamic operating conditions using calibrated electronic equipment" and "all inspection air samplers must be serviced and calibrated as recommended by the manufacturer."*	Yes		5.1, 5.1, 20

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 620288
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
33.2	The certification report includes the name of the certifier. *Inspector note: Per USP <797>, a qualified certifier may have received training and education from professional organizations such as the: American Society of Heating, Refrigerating, and Air-Conditioning Engineers (ASHRAE) and Controlled Environment Testing Association (CETA). Both organizations provide certification (Registered Certification Professional – Sterile Compounding Facilities), education, and resources.*	Yes		5
33.3	The certification report identifies the "dynamic conditions" including the number of personnel in the cleanroom suite. *Inspector note: Compounders can perform mock compounding activities and/or performing media-fill while the certifier is conducting testing. Number of personnel present in the SEC must be documented.*	Yes		5, 20
33.4	SECs airflow testing is performed and documented on the certification report to determine acceptability of the air volume and room air exchange rate (ACPH). *Inspector note: Per USP <797>, unclassified DCAs have no ACPH requirement.* *If pharmacy only compounds in an SCA, inspector should answer statement as N/A.*	Yes		4.2.4, 5 Table 5

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 602286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
33.5	SEC: All of the following ACPH required elements were documented on the certification report: the ACPH from HVAC, the ACPH contributed from the PEC, and the total ACPH. *If pharmacy only compounds in an SCA, inspector should answer statement as N/A.*	Yes		4.2.4, 5
33.6	The ISO Class 8 anteroom is certified and documented as having a minimum of 20 ACPH with at least 15 ACPH of the total air change rate coming from HVAC through HEPA filters located in the ceiling. *If the pharmacy has an ISO Class 7 anteroom, inspector should mark as N/A.*	N/A		4.2.4, b Table b
33.7	The ISO Class 7 buffer room and ISO Class 7 anteroom (if required) is certified and documented as having a minimum of 30 ACPH with at least 15 ACPH of the total air change rate in a room coming from the HVAC through HEPA filters located in the ceiling. *Inspector note: If the PEC is used to meet the minimum total ACPH requirements, the PEC must not be turned off, except for maintenance.*	Yes		4.2.4, b Table c

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 602286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
33.8	SEC: Airflow testing is performed and documented on the certification report to determine acceptability of the room pressure differential in doorways between adjacent rooms.	Yes		4.2.5, 5
33.9	SEC: The differential pressure measured was at least 0.020 inch water column positive from the cleanroom to the anteroom and between the anteroom and all adjacent spaces with the doors closed. *Inspector note: No pressure differential is required between the SCA and the surrounding area.*	Yes		4.2.1, 4.2.5, b
33.10	SEC: All SEC HEPA filters were leak tested (to confirm HEPA filter integrity).	Yes		b
33.11	SEC: All SEC HEPA filters with leaks were repaired. *If leaks were not repaired, describe what actions pharmacy took (e.g., pharmacy implemented mitigation strategies such as reduced BUDs or used alternative pharmacy location).* *If no repairs were needed, inspector should answer statement as N/A.*	N/A		b

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 602286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
33.12	PEC: (Dynamic airflow) Smoke pattern tests are performed for each PEC during dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the CSPs. *Inspector note: Per USP, "HEPA-filtered air must be supplied by the PEC at a velocity sufficient to sweep particles away from critical sites and maintain unidirectional airflow during operations. Proper design, control, and use minimizes turbulence and creation of eddies or stagnant air in the PEC."* *Describe if smoke pattern testing of PEC was documented thoroughly in the report or through video.*	Yes	Video were supplied and viewed by the inspector.	4.2.2, 4.2.3, b
33.13	PEC: Dynamic airflow smoke pattern confirms equipment and supplies necessary for performing compounding activities in the PEC do not disrupt unidirectional airflow. *Inspector note: Per USP, "Proper placement of equipment in a PEC must be initially verified by a dynamic airflow smoke pattern test to demonstrate minimal disruption in airflow. The dynamic airflow smoke pattern test must be repeated if equipment is placed in a different location."*	Yes		4.2.2, 4.2.3, 4.6, 5, 9.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 602286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
33.14	PEC: Total (nonviable) particle count testing was performed under dynamic operating conditions using calibrated electronic equipment. *Inspector note: Per USP, "Measurements of total airborne particles must be taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures. ...Measurements of total airborne particles in other classified areas, including the buffer room(s) and anteroom(s), should be taken at representative locations that reflect the quality of air in the room(s)."*	Yes		5, b.1
33.15	PEC: All PEC HEPA filters were leak tested (to confirm HEPA filter integrity). *Inspector note: The certification report for each PEC should show air velocities within the PEC.*	Yes		b
33.16	PEC: All PEC HEPA filters with leaks identified were repaired. *If leaks were not repaired, describe what actions pharmacy took (example: PEC taken out of service until HEPA filter could be replaced).* *If no repairs were needed, inspector should answer statement as N/A.*	N/A		b

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
33.17	PEC-VLFZ: Pharmacy's integrated vertical laminar flow zone (VLFZ) meets design, functional requirements, and certification requirements under USP <797>. *Inspector note: Per USP <797>, "Strategic location of air returns in addition to full coverage of HEPA-filters above the work surface is required. Both static and dynamic smoke studies of air returns in addition to full coverage of HEPA-filtered air void of turbulence, dead air zones, and refluxing from the HEPA filters to and across the entire work area and to the air returns must be documented (eg, with video)."* *If pharmacy does not have an IVLFZ, inspector should answer statement as N/A.*	N/A		4 2 3
33.18	If a robotic enclosure is used as the PEC, or placed within the PEC, a dynamic airflow smoke pattern test shall be performed initially and at least every 6 months thereafter to ensure that: 1) it is properly integrated into the facility; 2) there is no turbulence or refluxing at any critical site(s); 3) room air does not enter the PEC where sterile products and/or preparations may be exposed; and 4) all personnel can be performed without introducing contamination to the direct compounding area(s). *If pharmacy does not use a robotic enclosure, inspector should answer statement as N/A.*	N/A		4 2 3

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
34.0	Was smoke testing performed in PEC to confirm all particle generating equipment (eg, computers, printers, refrigerators, PECs) do not disrupt airflow? *Inspector note: This question will be N/A unless the pharmacy is new, has recently completed construction, of equipment has been moved within PEC since last certification.*	N/A		5
35.0	Does the pharmacy have an established environmental monitoring (eg, microbiological air and surface monitoring) program in compliance with USP <797> standards? *Inspector note: Per USP, "The goals of a microbiological air and surface monitoring program are to determine whether contamination is present at unacceptable levels and to assess whether proper personnel practices are being followed, cleaning and disinfecting agents are effective, and environmental quality is maintained."* If no, go to compliance statements	Yes		4, 8.1, 8.2
35.1	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed initially in the selected sampling sites to establish a baseline level of environmental quality for each classified area; ie, each ISO Class 5 PEC, each ISO Class 7, and ISO Class 8 room.	Yes		4, 8.1, 8.2

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		Observation	Inspector Notes	USP Reference(s)
35.2	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in conjunction with the certification of new facilities and equipment.	Yes		4, 8.1, 8.2
35.3	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed after any servicing of facilities or equipment.	Yes		4, 8.1, 8.2
35.4	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified problems (eg, positive growth in sterility tests of sterile compounded preparation).	Yes		4, 8.1, 8.2
35.5	Environmental monitoring program (eg, viable air and/or surface monitoring) is performed in response to identified trends (eg, repeated positive gloved fingertip and thumb sampling results, failed media fill testing, or repeated observations of air or surface contamination).	Yes		4, 8.1, 8.2

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		Observation	Inspector Notes	USP Reference(s)
35.6	Results from the environmental monitoring program (eg, viable air and/or surface monitoring) are reviewed in response to changes that could impact the sterile compounding environment (eg, change in cleaning agents) and in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination. *Inspector note: Per USP, the program is reviewed to "assess risks for: contamination, potential routes of contamination, and the adequacy of cleaning and disinfecting agents and procedures. Regular review of the sampling data must be performed to detect trends and the results of the review must be documented."*	Yes		4, 8.1, 8.2, 20, Table 4, Table 7, Table 8
35.7	The pharmacy ensures that viable air and surface sampling is performed by a trained and competent individual who is familiar with the methods and phenolcan for air sampling and surface testing. *If sampling is conducted by internal personnel, inspector should verify that documented training and competencies are located in the employee file.*	Yes	Air is conducted by Eterix every 6 months and surface sampling monthly internally.	4, 8.1, 8.2
35.8	Environmental monitoring program (eg, viable air and/or surface monitoring) describes/identifies corrective actions to minimize the risk of CSP contamination and that these corrective actions are documented.	Yes		4, 20

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
36.0	Is surface sampling performed at the end of a compounding activity or shift but before the area has been cleaned and disinfected to obtain a sample that is representative of the typical compounding conditions at the pharmacy? *Inspector note: this is a USP recommendation.*	No	Media Fill Only	6.1, 6.3
37.0	Does the pharmacy send all air quality for viable airborne samples to an external lab (third party) for incubation and processing? *If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.*	Yes		6.2.2
38.0	Does the pharmacy send out all surfaces for viable particle samples to an external lab (third party) for incubation and processing? *If pharmacy exclusively does internal incubation and results processing, inspector should answer statement as N/A.*	N/A		6.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
39.0	For any samples that are sent to an external lab (third party), does the pharmacy receive a report from the third party confirming incubation parameters met USP <797> requirements (eg, the correct temperatures and the correct length of incubation time are documented in the report)? *Inspector note: incubation parameters are the same as seen in statements 40.6-40.7 and 41.4-41.5.* *This question applies for any air or surface sample sent to an external lab. If no, describe observations.*	Yes		6.2.2
40.0	Are procedures for sampling and monitoring air quality for viable airborne particles in compliance with USP <797> standards? *Inspector note: Per USP <797>, facilities performing any Category 3 compounding must adhere to the increased environmental monitoring requirements for all classified areas where Category 3 CSPs are compounded and increased environmental monitoring requirements apply at all times regardless of whether Category 3 CSPs are being compounded on a given day.* *Review six months of air sampling data to verify. If no, go to compliance statements.*	Yes	Slone performs every 6 months.	6.2, 6.2.1, 6.2.2, 6.2.3, 14.4.2 Box 5, Table 7

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
40.1	All classified areas are sampled using a volumetric active air sampling device (inspection at sampler). *Inspector note: This sampling must be performed during dynamic operating conditions (to obtain a sample that is representative of the typical compounding conditions at the pharmacy).*	Yes		6.1, 6.2.1
40.2	All classified areas are sampled at the frequencies specified by USP for volumetric active air sampling. *Inspector note: Per USP <797>, Category 1 and Category 2 compounding frequency is every six months and Category 3 compounding frequency is monthly.* *For facilities compounding any Category 3 CSPs, this must be completed within 30 days prior to the commencement of any Category 3 compounding and at least monthly thereafter regardless of the frequency of compounding Category 3 CSPs.*	Yes		6.2.1, 14.4.2
40.3	At least one cubic meter (1000 L) of air is tested using the volumetric active air sampling device from each sample location.	Yes		6.2.3 Box 5

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
40.4	All impactors all samplers are sanitized and calibrated as recommended by the manufacturer.	Yes		6.1
40.5	The pharmacy uses an appropriate microbiological growth media for sampling. *Inspector note: An appropriate microbiological growth media means a media that supports the growth of bacteria and fungi (eg, TSA), as compared by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements.*	Yes		6.2.2 Box 5
40.6	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the one media device method. *Inspector notes: Per USP <797> (Box 5), when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C–35°C for no less than 48 hours. Then, prior examination and recounting of results, further incubated at 20°C–25°C for no less than five additional days.* *If the pharmacy does not utilize this method or sends affairs, inspector should answer statement as N/A.*	N/A	Certifiers perform every 6 months.	6.2.2 Box 5

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: [redacted]

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
40.7	The pharmacy incubates all air samples for time and temperature in compliance with USP <797> following the alternative (we media device) method. *Inspector note: Per USP <797> (first B), two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, malt extract agar [MEA] or sabouraud dextrose agar [SDA]). Each sample is incubated in a separate incubator, one sample at 30°C-35°C for no less than 48 hours; the other sample at 20°C-25°C for no less than five days. If fungal media is used, incubate at 20°C-25°C for no less than five days.* *If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.*	N/A		6.2.2 Box 6
40.8	Results for all plates are recorded for each sample and did not exceed USP <797> Table 7 action levels (or internal action levels if more restrictive). ISO Class 5: >1 cfu/m³/device ISO Class 7: >10 cfu/m³/device ISO Class 8: > 100 cfu/m³/device *Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be enumerated and action levels applied to each sampling media separately.*	Yes		6.2.3 Table 7

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		Observation	Inspector Notes	USP Reference(s)
40.9	For any air sample locations exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. *Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).*	Yes		6.2.3
40.10	For any areas that exceed action levels, an investigation is conducted to attempt to determine cause and a corrective action plan is implemented.	Yes		6.2.3
41.0	Are processes for sampling and monitoring surfaces for viable particles in compliance with USP <797> standards? *Review six months of surface sampling data to verify. If no, go to compliance statements.*	Yes		6.3
41.1	Surfaces and pass-through chambers in the cleanroom suite and SCA are sampled for microbial contamination for each classified area. *Inspector note: Sampling locations must include work surfaces in each classified room, the interior of each ISO Class 5 PEC, and all pass-through chambers connecting to classified areas. USP recommends samples be taken from: equipment contained within the PEC, staging or working area near the PEC, and frequently touched surfaces.*	Yes		6.3, 6.3.1

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		Observation	Inspector Notes	USP Reference(s)
41.2	Surfaces within the cleanroom suite and SCA are sampled at the frequencies specified by USP for viable particle surface sampling. *Inspector note: Category 1 and Category 2 CSP surface sampling frequency is monthly and Category 3 compounding is weekly, regardless of the frequency of compounding Category 3 CSPs.* *Additionally, surface sampling is to be performed within the PEC used to prepare Category 3 CSPs, at the end of each batch, before cleaning and disinfection occurs unless a self-enclosed robot is used: If a self-enclosed robot is used, frequency is at least once daily at the end of compounding operations.* *For facilities compounding any Category 3 CSPs, a surface sampling must be completed prior to assigning BUDs longer than the limits established in Table 13.*	Yes		6.3, 6.3.1, 14.4.2

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
41.3	The pharmacy uses an appropriate microbiological growth media for sampling. *Inspector note: An appropriate microbiological growth media means a surface sampling device with a raised convex surface for sampling flat surfaces is used that contains general microbial growth media that supports the growth of bacteria and fungi (eg, TSA supplemented with additives that neutralize effects of any disinfecting agent, eg, lecithin and polysorbate 80), accompanied by a COA that verifies that the media meets expected growth promotion, pH, and sterilization requirements. Per USP, "sterile swabs wetted with sterile water or a sterile neutralizing buffer may be used when sampling irregular surfaces and difficult-to-reach locations such as crevices, corners, and spaces between surfaces."*	Yes		6.3.2 Box 6
41.4	The pharmacy incubates all surface samples in compliance with USP <797> following the one media device method. *Inspector notes: Per USP <797>, when using the one media device method, sampling media is to be covered, inverted, and incubated at 30°C-35°C for no less than 48 hours. Then, after examination and recording of results, further incubated at 20°C-25°C for no less than five additional days.* *If the pharmacy does not utilize this method or sends offsite, inspector should answer statement as N/A.*	Yes		6.3.2 Box 6

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808296
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
41.5	The pharmacy incubates all surface samples in compliance with USP <797> following the alternative two media device method. *Inspector note: Per USP <797>, two samples may be collected for each sample location and incubated concurrently to shorten the overall incubation period. Both samples are TSA, or one sample is TSA and the other fungal media (eg, MEA or SDA). Media must be supplemented with neutralizing additives (eg, lecithin and polysorbate 80). Each sample is incubated in a separate incubator, one sample at 30°C–35°C for no less than 48 hours the other sample at 20°C–25°C for no less than five days. If fungal media is used, incubate at 20°C–25°C for no less than five days. If the pharmacy does not utilize this method of sample efficacy, inspector should review attachment as N/A.*	N/A		6.3.2 Box 7
41.6	Results for all plates are recorded for each sample and did not exceed USP <797> Table 8 action levels (or internal action levels if more restrictive). ISO Class 8: ≥ 5 chumedia device ISO Class 7: ≥5 chumedia device ISO Class 8: ≥ 50 chumedia device *Inspector note: Per USP <797>, if two sampling media devices are collected at a single location, all recovered growth on each must be documented and action levels applied to each sampling media device separately.*	Yes		6.3.3 Table 8

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808296
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
41.7	For any surface sample broth/agar exceeding action levels, pharmacy works with the assistance of a microbiologist to identify any microorganisms recovered to the genus level. *Inspector note: Per USP <797>, an attempt must be made (meaning the lab attempted to identify the microorganisms and was unsuccessful).*	Yes		6.3.3
41.8	For any areas that exceed action levels, an investigation is conducted to determine causes, and a corrective action plan is implemented.	Yes		6.3.3
42	Compounding Personnel Hygiene and Garbing			
42.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		5.1
42.1	Compounding personnel are required to report conditions that may contaminate the sterile preparation and environment in the designated person(s). *Inspector note: Per USP <797>, examples of conditions that have a higher risk of contaminating the CSP and sterile environment includes: rashes, recent tattoos, boring sores, conjunctivitis, or active respiratory infections.*	Yes		5.3.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808296
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
42.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in compounding areas before their conditions have been resolved. *Inspector note: Per USP <797>, the designated person(s) may permit accommodations as long as the quality of the CSP and environment will not be affected.*	Yes		5.3.1
42.3	Any accommodations permitted by the designated person(s) are documented.	Yes		5.1
42.4	Food (including mints, gum, etc) and drinks are not permitted in anteroom, buffer rooms, or segregated compounding areas.	Yes		5.1
43.0	Does the pharmacy stock the necessary garb to ensure maximum garbing requirements are continuously met in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		5.3
43.1	The pharmacy stocks gowns and/or coveralls that are low lint with sleeves that fit snugly around the wrists and an enclosed neck.	Yes		5.3
43.2	The pharmacy stocks shoe covers that are low lint.	Yes		5.3
43.3	The pharmacy stocks head covers that are low lint and cover the hair and ears.	Yes		5.3

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e-Profile ID: 808296
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
43.4	The pharmacy stocks facial hair covers (net beards) that are low lint. *If the pharmacy does not have personnel with beards, inspector should answer this statement as N/A.*	Yes		5.3
43.5	The pharmacy stocks masks that are low lint.	Yes		5.3
43.6	The pharmacy stocks sterile, powder-free gloves.	Yes		5.3
43.7	Category 1 and Category 2: All non-disposable garb used to prepare Category 1 and Category 2 CSPs is laundered before reuse. *If only disposable items are used, inspector should mark as N/A.*	N/A		5.3
43.8	Category 3 only: The pharmacy stocks low lint face and neck coverings that ensure no skin is exposed. *Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.* *If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.*	N/A		5.3, 14.4.2

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
43.9	Category 3 only: The pharmacy stocks sterile, low lint outer garb (including sterile sleeves over gauntlet sleeves when a RABS is used). *Inspector note: This is an additional garbing requirement for facilities preparing any Category 3 CSPs.* *If the pharmacy does not prepare Category 3 CSPs, inspector should answer statement as N/A.*	N/A		5.3
43.10	Category 3 only: All non-disposable garb used to prepare Category 3 CSPs is laundered and recertified with a validated cycle before each use. *Document whether laundering and sterilization is performed in-house or by an outside vendor.* *If only disposable items are used, inspector should answer statement as N/A.*	N/A		5.3, 14.4.2
	Media-Fill			
44.0	Is the media-fill testing simulation performed by the pharmacy in compliance with USP <797> standards? *Inspector note: Per USP, "When performing a media-fill test, simulate the most difficult and challenging aseptic compounding procedures encountered by the person replacing all the components used in the CSPs with soybean-casein digest media. The simulation must capture elements that could potentially affect the sterility of the CSP."* *If no, go to compliance statements.*	Yes		2.3

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
44.1	The simulation captures factors associated with the length of the process that can pose contamination risk (eg, operator fatigue, quality of equipment).	Yes		2.3
44.2	The simulation captures number of aseptic additions or transfers.	Yes		2.3
44.3	The simulation captures number, type, and complexity of manipulations.	Yes		2.3
44.4	The simulation captures number of personnel in the buffer room or ECA.	Yes		2.3
44.5	Does the facility define "the most difficult and challenging procedures" and the rationale for how they are the most challenging? *Inspector note: Best practice is for this to be documented in an SOP. Inspectors may also find the information documented on a "risk level/competency assessment checklist. For complex/variety of compounding practices, inspectors may find additional media fills are completed (more than what is required by the USP chapters).*	Yes		2.3, 20
45.0	Are the pharmacy's media-fill storage, review, and preparation processes in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		2.3

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
45.1	If pharmacy uses commercial sterile microbial growth media, a COA was obtained. *If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.*	N/A		2.3
45.2	The COA for the commercial sterile microbial growth media includes statements from the supplier that the lot of the growth media will support the growth of microorganisms. *If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.*	N/A		2.3
45.3	Storage of commercial sterile microbial growth media is in accordance with manufacturer instructions. *If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.*	N/A		2.3
45.4	Commercial sterile microbial growth media is stored and used before its expiration date. *Inspector note: Media is to be incubated by the expiration date, meaning that the test needs to be started (not that incubation needs to be completed) before the expiration date.* *If pharmacy does not use commercial sterile microbial growth media, inspector should answer statement as N/A.*	N/A		2.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
45.5	Sterile-to-sterile media-fill testing microbial growth media (non-commercial) was prepared and growth promotion capability was demonstrated prior to use, following USP <71>. *If pharmacy only uses commercial sterile microbial growth media, inspector should answer statement as N/A.*	N/A		7.3
45.6	Nonsterile starting components (commercially available nonsterile soybean-casein digest powder) are dissolved to make a 3% aerobically solution, manipulated in a manner that simulates nonsterile-to-sterile compounding activities, with a minimum of one positive control contained. *If pharmacy does not perform sterile compounding using nonsterile ingredients, inspector should answer statement as N/A.*	Yes		Box 2
	Cleaning and Disinfection			
46.0	Is the pharmacy equipped with the necessary cleaning and disinfecting equipment and supplies that comply with USP <797> standards? *If no, go to compliance statements.*	Yes		7.1, 7.1.1, 7.1.2 <1072>
46.1	All cleaning and disinfecting supplies (eg, wipers, sponges, pads, and mop heads), with the exception of tool handles and holders, are low lint (and sterile if used) within PEC.	Yes		7.1.2

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808256
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
46.2	Reusable cleaning tools are made of cleanable materials (no wood handles or any other porous material).	Yes		7.1.2
46.3	Reusable cleaning tools are dedicated for use in the cleanliness areas of SCA and are not removed from these areas except for disposal.	Yes		7.1.2
46.4	The pharmacy has the appropriate cleaners EPA-registered disinfecting agent(s) to adequately perform cleaning and disinfection. *Inspector note: Examples of EPA-registered disinfectants include, but are not limited to: phenolics; oxidizers, such as peroxyacetic acid and sodium hypochlorite; quaternary ammonium; and hydrogen peroxide. If the agent is EPA-registered, a registration number will be on the label.* *Compounding personnel should have access to SDS and information/knowledge as dwell times. Per USP, Box 7, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.*	Yes		7.1.1 Box 7 <1072>

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808256
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
46.5	The pharmacy has the appropriate EPA-registered sporicidal agent(s) to adequately perform sporicidal disinfection. *Inspector notes: Examples of EPA-registered agents include but are not limited to: oxidizers such as peroxyacetic acid, sodium hypochlorite, and hydrogen peroxide.* *Compounding personnel should have access to SDS and information/knowledge as dwell times. Per USP, Box 8, the pharmacy is to ensure the contact time specified by the manufacturer is achieved.* *Per USP, inspector should check to see if agent is effective against Clostridium difficile.*	Yes		7.1.1 Box 7 <1072>
46.6	All cleaning and disinfectant agents are appropriately labeled including expiration dates. *Inspector should verify that no expired agents are present.*	Yes		7.1.1
46.7	What is/are in the PEC any cleaning and disinfecting agents that are not "ready-to-use" sterile formulations are diluted using sterile water. *If only ready-to-use sterile formulations are used, inspector should answer statement as N/A.*	N/A		7.1.1
47.0	Does the pharmacy's documented cleaning and disinfection activities for surfaces in the classified areas and/or SCA comply with the frequencies specified in USP <797> Table 10? *Review cleaning logs to verify. If no, go to compliance statements.*	Yes		7.2 Table 10

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e-Profile ID: 808256
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
47.1	All interior surfaces of the PEC are cleaned and disinfected on days when compounding occurs.	Yes	Sterile agents are utilized within the PEC.	7.2 Table 10
47.2	All interior surfaces of the PEC are cleaned and disinfected when surface contamination is known or suspected.	Yes		7.2 Table 10
47.3	The removable work tray inside the PEC is cleaned and disinfected on days when compounding occurs. *If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.*	Yes		7.2 Table 10
47.4	All equipment inside the PEC is cleaned and disinfected on days when compounding occurs.	Yes		7.2, 9.1 Table 10
47.5	All work surfaces outside of the PEC (eg, counters, work tables) are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.6	All pass-through chambers are cleaned and disinfected on days when compounding occurs. *If the pharmacy is not equipped with a pass-through chamber, inspector should answer statement as N/A.*	Yes		7.2 Table 10

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e-Profile ID: 808256
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
47.7	Floors in the buffer room, anteroom, and/or SCA are cleaned and disinfected on days when compounding occurs.	Yes		7.2 Table 10
47.8	Sinks used for hand hygiene are cleaned and disinfected on each day of use.	Yes		4.4, 7.2, Table 10
47.9	Walls, doors, and door frames are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.10	Storage and shelving bins are cleaned and disinfected monthly.	Yes		7.2 Table 10
47.11	All equipment outside the PEC are cleaned and disinfected monthly. *Inspector note: Equipment in the SE/SCA may include, but is not limited to: carts, refrigerators, computers, barcode readers, and label printers.*	Yes		7.2 Table 10
47.12	Ceilings in the buffer room and anteroom are cleaned and disinfected monthly. *If the pharmacy performs compounding only in a SCA, inspector should answer statement as N/A.*	Yes		7.2 Table 10

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 809266

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
47.13	Casings in the SCA are required to be cleaned and disinfected only when visibly soiled and when surface contamination is suspected. *If the pharmacy performs compounding only in a cleanroom suite, inspector should answer statement as N/A.*	N/A		7.2 Table 10
47.14	The surface of the removable work tray and the area underneath the removable work tray of the PEC is cleaned and disinfected monthly. *If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.*	Yes		7.2 Table 10
48.0	Does the pharmacy's documented application of sporicidal disinfectant on surfaces comply with the frequencies specified for each CSP category in USP <797> Table 10? *Inspector note: Per USP <797>, if the pharmacy prepares any Category 3 CSPs, the cleaning requirements for Category 3 must be followed at all times regardless of whether a Category 3 CSPs is prepared on any given day.* *Review cleaning logs to verify. If no, go to compliance statements.*	Yes		7.2, 14.4.2 Table 10

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 809266

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
48.1	Sporicidal disinfectant is applied to all interior surfaces of the PEC at the specified frequency. *Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*	Yes		7.2, Table 10
48.2	Sporicidal disinfectant is applied to equipment inside the PEC at the specified frequency. *Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*	Yes		7.2 Table 10
48.3	Sporicidal disinfectant is applied to work surfaces outside the PEC (eg., counters, work tables) at the specified frequency. *Inspector note: For Category 1 and Category 2 compounding only, application frequency is monthly. For any Category 3 compounding, application frequency is weekly.*	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.4	Sporicidal disinfectant is applied to surfaces in the pass-through chambers at the specified frequency. *Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.* *If the facility is not equipped with a pass-through chamber, inspector should answer statement as N/A.*	Yes		7.2 Table 10
48.5	Sporicidal disinfectant is applied to the doors in the buffer room, anteroom, and SCA at least monthly. *Inspector note: For Category 1 and Category 2 compounding only, the application frequency is monthly. For any Category 3 compounding, the application frequency is weekly.*	Yes		7.2 Table 10
48.6	Sporicidal disinfectant is applied to walls, doors, and door frames at least monthly. *Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*	Yes		7.2 Table 10
48.7	Sporicidal disinfectant is applied to storage shelving and bins at least monthly. *Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*	Yes		7.2 Table 10

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		Observation	Inspector Notes	USP Reference(s)
48.8	Sporicidal disinfectant is applied to equipment stored outside the PEC at least monthly. *Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*	Yes		7.2 Table 10
48.9	Sporicidal disinfectant is applied to ceilings in the buffer room, anteroom, and SCA at least monthly. *Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types. Per USP, ceilings of the SCA are required to be cleaned, disinfected, and applied with sporicidal disinfectant only when visibly soiled and when surface contamination is suspected. The SCA may not have an accessible ceiling.*	Yes		7.2 Table 10
48.10	Sporicidal disinfectant is applied to sinks used for hand hygiene at least monthly. *Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.*	Yes		4.4, 7.2 Table 10

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808288

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
A8.11	Sporicidal disinfectant is applied to the work surfaces of the removable tray in the PEC and used underneath the removable work tray at least monthly. *Inspector note: Per USP <797> Table 10, the application frequency is monthly for all category types.* *If the PEC is not equipped with a removable work tray, inspector should answer statement as N/A.*	Yes		7.2 Table 10
	Components *For the purpose of this inspection, "components" are defined as the ingredients, containers, and closures. This includes the activities of procurement, receipt, and inventory. Whether sourced domestically or foreign, the items included here are the same.*			
49.0	Does the pharmacy compound CSPs using active pharmaceutical ingredients (APIs) and non-API components? *Inspector note: Per USP <797>, non-API components may include: pharmaceutical excipients, sterile containers, and container closure systems.* *If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.*	Yes		9.3
50.0	Is the pharmacy's selection of active API and non-API components in compliance with USP <797> standards? *Verify by selecting products from the shelf of different suppliers and ask to see the COAs for those products. If so, go to compliance statements.* *If the pharmacy does not compound using API or non-API components, inspector should answer this question as N/A.*	Yes		9.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808288

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
50.1	APIs: APIs used are compliant with the criteria in the USP–NF monograph, if one exists. *If pharmacy does not compound CSPs that have a USP monograph, inspector should answer this statement as N/A.*	Yes		9.3.1
50.2	APIs: All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that test results for the component show that the API meets expected quality.	Yes		9.3.1
50.3	APIs: All APIs used are manufactured by an FDA-registered facility. *Inspector note: This is a "Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered on FDA drug establishment https://apps.fda.gov/dicers.*	Yes		9.3.1
50.4	All non-API components comply with the criteria in the USP–NF monograph, if one exists.	Yes		9.3.1
50.5	All non-API components are assessed by documentation (eg, COA, labeling) that includes the specifications and test results and shows that the component meets the specifications.	Yes		9.3.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808288

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
50.6	All non-API components used are manufactured by an FDA-registered facility. *Inspector note: Per USP <797>, "If a component cannot be obtained from an FDA-registered facility, the designated person(s) must select an accessible and reliable source (see USP <1197> Good Distribution Practices for Bulk Pharmaceutical Excipients). The compounding facility must establish the identity, strength, purity, and quality of the ingredients obtained from that supplier by reasonable means. Reasonable means may include but are not limited to visual inspection, evaluation of a COA supplied by the manufacturer, and/or verification by analytically testing a sample to determine conformance with the COA or other specifications."*	Yes		9.3.1
51.0	Does the pharmacy have processes in place to evaluate API and non-API components upon receipt and before use in compliance with USP <797> standards? *Inspector note: Non-API components may be defined as excipients, containers, and container closure systems.* *If no, go to compliance statements.* *If the pharmacy does not compound with API or other non-API components, inspector should answer question as N/A.*	Yes		9.3.2, 9.3.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
51.1	APIs or other components have been evaluated for use in sterile drug preparation. *Inspector note: Per USP <797>, "Components labeled with "not for ... pharmaceutical use," "not for injectable use," "not for human use," or an equivalent statement must not be used to compound for these purposes."* *If no, photograph and describe in the notes column. Request copies of the invoices for products with these types of labels.*	Yes		9.3.2, 9.3.3
51.2	Upon receipt of each lot of a component, personnel verify the labeling and condition of each component and examine the external packaging for evidence of deterioration and other agents of unacceptable quality (eg, holes in packaging, damage), temperature-sensing indicators show that the component has been exposed to excessive temperatures).	Yes		9.3.2, 9.3.3
51.3	Each lot of commercially available sterile, depyrogenated containers and nonclosure closure systems are accompanied by a COA or other documentation showing conformance with established specifications for sterility and depyrogenation requirements.	Yes		9.3.1, 9.3.2, 9.3.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 630286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
51.4	The date of receipt by the pharmacy is clearly marked on each API or component package that lacks a vendor expiration date and are assigned and labeled with an expiration date not to exceed one year after receipt by the pharmacy.	N/A		9.3.2, 9.3.3
51.5	All components are reinspected before use. *Inspector note: Per USP <797>, all packages must be inspected to detect container breaks, looseness of the cap or closure, and deviation from the expected appearance, aseptic, and/or factors of the contents that might have occurred during storage. Sterile container closures are usually reinspected to ensure that they are free from defects that could compromise sterility and that they are otherwise suitable for their intended use.*	Yes		9.3.2, 9.3.3
51.6	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		9.3.2, 9.3.3
51.7	Any other lots of that component from that vendor are examined to determine whether other lots have the same defect.	Yes		9.3.2, 9.3.3

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 630286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
	Equipment and Supplies			
52.0	Is the pharmacy equipped with the appropriate supplies and equipment used for compounding in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		9, 9.1, 9.2
52.1	Supplies (eg, beakers, utensils, needles, syringes, filters, and tubing sets) that contact components are not reactive, additive, sorptive, and do not alter the quality of sterile compounded preparations. *Inspector note: The appropriate supplies are available as applicable to the type of CSPs prepared (eg, non-PVC, silicone-free, able to withstand high heat, able to be sterilized).*	Yes		9.2
52.2	Any supplies that are in direct contact with CSPs are sterile and/or depyrogenated.	Yes		9.2
52.3	The equipment must be able to be cleaned using the required agents and tools without damaging the equipment and/or contaminating the compounded preparation. *Inspector note: Equipment used in compounding are of suitable composition and the surfaces that contact components are not reactive or sorptive.*	Yes		9.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 630286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
52.4	When nonsterile ingredients, products, components, or devices (eg, nonsterile APIs and nonsterile vials and closures) are used for compounding, the pharmacy has the appropriate equipment to sterilize the finished product. *Per USP, "Aqueous preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, containers, tubing) during any phase of the compounding procedure must be sterilized within 6 hours after completing the preparation to minimize the generation of bacterial endotoxins in CSPs."* *If the pharmacy does not perform compounding that requires sterilization, inspector should answer statement as N/A.*	Yes		9.1, 9.2.1, 10
53.0	Does the pharmacy operate and maintain records for all equipment used for compounding in accordance with manufacturer specifications and USP <797> standards? *If no, go to compliance statements.*	Yes		9.1, 29
53.1	Automated, mechanical, or electronic equipment (monitoring equipment, autoclaves, ovens, etc) are periodically inspected and calibrated yearly or in accordance with the equipment manufacturer guidelines.	Yes		9.1, 9.3.4

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 630286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
53.3	Automated compounding devices (ACDs) and other similar equipment (pumps, channel or multi-channel) are reviewed for accuracy and calibrated daily, prior to initial use, and a daily record is maintained. *Inspector note: Per USP, "The precision of the equipment can be monitored based on an assessment of day-to-day variations in its accuracy measured. Compounding personnel must maintain a daily record of the accuracy measurements on the days the equipment is in use. Corrective actions must be implemented if accuracy measurements are outside the manufacturer's specification."*	N/A	The ACD is only used to filter large volumes from a beaker into a depyrogenated container to reduce the number of manipulations.	9.1
53.5	Incubators used for environmental and personnel monitoring are placed in a location outside of the sterile compounding area and calibrated in accordance with manufacturer's instructions. *If the pharmacy does not incubate samples and immediately in-house, inspector should answer statement as N/A.*	Yes		9.1, 9.3.2, 9.3.2

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 805236
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
c. 53.4	Incubators used for environmental and personnel monitoring are monitored for temperature during incubation periods either manually or by use of a continuous recording device. *Inspector note: Incubators store media at 20°C-25°C and 30°C-35°C. If the pharmacy has more than one incubator, review records for both incubators.* *View incubator temperature records to verify. Evaluate the size of the incubator and volume of media it can store. If the pharmacy does not incubate samples and/or media-fills in-house, inspector should answer statement as N/A.*	Yes	Continuous recording device	8.2.2, 8.3.2 Box 5
	Compounding Personnel Observation A trained, competent observer should observe the compounding personnel during gowning and garbing procedures. The observer should verify that the proper garbing procedures are followed and that the garbing process does not contaminate the sterile garb. Observation of garbing procedures may be performed by direct observation, video, or a combination of both. If a trained observer is not available to observe garbing procedures, garbing procedures may be performed by the compounding personnel in front of a mirror.			
54.0	Personnel Preparation Observation: Before entering the compounding area, do compounding personnel remove any items that are not sterile clean/lint or are not necessary for compounding in compliance with USP <797> standards? *If no, go to compliance statements*	Yes		5.1

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
54.1	All outer garments such as hats, scarves, sweaters, sandals, coats, boots, and jackets are removed.	Yes		5.1
54.2	Makeup and/or cosmetics are removed.	Yes		5.1
54.3	All hand, wrist, and other exposed jewelry, including piercings such as earrings, lip or eyebrow piercings, etc, are removed and any jewelry that cannot be removed is covered.	Yes		5.1
54.4	Earbuds or headphones are removed.	Yes		5.1
54.5	Electronic devices that are not necessary for compounding or other required tasks are prohibited from entering the compounding areas.	Yes		5.1
54.6	Nails are kept clean and neatly trimmed.	Yes		5.1
54.7	Any nail polish, artificial nails, or extenders are removed.	Yes		5.1
54.8	If worn, eyeglasses are wiped. *If none of the pharmacy staff wear glasses, inspector should answer statement as N/A.*	Yes	Eyeglasses were cleaned.	5.1

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
54.9	Any accommodations permitted by the designated person(s) have been documented. *Inspector note: Per USP <797>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.*	Yes	The pharmacy indicated that an accommodation has been made for the cleaning and wearing of earbuds in the SOPs but was not witnessed by the inspector.	5.1
55.0	Hand Hygiene Observation: Were compounding personnel entering the compounding area observed performing the appropriate hand washing procedures in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		5.2 Box 3
55.1	All personnel entering the compounding area performed hand hygiene.	Yes		5.2 Box 3
55.2	The order of hand washing was performed in the appropriate sequence in relation to the placement of the sink. *Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.*	Yes		5.2 Box 3

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
55.3	Fingernails are cleaned under warm running water using a disposable nail cleaner (eg, nail pick). *Inspector note: During observations, inspect whether nail picks are available for use when performing hand hygiene.*	Yes		5.2 Box 3
55.4	Brushes are not used for hand hygiene.	Yes		5.2 Box 3
55.5	Hands and forearms are washed up to the elbows with soap and warm water for at least 30 seconds. *Inspector note: Compounding personnel describe method for ensuring they have washed for 30 seconds (example: clock or timer is available near the sink).*	Yes		5.2 Box 3
55.6	Soap containers are not refilled or topped off.	Yes		5.2
55.7	Hands and forearms are completely dried up to the elbows with low-lint disposable towels or wipers.	Yes		5.2 Box 3
55.8	Hand dryers are not used for hand hygiene.	Yes	Hand dryer is on the wall but is never utilized. Low-lint disposable towels are utilized.	5.2 Box 3

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 838296
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
56.0	Garbing Observation: Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		3.3
56.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3
56.2	Compounding personnel entering the cleanroom suite and/or SCA adhere to the minimum garbing requirements in USP <797>. *Inspector note: Per USP <797>, additional garbing requirements must be consistently met in the buffer room where Category 3 CSPs are prepared, regardless of whether Category 3 CSPs are compounded on a given day.*	Yes		3.3
56.3	Donning procedures are performed in an order that reduces the risk of contamination. *Inspector note: USP recommends (but requires) the donning procedure to be performed in the anteroom.* *If no, inspector must describe in the notes column why a risk of contamination is a concern.*	Yes		3.3

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 838296
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
56.4	Donning procedures are performed in the appropriate sequence in relation to the placement of the sink. *Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.*	Yes		3.3
56.5	The order of garbing was performed in the appropriate sequence in relation to the placement of the sink. *Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb.*	Yes		3.2, 3.3
56.6	Sterile gloves are donned in a cleanroom or SCA. *Inspector note: If hand hygiene is completed outside of a classified area, alcohol-based hand rub must be used prior to donning garb and again before sterile gloves are donned, see USP <797> FAQ #37.*	Yes		3.2
56.7	Skin is not exposed inside the ISO Class 5 PEC.	Yes		3.3
56.8	Garb is replaced immediately if it becomes visibly soiled or if its integrity is compromised.	Yes		3.3

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
56.9	Category 1 and Category 2 only: Upon exit of the compounding area, all garb (except for gowns) is discarded or laundered prior to reuse. *Inspector note: Gowns (disposable and non-disposable) may be reused within the same shift by the same person only if stored appropriately.* *If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused, inspector should answer statement as N/A.*	Yes		3.3
56.10	Category 1 and Category 2 only: Gowns reused within the same shift and by the same person are maintained in a manner that prevents contamination. *Inspector note: Per USP <797>, gowns stored for reuse must be maintained in a classified area or adjacent to or within the SCA in a manner that prevents contamination (eg, away from sinks to avoid splashing).* *If the facility prepares any Category 3 CSPs, additional garbing requirements must be followed and gowns must not be reused; inspector should answer statement as N/A.*	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
57.0	List the name(s) of the CSP's observed by the inspector as part of the compounding observation(s).		Trimetrexate 20mg/ml 2ml	
58.0	Compounding Observation: Are compounding personnel observed using the appropriate aseptic technique that ensures the quality of the CSP and the environment is maintained in compliance with USP <797> standards? *If no, go to compliance statements*	Yes		1, 2.1, 2.3
58.1	All sterile compounding is performed in a PEC with ISO Class 5 conditions or better. *If the pharmacy only performs immediate use compounding, inspector should answer this statement as N/A.*	Yes		4.1.2

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
58.2	Category 2 and Category 3 only: All PECs are placed in a cleanroom suite. *Inspector note: Per USP, "If compounding only Category 1 CSPs, the PEC may be placed in an unclassified SCA." If the pharmacy only prepares Category 1 CSPs, inspector should answer this statement as N/A.*	Yes		4.1.2
58.3	Compounding personnel ascertain before use that components are of the correct identity, appropriate quality, within the expiration date, and have been stored under the proper conditions.	Yes		9.3.3
58.4	All items are wiped with a sporicidal disinfectant, EPA-registered disinfectant, or sterile 70% IPA prior to being introduced into the clean side of the room/vent, placed into a pass-through chamber, and/or brought into the SCA. *Inspector note: The wiping procedure or agents used should not compromise the packaging integrity or render the product label unreadable. Disinfectant shelf time minimums, as specified by the manufacturer, are to be followed.*	Yes		6.1
58.5	Before any item is introduced into the PEC, it is wiped with sterile 70% IPA using sterile low lint wipes and allowed to dry before use. *Inspector note: Per USP, "When sterile items are received in sealed containers designed to keep them sterile until opening, the sterile items may be removed from the covering as the supplies are introduced into the ISO Class 5 PEC without the need to wipe the individual sterile supply items with sterile 70% IPA. The wiping procedure must not render the product label unreadable."*	Yes		6.2
58.6	Aseptic procedures and manipulations are performed in a manner intended to minimize the risk of contamination. *Inspector note: Observe the compounder's technique to ensure proper aseptic technique is utilized such as: preparation occurs in the direct compounding area (DCA); the compounder does not interrupt first air during the compounding process; proper set up of equipment, supplies, and components that ensure first air is not interrupted; the compounder handles the syringe in a manner that does not introduce contaminates (touch contamination) as the plunger rod; proper entry and exit of materials in ISO Class 5 PEC; and frequent sanitization of gloves.*	Yes		2.3
58.7	All critical sites (eg, vial stoppers, ampule necks, and IV bag spikports) are wiped with sterile 70% IPA in the PEC and allowed to dry before puncturing.	Yes		7, 8.3

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
58.8	Gloves are disinfected with sterile 70% IPA immediately before compounding and regularly throughout the compounding process. *Inspector note: Per USP, best practice is to re-sanitize each time hands re-enter the PEC; This may not occur when compounder is staging the next batch.*	Yes		3.3
58.9	Gloves are regularly inspected for holes, punctures, or tears, and are replaced immediately if such defects are detected.	Yes		3.3
59.0	Do compounding personnel adhere to the USP established time limits for components after initial puncture or entry in compliance with USP <797> standards? Look at punctured, stored containers and confirm if puncture time or BUD is noted on the container and stored within time limits. If no, go to the compliance statements.	Yes		15

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		Observation	Inspector Notes	USP Reference(s)
59.1	Single-dose containers (unused or punctured only in an ISO Class 5 air or cleaner air) are not used beyond 12 hours after initial puncture or entry or assigned BUD, whichever is shorter. *Inspector note: This applies to conventionally manufactured single-dose vials, compounded single-dose CSPs used as components, and CSP stock solutions. The labeled storage requirements during that 12-hour period must be maintained. Additionally, per USP, "The time limit for entering or puncturing [a single-dose CSP or CSP stock solution] is not intended to restrict the BUD of the final CSP."*	Yes		10.1, 10.2
59.2	Multiple-use containers are not used for more than 28 days after initial puncture or entry, manufacturer specifications, or assigned BUD, whichever is shorter. *Inspector note: This applies to conventionally manufactured multiple-dose vials and compounded multiple-dose CSPs used as components. Multiple-dose CSPs are required to meet the criteria for antimicrobial effectiveness testing (USP <51>) and must be stored under the conditions upon which its BUD is based (eg, refrigerator or controlled room temperature).*	Yes		14.3, 15.2, 16.1

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		Observation	Inspector Notes	USP Reference(s)
59.3	The remaining contents of opened single-dose ampules (or vials where container closure system has been removed) are discarded immediately. *Inspector note: Ampules or vials where the container closure system has been removed must not be stored for any time period.*	Yes		5.1
59.4	Pharmacy bulk package containers of sterile drugs for parenteral use are only entered or punctured in an ISO Class 5 PEC. *Inspector note: Per USP, the pharmacy bulk package system must be used according to the manufacturer's labeling.*	Yes		5.3
60.0	Inspect several different finished compounded sterile preparations. Are all the finished compounded sterile preparations free from any evidence of particulates, filaments, floaters, or signs of contamination? *Inspector note: If found, reject the compounded preparation to be quarantined and notify NABP immediately. Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, filament or floater); number of preparations affected (eg, two of the five vials on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.*	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
61.0	Are there procedures for in-process checks performed by a pharmacist? *Inspector note: In-process checks are safety steps for complex, multi-step compounding processes or high risk drugs or high risk populations (eg, neonates). [redacted] Those checks indicate that appropriate procedures and packaging are followed for each step, including witnessing pharmacist verification of steps performed by non-pharmacists and visual inspection of product. Documentation of the compounding accuracy is recommended to be performed by someone other than the compounder to ensure proper assessment, reconstitution, and component usage. Some checks may be done retrospectively and with the assistance of technology.*	Yes	Pharmacists perform all sterile compounding.	7 Table 2, Table 3

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		Observation	Inspector Notes	USP Reference(s)
62.0	Cleaning and Disinfection Observation: Does the pharmacy perform cleaning and disinfection activities in compliance with USP <797> standards? *If inspector is unable to observe cleaning activities (due to timing of compounding activities observed), inspector should interview compounder(s) to have them walk through their normal process. If this occurs, inspector should record in notes column "process only." If no, go to compliance statements.*	Yes		7
62.1	All cleaning and disinfection activities are performed by appropriately garbed personnel.	Yes		7
62.2	Cleaning and disinfection are performed on all surfaces in the classified area and SCA.	Yes	Process only	7
62.3	Cleaning is performed in the direction of clean to dirty areas.	Yes		7
62.4	Reusable cleaning tools are disinfected prior to and after each use.	Yes	Process only	7, 7.2
62.5	Only sterile cleaning, disinfecting, and sporicidal agents are permitted for use in the PEC. *Inspector note: If pharmacy utilizes non-ready to use (RTU) agents, they must be diluted with sterile water. Per USP, "Once opened, sterile cleaning and disinfecting agents and supplies (eg, closed containers of sterile wipers) and sterile 70% IPA may be reused for a time period specified as by the manufacturer and/or described in the facility written SOPs."*	Yes		7.1.1, 7.1.2

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		Observation	Inspector Notes	USP Reference(s)
62.6	Only sterile supplies and equipment are permitted for use in the PEC. *Inspector notes: Non-disposable cleaning tools or handles must be properly disinfected prior to entering the PEC and prior to use.*	Yes		7.1.1, 7.1.2
62.7	Compounding personnel are using the appropriate sterile cleaning, disinfecting, and sporicidal agents within the PEC.	Yes		7.1.1
62.8	Compounding personnel are using the appropriate cleaning and disinfecting procedures and techniques within the PEC. *Inspector note: Per USP, "All cleaning, disinfecting, and application of sporicidal disinfectants must be documented according to the facility's SOPs"; "Cleaning must be performed in the direction of clean to dirty areas"; and when 70% sterile IPA is used, it is used last and allowed to dry. There are differing opinions on the best order of cleaning. Procedure includes using a sterile low-lint wiper to all surfaces. Allow surfaces to dry completely before beginning compounding.*	Yes		7.1.2 Ore 7, Row 8
62.9	The manufacturer's directions or published data for the minimum contact time is followed for each of the cleaning, disinfecting, and sporicidal disinfectant used. *Per USP, contact times should be included in the SOP based on the agent used.*	Yes	Process only (did not witness all agents being utilized)	7.1.1 Ore 7, Row 8

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		Observation	Inspector Notes	USP Reference(s)
62.10	Sterile 70% IPA is applied to all surfaces in the ISO Class 5 PEC at the frequencies specified by USP during active compounding. *Inspector note: Per USP <797>, sterile 70% IPA must be applied: immediately before initiating compounding procedures, to the work surface of the PEC at least every 30 minutes (if the compounding process takes 30 minutes or less), to the work surface of the PEC immediately after compounding (when the compounding process takes more than 30 minutes), after each batch or lot is completed, and after cleaning and disinfecting.*	Yes		7
	Sterilization and Depyrogenation			10.2
63.0	Does the pharmacy compound preparations with any nonsterile sterile components? . *If the pharmacy does not compound preparations with any nonsterile sterile components, inspector should answer question as N/A.*	Yes		10

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		Observation	Inspector Notes	USP Reference(s)
64.0	Are injectable compounded preparations that contain nonsterile components or that come into contact with nonsterile devices (eg, ventilators, tubing) during any phase of the compounding procedure, sterilized within six hours after completing the preparation? *If no, describe observations and collect a copy of the master formulation record, a copy of the compounding record, and a copy of the process for sterilization.* *If the pharmacy does not compound with nonsterile components or devices, or they only compound sterile ophthalmic and/or sterile drugs administered by inhalation, inspector should answer question as N/A.*	Yes		10
65.0	**Filter Sterilization:** Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards? *View compounding records for CSPs sterilized by filtration to verify.* *Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.* *If no, go to compliance statements.* *If the pharmacy does not use this sterilization method, inspector should answer question as N/A.*	Yes		10.2 USP <1229.4>

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		Observation	Inspector Notes	USP Reference(s)
65.1	Sterilization by filtration is performed in an ISO 5 environment.	Yes		4.1.2, 10.2
65.2	Filters used have enough capacity to filter the required volumes. *Inspector note: Per USP, "The filter dimensions and the CSP to be sterilized by filtration should permit the sterilization process to be completed without the need for replacement of the filter during the process."*	Yes		10.2
65.3	The 0.2 micron sterile micro-porous membrane filter used to sterilize CSP solutions is chemically and physically compatible with the CSP. Inspector note: Per USP <797>,"sterilizing filters must be appropriate for pharmaceutical use. Sterilizing filters labeled "for laboratory use" or equivalent must not be used." Sterilizing filters must be certified by the manufacturer to retain at least 107 microorganisms of a strain of Brevundimonas diminuta per square centimeter of upstream filter surface area under conditions similar to those in which the CSPs will be filtered (ie, pressure, flow rate, and volume filtered)."	Yes		10.2

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		Observation	Inspector Notes	USP Reference(s)
65.4	Confirmation of filter integrity (bubble testing) is performed and documented for each filter used with each batch sterilized by filtration. *Inspector note: If multiple filters are required for the compounding process, each of the filters must be tested.* *If no, collect a copy of the master formulation record and compounding record.*	Yes	✓	10.2
65.5	A prefiltration step is performed for any CSPs that are known to contain excessive particulate matter. *Inspector note: The prefiltration step consists of using a filter with a larger nominal pore size (eg, 1.2 micron) or a separate filter of larger nominal pore size should be placed upstream of (ie, prior to) the sterilizing filter to remove gross particulate contaminants before the CSP is passed through the sterilizing-grade filter.*	N/A		10.2
65.6	CSPs that are prepared using a filter that failed integrity tests are either discarded or, after investigating the cause of the failure and selection of an appropriate filter, refiltered for sterilization not more than one additional time. *If no, collect a copy of the master formulation record and compounding record.*	Yes		10.2
65.7	Single-use filters are only used once.	Yes		4.1.2, 10.2

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		Observation	Inspector Notes	USP Reference(s)
66.0	**Steam Sterilization: Does the pharmacy use the appropriate type of sterilization method, equipment (autoclave), documentation, and testing in compliance with USP <797> standards?** *Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity.* *View documentation on compounding records for CSPs sterilized by steam to confirm. If no, go to compliance statements.* *If the pharmacy does not use this sterilization method, inspector should answer question as N/A.*	Yes		10.3 USP <1229.1>
66.1	The pharmacy has evaluated if steam sterilization would cause degradation of the drug. *Inspector note: For USP, compounded preparations that are degraded by moisture, pressure, or temperatures used may not be sterilized by steam treatment.*	Yes	Potency testing was performed on this formulation.	10.3
66.2	Steam supplied is free of contaminants and generated using water per manufacturer's specifications.	Yes		10.3

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		Observation	Inspector Notes	USP Reference(s)
66.3	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	Yes		10.3
66.4	Items are placed in the autoclave in a manner that allows steam to reach them without entrapment of air. *Inspector note: The pharmacy should have the autoclave cycle validated for the size of the batch, sterilization temperature, and sterilization time to ensure the load will be sterile.*	Yes		10.3 USP <1229.1>
66.5	Sealed containers used are able to generate steam internally (eg, small amount of water in empty crimped vials).	Yes		10.3
66.6	The appropriate biological indicators (USP <1229>) are used to verify the sterilizeness of each sterilization run or load and documented in the compounding record. *Inspector note: Per USP <797>, "The effectiveness of steam sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Geobacillus stearothermophilus (ATCC 12980, ATCC 7953, or equivalent; see "Biological Indicators for Sterilization USP <1229.5>), and other confirmation methods such as physicochemical indicators (see "Physicochemical Integrators and Indicators for Sterilization USP <1229.6>). The date, run, and load numbers of the steam sterilizer used to sterilize a CSP is documented in the compounding record."*	Yes		10.3 USP <1229.5> USP <1229.6>

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		Observation	Inspector Notes	USP Reference(s)
66.7	All items are directly exposed to steam under adequate pressure for the length of time necessary as determined by use of appropriate biological indicators to render the items sterile. *Inspector note: Per USP <797>, the duration of the exposure period must include sufficient time for the entire contents of the CSP and other items to reach the sterilizing temperature. The CSP and other items must remain at the sterilizing temperature for the duration of the sterilization period (an example provided in the chapter is 30-60 minutes at 121°C saturated steam under a pressure of 15 psi, depending on the volume or size of the CSP being sterilized).* *Any parameters for the autoclave must be set through validation.*	Yes		10.3 USP <1229.5>
66.8	A calibrated data recorder or chart is used to monitor each cycle and to examine for cycle irregularities (eg, deviations in temperature or pressure) and results documented on the CR.	Yes		10.3, 20

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		Observation	Inspector Notes	USP Reference(s)
67.0	**Dry Heat Sterilization: Does the pharmacy use the appropriate type of sterilization method, equipment, documentation, and testing in compliance with USP <797> standards?** *Inspector note: The sterilization method used must sterilize the CSP without degrading its physical and chemical stability (eg, affecting its strength, purity, or quality) or the packaging integrity. USP <1228.8> also applies.* *View documentation on compounding records for CSPs sterilized by dry heat to confirm. If no, go to compliance statements.* *If the pharmacy does not use this sterilization method, inspector should answer question as N/A.*	N/A		10.4 USP <1228.8>
67.1	The pharmacy has the appropriate dry heat sterilization equipment. *Inspector note: Dry heat sterilization is usually performed in an oven designed for sterilization at 160°C or higher. The dry heat oven should be used to get to the appropriate temperature and pressure, for example, not be a toaster oven.*	N/A		10.4
67.2	Solutions are passed through a 1.2 micron or smaller filter into the final containers to remove particulates before sterilization.	N/A		10.4
67.3	During sterilization, sufficient space is left between materials to allow for circulation of hot air.	N/A		10.4

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		Observation	Inspector Notes	USP Reference(s)
67.4	CSPs and other items are exposed to dry heat for the length of time necessary for all items to reach sterilizing temperature of 360°C or higher. *Inspector note: For USP <797>, if lower temperatures are used, they are validated by biological indicators (see USP <1229.8>, Validation of Dry Heat Sterilization, Biological Indicators). The calibrated oven must be equipped with temperature controls and a timer.*	N/A		10.4
67.5	The appropriate biological indicators are used to verify the effectiveness each sterilization run or load and documented in the compounding record. *Inspector note: Per USP <797>, "The effectiveness of dry heat sterilization must be verified and documented with each sterilization run or load by using appropriate biological indicators, such as spores of Bacillus atrophaeus (ATCC 9372; see Biological Indicators for Sterilization USP <1229.8>) and other confirmation methods (e.g., temperature-sensing devices). The date, run, and load numbers of the dry heat oven used to sterilize a CSP must be documented in the CR."*	N/A		10.4 USP <1229.8>
67.6	A calibrated data recorder or chart is used to monitor each cycle and the data is reviewed to identify cycle irregularities (eg, deviations in temperature or exposure time) and results documented on the CR.	N/A		10.4, 20

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		Observation	Inspector Notes	USP Reference(s)
68.0	Dry Heat Depyrogenation: Is the appropriate depyrogenation method used and documented in compliance with USP <797> standards? *View documentation records of items depyrogenated to confirm. If the pharmacy does not use this method, inspector should answer question as N/A.*	Yes		10.1 USP <1228.9>
68.1	Glassware, vials, and other thermostable containers are exposed to dry heat for the length of time necessary for all items to be rendered pyrogen free.	Yes		10.1
68.2	The effectiveness of the dry heat depyrogenation cycle is established and documented. *Inspector note: Per USP <797>, this must be done initially, re-established any time there are changes made to the cycle (eg, load conditions, duration, temperature), and verified at least annually by using endotoxin challenge vials (ECVs) to demonstrate that the cycle is capable of achieving a ≥ 3-log reduction in endotoxins (see Bacterial Endotoxins Test USP <85>). The verification must be documented.*	Yes		10.1 USP <1228.1> USP <85>
68.3	Items that are not thermostable are depyrogenated by multiple rinses with sterile, nonpyrogenic water (eg, sterile water for injection or sterile water for irrigation) and then thoroughly drained or dried immediately before use in compounding. *Inspector note: USP <1228.4> Depyrogenation by Rinsing also applies.*	Yes		10.1 USP <1228.4>

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		Observation	Inspector Notes	USP Reference(s)
	Master Formulation and Compounding Records			
69.0	Are Master Formulation Records (MFRs) created and maintained in compliance with USP <797> standards? *If no, go to the compliance statements.*	Yes		11.1
69.1	The pharmacy creates and maintains MFRs for CSPs that are prepared for more than one patient.	Yes		11.1, 20
69.2	MFR changes and alterations are approved and documented according to the pharmacy's SOPs.	Yes		11.1
69.3	The pharmacy creates and maintains MFRs for CSPs that are prepared from nonsterile ingredients.	Yes		11.1, 20
69.4	The MFR includes the name, strength or potency, and dosage form of the sterile compounded preparation.	Yes		11.1, 20

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		Observation	Inspector Notes	USP Reference(s)
69.5	The MFR includes the identities and amounts of all ingredients.	Yes		11.1, 20
69.6	The MFR includes the type and size of container closure.	Yes		11.1, 20
69.7	The MFR includes complete instructions for preparing the sterile compounded preparation, including equipment, supplies, a description of the compounding steps, and any special precautions.	Yes		11.1, 20
69.8	The MFR includes a physical description of the final CSP.	Yes		11.1, 20
69.9	The MFR includes the BUD and storage requirements.	Yes		11.1, 14.2, 20
69.10	The MFR includes the reference source to support the stability of the CSP.	Yes		11.1, 20
69.11	The MFR includes quality control procedures (eg, pH testing, filter integrity testing).	Yes		11.1, 20

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 626296
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
69.12	The MFR includes other information as needed to describe the compounding process and ensure repeatability (eg, adjusting pH and tonicity, sterilization method).	Yes		11.1, 30
69.13	The MFR includes all required finished tests, and if applicable, sterility test methods, process, number and endotoxin test and limits.	Yes		11.1, 12, 30
70.0	Are Compounding Records (CR) created and maintained in compliance with USP <797> standards? *Inspector note: Per USP, a prescription or medication order or label may serve as the CR. Also, a copy of the MFR can be made that contains spaces for recording the information needed to complete the CR (eg, both the MFR and CR are on the same document/form). A CR may be kept electronically, if readily retrievable, as long as it contains all required information.* *If no, go to compliance statements.*	Yes		11.2 Box 10
70.1	The pharmacy creates and maintains CRs for all its immediate-use CSPs prepared for more than one patient. *Inspector note: If pharmacy does not prepare any CSPs for immediate-use, inspector should answer compliance statement as N/A.*	Yes		11.2 Box 10

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
70.2	The pharmacy creates and maintains CRs for all Category 1, Category 2, and Category 3 CSPs.	Yes		11.2 Box 10
70.3	The CR includes the name, strength or activity, dosage form of the CSP, and (if applicable) the MFR reference.	Yes		11.2 Box 10
70.4	The CR includes the date and time of preparation.	Yes		11.2 Box 10
70.5	The CR includes an assigned internal identification number (eg, patient name, order, or lot number).	Yes		11.2 Box 10
70.6	The CR includes the identity of the individual(s) involved in the compounding process.	Yes		11.2 Box 10
70.7	The CR includes identity of the individual(s) verifying the final CSP.	Yes		11.2 Box 10
70.8	The CR includes the name of each component.	Yes		11.2 Box 10

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
70.9	The CR includes the vendor/manufacturer, lot number, and expiration date for each component. *Inspector note: this is required for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredient(s).*	Yes		11.2 Box 10
70.10	The CR includes the weight or volume of each component.	Yes		11.2 Box 10
70.11	The CR includes the strength or activity of each component.	Yes		11.2 Box 10
70.12	The CR includes the total quantity compounded.	Yes		11.2 Box 10
70.13	The CR includes the final yield (eg, quantity, containers, number of units).	Yes		11.2 Box 10
70.14	The CR includes the assigned BUD and storage requirements.	Yes		11.2 Box 10
70.15	The CR includes results of quality-control procedures (eg, visual inspection, filter integrity testing, pH testing).	Yes		11.2, 12 Box 10

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
70.16	The CR includes calculations made to determine and verify quantities and/or concentrations of components. *Inspector note: Per USP, "If applicable, the CR must also include...Calculations."*	Yes		11.2 Box 10
70.17	The CR is verified by the pharmacist for appropriateness and accuracy with all process and final checks. *Inspector note: "Documentation must comply with all laws and regulations of the applicable regulatory jurisdiction."*	Yes		2, 11.2, 12.1, 13, 20 Box 10
71.0	Are the pharmacy's labels for CSPs in compliance with USP <797> standards and display all required information? *If no, go to compliance statements.*	Yes		13 USP <7>
71.1	Information on the label is prominently and legibly displayed. *Inspector note: Definition of labeling includes other accompanying materials with the CSP, which includes, "written, printed, or graphic matter on the immediate container or on or inside any package or wrapper in which it is enclosed. The shipping container is not included in the definition of the "label."*	Yes		13
71.2	Labeling meets any state or federal regulatory requirements.	Yes		13

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 868286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
71.3	Labeling on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		13
71.4	Labeling on the immediate container includes the active ingredients and their amounts, activity, or concentration.	Yes		13
71.5	Labeling on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		13
71.6	Labeling on the immediate container includes the BUD. *Per USP, "Each CSP label must state the date, or the hour and date, beyond which the preparation must not be used and must be discarded (ie, the BUD)."*	Yes		13, 14.1
71.7	The compounded CSP label does not use the term "expiration date" or equivalent.	Yes		13, 14.1 USP <7>
71.8	Labeling on the immediate container includes the dosage form.	Yes		13
71.9	Labeling on the immediate container includes the total amount or volume when not the total it was the container.	Yes		13

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
71.10	Labeling on the immediate container states that the CSP is a single-dose container (when space permits).	Yes		13
71.11	Labeling on the immediate container states that the CSP is a multiple-dose container.	Yes		13
71.12	Labeling includes the route of administration, as applicable.	Yes		13
71.13	Labeling includes any special handling instructions and/or warning statements, as applicable.	Yes		13
71.14	Labeling includes the compounding facility name and contact information if the CSP is to be used outside of the facility or health care system in which it was compounded.	Yes		13
72.0	Does the label contain information identifying the CSP is a compounded preparation? *Inspector note: Per USP, this is a recommendation/should.*	Yes		13 USP <7>

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		Observation	Inspector Notes	USP Reference(s)
	Establishing BUDs			14
73.0	Category 1 and Category 2 CSPs: Does the pharmacy assign BUDs for Category 1 and Category 2 CSPs in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes	Testing is conducted by ARL or Eagle.	14, 14.1, 14.2
73.1	The assigned BUD does not exceed the shortest expiration date of any of the individual commercially available starting components.	Yes		14.3
73.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and that the packaging maintains its integrity for the duration of the assigned BUD.	Yes		14.3
73.3	Category 1 CSPs: BUDs for Category 1 CSPs prepared in an SCA do not exceed the limits established in Table 12. *Inspector note: Per USP <797> Table 12, BUD maximum limits for Category 1 CSPs are defined as 12 hours at controlled room temperature (CRT 20°C-25°C) or 24 hours refrigerated (2°C-8°C). If no Category 1 CSPs are prepared, inspector should answer statement as N/A.*	N/A		14.3, Table 12

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
73.4	Category 2 CSPs: BUDs for aseptically processed (by filtration) Category 2 CSPs that do not undergo sterility testing do not exceed the limits established in Table 13. *Inspector note: Per USP <797> Table 13, BUD maximum limits for aseptically processed Category 2 CSPs using are at more nonsterile starting components are defined as: use (by CRT) four days refrigerator; and 45 days freezer. Aseptically processed Category 2 CSPs using any sterile starting components are defined as: four days CRT; 10 days refrigerator; and 45 days freezer. If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.*	Yes		14.3, Table 13
73.5	Category 2 CSPs: BUDs for aseptically processed (by filtration) Category 2 CSPs where sterility testing and endotoxin testing (if applicable) are performed and passed do not exceed the limits established in Table 13. *Inspector note: Per USP <797> Table 13, BUD maximum limits for, aseptically processed Category 2 CSPs, that were sterility tested and passed, regardless of starting components being sterile or nonsterile, are defined as: 30 days CRT; 45 days refrigerator; and 60 days freezer. If no aseptically processed Category 2 CSPs are prepared, inspector should answer statement as N/A.*	Yes		14.3, 14.3.1, 14.3.3, Table 13

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Sterile Compounding Inspection for USP-<797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 800286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
73.8	Category 2 CSPs: BUDs for terminally sterilized Category 2 CSPs that do not undergo sterility testing do not exceed the limits established in Table 13. *Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized is probability of nonsterile unit (PNSU) of 10⁻⁶ (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 14 days CRT; 28 days refrigerator; and 45 days freezer.* *If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.*	N/A		14.3, 14.2.1, Table 13
73.7	Category 2 CSPs: BUDs for terminally sterilized Category 2 CSPs where sterility testing and endotoxin testing (if applicable) are performed and passed do not exceed the limits established in Table 13. *Inspector note: Per USP <797> Table 13, BUD maximum limits for terminally sterilized is PNSU of 10⁻⁶ (eg, dry heat, steam, irradiation) Category 2 CSPs are defined as: 45 days CRT; 60 days refrigerator; and 90 days freezer. Endotoxin testing is required for Category 2 injectable CSPs compounded from one or more nonsterile component(s) and assigned a BUD that requires sterility testing.* *USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components are also endotoxin tested.* *If no terminally sterilized Category 2 CSPs are prepared, inspector should answer statement as N/A.*	Yes	E-Beam sterilization for pellets	14.3, 14.2.1, 14.2.1 Table 13

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		Observation	Inspector Notes	USP Reference(s)
74.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest beyond use date of any individual compounded components? *Inspector note: Per USP, "the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CSP exceeds the BUD assigned to compounded components (eg, pH-altering solutions). If the assigned BUD of the final CSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CSP must not be negatively impacted." Other examples where this may occur, formulation a formula, preservative-free compounded component used in a preserved final CSP, "in-use" rules for pharmacy bulk packages, and cyclosporine ophthalmic stock solution.* *If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.*	Yes		14.3

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Sterile Compounding Inspection for USP-<797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
75.0	Are BUDs for Category 3 CSPs assigned in compliance with all conditions outlined in USP <797> standards and do not exceed the maximum limits established in Table 14? *Inspector note: If all of the conditions described for Category 3 CSPs are not met, the applicable BUD must not exceed the established maximum limits in Table 13 for Category 2 CSPs.* *If no, go to compliance statements.* *If the pharmacy does not prepare Category 3 CSPs, inspector should answer question as N/A.*	N/A		14.3, 14.4, 14.4.1, 14.4.2, 14.4.3, 14.4.4, Table 14
75.1	The assigned BUD does not exceed the shortest expiration date of any of the individual starting components.	N/A		14.3 Table 14
75.2	When assigning BUDs, the pharmacy ensures that the CSP formulation remains chemically and physically stable and its packaging maintains its integrity for the duration of the assigned BUD.	N/A		14.3 Table 15
75.3	BUDs for Category 3 CSPs do not exceed the maximum limits for aseptically processed (sp), (Manip) established in Table 14. *Inspector note: Per USP <797> Table 14, BUD maximum limits for aseptically processed Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 90 days refrigerator; and 120 days frozen.*	N/A		14.4.1 Table 14

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		Observation	Inspector Notes	USP Reference(s)
75.4	BUDs for Category 3 CSPs do not exceed the maximum limits for terminally sterilized established in Table 14. *Inspector note: Per USP <797> Table 14, BUD maximum limits terminally sterilized Category 3 CSPs where sterility testing (and endotoxin testing, if applicable) had been performed and passed are defined as: 60 days CRT; 120 days refrigerator; and 180 days frozen.*	N/A		14.4.1 Table 14
75.5	Category 3 CSPs are supported by stability data obtained using methods described in USP <1225> or a validated nonisotonic stability-indicating analytical method. *Inspector note: Per USP <797>, Category 3 CSPs must prepared according to the EXACT formulation (API and other ingredients of identical grade and procedures) from which the stability data is derived. Category 3 CSPs must be packaged and stored in container closure of the same materials of composition as used in study and the facility must have documentation of the stability study.* *View records to verify the preparation exactly matches the preparation cited in the documentation including concentration of all active ingredients, excipients, etc.*	N/A		14.4.3 Table 14 USP <1225>
75.6	Category 3 CSPs undergo sterility testing. *Inspector note: Sterility testing is performed on all Category 3 CSPs.*	N/A		14.4.4 Table 14 USP <71>

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e-Profile ID: 808298
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
75.7	Category 3 CSPs undergo bacterial endotoxin testing... *If all compounds prepared are ophthalmics and/or drug administered by inhalation, bacterial endotoxin is not required, inspector should answer statement as N/A.*	N/A		12.3, 14.4.4 Table 14 USP <16>
75.8	Category 3 CSPs undergo particulate matter testing... *Inspector note: If the Category 3 CSP is an injection or an ophthalmic solution, particulate matter testing is also conducted once per formulation with acceptable results (See USP <788> Particulate Matter in Injections and USP <789> Particulate Matter in Ophthalmic Solutions).*	N/A		14.4.3 Table 14 USP <788>, <789>
75.9	Category 3 CSPs undergo an evaluation for the container closure system... *Inspector note: The container closure system used is evaluated for and conforms to container closure integrity to the end of the BUD (see USP <1207> Package Integrity Evaluation—Sterile Products). Evaluation must be done once for each formulation and for each container closure system in which it will be packaged.*	N/A		14.4.3 Table 14 USP <1207>

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		Observation	Inspector Notes	USP Reference(s)
76.0	Are multiple-dose CSPs prepared in compliance with USP <797> standards? *If no, go to compliance statements.* *If the pharmacy does not prepare multiple-dose CSPs, inspector should answer question as N/A.*	Yes		14.5
76.1	Multiple-dose CSPs are prepared as a Category 2 or Category 3 CSP only.	Yes		14.5
76.2	When preservatives are used, they are appropriate for the CSP formulation and the route of administration. *Inspector note: Per USP <797>, "The preservative must not be inactivated by any ingredients in the CSP, and some preservatives are not always appropriate for the patient (eg, neonates) or route of administration (eg, intrathecal or ophthalmic injection)."*	Yes		14.5

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		Observation	Inspector Notes	USP Reference(s)
76.3	Aqueous multiple-dose CSPs pass antimicrobial effectiveness testing in accordance with USP <51>. *Inspector note: Per USP <797>, a test can be one test done for each formulation in the particular container-closure system in which it will be packaged, or test results provided by an FDA-registered facility or in appropriate peer-reviewed literature, provided the sterile compounded preparation formulation and container-closure system used are exactly the same as those tested, unless a bracketing study is performed. The concentration of all other ingredients (including preservatives) must be the same throughout the bracketing study.* *Additionally, multiple-dose, nonpreserved, aqueous topical, and topical ophthalmic CSPs prepared as a Category 2 or Category 3 CSP are not required to pass antimicrobial effectiveness testing if the preparation is: For use by a single patient, labeled (in the label or labeling) to indicate that, once opened, it must be discarded after 24 hours when stored at controlled room temperature and/or that, once opened, it must be discarded after 72 hours when stored under refrigeration.*	Yes		14.5 USP <51>

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		Observation	Inspector Notes	USP Reference(s)
76.4	Multiple-dose CSPs are labeled to indicate the beyond-use date of the CSP once it is opened or punctured. *Inspector note: Labeling on the CSP should indicate that once the CSP container is opened or punctured, it must not be used for longer than the assigned BUD or 28 days (if supported by antimicrobial effectiveness testing results), whichever is shorter.* *Inspector should review the CR of final compounded preparation to verify the label contains this information.*	Yes		14.5
76.5	Container-closure systems used are evaluated for maintaining integrity (USP <1207>) for each formulation and fill volume. *Inspector note: Per USP <797>, the container closure integrity test needs to be conducted only once on each formulation and on fill volume in the particular container closure system in which the multiple-dose CSP will be packaged.*	Yes		14.5 USP <1207>
	Finished Preparation Release Checks and Tests			
77.0	Are all CSPs visually inspected for quality prior to release or dispensing in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
77.1	The CSP label is visually inspected to confirm that the CSP and its labeling match the prescription or medication order.	Yes		12.1
77.2	CSPs are visually inspected for quality characteristics such as discoloration, visible particulates, or cloudiness.	Yes		12.1
77.3	CSPs are visually inspected to verify container closure integrity (eg, checking for leakage, cracks in the container, or improper seals).	Yes		12.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
77.4	A visual inspection is also repeated prior to release or dispense for CSPs that have been stored in the pharmacy and not released or dispensed on the day of preparation.	Yes		12.1
77.5	Any CSPs found to be of unacceptable quality (eg, observed defects) are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		12.1
78.0	For any CSPs assigned beyond-use dates that require sterility testing, does the pharmacy ensure that all testing is performed, evaluated, and documented in accordance with USP <71> or a validated alternative method that is noninferior to USP <71> testing and USP <797> standards? *Inspector note: Alternative testing methods may not be accepted in all regulatory jurisdictions that the pharmacy conducts business.* *If no, go to compliance statements.* *If the pharmacy does not prepare any CSPs that require sterility testing, inspector should mark as N/A.*	Yes		12.2

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
78.1	The required number of sterile compounded preparation units, as described in USP <715> and USP <797>, are tested. *Inspector note: Per USP <71> Table 3, the minimum number of items to be tested for each medium is:* *Parenterals* *Not more than 100 containers = 10% or four containers, whichever is greater* *More than 100, but not more than 250 containers = 10 containers* *Large volume parenterals* *2% or 10 containers, whichever is less* *Non-parenterals (eye drops, inhalation, patch, etc.)* *Not more than 200 containers = 5% or two containers, whichever is greater* *More than 200, but not more than 250 containers = 10 containers* *Per USP <797>, if the number of CSPs compounded in a single batch is less than what is needed for testing as specified in USP <71> Table 3, additional units must be compounded to be able to perform testing as follows:* *"If 1-39 CSPs are compounded in a single batch, the sterility testing must be performed on a number of units equal to 10% of the number of CSPs prepared, rounded up to the next whole number."* *"If more than 40 CSPs are prepared in a single batch, the sample sizes specified in USP <71> Table 3 must be used."*	Yes		12.2, 14.2.1 USP <71>

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
78.2	Batch sizes of sterile CSPs do not exceed 250. *Inspector note: Per USP <797>, the maximum batch size for all sterile compounded preparation requiring sterility testing is limited to 250 final yield units.*	Yes		12.2, 14.2.4
78.3	Pharmacy is utilizing an alternative method for sterility assurance testing (other than USP <71>). *Inspector note: Per USP, "If an alternative method is used for sterility testing, the method must be validated (see USP <1223>) and demonstrated to be suitable for that CSP formulation."* *If an alternative method is used, describe the method used and how the pharmacy ensures they are compliant with state-specific regulations.*	Yes	Scan RDI	12.2 USP <71> <1223>

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808208
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
79.4	When sterility testing identifies a failure, the pharmacy has processes to investigate and identify any contributing factors. *Inspector note: Per USP, "Sterility tests resulting in failures must prompt an investigation into the possible causes and must include identification of the microorganism, as well as an evaluation of the sterility testing procedure, compounding facility, process, and/or personnel that may have contributed to the failure. The source(s) of the contamination, if identified, must be corrected, and the facility must determine whether the conditions causing the sterility failure affect other CSPs. The investigation and resulting corrective actions must be documented."* *Additionally, some rapid sterility test methods do not allow for the identification of the recovered microorganisms. If one of these methods is used, the pharmacy is not in compliance with the chapter, as the investigation must include identification of the recovered microorganism.*	Yes		12.7

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808208
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
79.0	For any CSPs assigned BUDs that require bacterial endotoxin testing, does the pharmacy ensure that all testing is performed and documented in compliance with USP <85> and USP <797> standards? *Inspector note: Endotoxin limits reflect limits in an official monograph, or calculated as described by USP Chapter <85> for the route of administration for humans, and for animals based on weight. Although USP <797> refers to USP <85> Bacterial Endotoxins Test for calculating endotoxin limits for the appropriate route of administration, it does not address products administered epidurally or administered directly into the central nervous system. CSPs administered epidurally should have the same endotoxin limit as that of intrathecally administered CSPs.* *If no, go to compliance statements.* *If the pharmacy does not prepare CSPs that require bacterial endotoxin testing, inspector should answer question as N/A.*	Yes		12.3 USP <85>

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808208
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
79.1	The pharmacy has an appropriate procedure for calculating/determining endotoxin limits. *For USP, there are endotoxin limits listed in USP product and compounded preparation monographs. The laboratory may be performing the calculation rather than the pharmacy; however, if done in house, this should be included in the pharmacy SOPs.* *If the dosage form does not require, inspector should answer statement as N/A.*	Yes		12.3
79.2	The pharmacy collects patient weight to make bacterial endotoxin calculation for an animal patient. *If the dosage form does not require or the pharmacy does not compound sterile preparations for animals, inspector should answer statement as N/A.*	Yes		12.3
79.3	Bacterial endotoxin testing (USP <85>) is performed on all injectable Category 2 CSPs compounded from one or more nonsterile components that are assigned a BUD requiring sterility testing per Table 13. *Inspector note: USP <797> recommends that all injectable Category 2 CSPs made from one or more nonsterile components is also endotoxin tested.*	Yes		12.3 Table 13 USP <85>

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808208
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
79.4	Bacterial endotoxin testing (USP <85>) is performed on all injectable Category 3 CSPs compounded from one or more nonsterile components	N/A		12.3 Table 13 USP <85>
79.5	Any CSPs with failed endotoxin testing are quarantined, not further released, and action is taken for any product released prior to receipt of failed test results. *View testing records and note any products with failed results and actions taken.*	Yes		12.2, 12.3
	CSP Packaging, Shipping and Transport			
80.0	Are processes and techniques for packaging and transporting CSPs in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		19.1, 19.2, 19.3
80.1	The pharmacy uses the appropriate shipping containers and packaging materials (eg, coolers and light-resistant packaging) based on the product specifications.	Yes		19.2

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Sterile Compounding Inspection for USP <797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: [redacted]
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
80.2	CSPs are appropriately packaged to protect against damage, leakage, contamination, degradation, and adsorption during storage and transport. *Inspector should look at packaging materials used to ensure overbagging to prevent breakage of glass vials and ensure that container is generally clean without non-microbial growth that would come in direct contact with CSPs.*	Yes		19.2
80.3	Specific handling instructions when applicable, are included on the exterior of the container.	Yes		19.3
80.4	The pharmacy selects transport modes that ensure CSPs are delivered properly in undamaged, sterile, and stable conditions (eg, no undue exposure to heat, cold, or light). *Inspector note: Transport modes include pneumatic tube transport systems and should not be used if the CSP is sensitive to shaking.*	Yes		19.3
	Quality Assurance and Quality Control			18
81.0	Quality Assurance and Quality Control (QA/QC): Does the pharmacy's SOP on quality assurance and quality control meet the requirements in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		18 USP <1163>

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e-Profile ID: [redacted]
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
81.1	Description of procedures for complaint handling, adverse events, and recalls that include corrective action, investigation, reporting, and documentation requirements.	Yes		18.1, 18.2
81.2	QA/QC Out-Of-Specification (OOS) SOPs: The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the severity of the problem and the urgency for implementation and completion of the recall.	Yes		18.1
81.3	QA/QC OOS SOPs: The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to determine the distribution of any affected CSP, including the date and quantity of distribution.	Yes		18.1
81.4	QA/QC OOS SOPs: The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to identify patients who have received the CSP.	Yes		18.1
81.5	QA/QC OOS SOPs: The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process for the disposal and documentation of the recalled CSP.	Yes		18.1

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e-Profile ID: [redacted]
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
81.6	QA/QC OOS SOPs: The pharmacy's procedures for recall of out-of-specification dispensed CSPs includes a process to investigate and document the reason for failure.	Yes		18.1
82.0	Does the pharmacy ensure that QA and QC programs are conducted in compliance with USP <797> standards? *If no, go to compliance statements.*	Yes		18, 20
82.1	The pharmacy has a formal QA/QC program with documented activities. *Inspector note: Per USP, "Designated person(s) must ensure that the facility has formal, written QA and QC programs that establish a system for adherence to procedures, prevention and detection of errors and other quality problems; evaluation of complaints and adverse events; and appropriate investigations and corrective actions."*	Yes		18
82.2	The pharmacy's QA/QC program is reviewed at least once every 12 months by the designated person(s) and the results of the review are documented.	Yes		18
82.3	The designated person(s) reviews all complaints to determine whether the complaint indicates a potential quality problem with the CSP.	Yes		18.2, 20

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: [redacted]
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
82.4	All complaints and adverse events are thoroughly investigated. *Inspector note: Per USP <797>, the timeframe is specified in the facility's SOP. Additionally, USP states, "The investigation must consider whether the quality problem extends to other CSPs." If facility SOP permits a long investigation period, include in the inspector notes the SOP's expected time frame to complete an investigation. State may have a more aggressive time frame to complete an investigation and report quality events to the state."*	Yes		18.2, 18.3, 20
82.5	The record of each complaint is maintained by the pharmacy regardless of the source of the complaint (eg, email, telephone, or mail) and includes the minimum required information. *Inspector note: Per USP <797>, the complaint record must contain the following information: -Name of the complainant or other unique identifier; -Date the complaint was received; -Nature of the complaint; -The response to the complaint; and -Results of any investigation and any follow-up. In addition, to the extent that the information is known, the following should be recorded: -The name and strength of the CSP and the assigned internal identification number (eg, prescription, order, or lot number). If no, inspector should document what is missing in the notes column.*	Yes		18.2, 20

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Sterile Compounding Inspection for USP-<797>

Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
82.0	The pharmacy's CAPQC program includes documentation of steps necessary for completing a recall, including reporting the recall to appropriate regulatory agencies. *Inspector note: Per USP, "The recall must be reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction."*	Yes		19.1, 19.2
83.0	If a CSP is dispensed or administered before the results of release testing are known, does the pharmacy ensure procedures for recalls and out-of-specification notifications are conducted and documented in compliance with USP <797> standards? *Inspector note: Per USP <797>, If a CSP is dispensed or administered before the results of release testing are known, the facility must have procedures in place to notify, recall, and investigate.* *If no, go to the compliance statements.*	Yes		19.1, 20
83.1	The pharmacy has a process in place to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes).	Yes		19.1
83.2	The pharmacy has a process in place to recall any unused dispensed CSPs and quarantine any stock remaining in the pharmacy.	Yes		19.1
83.3	The pharmacy has a process in place to investigate if other lots are affected and recall if necessary.	Yes		19.1

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Inspector Notes	USP Reference(s)
	Personnel Training and Evaluation (review of all non-pharmacist personnel involved in the compounding process)			
84.0	Is the pharmacy's documented hand hygiene and garbing competency evaluation compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no* *If no, refer to the records review worksheet for details.*	Yes		12.3, 20 Box 1, Table 1
85.0	Is the pharmacy's documented aseptic manipulation competency evaluation compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no.* *If no, refer to the records review worksheet for details.*	Yes		12.3, 20 Box 2, Table 1
86.0	Is the pharmacy's documented training program and ongoing competency evaluation compliant with USP <797> standards? *Inspector note: Only "No" or "Missing" documents would cause this question to be answered no* *If no, refer to the records review worksheet for details*	Yes		12.2.1, 17 Tables 2, 3 and 3

Sterile Compounding Personnel Records Review

Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file;
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound

(Note: frequency of competency assessment will be defined by pharmacy SOPs).

Review for personnel files and document your observations. (For applications making a Class 5-8 Non-Buffered Sterile Compounding Inspection [Terse Direction], review a total of 10 personnel records.)

Inspector Instructions	Competency Assessment of Core Skills (Section 2.1)
1. Use the drop-down list and make the appropriate selections for the Employee Title, Personnel Function, and CSP Category Type for the files reviewed. *Do not record the employee name, only the role or position.* 2. Review the selected files to verify that the required training and competency records are present in the personnel file and comply with USP <797> standards for training and competency assessments. 3. Select the appropriate response for each item reviewed. Select "Yes" if the document is present in the records and the competency evaluation was conducted in compliance USP <797> standards. If select "No" if the document is present but is not compliant with USP <797> standards (eg, lacks frequency of task, GHT and duties to include this task specific for media fill, failed hand, did not train as a preceptee before, etc). Document the event(s) of non-compliance in the notes column. Select "Missing" if the document is not present in the file. Select "N/A" if the training does not apply, (ie, female sterile compounder does not have to do final gowning inspection). Document further in the notes column. 4. Use the notes column to document any pertinent information.	USP <797> requirements 1. Personnel who perform or oversee compounding or support activities must be trained on the SOPs and trained on maintaining the quality of the environment (See Table 9). 2. Compounding personnel and supervising personnel must complete training needed to demonstrate knowledge of principles and competency of skills for compounding sterile preparations at initial training and ongoing assessments, as recommended in guidelines (See Table 2 and Table 3). This must be completed initially and every 12 months or as need for ongoing areas - Hand hygiene - Gowning - Cleaning and disinfecting - Calculations, measuring, and mixing - Aseptic technique - Accessing vendor packaging (and appropriately if compounding from nonsterile components) - Use of equipment - Documentation of the compounding process (eg, master formularies and compounding records) - Principles of high-efficiency particulate air (HEPA) filtered unidirectional airflow within the ISO Class 5 area - Proper use of PECs - Principles of movement of materials and personnel within the compounding area 3. Personnel who only perform reworking or staging and distribution duties outside of the primary engineering control (PEC) must complete training in any tasks performed by the facility's SOPs (See Table 3). 4. Personnel compounding only immediate-use CSPs must complete training required by the facility's SOPs (See Table 3). 5. All training and assessments must be documented.

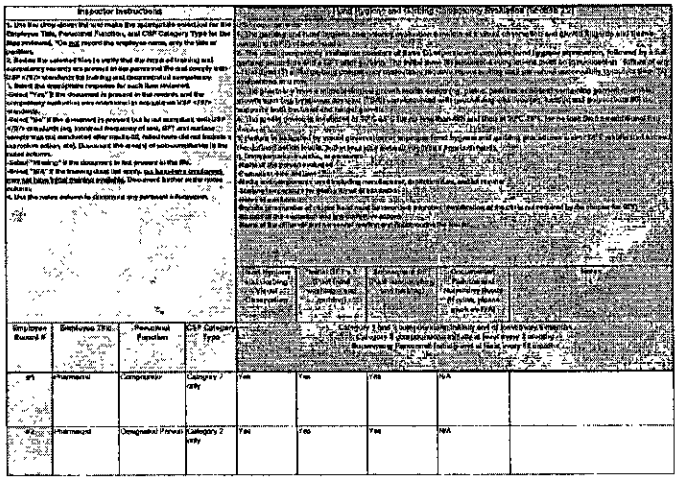
Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	Initial Training and Competency in the Compounding Process, Quality of the Environment	Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Process	Notes
				- Compounders and Supervising Personnel, initially and at least every 12 months - Other Personnel (personnel primarily who do not compound but perform duties in the sterile compounding area, such as janitorial staff, who only complete intermediate cleaning, initially and as defined by pharmacy SOPs)				
#1	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	N/A	Initial training is the only training this pharmacist has completed. Ongoing is due the middle of October

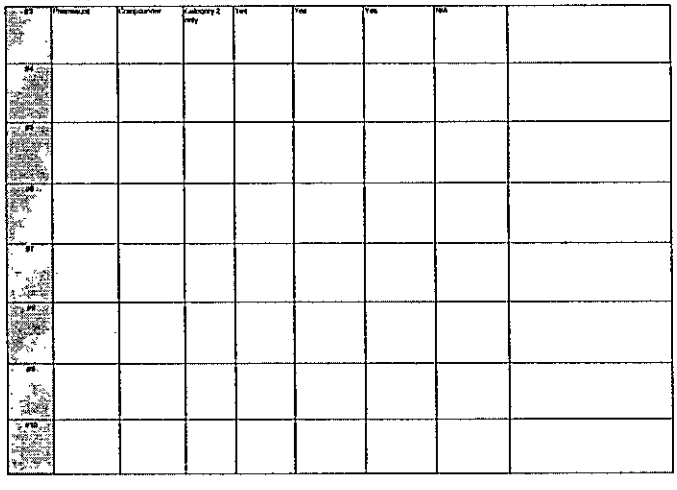
Sterile Compounding Personnel Records Review

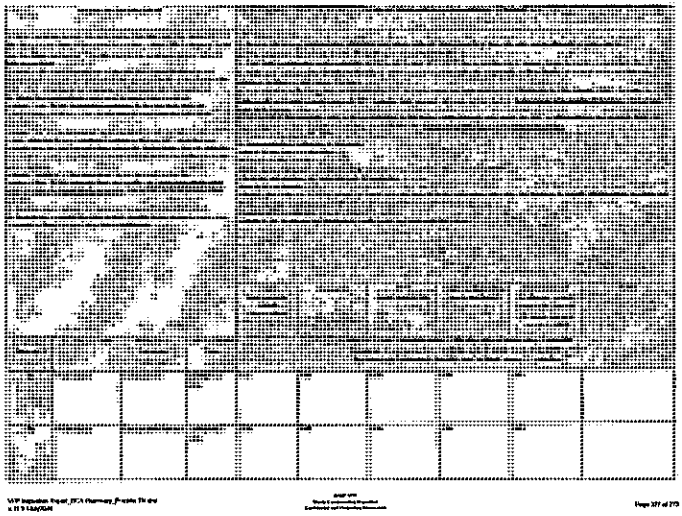
Select personnel with compounding responsibilities for your records review; preferably select staff performing compounding duties at time of inspection or staff identified during CR review.
- Recommend also pulling supervising personnel file;
- Inspector can consider pulling non-compounder employee file ("Other") who cleans and stocks compounding area but who does not compound

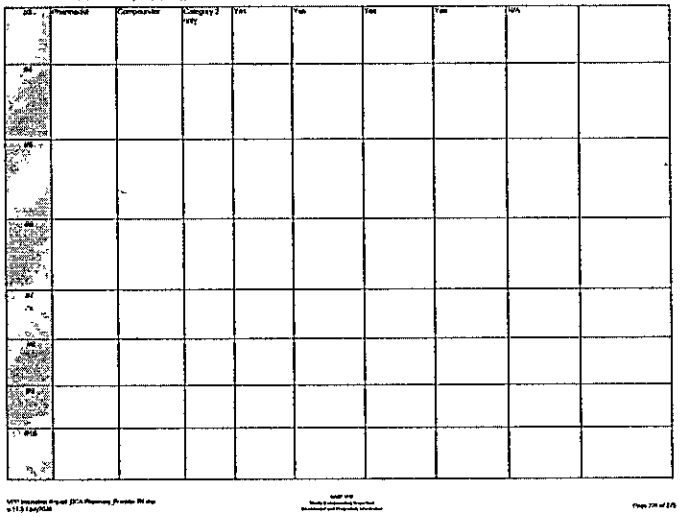
(Note: frequency of competency assessment will be defined by pharmacy SOPs).

Employee Record #	Employee Title	Personnel Function	CSP Category Type	Compounding SOPs	Initial Training and Competency in the Compounding Process, Quality of the Environment	Initial Training and Competency in Sterile Compounding Principles and Practices	Ongoing Training and Competency in Sterile Compounding Principles and Process	Notes
#1	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#2	Pharmacist	Compounder	Category 2 only	Yes	Yes	Yes	Yes	
#3								
#4								
#5								
#6								
#7								
#8								
#9								
#10								









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GLOSSARY USP <797>
ACD: Automated compounding device.
ACPH: As changes per hour.
Active pharmaceutical ingredient (API): Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans and animals or affecting the structure and function of the body. Also referred to as *bulk drug substance*. A conventionally manufactured drug product is not an API, but is typically manufactured from an API(s).
Added substance: An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with the terms *inactive ingredient, excipient, and pharmaceutical ingredient*.
Administration: The direct application of a sterile product or preparation to a single patient by injecting, infusing, or otherwise placing a sterile product or preparation in its final form.
Airlock: A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas (generally with different air cleanliness standards). The intent of an airlock is to prevent ingress of particulate matter and microbial contamination from a lower-controlled area.
Alcohol-based hand rub: An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Allergenic extract compounding area (AECA): A designated space, area, or room that is not required to be classified, with a visible perimeter that is suitable for preparation of allergenic extract prescription vials.
Allergenic extract preparation set: Combinations of licensed allergenic extracts that would be mixed and diluted to provide subcutaneous immunotherapy to an individual patient, even though these allergenic extract combinations are not specified in the approved BLAs for the licensed biological products.
Allergenic extract: A biological substance used for the diagnosis and/or treatment of allergic diseases such as allergic rhinitis, allergic sinusitis, allergic conjunctivitis, bee venom allergy, and food allergy.
Anteroom: An ISO Class 8 or cleaner room with fixed walls and doors where personnel hand hygiene, gowning procedures, and other activities that generate high particulate levels may be performed. The anteroom is the transiting room between the unclassified area of the facility and the buffer room.
Aseptic processing: A method by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility. The components can either be purchased as sterile or, when starting with nonsterile components, can be separately sterilized prior to combining (eg, by membrane filtration or by autoclave).

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GLOSSARY USP <797>
Aseptic technique: A set of methods used to keep objects and areas free of microorganisms and thereby maintain infection risk to the patient. It is accomplished through practices that maintain the microbial count at an introduced minimum.
Assigned trainer: One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CSPs.
Batch: More than one CSP prepared as described in the MFR in a single, discrete process, and expected to have uniform character and quality, within specified limits.
Beyond-use date (BUD): The date, or the hour and date, after which a CSP must not be used, stored, or transported. The date is determined from the date and time the preparation is compounded.
Biological safety cabinet (BSC), Class II: A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. A BSC used to prepare a CSP must be capable of providing an ISO Class 5 or better environment for preparation of the CSPs.
Biological safety cabinet (BSC): A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
BLA: Biological license application.
Blood component: Any therapeutic constituent of blood separated by physical or mechanical means (eg, white cells, red cells, platelets, plasma, serum). It is not intended to include plasma-derived products (eg, albumin, coagulation factors, immunoglobulins) manufactured under an approved BLA or equivalent.
BMBL: Biosafety in Microbiological and Biomedical Laboratories.
Buffer room: An ISO Class 7 or cleaner room with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.
Bulk drug substance: See the entry for *Active pharmaceutical ingredient*.
Category 1 CSP: A CSP that is assigned a BUD of 12 hours or less at controlled room temperature or 24 hours or less refrigerated that is compounded in accordance with all applicable requirements for Category 1 CSPs in this chapter.
Category 2 CSP: A CSP that may be assigned a BUD of greater than 12 hours at controlled room temperature or greater than 24 hours refrigerated that is compounded in accordance with all applicable requirements for Category 2 CSPs in this chapter.

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Category 3 CSP: A CSP that may be assigned a BUD exceeding the limits in *Table 13* for Category 2 CSPs and is compounded in accordance with all applicable requirements for Category 3 CSPs in this chapter.
CDC: Centers for Disease Control and Prevention.
Certificate of analysis (COA): A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
CFU: Colony-forming units.
Classified area: An area that maintains an air quality classification based on the ISO standards required in this chapter (see also the definition for *ISO class*).
Cleaning agent: An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Cleaning: The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleanroom suite: A classified area that consists of both an anteroom and buffer room.
Component: Any ingredient used in the compounding of a preparation, including any active ingredient, added substance, or conventionally manufactured product.
Compounded sterile preparation (CSP): A preparation intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance.
Compounded stock solution: A sterile mixture of components that is used to compound additional CSPs.
Compounding area: The area where compounding is occurring (ie, a cleanroom suite, inside the perimeter of the BCA, or AECA).
Compounding aseptic containment isolator (CACI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for the compounding of sterile HDs.
Compounding aseptic isolator (CAI): A type of RABS that uses HEPA filtration to provide an ISO Class 5 unidirectional air environment designed for compounding of sterile non-HDs.

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Compounding record (CR): Documents the compounding of each CSP.
Compounding: The process of combining, admixing, diluting, pooling, reconstituting, repackaging, or otherwise altering a drug product or bulk drug substance to create a sterile preparation.
Container closure system: Packaging components that together contain and protect the dosage form. This includes primary packaging components and secondary packaging components, if the latter are intended to provide additional protection.
Containment glove bag: A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE): A non-ISO classified full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through HEPA filtration and prevent their release into the work environment.
Conventionally manufactured product: A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Critical site: A location that includes any component or fluid pathway surfaces (eg, vial septa, injection ports, and beakers) or openings (eg, opened ampules and needle hubs) that are exposed and at risk of direct contact with air (eg, ambient room or HEPA filtered), moisture (eg, oral and mucosal secretions), or touch contamination.
Designated person(s): One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel related to the preparation of CSPs.
Direct compounding area (DCA): A critical area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Dynamic airflow smoke pattern test: A PEC test in which a visible source of smoke, which is neutrally buoyant, is used to observe air patterns within the unidirectional space (i.e., the DCA) under dynamic operating conditions (see the entry for *Dynamic operating conditions*). This test is not appropriate for ISO Class 7 or ISO Class 8 cleanrooms that do not have unidirectional airflow (see the entry for *Visual smoke study*).
Dynamic operating conditions: Conditions in the compounding area in which operating personnel are present and simulating or performing compounding. The conditions should reflect the largest number of personnel and highest complexity of compounding expected during routine operations as determined by the designated person(s).

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ECV: Endotoxin challenge vial.

EPA: US Environmental Protection Agency.

Excipient: See the entry for *Added substances*.

FDA: US Food and Drug Administration.

Filter integrity test: A test (eg, bubble point test) of the integrity of a sterilizing-grade filter performed after the filtration process to detect whether the integrity of the filter has been compromised.

Final yield: The total number of containers prepared at the end of the compounding process prior to terminal sealing.

First air: The air exiting the HEPA filter in a unidirectional air stream.

Formulation: The specific qualitative and quantitative composition of the final CSP.

Garb: Items such as gloves, garments (eg, gowns), shoe covers, head and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of contamination of CSP(s).

GFT: Gloved fingertip and thumb testing.

Hazardous drug (HD): Any drug identified by at least one of the following six criteria: carcinogenicity, teratogenicity or developmental toxicity, reproductive toxicity in humans, organ toxicity at low dose in humans or animals, genotoxicity, or new drugs that mimic existing HDs in structure or toxicity.

High-efficiency particulate air (HEPA) filtration: Being clean, or containing a filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter passing through it.

HVAC: Heating, ventilation, and air conditioning.

Integrated vertical laminar flow zone (IVLFZ): A designated ISO Class 5 area serving as the PEC within an ISO Class 7 or cleaner buffer room. In the IVLFZ, unidirectional airflow is created by placing HEPA filters over the entire surface of the worksurfaces and by situating placement of air returns.

IPA: Isopropyl alcohol.

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ISO class: An air-quality classification from the International Organization for Standardization.

ISO: International Organization for Standardization.

Label: The part of the labeling on the immediate container.

Labeling: All labels and other written, printed, or graphic matter on the immediate container or on or in any package, system or wrapper in which the article is enclosed, except any outer shipping container.

Laminar airflow system (LAFS): A device or zone within a buffer room that provides an ISO Class 5 or better air quality environment for sterile compounding. The system provides a unidirectional HEPA-filtered airflow.

Laminar airflow workbench (LAFW): A device that is a type of LAFS that provides an ISO Class 5 or better air quality environment for sterile compounding. The device provides a unidirectional HEPA-filtered airflow.

Line of demarcation: A visible line on the floor that separates the clean and dirty sides of the anteroom.

Low-lint wiper: A wiper exhibiting low, if any, fibers or other contamination, visible without magnification, which is separate from or easily removed from the wiper material in a dry condition.

Master formulation record (MFR): A detailed record of procedures that describes how the CSP is to be prepared.

MEA: Malt extract agar.

Media-fill test: A simulation used to qualify processes and personnel engaged in sterile compounding to ensure that the processes and personnel are able to prepare CSPs without contamination.

Monograph: A quality documentary standard within *USP–NF* that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients must these criteria.

Multiple-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed to contain more than one dose of the sterile product. A multiple-dose container is usually required to meet the antimicrobial effectiveness testing criteria. See <659>Injection Packaging Systems, Multiple-dose container.

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One-step disinfectant cleaner: A product with an EPA-registered (or equivalent) claim that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.

Oversight: The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for these actions, and being available for consultation if and when needed, even if not physically present.

Pass-through chamber: An enclosure with sealed doors on both sides that should be interlocked. The pass-through chamber is positioned between two spaces for the purpose of transferring particulate transfer while having maintain from one space to another.

Perimeter: A visible demarcation (such as a door, walls, or visible marking on the floor) that defines the SCA or AECA.

Pharmaceutical isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer. [Note—A CAI or CACI is not a pharmaceutical isolator.]

Pharmacy bulk package: A conventionally manufactured sterile product for parenteral use that contains many single doses intended for use in a pharmacy admixture program. A pharmacy bulk package may either be used to prepare admixtures for infusion or, through a sterile transfer device, for filling sterile containers. See <659>*Injection Packaging Systems, Pharmacy bulk package*.

Positive-pressure room: A room that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the room.

PPE: Personal protective equipment.

Preservative: A substance added to inhibit microbial growth.

Primary engineering control (PEC): A device or zone that provides an ISO Class 5 air-quality environment for sterile compounding.

Probability of a nonsterile unit (PNSU): The probability of an item being nonsterile after it has been exposed to a verified sterilization process. A PNSU value can only be applied to terminal sterilization. [Note—This is also called the sterility assurance level (SAL).]

Pyrogen: A substance that induces a febrile reaction in a patient.

Quality assurance (QA): A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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Quality control (QC): The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the CSP.

Reconstitution: The process of adding a diluent to a commercially manufactured product to prepare a sterile solution or suspension.

Release inspection and testing: Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.

Repackaging: The act of removing a sterile product or preparation from its original primary container and placing it into another primary container, usually of smaller size without further manipulation.

Restricted-access barrier system (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of materials through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.

SDA: Sabouraud dextrose agar.

Secondary engineering control (SEC): The area where the PEC is placed (eg, a cleanroom suite or an SCA). It incorporates specific design and operational parameters required to minimize the risk of contamination within the compounding area.

Segregated compounding area (SCA): A designated space, area, or room that is not required to be classified and is defined with a visible perimeter. The SCA must contain a PEC and is suitable for preparation of Category 1 CSPs only.

Single-dose container: A container of sterile product for parenteral administration (eg, injection or infusion) that is designed for use with a single patient as a single injection/infusion. A single-dose container usually does not contain a preservative. See <659> Injection Packaging Systems, Single-dose container.

SOP: Standard operating procedure.

Specification: The tests, analytical methods, and acceptance criteria to which any component, CSP, container closure system, equipment, or other material used in compounding CSPs must conform to be considered acceptable for its intended use.

Sporicidal disinfectant: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.

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CLOSSARY OF TERMS
Stability: The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its period of use (BUD).
Sterility assurance level (SAL): See the entry for *Probability of a nonviable unit (PNSU)*.
Strip fills: The placement of various microorganisms.
Sterilization by filtration: Passage of a gas or liquid through a sterilizing-grade membrane to yield filtrates that are sterile.
Sterilizing-grade filter: Filter membranes that are documented to retain 100% of a culture of 10^7 microorganisms of a strain of *Brevundimonas diminuta* per square centimeters of membrane surface under a pressure of not less than 30 psi. Such filter membranes are nominally 0.22- or 0.2-µm pore size.
Terminal sterilization: The application of a lethal process (eg, steam, dry heat, irradiation) to sealed containers for the purpose of achieving a predetermined PNSU of greater than 10^{-6} or a probability of less than one in one million of a nonsterile unit.
TSA: Trypticase soy agar.
Unclassified space: A space not required to meet any air cleanliness classification based on the ISO.
Unidirectional airflow: Air within a PEC moving in a single direction in a uniform manner and at sufficient velocity to sweep particles away from the DCA.
Verify: To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Visual smoke study: A test, used in ISO Class 7 and ISO Class 8 rooms that do not have unidirectional airflow, in which a visible source of smoke, which is neutrally buoyant, is used to verify an absence of stagnant airflow. The test does not need to be performed under dynamic operating conditions and is not appropriate for PECs (see the entry for *Dynamic airflow smoke pattern test*).
Workflow management system: Technology composed of hardware and/or software that allows for automation to assist in the verification of components of, and preparation of, CSPs and to document components and processes.

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Hazardous Drugs - Handling in Health Care Settings

This information and comments obtained in the Hazardous Drugs - Handling in Health Care Settings inspection is based on USP Chapter <800>.
Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 806298
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
General Information and Scope:			
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that require all the containment requirements of USP <800>?	Yes	The PEC, the state did not inspect for USP 800 when inspector was here in March.
1.01	Does the pharmacy handle any *hazardous drug* active pharmaceutical ingredients (HD API)? *If yes, please list*	Yes	Apomorphine, Estradiol, Implitucle, metirmandate, progesterone, spironolactone, lacrolimus, clomiphene, dutasteride, finasteride, oxycoun, testosterone, Retinoin, zonisamide
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gases)? *If yes, please list*	Yes	
2.00	Does the pharmacy handle any drugs on the NIOSH list that do not require all containment requirements of <800>?	Yes	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless prepared by the manufacturer) that do not require further manipulation other than counting and repackaging? If *yes, please list*	Yes	Tablets, creams, capsules, inhaler, suppositories, oral suspensions, pellet

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e-Profile ID: 806298
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
2.00	Does the pharmacy handle any dosage forms of other HDs that are handled in full compliance with containment requirements of <800>? *If yes, please list*	N/A	
2.00	Does the pharmacy handle any dosage forms of other HDs that are not handled using all containment requirements of <800>? *If yes, please list*	N/A	
List of Hazardous Drugs			
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. *Review and obtain list; verify that pharmacy has a process to keep a current list.*	Yes	List_of_HDs.xls
4.00	The pharmacy reviews the list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify list is reviewed and that date of last review is current.*	Yes	11/1/2023
5.00	The pharmacy reviews the list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 806298
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documented risk assessment and SOP. Assess to verify implementation and compliance.*	Yes	
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The risk for HD items that are not to be excluded in the calculations in order to be compliant.*	Yes	
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	Yes	
8.02	Dosage form;	Yes	
8.03	Risk of exposure;	Yes	
8.04	Packaging;	Yes	
8.05	Manipulation; and	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808296

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
8.03	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	Yes	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. Date of risk assessment review by Kristin Hall.	Yes	11/1/2023
Personnel Responsibilities			
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of this facility, including testing/sampling programs, maintaining, and documentation, and acting on results	Yes	
Documentation and Standard Operating Procedures (SOPs)			
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the scenarios that present an opportunity for exposure.		
10.01	Receiving: Contacting HD residues on packaging, work surfaces, floors	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808296

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
10.02	Dispensing, Crushing or packaging tablets and capsules	Yes	
10.03	Compounding/other manipulations: Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, or refilling/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	
10.04	Administration and other patient care activities (if applicable).	N/A	
10.05	Spills: Spill generation, management, and disposal.	Yes	
10.06	Transport	Yes	
10.07	Waste, Collection and disposal of HD waste and trace contaminated waste	Yes	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy personnel, housekeeping, nursing personnel, delivery personnel, etc). Confirm that whether PDF or web-based access is by paper or both.	Yes	Maintained electronically and paper.

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808296

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
13.00	SOPs address at a minimum, Confirm documented "training" in respective forms for each SOP listed		Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.
13.01	Hazard communication program plan	Yes	3.10 (Safety Procedures)
13.02	Competent personnel	Yes	3.10 (Safety Procedures)
13.03	Occupational safety program	Yes	3.10 (Safety Procedures)
13.04	Designation of HD areas	Yes	7.01 (Receiving, Storing and Handling of HDs)
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	7.01 (Receiving HD)
13.06	A list of HDs	Yes	7.01 (Responsibility for HD)
13.07	Storage of HDs	Yes	7.01 (Storage of HD)
13.08	Compounding of HDs	Yes	7.01 (Handling HD)

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Hazardous Drugs - Handling in Health Care Settings

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808296

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
13.10	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C PTCA], containment secondary engineering control [C SECA], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	4.14 (Use and Maintenance of Hood)
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	3.09 (Hand Hygiene)
13.11	Decontamination, deconstamination, cleaning, disinfection SOPs include all of the following:		3.02 (Cleaning of Clean Room), 3.04 (Cleaning of Non-Sterile Compounding Area)
13.11.01	Agents used	Yes	
13.11.02	Dilutions, if used	N/A	
13.11.03	Frequency	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
13.11.04	PPE to be worn (gloves/sterile PPE, coverall to the specific used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted- addressed in SOPs)	Yes	7.03 (Receiving, Storage and Handling of HDs) and 3.02 (Cleaning of Nonsterile Area)
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and does not need to be opened		7.01 Receiving, Storage and Handling of Hazardous Drugs
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "Hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	
13.14	If a damaged shipping container must be opened:		
13.14.01	Container is sealed in plastic or an impervious container,	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
13.14.02	It is transported to the C-PEC before opening, preferably noted/same compounding C-PEC, if available;	Yes	
13.14.03	Contents is placed on a plastic-backed preparation mat;	Yes	
13.14.04	It is opened and undamaged items are removed and wiped down with a deposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous",	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Doors/vents, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	N/A	
13.15	Safe work Practices SOPs	Yes	9.16 (Safety procedures)
13.16	Dispensing SOPs	Yes	6.04 (Billing and Delivery) Delivery)
13.17	Packaging and labeling SOPs	Yes	6.02 (Product Labeling)
13.18	Transport SOPs	Yes	6.04 (Billing and Delivery)

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e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
13.19	Administering SOPs, if applicable	N/A	
13.20	Recommendation: *Environmental monitoring (eg, wipe sampling)* SOPs	N/A	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	7.02 (Segregation of Hazardous Drug Waste)
13.22	Spill prevention and response of spill cleanup and control SOPs and address the following:		7.03 (Hazardous Drug Spills)
13.22.01	Size and scope of spill,	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits,	Yes	
13.22.05	PPE to be worn during spills,	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE,	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
13.22.07	Use of appropriate full-face, chin/nose cartridge-type respirator or powered air purifying respirators (PAPR) if capability of spill kit is exceeded or known or suspected airborne exposure to vapors/gases, and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/written handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	9.16 (Safety Procedures)
13.23	Recommendation: *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	N/A	
14.00	The hazard communication program SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	9.16 (Safety Procedures, 9.3 (Hazardous Communication Program)
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented,	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200).	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas.	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	
	Personnel Training - Select the evidence that best demonstrates:		
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous chememention program).	Yes	
18.00	For non sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	Yes	
20.00	After initial HD training, personnel are trained prior to installation of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee risk review, all of the following are present.		
23.01	Overview of pharmacy's HD list and their risks;	Yes	
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
23.05	Appropriate procedures for disinfection, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator	Yes	
	Personnel Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns, head, hair, and shoe covers, and two pairs of chemotherapy gloves.	Yes	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:	Yes	
26.01	Hazard (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	
26.05	Sterile Compounding (if performed by the pharmacy);	Yes	
26.06	Administration, if applicable;	N/A	
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectables antineoplastics, two pairs of chemotherapy gloves and impermeable resistant gowns are worn.	N/A	
27.00	Disposable PPE is not reused	N/A	
28.00	Reusable PPE is decontaminated and cleaned after each use.	No	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808206
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
29.00	Gloves: The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 – or its successor – and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	Recommendation: Are chemotherapy gloves worn for handling all HDs including non-active ingredients and for reproductive risk only HDs?	Yes	
29.02	Chemotherapy gloves are powder free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	Yes	
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	Recommendation: Are chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?	N/A	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808206
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
30.00	Gowns: The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808206
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
31.00	Head, hair (beard and moustache, if appropriate), and shoe and sleeve covers. The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C SEC and doffed when exiting the C SEC.	Yes	
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	Eye and Face Protection: The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HD is are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C PEC), if required.	Yes	
32.01	If a risk to eyes, goggles (or a full face respirator) are worn. *Compliance of safety glasses with side shields are not substitutes for goggles*	Yes	
32.02	If a risk to face and eyes, goggles plus a face shield (or a full face respirator) are worn.	Yes	

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e-Profile ID: 808206
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
33.00	Respiratory Protection: The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Potential small type of PPE which is available to employees (and is in place), when required.*	Yes	
33.01	A N-tested N95/2 certified N95 respirator;	No	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100 filter;	Yes	
33.03	Full-face piece, chemical cartridge-type respirator;	No	
33.04	PAPR; and/or	No	
33.05	Other (describe in notes).	Yes	N 95 masks
34.00	Surgical masks are not used as PPE, when respiratory protection is worn.	Yes	

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. [Include exact type of PPE which is available in employee hand by Electrical, when required].	Yes	
35.01	Fit-tested NIOSH-certified N95 respirator,	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100 filter;	Yes	
35.03	Full facepiece, chinmost cartridge-type respirator;	No	
35.04	PAPR; and/or		
35.05	Other (describe in notes)	Yes	
36.00	Surgical masks are not used as PPE when respiratory protection is needed.	Yes	
37.00	Disposal of Used PPE: is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	

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e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	Yes	
	Facilities and Engineering Controls		
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
39.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
39.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
40.00	There are designated HD areas for any of the following:		
40.01	Receiving and unpacking of HDs	Yes	

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Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
39.03	Storage of HDs	Yes	
39.03	Non-sterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	Yes	
40.01	Recommendation - If there is a requirement for certain unventilated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?	Yes	Generator
41.00	Receipt: Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? [Yes/No]	Yes	Removed in the nonsterile hazardous compounding room.
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure relative to the ANSI/ASHRAE standard, if the requirement is primary containers, if applicable?	Yes	
41.01.01	Neutral	N/A	
41.01.02	Negative	Yes	

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Hazardous Drugs - Handling in Health Care Settings

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy
e-Profile ID: 808286
Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C-SEC)	Yes	
43.00	Storage: Are HDs stored in a manner to minimize accidental exposure? [Yes/No]	Yes	HD APIs are stored in negative pressure room
43.01	HDs are not stored on the floor;	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage;	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, mixed front line on shelving in earthquake prone areas)	Yes	
44.00	Antineoplastic HDs that require reconstitution (other than counting and repackaging final dosage forms) and HD APIs are stored separately from non-HDs.	Yes	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	
44.02	The HD storage room has at least 12 air changes per hour (ACPH)	Unknown	The nonsterile HD storage area has negative pressure but the ACPH were not stated in the certification report.

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observed	Notes
44.03	Nonsterile antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C-SCA])	No	
44.04	Recommendation: *If the refrigerator is located in a buffer room, access should be from the anteroom to the refrigerator's maintenance and service side.*	N/A	
45.00	If non-antineoplastic, reproductive risk only, and oral dosage forms of antineoplastics are stored with other non-HD inventory, there is a written policy/SOP addressing it	Yes	
46.00	Compounding. There are appropriate engineering controls to protect the HD preparation from cross contamination, and it limits compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C-PEC located in a C-SCA room.	Yes	
47.01	The C-SCA for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has hard walls,	Yes	
47.01.02	Is externally vented,	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observed	Notes
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Unknown	The sterile buffer room has been certified within the last 6 months (exclusive ACPH). The USC for the HD nonsterile compounding is installed annually and has negative pressure but the report did not identify ACPH in the HD or the nonsterile compounding area. Per designated person, this will be addressed and corrected at the next certification.
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C-PEC operates continuously if it supplies some or all of the negative pressure in the C-SCA or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water hoses and drains are a minimum of 1 meter away from the C-PEC.	Yes	
50.00	Does the pharmacy engage in nonsterile HD compounding? If yes, complete 50.01-54. If no, skip to 55.	Yes	
50.01	Select the location where nonsterile HD compounding is performed type(s)*		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observed	Notes
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N/A	
50.02	Select the type(s) of containment primary engineering control(s) used for nonsterile HD compounding.		
50.02.01	Class II biological safety cabinet (BSC)	N/A	
50.02.02	Class II BSC	Yes	
50.02.03	Containment ventilated enclosure (CVE)	N/A	
50.02.04	Compounding aseptic containment isolator (CACI)	N/A	
50.02.05	Other, describe:	N/A	
51.00	Indicate if the C-PEC used for nonsterile HD compounding (must be one of two below in order to be compliant):		
51.01	Is externally vented (ducted); and/or	Yes	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	N/A	
52.00	Does the pharmacy use the same C-PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	No	
52.01	Is nonsterile HD compounding only "occasional"? *If yes, please describe what frequency and quantity.*	N/A	
52.02	Is the nonsterile HD compounding activity only occurring when sterile HD compounding is not being performed?	N/A	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806298

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observed	Notes
52.03	Is the C-PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	
53.00	The C-SCA has at least 12 ACPH. *Verify documentation and observe.*	N/A	
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding *Observe and take notes*	Yes	
55.00	Does the pharmacy engage in sterile HD compounding? If yes, complete 55.01-61 02.03. If no, skip to 62	Yes	
55.01	Select the type(s) of containment primary engineering control(s) used for sterile HD compounding.		
55.01.01	CACI	N/A	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile fume chemicals and volatile radionuclides)	N/A	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	Yes	
55.01.04	Class II BSC, Type B1	N/A	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	N/A	
55.01.06	Class III BSC	N/A	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
55.01.01	LAFW (not for antineoplastics)	N/A	
56.01.01	CAI (not for antineoplastics)	N/A	
56.00	The C PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	Yes	
57.00	Is the C-PEC used for sterile HD compounding externally vented?	Yes	
58.00	If a BSC or CACI that is used for sterile HD compounding is also used for non HD preparations, is the non HD preparation placed into a protective outer wrapper during removal from the C PEC?	No	APIs for non ID compounding are weighed in the HAZ BSC, but compounding takes place in the non Haz PEC
58.01	If used for both, is the non HD preparation labeled to require PPE handling precautions?	No	
59.00	If the C SEC is an unclassified containment segregated HD compounding area (C SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C SEC (C-SCA) has at least 12 ACPH. *Verify compliance by test monitoring.*	N/A	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
59.02	A hand-washing sink is at least one meter or more away from the C-PEC	N/A	
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		N/A
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	Yes	
60.01	The buffer room has fixed walls	Yes	
60.02	The buffer room is externally vented	Yes	
60.03	The buffer room has HEPA filtered supply air	Yes	
60.04	The buffer room has at least 30 ACPH	Yes	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	Yes	
60.06	The anteroom has fixed walls	Yes	
60.07	The ante room has a minimum of 30 ACPH of HEPA filtered supply air	Yes	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	Yes	
61.00	If the negative pressure HD buffer room is entered through a sanitary anteroom non HD buffer room, there is a loss of demarcation within the buffer room for donning and doffing PPE	N/A	
61.01	There is a design and method to contain and minimize HD contamination when transporting HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room.	Yes	HD CSP's are sealed in a bag and wiped before removing from the HAZ buffer room.
61.02	Indicate how HD contamination is minimized		
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space excluded in the facility's certification not compromising air quality in the buffer room (verified in the facility's semi-annual verification report that room strength has not compromised air quality in the buffer room)	Yes	SHD did certified the buffer room
61.02.02	Use of sealed containers	Yes	
61.02.03	Other, specify	N/A	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808286

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
	Environmental Quality and Control - Surface wipe sampling		
62.00	Recommendation: Surface wipe sampling is performed routinely (ideally on all at least every six months) to examine HD contamination problems and builds which includes all of the following.	N/A	
62.01	Inside of C-PEC and equipment within the C-PEC	N/A	
62.02	Pass-through chambers	N/A	
62.03	Surfaces in staging or work areas near the C-PEC	N/A	
62.04	Areas adjacent to the C-PEC (eg, floors directly under, staging, and dispensing areas)	N/A	
62.05	Areas immediately outside the HD buffer room or the C-SCA	N/A	
	Receiving		
63.01	Recommendation: HDs are packaged by the supplier in shipping containers designed to segregate them from other drugs and minimize possibility of exposure during unpacking and damage therefrom	Yes	
64.01	HDs are delivered to the HD storage areas immediately after unpacking.	Yes	
65.02	A spill kit is readily accessible in the receiving area.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806286

Inspection Date: 08/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observable	Notes
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous," on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOP's, to include sealing the container in plastic or an impervious container, transporting it to the C-PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, bagging the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and decontaminating, decontaminating, and cleaning the C-PEC.1	Yes	
68.00	Damaged packages are contained, quite and reported to the designated person. *List last date all damaged package received.*	Yes	None to date.

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806286

Inspection Date: 08/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observable	Notes
	Labeling, Packing, Transport, and Disposal		
68.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non-HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pharmacist takes and not used for transporting any liquid HDs or antineoplastic HDs.	Yes	
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		
73.01	Labeling specified in USP for transport.	Yes	
73.02	Storage and disposal instructions; and	Yes	
73.03	Labeled with HD category.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 806286

Inspection Date: 08/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observable	Notes
	Dispensing, Packaging, and Compounding Processes		
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	Yes	
75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	Recommendation: Equipment is decontaminated after every use.	Yes	
75.02	Recommendation: When compounding, a purple luer-lock separation mat is placed on the C-PEC work surface and changed and discarded appropriately as HD waste. All of the following should be done to initiate the 3 Year	N/A	
75.02.01	Immediately if a spill occurs	N/A	
75.02.02	Regularly during use	N/A	
75.02.03	At the end of a shift	N/A	
76.00	APIs or other powdered HDs are handled in a C-PEC during particle generating activities, such as crushing, opening capsules, and weighing powders.	Yes	

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e-Profile ID: 806286

Inspection Date: 08/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observable	Notes
	Deactivating and Decontaminating (Cleaning and Disinfecting) are performed in accordance with Chapters <795> and <797>)		
77.00	The pharmacy has chosen appropriate cleaning agent(s) for deactivation and decontamination and proven effective by testing.	Yes	
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated *At what frequency must be done to be compliant*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation fan is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C-PEC and the antiseptic used does not alter the product label.	Yes	

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Facility Name: Diabetes Corporation of America dba DCA Pharmacy

e-Profile ID: 808299

Inspection Date: 09/30/2024; 10/1/2024; 10/2/2024; 10/3/2024

		Observation	Notes
01.00	Areas, other than the work surface of the C PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
02.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
03.00	Spills are contained and cleaned immediately.	Yes	
04.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
05.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
06.00	There are signs available to restrict access to spill areas.	Yes	
07.01	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
08.00	Spill materials are disposed of as hazardous waste.	Yes	
09.00	The reconciliation and management of all spills are documented. *Review documentation for spills for the last year and list the most recent date.*	Yes	None to date.

Last Updated: 3/4/2025

For more information, please contact
Health Care Facilites
(615)741-7221 or 800-310-4650

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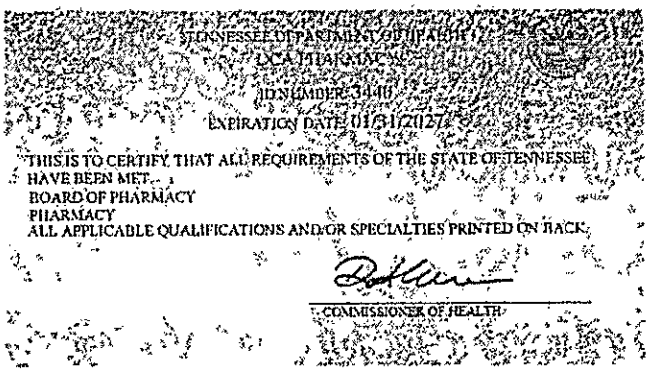
1

DCA Pharmacy
233 BEDFORD WAY
Franklin, TN 37064
615-832-7232

Qualifications
Controlled Subs, Sterile Compoun

Pharmacist: MYATT, BENJAMIN MICHAEL

Facility License Number: 00003440
Status: Licensed
Date of Original Licensure:
Date of Expiration: 01/31/2027
No Disciplinary Actions


TENNESSEE DEPARTMENT OF HEALTH
DCA PHARMACY
ID NUMBER: 3440
EXPIRATION DATE: 01/31/2027
THIS IS TO CERTIFY THAT ALL REQUIREMENTS OF THE STATE OF TENNESSEE
HAVE BEEN MET...
BOARD OF PHARMACY
PHARMACY
ALL APPLICABLE QUALIFICATIONS AND/OR SPECIALTIES PRINTED ON BACK.
COMMISSIONER OF HEALTH

JOYCRAFTERS, LLC DBA DCA PHARMACY
233 BEDFORD WAY
FRANKLIN, TN 37064

State of Tennessee
Department of Health

Renewal No. 59119

Board of Pharmacy
Pharmacy

DCA PHARMACY
233 BEDFORD WAY,
FRANKLIN, TN 37064

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 3440

EXPIRATION DATE: January 31, 2027

CONTROLLED SUBSTANCE REGISTRATION
STERILE COMPOUNDING

Commissioner, Dept of Health

Assistant Commissioner, Health Licensure & Regulation

3126

NABP ACCREDITED
COMPOUNDING PHARMACY

DCA Pharmacy

located at

233 Bedford Way, Franklin, TN 37064

This business has met all the compounding pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the compounding pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/compounding.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

10/31/2024 - 10/30/2027
Period of Accreditation

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: DCA Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH02736

Physical Address: 233 Bedford Way

City: Franklin State: TN Zip: 37064

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 615-832-7232 Website: www.dcapharmacy.com

Licensing Company Email: bmyatt@diabcorp.com

Section 2: Personal Information

First: Benjamin Middle: Michael Last: Myatt

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Franklin State: TN Zip: [redacted]

Telephone: 615-832-7232 Email: bmyatt@diabcorp.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Tennessee College of Pharmacy		08/03 - 05/07	
Address	City	State	Zip
881 Madison Ave	Memphis	TN	38163
Diploma/Degree obtained, if any			
PharmD			
School Name		From - To (MM/YY – MM/YY)	
University of Tennessee		08/990 - 05/03	
Address	City	State	Zip
The University of Tennessee	Knoxville	TN	37996
Diploma/Degree obtained, if any			
Bachelor of Arts			
School Name		From - To (MM/YY – MM/YY)	
Houston High School		08/98 - 05/99	
Address	City	State	Zip
9755 Wolf River Blvd	Germantown	TN	38139
Diploma/Degree obtained, if any			
High school Diploma			
School Name		From - To (MM/YY – MM/YY)	
Concord High School		08/95 - 08/98	
Address	City	State	Zip
2501 Ebright Rd	Wilmington	DE	19810
Diploma/Degree obtained, if any			
n/a			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/22 - 01/25	[redacted]	Franklin	TN	[redacted]
From - To (MM/YY – MM/YY)		City	State	
01/15 - 07/22		Franklin	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Joycrafters, LLC			09/22 - 01/25
Business Address	**City**	**State**	**Zip**
1187 Glenbrook Dr	Franklin	TN	37064
Phone	**Title**		
205-937-7871	Owner		
Description of Duties			
Operation and Management of Business			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Myatt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 1/21/2025

Please have this section completed in the presence of a Notary Public.

State of TN, ss. County of Williamson

I, Benjamin Myatt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date 1/21/2025

Subscribed and Sworn to before me this 21 day of Jan. 2025

Bridget Fields Hatchett

Notary Public Signature

BRIDGET FIELDS HATCHETT
STATE OF TENNESSEE NOTARY PUBLIC
WILLIAMSON COUNTY
MY COMMISSION EXPIRES FEBRUARY 16, 2027
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

An application for a license, or a licensee with a license, to conduct a pharmacy or to operate as a wholesaler shall designate at least one natural person to serve as the representative of the pharmacy or wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a pharmacy or wholesaler unless the Board determines that the designated natural person meets the following qualifications per NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler):

1. Is at least 21 years of age;
2. Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

The designated representative of a pharmacy or a wholesaler:

1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
3. Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

A pharmacy or wholesaler that is required to designate a natural person as its representative shall not open or operate the pharmacy or wholesaler unless that representative is actually employed full-time in the operation of the pharmacy or wholesaler and is physically present at the site of the pharmacy or wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a pharmacy leaves the employ of the pharmacy or wholesaler, thus leaving the pharmacy or wholesaler without a representative in violation of this section, the pharmacy or wholesaler shall:

1. Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the pharmacy or wholesaler; and
2. Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the pharmacy or wholesaler has left the employ of the pharmacy or wholesaler.

Before a pharmacy or wholesaler, that is in violation of NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler) because the natural person designated as the representative of the pharmacy or wholesaler left the employ of the pharmacy or wholesaler, may continue conducting business:

1. The pharmacy or wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the pharmacy; and
2. The Board must approve the natural person so designated.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler DCA Pharmacy

Pharmacy/Wholesaler License # (if applicable) PH02736

Physical Address 233 Bedford Way

City Franklin State TN Zip 37064

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 615-832-7232 Website www.dcapharmacy.com

Licensing Company Email bmyatt@diabcorp.com

Section 2: Personal Information

First Benjamin Middle Michael Last Myatt

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITI[redacted] Sex ■ M ☐ F ☐ X

Mailing Addres[redacted]

City Franklin State TN Zip [redacted]

Telephone 615-832-7232 Email bmyatt@diabcorp.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Tennessee College of Pharmacy			08/03 - 05/07	
Address		City	State	Zip
881 Madison Ave		Memphis	TN	38163
Diploma/Degree obtained, if any				
PharmD				

School Name			From - To (MM/YY – MM/YY)	
University of Tennessee			08/99 - 05/03	
Address		City	State	Zip
The University of Tennessee		Knoxville	TN	37996
Diploma/Degree obtained, if any				
Bachelor of Arts Degree				

School Name			From - To (MM/YY – MM/YY)	
Houston High School			08/98 - 05/99	
Address		City	State	Zip
9755 Wolf River Blvd		Germantown	TN	38139
Diploma/Degree obtained, if any				
High school Diploma				

School Name			From - To (MM/YY – MM/YY)	
Concord High School			08/95 - 08/98	
Address		City	State	Zip
2501 Ebright Rd		Wilmington	DE	19810
Diploma/Degree obtained, if any				
n/a				

School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/22 - 01/25	[redacted]	Franklin	TN	[redacted]
01/15 - 07/22		Franklin	TN	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Diabetes Corporation of America			01/11 - 01/25	
Business Address		**City**	**State**	**Zip**
233 Bedford Way		Franklin	TN	37064
Phone	**Title**		**Number of Employed Hours**	
615-832-7232	Pharmacist		6000+	
Description of Duties				
patient and prescriber consults, compounding, data entry verification, dispensing, DUR				

Business Name			From - To (MM/YY – MM/YY)	
Walgreens			06/07 - 12/10	
Business Address		**City**	**State**	**Zip**
9325 Parkway East		Birmingham	AL	35215
Phone	**Title**		**Number of Employed Hours**	
205-833-6882	Pharmacist		6000+	
Description of Duties				
patient and prescriber consults, data entry verification, dispensing, DUR				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Benjamin Myatt, **certify that as the designated representative for**

Joycrafters, LLC dba DCA Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BM I am at least 21 years of age;
3. BM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Benjamin Myatt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 1/21/2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Benjamin Myatt

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date 1/21/2025

Please have this section completed in the presence of a Notary Public.

State of TN, ss. County of Williamson

I, Benjamin Myatt, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

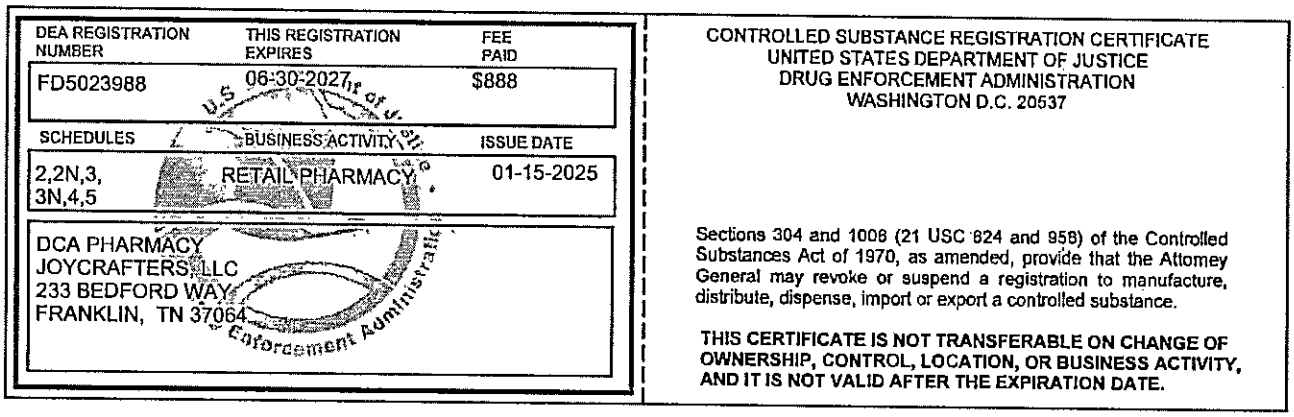
Date 1/21/2025

Subscribed and Sworn to before me this 21 day of Jan. 2025

Bridget Fields Hatchett

Notary Public Signature

BRIDGET FIELDS HATCHETT
STATE OF TENNESSEE NOTARY PUBLIC
WILLIAMSON COUNTY
MY COMMISSION EXPIRES FEBRUARY 16, 2027



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD5023988	06-30-2027	$888

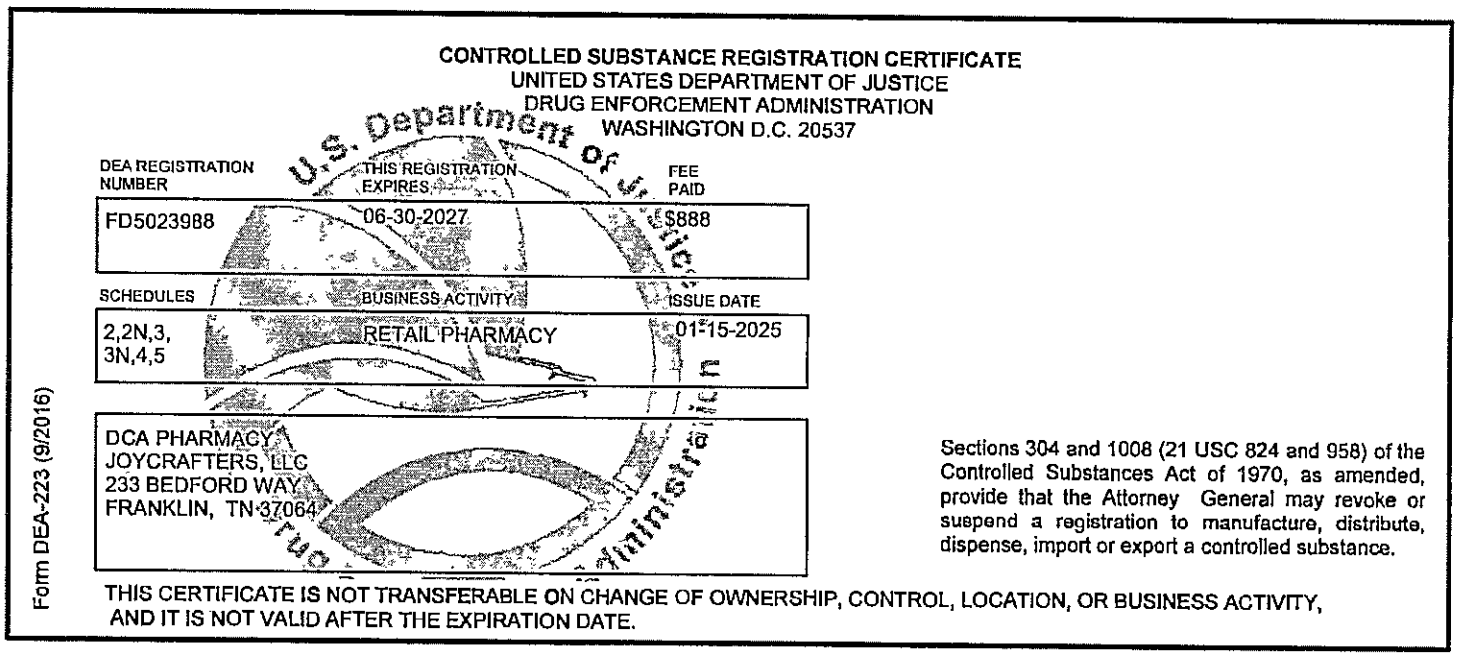
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-15-2025

DCA PHARMACY
JOYCRAFTERS, LLC
233 BEDFORD WAY
FRANKLIN, TN 37064

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD5023988	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-15-2025

DCA PHARMACY
JOYCRAFTERS, LLC
233 BEDFORD WAY
FRANKLIN, TN 37064

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FD5023988	06-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-15-2025

DCA PHARMACY
JOYCRAFTERS, LLC
233 BEDFORD WAY
FRANKLIN, TN 37064

CONTROLLED SUBSTANCE/REGULATED CHEMICAL
REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223/511 (9/2016)

REPORT CHANGES PROMPTLY

REQUESTING MODIFICATIONS TO YOUR REGISTRATION CERTIFICATE

To request a change to your registered name, address, the drug schedule or the drug codes you handle, please

1. visit our web site at **deadiversion.usdoj.gov** - or
2. call our customer Service Center at **1-(800) 882-9539** - or
3. submit your change(s) in writing to:

Drug Enforcement Administration
P.O. Box 2639
Springfield, VA 22152-2639

See Title 21 Code of Federal Regulations, Section 1301.51 for complete instructions.

You have been registered to handle the following chemical/drug codes:

4JJJ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FI0147252 ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Innovative Compounding Pharmacy

Physical Address: 820 Wales Dr #3

City: Folsom State: CA Zip: 95630

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (916) 984-9222 Toll Free # (NAC 639.708, NRS 639.23286): 866.470.9197

Fax: 855-946-1819 Contact Email: innovativecompoundingpharmacy@outlook.com

Website: https://icpfolsom.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): KUNS, NATHAN

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 18699

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: KUNS, NATHAN	NV Pharmacist Registration #: 18699
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials: NA	%: NA
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: California

Parent Company (if any): Innovative Compounding Inc.

Corporation/Organization Name: Innovative Compounding Inc.

Mailing Address: 820 Wales Dr #3

City: Folsom State: CA Zip: 95630

Telephone: (916) 984-9222 Email: innovativecompoundingpharmacy@outlook.com

Contact Person Name: Masoud Rashidi

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Innovative Compounding Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Masoud Rashidi

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

9/20/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Masoud Rashidi

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

9/20/2024

Date

Board Use Only	Date Received: 12/9/24	Amount: $500-cc

LIST OF OWNERS/OFFICERS:

Masoud Rashidi, Pharm.D., FAPC
President/CEO
Innovative Compounding Pharmacy
820 Wales Dr. Suite 3
Folsom, CA 95630
916-984-9222

PERCENT OWNERSHIP: 100%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: INNOVATIVE COMPOUNDING PHARMACY

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 820 WALES DR #3

City: FOLSOM State: CA Zip: 95630

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 916.984.9222 Toll Free # (NAC 639.708, NRS 639.23286): 866.470.9197

Fax: 855-946-1819 Contact Email: innovativecompoundingpharmacy@outlook.com

Website: https://icpfolsom.com/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Nathan Kuns

Supervising/Managing Pharmacist NV Pharmacist Registration #: 18699

Name of Designated Person(s) as defined by revised USP-797 guidelines: Nathan Kuns

Email of Designated Person(s): innovativecompoundingpharmacy@outlook.com

Telephone of Designated Person(s): 916.984.9222

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ☒ Category 1 ☒ Category 2 ☐ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☒ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ☒ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☒ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? August 2024

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☐ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☒ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Every Month

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ☐ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Fortified eye drops

Tri-mix eyedrops

GLP1

12. What laboratory performs your sterility or endotoxin testing?

Name: Eagle Analytical

Address: 11111 S. Wilcrest Dr. St 100

City: Houston State: TX Zip: 7

Telephone: 8007458916

13. What is your procedure for visual inspection of compounded sterile products?

Check For Cracks, leaks in vials or eye droppers
make sure There is no Particulate in the solution
using Black & White Background in a well lit area
color & clarity

14. How often do you perform glove fingertip and medial fill testing?

every 6 months For Compounders
every 1 year For overseeing The compounder.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

1) Didactic Tang. — Proper gowing, hand washing- Cleaning disinfect.
Visual inspetion, Regulatory Requirt Chng on 797 - 800
2) Hands on Training — Demonstraty Proper Techniques.
3) Media Fill Testing. Initially & every 6 months For cat 2.
4) environmental monitory Training & continued ed.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Clean all surface & floor on compounding days -
Clean walls, ceiling carts window every month.
anything used must be cleaned —
Hoods must be cleaned before start of compounding & after
compounding is over in between when change the compound.

1) Pardox RTU sterlet non sterile.
2) Sterile IPA 70%
3) Sterile water

17. Who performs the sterile compounding process at your facility?

either a Trained Tech or Pharmacist.

18. Who is responsible and accountable for the sterile compounding process at your facility?

PIC & RPh over seeing compound.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Cold Pack & Ice Pack one with WarmMark To ensure
The temp. is in good range.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? BSC vented out -		
2. Are you complying with all USP 800 guidelines?	☑ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☑ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☑ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☑ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☑ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☑ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☑ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

- Storage condition such as Refrigration or room Temp.
- disposal info specify if its hazardous.
- Information on side effect if exist can call Pharmacy also can report to FDA w1 # available for pt to call
- if not resolved they can also call ACHC / PCAB
- They can call for consult if they have any question.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

1) Read SOP + ensure they understand the risk
2) Take a quiz on Hazardous compounding + Pass w/ 80% or Better.
3) Know How to clean up spills + Show where the spill kit
4) Proper Gowning + Fit-test to ensure Proper mask used.
5) Currently we are only doing Sterile to Sterile haz compounding.
6) Visually watch the Process by To ensure safety.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

NA

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?	
6. What is the frequency for using sporicidal agents?	
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐ Yes ☐ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐ Yes ☐ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Nathan Kuns

Name of Person who Completed the Form

Pharmacist in Charge

Title

Nathan Kuns

Signature (copies or stamps not accepted)

11/27/24

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	INNOVATIVE COMPOUNDING INC.
Entity No.:	2933314
Registration Date:	11/09/2006
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of November 18, 2024.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 267193534

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 12/20/2023 Inspector: Lesa Fitzpatrick

Firm: INNOVATIVE COMPOUNDING PHARMACY Phone: (916) 984-9222

Address: 820 WALES DR STE 3 City: FOLSOM Zip: 95630

Ownership: CORPORATION

Permit #: LSC99600 PHY48417 Permit Exp: 2/1/2024 DEA#: FI0147252 DEA Exp: 11/30/2024

Date of Self Assessment Form: 6/22/2023 Other Permit #: N/A Date of DEA Inventory: 6/22/2023

Hours M-F: 10AM-6PM Hours Saturday CLOSED Hours Sunday: CLOSED

PIC MASOUD RASHIDI RPH56324 Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:	Staff Name:	License #:
ANNA RASHIDI	RPH56323	JUDITH R STIGGE	TCH194054
SHAWN M WEDWORTH	RPH47280	KAYLA C FOX	TCH154617
NATHAN B KUNS	RPH78756	KO W KANG	TCH188442
		LYNETTE BUNYI	CLERK
		TAYLOR WEST	CLERK

Inspector Remarks:

Annual Sterile Compound Renewal Inspection

The inspection documents were sent via e-mail prior to the inspection by PIC Rashidi. An onsite inspection of the compounding area was performed on 12/20/23 with the assistance of PIC Rashidi

PIC contact information: masoud@icpfolsom.com

Description of pharmacy- Independent open door community compounding pharmacy
Fills very small volume of regular prescription meds
Performs Category 2 compounding
Sterile to sterile (antibiotic eye drops), non-sterile to sterile (trimix, various strengths), sterile HD (gemcitabine, docetaxel, 5 FU eye drops), and non-sterile compounding performed (creams, ointments, caps, supp, troches, oral solns.)
Average number of sterile- to -sterile products compounded daily: low volume
Non-Sterile to sterile: average 300 x 1ml vials monthly
Sterile to sterile average: 2 per week (eye drops)
Non-sterile daily average compounded- 40 to 50, majority of the compounding performed

Wholesaler: Amerisource Bergin, PCCA, Medisca, Anda, Fagron, Parmed, Spectrum

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Sacramento, CA 95833
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Business, Consumer Services and Housing Agency
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INSPECTION REPORT

Reverse distributor: InMar
Waste: Sharps Solution

Shipping: Fed Ex, UPS next day. Consultation: Documentation sent with receipt stating consultation is available with contact info for the pharmacy. Consultation available Mon.- Sat.

Confirmed pharmacists are receiving BOP e-mail subscriber alerts

Per documents provided by PIC Rashidi
No physical layout changes to the sterile compounding facility in the past 12 months
No changes in types of sterile products compounded in the past 12 months
No adverse events or recalls related to pharmacy's CSPs from the past 12 months
No FDA, DEA, or accreditation inspections in last 12 months
No changes to the sterile compounding equipment in the past 12 months

Posted:
Original license with renewal
DEA license
Notice to consumer/ interpretive

Compounding Area:
ISO 7 anteroom which contains a sink, powder hood, garbing supplies, computer station which leads into 2 rooms:
. ISO 7 positive pressure buffer room with one ISO 5 Baker LAFW
. A negative pressure ISO 7 anteroom with sink with eyewash, drug storage, externally vented powder hood that leads into and ISO 7 negative pressure buffer room with an externally vented ISO 5 Germfree BSC
Certification: Last done by Enviro Certification Services on 8/28/23, 9/7/23, 9/11/2 under operational/ dynamic conditions.

- Non-viable air sampling performed
- HEPA leak filter test passed
- ACPH criteria met
- Video of smoke studies reviewed

Non-Sterile compounding area

- Rooms referred to as Pods. POD 1 and 2 for HD compounding has externally vented powder hoods and are negative pressure. Also contain HD drugs used in NS compounding.
- Pods 3 and 4 and for non-HD compounding. Room with 2 sinks and dishwasher located in the non-sterile suite

Items Reviewed:

- Previous inspection-12/21/22, no corrections
- Compounding and Hospital self -assessments
- Designated person(s) assigned
- Viable air and surface sampling performed in house in all the ISO certified areas. Air sampling performed in 8-2-2023 reviewed. No growth detected. Surface samplings performed 9-2023 to 11-2023 reviewed. No

INSPECTION REPORT

growth detected

- Master formula, compounding log, and label examples reviewed for
- **Non-Sterile to Sterile:** Trimix Lot # 10162023@-sterility and endotoxin performed by Eagle, potency testing performed by ARL, 45 day BUD frozen assigned, filtration sterilization (bubble point documented)
- **Sterile to Sterile:** atropine eye drops(single use patient specific)- BUD assigned 30 days refrigerated*, gemcitabine bladder irrigation- BUD assigned 7 days refrigerated, vanco eye drops- BUD assigned 14 days refrigerated*

***see discussion on BUDS**

Labels include the required elements, Medkeeper used for compounding logs. Compounding records include the required elements

- References materials include: Trissels, USP

60 days of the following reviewed

- Room, refrigerator, incubator (facility has 2), freezer temps monitored. Monitoring system used- ISO temp. Sends notification alerts if out of range
- Pressures-not on continual monitoring- see discussion
- Humidity

Cleaning logs- Agents used: sterile water and

- Germicidal: Peridox RTU used in PECs and rooms
- Disinfecting: SIPA 70%
- Sporicidal: Peridox RTU
- Decontamination- Peridox RTU

tems Observed:

- Visual inspection of compounding areas
- No active compounding occurring at the time of the inspection
- Drug storage (HD stored separate from non -HD)
- Hot/cold running water
- Eye wash area
- Lint free towels
- Pressure differentials between rooms
- Dedicated cleaning supplies
- **Chemo/Hazardous Compounding:**
  - Spill kit present
  - Exhausted IV hood in negative pressure buffer room
  - Chemo PPE
  - Chemo/hazardous auxiliary labels/bags

olicies and Procedures Reviewed: Reflect the current USP which became official 11/1/23

- Annual review of Policies & Procedures by PIC, 11/9/23
- Staff notification of any changes in processes or to the policy and procedure manual

INSPECTION REPORT

- Staff training and ongoing evaluation. Hand hygiene and garbing
- Facility & Equipment cleaning & sanitizing-sterile PEC
- Plan for recall of CSP
- Sterilization of CSPs
- Responsibilities of designated person(s)
- Monthly surface sampling
- End-Product Testing- sterility, potency, endotoxin at least annually and action plan if a compounded product is outside minimum standards
- Beyond Use Dating
- Action level for CFUs detected during viable surface sampling, glove fingertip, and viable air sampling
- Viable air, surface sampling, and glove fingertip- action to be taken when CFU's have been exceeded
- Hazardous compounding
    - Procedures for handling/disposal of hazardous drugs
    - Compounding of hazardous drugs
    - Spill clean- up protocol
    - Proper garbing (double shoe covers, double gloves)
    - Decontamination/deactivation step in cleaning

Training: Viewed for PIC Rashidi. Per PIC Rashidi he is the only sterile compounder at this time. Gloved ingertip/ media fill- performed every 6 mos.- performed by PIC Rashidi and RPH A. Rashidi. Supervising harmacists perform every 12 months. Currently no TCHs perform sterile compounding

- Aseptic technique/compounding/cleaning/hand hygiene&garbing competencies
- Didactic and math skills assessment
- Hazardous drug handling/compounding

Reviewed training records for TCHS and RPHS. They included USP 2023 training in 795,797,800

Discussion/Education:

- **Please** note the board may be in further communication with the facility post inspection

- The recall policy for CSPs does not include notification to the Board. Please update accordingly (BPC 4127.1)
- November 1, 2023, is the compendial date for several USP General Chapters, including General Chapters <795> Pharmaceutical Compounding—Nonsterile Preparations, <797> Pharmaceutical Compounding—Sterile Preparations, <800> Hazardous Drugs—Handling in Healthcare Settings, and <825> Radiopharmaceuticals—Preparation, Compounding, Dispensing, and Repackaging. Consistent with the policy statement the Board released on September 12, 2023, it is the Board's expectation that licensees are moving forward with all necessary implementation activities to comply with the updated USP compounding standards. During this transition period, licensees are encouraged to monitor the regulation process for updates, including signing up for the Board's subscriber alert system and by checking the Board's website
- USP discussion:
- BUD assignments for Category 2 CSPs. Specifically, the atropine ophthalmic soln. Reviewed with PIC

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Rashidi with SI Acosta on phone -section 14.3 of USP including table 13 (BUD limits for Category 2 sterile to sterile CSPs) and section 14.5 Multiple Dose CSPs and that it must be discarded at 24 hours if room temp and 72 hours if refrigerated once opened in absence of 51 testing

- USP section 4.2.5- Where pressure differentials are required, a pressure differential monitoring device must be used to continuously monitor the pressure differentials. The quantitative results from the pressure monitoring device must be reviewed and documented at least daily on the days when compounding is occurring. At the time of the inspection, the facility did not have a continuous monitoring system in place for measuring differential pressures
- USP 800 section 5.4-A CSTDs should be used when compounding HDs when the dosage form allows.
- The October 2023 issue of the Board of Pharmacy's newsletter, The Script, is now published online. A link to the newsletter can be found under "What's New" at the Board's website, www.pharmacy.ca.gov. It includes updated information on the new compounding standards and the transition period to implement
- Revisions to USP Compounding General Chapters <795> and <797> https://go.usp.org/2022_Revisions_795_797
- Send notification of all recalls, ADRs and complaints to: compounding.report@dca.ca.gov
- Law book: **https://www.pharmacy.ca.gov/laws_regs/lawbook.pdf**
- For questions pertaining to pharmacy law, please contact the board Monday through Thursday from 9am to 1pm. Email: ask.inspector@dca.ca.gov (Include name, organization, phone, and best time to call) Fax: (916) 574-8618 Phone: (916) 518-3100

Action items:

- Please send plan of compliance for continual monitoring of the pressures and a plan of compliance for assigning BUDs to Category 2 CSPs to Inspector Fitzpatrick at lesa.fitzpatrick@dca.ca.gov by end of business 1/3/24

Please keep a signed copy of this inspection report on file and readily available for three years.

Inspector Fitzpatrick
lesa.fitzpatrick@dca.ca.gov
(707)771-5113

Licensee Remarks:

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) _____

Pharmacist (print) Masoud

Inspector (sign) Lesa Fitzpatrick

Inspector (print) Lesa Fitzpatrick

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

CALIFORNIA STATE BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Retail Pharmacy Permit

LICENSE NO. PHY 48417
RECEIPT NO. 40032017

VALID UNTIL FEBRUARY 01, 2025

INNOVATIVE COMPOUNDING PHARMACY
820 WALES DR STE 3
FOLSOM CA 95630

01/03/24
01/03/24

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

FORM WPHPHY (09/30/19) PH

BOARD OF PHARMACY
2720 GATEWAY OAKS DRIVE, SUITE 100
SACRAMENTO, CA 95833
(916) 518-3100

Renewal Certificate

Sterile Compounding License

LICENSE NO. LSC 99600
RECEIPT NO. 00190290

VALID UNTIL FEBRUARY 01, 2025

INNOVATIVE COMPOUNDING PHARMACY
820 WALES DR STE 3
FOLSOM CA 95630

01/08/24
01/08/24

In accordance with the Provisions of Chapter 9 of Division 2 of the Business and Professions Code, the firm name hereon is licensed at the address shown, and is subject to the rules and regulations of the California State Board of Pharmacy.
This permit is non-transferable. Contact the California State Board of Pharmacy within 30 days when there is a change of ownership, location, corporate officer, director, shareholder (more than 10 percent share change) administrator or pharmacist-in-charge.
This permit is valid only at the address shown.

The official status of this license can be verified at www.pharmacy.ca.gov

----- NON-TRANSFERABLE --- POST IN PUBLIC VIEW -----

WPHLSC 09/30/1

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler INNOVATIVE COMPOUNDING PHARMACY

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 820 WALES DR #3

City FOLSOM State CA Zip 95630

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 916.984.9222 Website https://icpfolsom.com/

Licensing Company Email INNOVATIVECOMPOUNDINGPHARMACY@OUTLOOK.COM

Section 2: Personal Information

First NATHAN Middle B Last KUNS

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address 820 WALES DR #3

City FOLSOM State CA Zip 95630

Telephone 820 WALES DR #3 Email INNOVATIVECOMPOUNDINGPHARMACY@OUTLOOK.COM

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Union University		8/2009 – 5/2013	
Address	City	State	Zip
1050 Union University Dr	Jackson	TN	38305
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		8/2004 – 5/2008	
Address	City	State	Zip
2801 W. Bancroft St	Toledo	OH	43606
Diploma/Degree obtained, if any			
Bachelor of Science in Pharmaceutical Science; Minor in Chemistry			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Innovative Compounding Pharmacy			10/2023 - present
Business Address	**City**	**State**	**Zip**
820 Wales Dr #3	Folsom	CA	
Phone	**Title**	**Number of Employed Hours**	
916-984-9222	Pharmacist in Charge	2000 + hrs	
Description of Duties			
Responsible for all aspects of daily pharmacy operations			

Business Name			From - To (MM/YY – MM/YY)
CVS Health			1/2019 – 10/2023
Business Address	**City**	**State**	**Zip**
515 CA-49	Jackson	CA	95642
Phone	**Title**	**Number of Employed Hours**	
209-223-3784	Staff Pharmacist	9500 + hrs	
Description of Duties			
Responsible for all aspects of daily pharmacy operations			

Business Name			From - To (MM/YY – MM/YY)
Sierra Family Pharmacies			5/2017 - 12/2018
Business Address	**City**	**State**	**Zip**
9738 S Virginia St	Reno	NV	89511
Phone	**Title**	**Number of Employed Hours**	
775-853-3502	Staff Pharmacist	3000 + hrs	
Description of Duties			
Responsible for all aspects of daily pharmacy operations including long term care, hospice, compounding			

Business Name			From - To (MM/YY – MM/YY)
St Mary's Outpatient Pharmacy			5/2016 - 5/2017
Business Address	**City**	**State**	**Zip**
6255 Sharlands Ave	Reno	NV	89523
Phone	**Title**	**Number of Employed Hours**	
775-770-6672	Staff Pharmacist	2000 + hrs	
Description of Duties			
Responsible for all aspects of daily pharmacy operations			

Business Name			From - To (MM/YY – MM/YY)
CVS Health			4/2014 - 5/2016
Business Address	**City**	**State**	**Zip**
55 Damonte Ranch Pkwy	Reno	NV	89521
Phone	**Title**	**Number of Employed Hours**	
775-852-9304	Staff Pharmacist	4000 + hrs	
Description of Duties			
Responsible for all aspects of daily pharmacy operations			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, NATHAN KUNS, **certify that as the designated representative for**

INNOVATIVE COMPOUNDING PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. N.K. I am at least 21 years of age;
3. N.K. I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. N.K. I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. N.K. I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. N.K. I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. N.K. I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

NATHAN KUNS

Print Name (First, Last)

Nathan Kuns

Original Signature (electronic, copies or stamps not accepted)

11/27/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

NATHAN KUNS

Print Name (First, Last)

Nathan Kuns

Original Signature (electronic, copies or stamps not accepted)

11/27/24

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Sacramento

I, Nathan B Kuns, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Nathan Kuns

Original Signature

11/27/24

Date

Subscribed and Sworn to before me this 27th day of November 2024

Jeanne A Kotsios

Notary Public Signature

JEANNE A. KOTSIOS
COMM. #2433159
Notary Public - California
Sacramento County
My Comm. Expires Jan. 2, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Innovative Compounding Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 820 Wales Dr. Suite 3

City Folsom State CA Zip 95630

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email innovativecompoundingpharmacy@outlook.com

Section 2: Personal Information

First Anna Middle _____ Last Rashidi

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address 820 Wales Dr. Ste 3

City Foslom State CA Zip 95630

Telephone 916-984-9222 Email anna@icpfolsom.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western University Of Health Sciences		08/2000-05/04	
Address	**City**	**State**	**Zip**
309 E. 2nd St.	Pomona	CA	91766
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
University of Utah		1995 – 2000	
Address	**City**	**State**	**Zip**
201 Presidents' Cir	Salt Lake City	UT	84112
Diploma/Degree obtained, if any			
BS Biology			

School Name		From - To (MM/YY – MM/YY)	
Olympus High School		1992 – 1995	
Address	**City**	**State**	**Zip**
4055 S 2300 E	Salt Lake City	Ut	84124
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16-preent	[redacted]	El Doraho Hills	CA	[redacted]
02/05-08/16		Folsom	CA	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Innovative Compounding Pharmacy			04/07-present	
Business Address		**City**	**State**	**Zip**
820 Wales Dr. Ste 3		Folsom	CA	95630
Phone	**Title**			
916-984-9222	CFO, RPH			
Description of Duties				
oversee technician, clerk and other pharmacist fill prescriptions				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

02/24/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Anna, Rashidi

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/24/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Sacramento

I, Anna Rashidi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/24/25

Date

Subscribed and Sworn to before me this 24 day of February 2025,

Jeanne A Kotsios

Notary Public Signature

JEANNE A. KOTSIOS
COMM. #2433159
Notary Public - California
Sacramento County
My Comm. Expires Jan. 2, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler Innovative Compounding Pharmacy

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 820 Wales Dr. Suite 3

City Folsom State CA Zip 95630

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email innovativecompoundingpharmacy@outlook.com

Section 2: Personal Information

First Masoud Middle _____ Last Rashidi

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 820 Wales Dr. Ste 3

City Foslom State CA Zip 95630

Telephone 916-984-9222 Email masoud@icpfolsom.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Western University Of Health Sciences		08/2000-05/04	
Address	**City**	**State**	**Zip**
309 E. 2nd St.	Pomona	CA	91766
Diploma/Degree obtained, if any			
Pharm.D.			

School Name		From - To (MM/YY – MM/YY)	
University of California Irvine		1997-2000	
Address	**City**	**State**	**Zip**
260 Aldrich Hall	Irvine	CA	92697
Diploma/Degree obtained, if any			
BS Ecology and Biology			

School Name		From - To (MM/YY – MM/YY)	
Out of country		1988-1992	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
High school			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/16-preent	[redacted]	El Doraho Hills	CA	[redacted]
From - To (MM/YY – MM/YY)		City	State	
02/05-08/16		Folsom	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Innovative Compounding Pharmacy			From - To (MM/YY – MM/YY): 04/07-present
Business Address: 820 Wales Dr. Ste 3	City: Folsom	State: CA	Zip: 95630
Phone: 916-984-9222	Title: CEO, RPH, President		
Description of Duties: oversee technician, clerk and other pharmacist fill Rx			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # NA **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent		Lawsuit/Arbitration/Bankruptcy		
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

02/24/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MASOUD RASHIDI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Sacramento

I, Masoud Rashidi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/24/25

Date

Subscribed and Sworn to before me this 24 day of February 2025,

Notary Public Signature

JEANNE A. KOTSIOS
COMM. #2433159
Notary Public - California
Sacramento County
My Comm. Expires Jan. 2, 2027

(Seal)

4KKK

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: BS7232046
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH n/a		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: SBH MEDICAL, LTD d/b/a OPTIORX - 290

Physical Address: 7654 CROSSWOODS DRIVE

City: COLUMBUS State: OH Zip: 43235

Mailing Address (if different from physical address): (SAME AS ABOVE)

City: _____ State: _____ Zip: _____

Telephone: 614-847-6007 Toll Free # (NAC 639.708, NRS 639.23286): 866-724-6333

Fax: 614-847-6015 Contact Email: LICENSES@OPTIORX.COM

Website: https://sbhmed.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): DOUGLAS NAVARRO

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24452

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: DOUGLAS NAVARRO	NV Pharmacist Registration #: 24452
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: OHIO

Parent Company (if any): SBH MEDICAL, LLC

Corporation/Organization Name: SBH MEDICAL LTD d/b/a OPTIORX - 290

Mailing Address: 7654 CROSSWOODS DR.

City: COLUMBUS State: OH Zip: 43235

Telephone: 614-847-6007 Email: LICENSES@OPTIORX.COM

Contact Person Name: DONNA UNSINN

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CFO (title) for SBH MEDICAL, LTD (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

LEO LAFRANCO

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

1/22/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LEO LAFRANCO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/22/25

Date

Board Use Only	Date Received: 1/30/25	Amount: $500 CK 1031

SBH Medical Ltd.
7654 Crosswoods Dr.
Columbus, OH 43235

Nevada Out-of-State Pharmacy Application Addendum

List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)

Benjamin David, Chief Executive Officer, OptioRx
Leo LaFranco, Chief Financial Officer, OptioRx

List the top four stockholders and their percent ownership. NRS 639.231(3)

SBH MEDICAL, LLC (100%)

List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)

SBH MEDICAL, LLC (100%)

phone (614) 847-6007 - **toll free** (866) 724-6333 - **fax** (614) 847-6015

UNITED STATES OF AMERICA
STATE OF OHIO
OFFICE OF THE SECRETARY OF STATE

I, Frank LaRose, do hereby certify that I am the duly elected, qualified and present acting Secretary of State for the State of Ohio, and as such have custody of the records of Ohio and Foreign business entities; that said records show SBH MEDICAL, LTD., an Ohio Limited Liability Company, Registration Number 1219084, was organized in the State of Ohio on March 29, 2001, is currently in FULL FORCE AND EFFECT upon the records of this office.

Witness my hand and the seal of the Secretary of State at Columbus, Ohio this 22nd day of November, A.D. 2024.

Ohio Secretary of State

Validation Number: 202432702122

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler SBH MEDICAL LTD d/b/a OPTIORX - 290

Pharmacy/Wholesaler License # (if applicable) PENDING

Physical Address 7654 CROSSWOODS DRIVE

City COLUMBUS State OH Zip 43235

Mailing Address (if different from physical address) (SAME AS ABOVE)

City _____ State _____ Zip _____

Telephone 614-847-6007 Website https://sbhmed.com/

Licensing Company Email LICENSES@OPTIORX.COM

Section 2: Personal Information

First DOUGLAS Middle JAMES Last NAVARRO

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City NEW ALBANY State OH Zip [redacted]

Telephone [redacted] Email DNAVARRO@OPTIORX.COM

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

An application for a license, or a licensee with a license, to conduct a pharmacy or to operate as a wholesaler shall designate at least one natural person to serve as the representative of the pharmacy or wholesaler. The Board will not issue or renew a license of an applicant or licensee that is required to designate a representative of a pharmacy or wholesaler unless the Board determines that the designated natural person meets the following qualifications per NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler):

1. Is at least 21 years of age;
2. Has been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.

The designated representative of a pharmacy or a wholesaler:

1. Must be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
2. Must be employed full-time in a managerial level position with the pharmacy or wholesaler;
3. Must be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
4. May serve in this representative capacity for only one pharmacy or wholesaler at a time

A pharmacy or wholesaler that is required to designate a natural person as its representative shall not open or operate the pharmacy or wholesaler unless that representative is actually employed full-time in the operation of the pharmacy or wholesaler and is physically present at the site of the pharmacy or wholesaler during regular working hours, not including sick leave, vacation leave and other authorized absences from work. If the natural person designated as the representative of a pharmacy leaves the employ of the pharmacy or wholesaler, thus leaving the pharmacy or wholesaler without a representative in violation of this section, the pharmacy or wholesaler shall:

1. Immediately cease conducting business until another qualified natural person is approved by the Board to serve as the representative of the pharmacy or wholesaler; and
2. Not later than 48 hours after that person leaves its employ, notify the Board that the person designated as the representative of the pharmacy or wholesaler has left the employ of the pharmacy or wholesaler.

Before a pharmacy or wholesaler, that is in violation of NAC 639.5005 (Pharmacy) or NAC 639.5935 (Wholesaler) because the natural person designated as the representative of the pharmacy or wholesaler left the employ of the pharmacy or wholesaler, may continue conducting business:

1. The pharmacy or wholesaler must designate, on a form provided by the Board, a new natural person to serve as the representative of the pharmacy; and
2. The Board must approve the natural person so designated.

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
The Ohio State University		09/94-09/99	
Address	**City**	**State**	**Zip**
217 Loyd M Parks Hall 500 West 12th Ave College of Pharmacy	Columbus	OH	43210
Diploma/Degree obtained, if any			
BS In Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Champion High School		08/91-06/94	
Address	**City**	**State**	**Zip**
5976 Mahoning Ave NW	Warren	OH	44483
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/08-Present	[redacted]	New Albany	OH	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
SBH MEDICAL, LTD			FEB 2023 - PRESENT
Business Address	**City**	**State**	**Zip**
7654 CROSSWOODS DRIVE	COLUMBUS	OH	43235
Phone	**Title**		**Number of Employed Hours**
614-847-6007	PHARMACIST-IN-CHARGE		40 HRS/WEEK
Description of Duties			
Oversee Pharmacy regulatory compliance. Assist in daily work flow with data entry and product verification. Engage in supervision and participation in pharmacy compounding. Supervise pharmacy technicians.			

Business Name			From - To (MM/YY – MM/YY)
PHARMERICA			DEC 2006 - FEB 2023
Business Address	**City**	**State**	**Zip**
720 LAKEVIEW PLAZA BLVD.	WORTHINGTON	OH	43085
Phone	**Title**		**Number of Employed Hours**
614-430-9720	Lead Pharmacist		40RS/WEEK
Description of Duties			
Monitor daily workflow. Data entry/Product verification. Supervise 797 Cleanroom/Compliance.			

Business Name			From - To (MM/YY – MM/YY)
MEIJER PHARMACY			SEPT 1999 - DEC 2006
Business Address	**City**	**State**	**Zip**
5050 N HAMILTON RD.	COLUMBUS	OH	43230
Phone	**Title**		**Number of Employed Hours**
614-855-4910	Pharmacy Team Leader		40HRS/WEEK
Description of Duties			
Supervise daily functions of retail pharmacy including regulatory compliance. Supervise Pharmacy technicians. Data entry/Product verification.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, DOUGLAS NAVARRO, **certify that as the designated representative for**

SBH MEDICAL LTD d/b/a OPTIORX - 290,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. DJN I am at least 21 years of age;
3. DJN I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. DJN I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. DJN I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. DJN I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. DJN I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

DOUGLAS NAVARRO

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/24/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DOUGLAS NAVARRO

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of Ohio, ss. County of Franklin

I, Doug Navarro, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/24/25

Date

Subscribed and Sworn to before me this 24 day of January 2025

Notary Public Signature

NADER WAHBA - NOTARY PUBLIC
MY COMMISSION EXPIRES 11-[illegible]-2028
(Seal) STATE OF OHIO


NADER WAHBA - NOTARY PUBLIC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: SBH MEDICAL LTD d/b/a OPTIORX - 290

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PENDING

Physical Address: 7654 CROSSWOODS DRIVE

City: COLUMBUS State: OH Zip: 43235

Mailing Address (if different from physical address): (SAME AS ABOVE)

City: State: Zip:

Telephone: 614-847-6007 Website: https://sbhmed.com/

Licensing Company Email: LICENSES@OPTIORX.COM

Section 2: Personal Information

First: Leo Middle: Anthony Last: LaFranco

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: LAKE FORREST State: IL Zip: [redacted]

Telephone: [redacted] Email: LLAFRANCO@OPTIORX.COM

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✓	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✓	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Chicago		08/06 - 05/08	
Address	**City**	**State**	**Zip**
5807 S Woodlawn Ave	Chicago	IL	60637
Diploma/Degree obtained, if any			
MBA, Finance and Strategic Management			

School Name		From - To (MM/YY – MM/YY)	
University of Notre Dame		08/94 - 06/98	
Address	**City**	**State**	**Zip**
Holy Cross Dr	Notre Dame	IN	46556
Diploma/Degree obtained, if any			
BBA, Accounting			

School Name		From - To (MM/YY – MM/YY)	
Lake Forest High School		08/89 - 06/93	
Address	**City**	**State**	**Zip**
1285 N McKinley Rd	Lake Forest	IL	60045
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2014 - present	[redacted]	Lake Forest	IL	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Optio Rx LLC			05/22 - present	
Business Address		**City**	**State**	**Zip**
3701 Commercial Ave		Northbrook	IL	60062
Phone	**Title**			
630-242-8969	CFO			
Description of Duties				
Responsible for all accounting, finance and treasury activities				

Business Name			From - To (MM/YY – MM/YY)	
Allure Healthcare Services			02/21 - 04/22	
Business Address		**City**	**State**	**Zip**
2711 W Howard St		Chicago	IL	60645
Phone	**Title**			
773-338-4400	CFO			
Description of Duties				
Responsible for all accounting, finance and treasury activities				

Business Name			From - To (MM/YY – MM/YY)	
Freelance, Financial Consulting			06/20 - 01-21	
Business Address		**City**	**State**	**Zip**
N/A				
Phone	**Title**			
	Consultant CFO			
Description of Duties				
Consult on financial matters per clients' needs				

Business Name			From - To (MM/YY – MM/YY)	
Medical Management			11/17 - 06/20	
Business Address		**City**	**State**	**Zip**
4141 Dundee Rd		Northbrook	IL	60062
Phone	**Title**			
(847) 897-6900	Controller			
Description of Duties				
Responsible for all accounting, finance, and treasury activities				

Business Name			From - To (MM/YY – MM/YY)	
Physicians Immediate Care			08/12 - 11/17	
Business Address		**City**	**State**	**Zip**
311 N Green St, 17th Fl		Chicago	IL	60607
Phone	**Title**			
	Director of Financial Planning & Analysis			
Description of Duties				
Budgeting, forecasting, M&A analysis, operational analysis				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✓	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
01/13/2020	08/23/2024	IL	HIGHLAND PARK	COOK
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
20DT79		19th JUDICIAL CIRCUIT, LAKE COUNTY		
Reason/Charge				
RECKLESS DRIVING (MISDEMEANOR)				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
LEO LAFRANCO			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Single car accident resulting from reckless driving

JAL

Original Signature (electronic, copies or stamps not accepted)

1/22/25

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
06/07/2024	06/07/2024	DE	Wilmington	New Castle County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
24-11188	District of Delaware

Reason/Charge
Chapter 11 Bankruptcy

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Optio et al. / Debtors	Bankruptcy

Name of Business/Industry/Entity
OptioRx LLC

Provide explanation below:

To better position ourselves for the future, we have made the strategic and very positive decision to enter into a restructuring support agreement (RSA) with our lenders. This RSA facilitates a comprehensive financial restructuring, enabling us to drastically reduce our debt and secure the capital needed to grow the Company and continue delivering best-in-class products and solutions to our patients.

To expedite the financial restructuring process, on June 7, 2024, the Company voluntarily filed for Chapter 11 protection in the U.S. Bankruptcy Court as part of this agreement. This move allows us to improve our balance sheet quickly and efficiently, positioning us to capitalize on the numerous opportunities ahead for our company and all our stakeholders, including our strategic partners like you. Please be assured that these decisions were not made lightly; they were made after thoughtful consideration and numerous discussions with the Company's financial partners and will permit us to align our financial structure with our growth objectives. This involves growing our pharmacies, concentrating our resources on productivity, reducing costs, and improving efficiency to better serve our customers and patients.

If you need any additional information on this matter, please contact us at legal@optiorx.com or (630) 566-2636 and we'll be happy to address your questions.

JL — 11/22/25

Original Signature (electronic, copies or stamps not accepted) — Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leo LaFranco

Print Name (First, Last)

LHL

Original Signature (electronic, copies or stamps not accepted)

1/23/25

Date

Please have this section completed in the presence of a Notary Public.

State of Illinois, ss. County of Cook

I, Leo LaFranco, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

LHL

Original Signature

1/23/25

Date

Subscribed and Sworn to before me this 23rd day of January, 2025.

Notary Public Signature

Official Seal
KEVIN DANIEL HONAN
Notary Public, State of Illinois
Commission No. 978807
My Commission Expires September 28, 2027

(Seal)

This is in response to Question # 1

IN THE CIRCUIT COURT OF THE NINETEENTH JUDICIAL CIRCUIT
LAKE COUNTY, ILLINOIS

PEOPLE OF THE STATE OF ILLINOIS)
)
vs) Case No. 20 DT 79
Leo LaFranco)
)

ORDER AND CERTIFICATE OF MISDEMEANOR PROBATION / ~~SUPERVISED SUPERVISION~~

This cause coming on for sentencing, pursuant to a: ☐ finding of guilty ☒ negotiated plea of guilty, ☐ open plea of guilty, Defendant having been adjudged guilty of Reckless Driving, being a Class A Misdemeanor.

The Court after conducting a hearing or having accepted a negotiated plea, and after considering the factors and the nature and circumstances of the offense, and the history, character, and condition of the offender, and after considering Defendant's financial ability to pay the amount hereinafter assessed,

ORDERS:

Defendant is hereby sentenced to a term of 24 months ☒ probation / ☐ ~~supervised supervision.~~ The conditions of which are that Defendant shall:

☒ 1. Not violate any laws or ordinances of any jurisdiction, including traffic regulations;

☒ 2. Not leave the State without the consent of the Court; however, upon verification and approval of the Probation Officer, the Defendant may leave the State for work, school, vacation, treatment, family emergencies and _____

_____

_____;

☒ 3. Pay all fines, fees, court costs, assessments and restitution set forth on **Exhibit A** through the Office of the Clerk of the Circuit Court in equal monthly installments by the first of each month to be paid in full not later than 90 days before the termination date unless the Court orders otherwise;

☒ 4. Obtain/continue employment and/or attend educational programs unless otherwise ordered by the Court;

☒ 5. Not use or be in possession of any illegal substance, cannabis, prescription medication of another, or use any substance designed to have the effects of an illegal substance, or be in the presence of anyone using or in possession of such substances;

☒ 6. Appear in Court on the oral or written notice of the Circuit Clerk, Compliance Officer, Probation Officer, State's Attorney, or the Court;

☒ 7. Unless otherwise ordered by this Court, not less than 90 days prior to the termination of this case, provide proof of completion of all terms and conditions of sentence to the Lake County Adult Probation Services Division;

☒ 8. Strictly comply with the terms and provisions of any and all Orders of Protection;

☒ 9. Not operate a motorized vehicle without a valid driver's license;

☒ 10. Appear immediately in person before the Lake County Adult Probation Services Division at 215 W. Water Street, Waukegan, Illinois 60085, or if in custody immediately upon release from custody, to have an intake interview and thereafter report as often as directed by the Probation Officer;

☒ 11. Notify Probation Officer of telephone contact information and notify Probation Officer immediately of any changes of telephone contact information;

☒ 12. Notify Probation Officer within 24 hours of any new arrests and/or the issuance of a citation for any violation of law including traffic tickets;

☒ 13. Upon a violation of any term or condition of this Order, the Lake County Adult Probation Services Division may invoke any sanctions from the list of intermediate sanctions adopted by the Chief Judge;

☒ 14. Permit the Probation Officer to visit Defendant at home or elsewhere to the extent necessary to discharge probation duties;

☒ 15. Consent to and submit to searches of his/her person, residence, papers, automobiles, computers, any device capable of accessing the internet or storing electronic data, and/or other personal or real property accessible to Defendant at any time such requests are made by a Probation Officer. Defendant consents to the use of anything located, found or seized as evidence in any court proceeding and consents to the destruction of any contraband seized;

☒ 16 Provide executed releases and execute such releases as requested by the Probation Officer including but not limited to all medical treatment, psychological, substance abuse, employment, financial, military, governmental, disability, phone records, internet provider, media, social network or other probation and criminal justice system records;

☒ 17. Provide such proof of Defendant's details of employment, income, job search and/or attendance at educational programs as directed by the Probation Officer;

☒ 18. Submit to random testing of urine and/or breathalyzer and/or blood testing, submitting a sample at such time and place as directed by a Probation Officer and pay the assessed fees;

☒ 19. Not change present place of residence or move outside the County or the State without prior permission of the Court or Probation Officer;

☒ 20. Upon request, provide the Probation Officer with immediate access to any e-mail, text or messaging services, internet chat rooms, blogs, and social media websites Defendant uses to communicate with anyone, as well as any electronic devices including but not limited to telephones, cellphones, smartphones, computer tablets and computers with internet capability.

IF CHECKED, THE FOLLOWING PROVISIONS APPLY

☒ 21. Defendant shall not possess any firearm or other dangerous weapon because:

☐ the offense involved the intentional or knowing infliction of bodily harm or the threat of bodily harm (mandatory for probation sentence);

☐ the offense involved a family or household member as defined in the Illinois Domestic Violence Act of 1986 (750 ILCS 60/101 *et seq.*);

☒ the court finds it is necessary and appropriate in this case.

☒ 22. Defendant shall not consume or possess alcoholic beverages and not be in any establishment whose primary purpose is the sale of alcohol.

☐ 23. Defendant shall submit a sample for DNA indexing as required by law.

☐ 24. Defendant shall register as required by law as a ☐ sex offender ☐ other _____

_____

_____

Defendant shall submit to such testing as required by law or specifically required by separate order.

☐ 25. Defendant is sentenced to a determinate term of _____ days in the custody of the County Sheriff.

☐ No good time shall be awarded as injury resulted from offense.

☐ 26. Defendant shall serve a term of periodic imprisonment to be confined for twenty-four (24) hours, seven (7) days each week for a period of _____ months ☐ in the Sheriff's Community Based Corrections Center (CBCC) and shall follow all rules of the CBCC program, or ☐ if eligible, through the Sheriff's Electronic Home Monitoring program (EHM) and shall follow all rules of the EHM program. Defendant shall follow all rules of periodic imprisonment and shall be released to ☐ seek employment ☐ work ☐ attend school ☐ obtain treatment as ordered ☐ perform public service ☐ perform probation obligations ☐ other _____

_____

_____

☐ 27. Defendant shall serve a term in the County Work Release Program for a period of _____ months, which does not exceed the statutory term of 12 months, as required by 730 ILCS 5/5-7-1(d).

☐ 28. Defendant shall pay a fee for ☐ room and board ☐ electronic home monitoring at the rate established by Lake County Board Ordinance with the concurrence of the Chief Judge pursuant to statute.

☒ 29. Defendant shall perform 240 hours of public service at a minimum rate of 15 hours per month and report immediately to and register with the Public Service Unit of the Lake County Adult Probation Services Division. Defendant shall perform this service at the time and places directed and shall comply with all Public Service Unit protocols and shall serve upon the Public Service Unit written evidence of completion of the public service hours at least 90 days prior to the termination of this sentence.

☐ 30. Good cause having been shown, Defendant shall perform _____ hours of community service at a minimum rate of _____ hours per month and report immediately to and register with the Lake County Adult Probation Services Division. Defendant shall perform this service at a self-selected not-for-profit organization, public body, religious institution, charitable organization, or individual agreeing to accept community service from offenders as verified by the Lake County Adult Probation Services Division and shall serve upon the Lake County Adult Probation Services Division written evidence of completion of the community service hours at least 90 days prior to the termination of this sentence.

☐ 31. Defendant shall complete all requirements for ☐ high school graduation ☐ GED ☐ other _____

☐ 32. Defendant shall:

- ☐ reside at _____
- ☐ not reside at _____
- ☐ not engage in any abusive, violent, or harassing conduct of any kind with _____
- ☐ not be present at _____
- ☐ not have any contact of any kind directly or indirectly with members of street gangs and drug users or dealers and not wear clothing associated with any street gang, communicate or exhibit gang signs
- ☐ not have any contact of any kind directly or indirectly with _____

☒ 33. Defendant shall comply with the following evaluations, treatment recommendations, educational or vocational requirements by approved providers including the payment of fees:

- ☐ The Cognitive Program, "Thinking for a Change"
- ☐ Mental health/psychiatric treatment
- ☐ Repatriate Project
- ☐ Physician/psychiatrist/psychologist treatment plans
- ☐ Victim impact panel
- ☒ Live victim impact panel
- ☐ Parenting classes
- ☐ Substance abuse evaluation and treatment
- ☐ Sex offender evaluation and treatment
- ☐ Domestic violence evaluation and treatment
- ☐ DCFS Service/Safety Plan
- ☐ Traffic Safety School
- ☐ Youthful Offender Program

☐ Comply with medication plan as directed by physician, taking medications only as prescribed

☒ DUI Project: ☐ Level 1 ☐ Level 2 Moderate ☒ Level 2 Significant ☐ Level 3

☒ Other: Open mandate per probation officer

Defendant shall obtain all required evaluations or be actively engaged or enrolled in treatment, educational or vocational programs as ordered above within 45 days of today's date or, if in custody, within 45 days of release date, providing proof of same to the Lake County Adult Probation Services Division. Defendant shall meet all program and treatment schedules as set by the Lake County Adult Probation Services Division and provide proof as required in Paragraph 7 of this order. Defendant must follow all programs/treatment/class rules, participate in a respectful, cooperative and constructive manner and complete all requirements.

☒ 34. Defendant shall be assessed for all risk factors and criminogenic needs by the Lake County Adult Probation Services Division at the time of his / her initial in-take interview as well as periodically throughout the term of probation, and based upon these assessments (which must include consideration of Defendant's criminal, psychological, intellectual, behavioral and social history), Defendant shall undergo all further assessments and evaluations including but not limited to, medical, psychological, psychiatric, substance abuse, anger management, domestic violence, sexual offender, educational and vocational, and successfully complete all necessary classes, programs, and treatment relating to the nature of the offense, or the rehabilitation of Defendant, or the protection of the public, or that may be beneficial to Defendant ("Rehabilitative Assessment and Services") as directed by the Lake County Adult Probation Services Division. This process requires Defendant to comply with all program and treatment schedules as set by the Lake County Adult Probation Services Division and provide proof of successful completion as set forth in Paragraph 7. Defendant must follow all programs/treatment/class rules, participate in a respectful, cooperative and constructive manner and complete all requirements including the payment of all fees.

☐ 35. Upon the approval of the receiving State, pursuant to the Interstate Compact Rules, Defendant may reside in _____. Defendant is required to pay a $125.00 processing fee prior to submission of a transfer request. The Lake County Adult Probation Services Division fees will be assessed up to the date a transfer is accepted by the receiving State, and waived thereafter. Defendant will be required to pay supervision fees imposed by the receiving State. Any subsequent out-of-state transfers must obtain the approval from the 19th Judicial Circuit Court, prior to the relocation. Defendant will continue to remain under the jurisdiction of this Court and must continue to comply with all the Lake County Adult Probation Services Division requests and directives.

☐ 36. Upon the approval of the Lake County Adult Probation Services Division and acceptance of the probation supervision by another circuit of Illinois, Defendant may reside in a county (_____) within that circuit. Defendant is responsible for all the Lake County Adult Probation Services Division fees incurred up to the date a transfer is accepted by the receiving circuit and waived thereafter. Defendant will be required to pay probation fees imposed by the receiving circuit. Defendant will continue to remain under the jurisdiction of this Court and must continue to comply with all the Lake County Adult Probation Services Division requests and directives.

☐ 37. Defendant shall comply with a daily curfew of _____ to _____ requiring Defendant to be in his/her residence except when performing probation obligations, attending treatment, working at employment approved by Probation Officer, attending court, or attending to other specific activities which have been approved in advance by his/her Probation Officer. The Defendant's Probation Officer may lessen or reinstate this curfew based upon Defendant's compliance and performance.

☒ 38. Defendant shall follow and comply with all of the additional terms and conditions of the following specialized probation supervision units as set forth in **Exhibit B** which is attached hereto and incorporated by reference:

☐ Domestic Violence Unit

☐ Sex Offender Unit

☒ DUI Unit

☐ 39. Defendant shall follow and comply with all of the additional terms and conditions of the following Therapeutic Intensive Monitoring (TIM) Court specialized probation set forth in **Exhibit B** which is attached hereto and incorporated by reference:

☐ TIM Drug Court

☐ TIM Mental Health Court

☐ TIM Veterans Treatment and Assistance Court

Additionally, Defendant must follow, comply and complete all of the obligations undertaken by him/her in the Specialty Court Contract which is attached to and incorporated into both **Exhibit B** and this Probation Order by reference.

☒ 40. Defendant shall also comply with **OTHER** requirements as follows: _____

All fines and court assessments to be paid within 24 hours of plea being accepted

Defendant shall have a BAIID installed in his vehicle and may not operate any vehicle without a BAIID

☒ 41. If the sentence is to supervised supervision, upon successful completion Defendant shall be discharged and the charges dismissed without further order of the Court.

☒ 42. Probation will terminate and the Circuit Clerk shall transfer the case to closed status on August 23, 2024 unless there is pending an unresolved petition to revoke probation or this order has been otherwise modified or extended.

☒ 43. The Clerk of this Court is directed to make all notifications and take all actions as required by law.

ENTER:

_____
JUDGE

Dated this _____ day of _____, 20____

Order prepared by Lawrence R. Lehuzenne

I, the above-named Defendant, acknowledge reading and receipt of this document.

I understand and have been advised in open court that if I am not a citizen of the United States, that a conviction or a sentence of supervision or probation for the offense for which I have been charged may have the consequences of deportation, exclusion from admission to the United States, or denial of naturalization under the laws of the United States.

I understand that any individual convicted of domestic battery may be subject to federal criminal penalties for possessing, transporting, shipping, or receiving any firearm or ammunition in violation of the federal Gun Control Act of 1968 [18 U.S.C. 922(g)(8) and (9)].

I understand that upon a finding of any violation of a condition contained in this Order or accompanying Exhibits, and after due notice and hearing, the Court may revoke this sentence, enter judgment of conviction and impose any penalty originally provided for by applicable statute or ordinance including a jail sentence.

I UNDERSTAND THAT FAILURE TO APPEAR IN COURT WHEN REQUIRED CONSTITUTES A **WAIVER** OF MY RIGHT TO CONFRONT WITNESSES AGAINST ME, AND A HEARING TO REVOKE MY SENTENCE CAN PROCEED IN MY ABSENCE AND RESULT IN RE-SENTENCING **WITHOUT MY BEING PRESENT.**

Street Address: [redacted]

City/State/Zip: [redacted]

Telephone No.: [redacted]

Date of Birth: [redacted]

_____
Defendant

This is in response to Question # 5

Fill in this information to identify your case:

United States Bankruptcy Court for the:

DISTRICT OF DELAWARE

Case number *(if known)* _____ Chapter 11

☐ Check if this an amended filing

Official Form 201

Voluntary Petition for Non-Individuals Filing for Bankruptcy

06/22

If more space is needed, attach a separate sheet to this form. On the top of any additional pages, write the debtor's name and the case number (if known). For more information, a separate document, *Instructions for Bankruptcy Forms for Non-Individuals,* is available.

1. Debtor's name Optio Rx, LLC

2. All other names debtor used in the last 8 years

Include any assumed names, trade names and *doing business as* names

3. Debtor's federal Employer Identification Number (EIN) 82-5158436

4. Debtor's address

Principal place of business

3701 Commercial Avenue
Suite 14
Northbrook, IL 60062
Number, Street, City, State & ZIP Code

Cook
County

Mailing address, if different from principal place of business

P.O. Box, Number, Street, City, State & ZIP Code

Location of principal assets, if different from principal place of business

Number, Street, City, State & ZIP Code

5. Debtor's website (URL) www.optiorx.com

6. Type of debtor

■ Corporation (including Limited Liability Company (LLC) and Limited Liability Partnership (LLP))

☐ Partnership (excluding LLP)

☐ Other. Specify: _____

Debtor **Optio Rx, LLC** Case number (*if known*) _____
Name

7. Describe debtor's business

A. *Check one:*

- ☐ Health Care Business (as defined in 11 U.S.C. § 101(27A))
- ☐ Single Asset Real Estate (as defined in 11 U.S.C. § 101(51B))
- ☐ Railroad (as defined in 11 U.S.C. § 101(44))
- ☐ Stockbroker (as defined in 11 U.S.C. § 101(53A))
- ☐ Commodity Broker (as defined in 11 U.S.C. § 101(6))
- ☐ Clearing Bank (as defined in 11 U.S.C. § 781(3))
- ■ None of the above

B. *Check all that apply*

- ☐ Tax-exempt entity (as described in 26 U.S.C. §501)
- ☐ Investment company, including hedge fund or pooled investment vehicle (as defined in 15 U.S.C. §80a-3)
- ☐ Investment advisor (as defined in 15 U.S.C. §80b-2(a)(11))

C. NAICS (North American Industry Classification System) 4-digit code that best describes debtor. See http://www.uscourts.gov/four-digit-national-association-naics-codes.

4242

8. Under which chapter of the Bankruptcy Code is the debtor filing?

A debtor who is a "small business debtor" must check the first sub-box. A debtor as defined in § 1182(1) who elects to proceed under subchapter V of chapter 11 (whether or not the debtor is a "small business debtor") must check the second sub-box.

Check one:

- ☐ Chapter 7
- ☐ Chapter 9
- ■ Chapter 11. *Check all that apply:*
  - ☐ The debtor is a small business debtor as defined in 11 U.S.C. § 101(51D), and its aggregate noncontingent liquidated debts (excluding debts owed to insiders or affiliates) are less than $3,024,725. If this sub-box is selected, attach the most recent balance sheet, statement of operations, cash-flow statement, and federal income tax return or if any of these documents do not exist, follow the procedure in 11 U.S.C. § 1116(1)(B).
  - ☐ The debtor is a debtor as defined in 11 U.S.C. § 1182(1), its aggregate noncontingent liquidated debts (excluding debts owed to insiders or affiliates) are less than $7,500,000, **and it chooses to proceed under Subchapter V of Chapter 11.** If this sub-box is selected, attach the most recent balance sheet, statement of operations, cash-flow statement, and federal income tax return, or if any of these documents do not exist, follow the procedure in 11 U.S.C. § 1116(1)(B).
  - ■ A plan is being filed with this petition.
  - ☐ Acceptances of the plan were solicited prepetition from one or more classes of creditors, in accordance with 11 U.S.C. § 1126(b).
  - ☐ The debtor is required to file periodic reports (for example, 10K and 10Q) with the Securities and Exchange Commission according to § 13 or 15(d) of the Securities Exchange Act of 1934. File the *Attachment to Voluntary Petition for Non-Individuals Filing for Bankruptcy under Chapter 11* (Official Form 201A) with this form.
  - ☐ The debtor is a shell company as defined in the Securities Exchange Act of 1934 Rule 12b-2.
- ☐ Chapter 12

9. Were prior bankruptcy cases filed by or against the debtor within the last 8 years?

If more than 2 cases, attach a separate list.

- ■ No.
- ☐ Yes.

District _____ When _____ Case number _____
District _____ When _____ Case number _____

Debtor **Optio Rx, LLC** Name

Case number (*if known*) _____

10. Are any bankruptcy cases pending or being filed by a business partner or an affiliate of the debtor?

☐ No
■ Yes.

List all cases. If more than 1, attach a separate list

Debtor **See Attached Schedule** Relationship _____

District _____ When _____ Case number, if known _____

11. Why is the case filed in *this district?*

Check all that apply:

■ Debtor has had its domicile, principal place of business, or principal assets in this district for 180 days immediately preceding the date of this petition or for a longer part of such 180 days than in any other district.

☐ A bankruptcy case concerning debtor's affiliate, general partner, or partnership is pending in this district.

12. Does the debtor own or have possession of any real property or personal property that needs immediate attention?

■ No
☐ Yes. Answer below for each property that needs immediate attention. Attach additional sheets if needed.

Why does the property need immediate attention? (*Check all that apply.*)

☐ It poses or is alleged to pose a threat of imminent and identifiable hazard to public health or safety.
What is the hazard? _____

☐ It needs to be physically secured or protected from the weather.

☐ It includes perishable goods or assets that could quickly deteriorate or lose value without attention (for example, livestock, seasonal goods, meat, dairy, produce, or securities-related assets or other options).

☐ Other _____

Where is the property? _____
Number, Street, City, State & ZIP Code

Is the property insured?

☐ No
☐ Yes. Insurance agency _____
Contact name _____
Phone _____

Statistical and administrative information

13. Debtor's estimation of available funds

Check one:

■ Funds will be available for distribution to unsecured creditors.

☐ After any administrative expenses are paid, no funds will be available to unsecured creditors.

14. Estimated number of creditors

☐ 1-49	☐ 1,000-5,000	☐ 25,001-50,000
☐ 50-99	☐ 5001-10,000	☐ 50,001-100,000
☐ 100-199	☐ 10,001-25,000	☐ More than100,000
■ 200-999		

15. Estimated Assets

☐ $0 - $50,000	☐ $1,000,001 - $10 million	☐ $500,000,001 - $1 billion
☐ $50,001 - $100,000	■ $10,000,001 - $50 million	☐ $1,000,000,001 - $10 billion
☐ $100,001 - $500,000	☐ $50,000,001 - $100 million	☐ $10,000,000,001 - $50 billion
☐ $500,001 - $1 million	☐ $100,000,001 - $500 million	☐ More than $50 billion

Debtor **Optio Rx, LLC** Case number (*if known*) _____
Name

16. Estimated liabilities

☐ $0 - $50,000	☐ $1,000,001 - $10 million	☐ $500,000,001 - $1 billion
☐ $50,001 - $100,000	☐ $10,000,001 - $50 million	☐ $1,000,000,001 - $10 billion
☐ $100,001 - $500,000	☐ $50,000,001 - $100 million	☐ $10,000,000,001 - $50 billion
☐ $500,001 - $1 million	■ $100,000,001 - $500 million	☐ More than $50 billion

Debtor **Optio Rx, LLC** Case number (*if known*)
Name

Request for Relief, Declaration, and Signatures

WARNING -- Bankruptcy fraud is a serious crime. Making a false statement in connection with a bankruptcy case can result in fines up to $500,000 or imprisonment for up to 20 years, or both. 18 U.S.C. §§ 152, 1341, 1519, and 3571.

17. Declaration and signature of authorized representative of debtor

The debtor requests relief in accordance with the chapter of title 11, United States Code, specified in this petition.

I have been authorized to file this petition on behalf of the debtor.

I have examined the information in this petition and have a reasonable belief that the information is true and correct.

I declare under penalty of perjury that the foregoing is true and correct.

Executed on **June 7, 2024**
MM / DD / YYYY

X **/s/ Leo LaFranco**
Signature of authorized representative of debtor

Leo LaFranco
Printed name

Title **Chief Financial Officer**

18. Signature of attorney

X **/s/ William E. Chipman, Jr.**
Signature of attorney for debtor

Date **June 7, 2024**
MM / DD / YYYY

William E. Chipman, Jr.
Printed name

Chipman Brown Cicero & Cole, LLP
Firm name

Hercules Plaza
1313 North Market Street, Suite 5400
Wilmington, DE 19801
Number, Street, City, State & ZIP Code

Contact phone **(302) 295-0191** Email address **chipman@chipmanbrown.com**

3818 DE
Bar number and State

4.	Pet Apothecary LLC	83-2024315	Delaware
5.	The Pet Apothecary LLC	39-1956074	Wisconsin
6.	Crestview Holdings, LLC	83-2511907	Delaware
7.	Crestview Pharmacy, LLC	59-3718091	Florida
8.	Dr. Ike's PharmaCare LLC	83-3812237	Delaware
9.	Enovex Pharmacy LLC	83-3830693	Delaware
10.	H&H Pharmacy LLC	83-3856793	Delaware
11.	SMC Pharmacy LLC	83-3145428	Delaware
12.	SMC Lyons Holdings LLC	83-3185441	Delaware
13.	SBH Medical LLC	84-2663260	Delaware
14.	SBH Medical, Ltd.	31-1763230	Ohio
15.	Rose Pharmacy RM LLC	84-4544205	Delaware
16.	Rose Pharmacy SA LLC	84-4505738	Delaware
17.	Rose Pharmacy SF LLC	84-4501438	Delaware
18.	Baybridge Pharmacy, LLC	84-3875518	Delaware
19.	Central Pharmacy, LLC	84-3906195	Delaware
20.	Pro Pharmacy, LLC	84-3916299	Delaware
21.	Healthy Choice Compounding LLC	38-3678770	New York
22.	Healthy Choice Compounding LLC	85-2021745	Delaware
23.	Oakdell Compounding Pharmacy LLC	74-2387537	Texas

	DEBTOR'S NAME	DEBTOR'S EIN	STATE OF INC.
24.	Concierge Pharmacy LLC	30-0975410	California
25.	Firstcare Pharmacy LLC	47-5351203	California
26.	Easycare Pharmacy LLC	81-2809408	California
27.	Primecare Pharmacy LLC	47-5117645	California

IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE

In re:	Chapter 11
Optio Rx, LLC, *et al.*,	Case No. 24-xxxxx (xxx)
Debtors.[1]	(*Joint Administration Pending*)

DEBTORS' CONSOLIDATED CORPORATE OWNERSHIP STATEMENT AND LIST OF EQUITY INTEREST HOLDERS PURSUANT TO FED. R. BANKR. P. 1007(a)(1), 1007(a)(3), AND 7007.1

Pursuant to Rules 1007(a)(1), 1007(a)(3), and 7007.1 of the Federal Rules of Bankruptcy Procedure (the "**Bankruptcy Rules**"), the above-captioned debtor and its debtor affiliates, as debtors and debtors in possession (each, a "**Debtor**" and, collectively, the "**Debtors**"), to the best of their knowledge, information, and belief, hereto state as follows:

1. Debtor Optio Rx, LLC is wholly owned by CBC Pharma HoldCo, LLC.

2. Each remaining Debtor is wholly owned by its respective parent entity that holds 100% of such Debtor's membership interests. The remaining Debtors in these chapter 11 cases are listed with their respective parent entities, together with the nature of their equity interests, in the following table:

[1] The Debtors in these chapter 11 cases, along with the last four digits of their respective tax identification numbers, are as follows: (1) Optio Rx, LLC (8436); (2) Braun Pharma, LLC (6643); (3) Dr. Ike's PharmaCare LLC (2237); (4) Rose Pharmacy SA LLC (5738); (5) Rose Pharmacy SF LLC (1438); (6) Rose Pharmacy RM LLC (4205); (7) Pet Apothecary LLC (4315); (8) Crestview Holdings, LLC (1907); (9) SBH Medical, LLC (3260); (10) H&H Pharmacy LLC (6793); (11) Enovex Pharmacy LLC (0693); (12) SMC Pharmacy LLC (5428); (13) SMC Lyons Holdings LLC (5441); (14) Baybridge Pharmacy, LLC (5518); (15) Central Pharmacy, LLC (6195); (16) Pro Pharmacy, LLC (6299); (17) Healthy Choice Compounding LLC (8770); (18) Healthy Choice Compounding LLC (1745); (19) Oakdell Compounding Pharmacy LLC (7537); (20) The Pet Apothecary, LLC (6074); (21) Crestview Pharmacy, LLC (8091); (22) SBH Medical, Ltd. (3230); (23) Concierge Pharmacy LLC (5410); (24) Firstcare Pharmacy, LLC (1203); (25) Easycare Pharmacy LLC (9408); (26) Primecare Pharmacy LLC (7645); and (27) HCP Pharmacy LLC (5216). The address of the Debtors' corporate headquarters is 3701 Commercial Avenue, Suite 14, Northbrook, Illinois 60062.

DEBTOR	KIND/CLASS OF INTEREST (MEMBER INTEREST)	NAME OF INTEREST HOLDER & PERCENTAGE OF INTERESTS HELD
Optio Rx, LLC	Membership Interests	100% owned by: CBC Pharma HoldCo, LLC 1420 Kensington Rd, Suite 102 Oak Brook, IL 60523-2143
Braun Pharma, LLC	Membership Interests	100% owned by Optio Rx, LLC
HCP Pharmacy LLC	Membership Interests	100% owned by Optio Rx, LLC
Pet Apothecary LLC	Membership Interests	100% owned by Optio Rx, LLC
The Pet Apothecary LLC	Membership Interests	100% owned by Pet Apothecary LLC
Crestview Holdings, LLC	Membership Interests	100% owned by Optio Rx, LLC
Crestview Pharmacy, LLC	Membership Interests	100% owned by Crestview Holdings, LLC
Dr. Ike's PharmaCare LLC	Membership Interests	100% owned by Optio Rx, LLC
Enovex Pharmacy LLC	Membership Interests	100% owned by Optio Rx, LLC
H&H Pharmacy LLC	Membership Interests	100% owned by Optio Rx, LLC
SMC Pharmacy LLC	Membership Interests	100% owned by Optio Rx, LLC
SMC Lyons Holdings LLC	Membership Interests	100% owned by Optio Rx, LLC
Concierge Pharmacy LLC	Membership Interests	100% owned by SMC Lyons Holdings LLC
FirstCare Pharmacy LLC	Membership Interests	100% owned by SMC Lyons Holdings LLC
Easycare Pharmacy LLC	Membership Interests	100% owned by SMC Lyons Holdings LLC
Primecare Pharmacy LLC	Membership Interests	100% owned by SMC Lyons Holdings LLC
SBH Medical LLC	Membership Interests	100% owned by Optio Rx, LLC
SBH Medical, Ltd.	Membership Interests	100% owned by SBH Medical LLC
Rose Pharmacy RM LLC	Membership Interests	100% owned by Optio Rx, LLC

DEBTOR	KIND/CLASS OF INTEREST (MEMBER INTEREST)	NAME OF INTEREST HOLDER & PERCENTAGE OF INTERESTS HELD
Rose Pharmacy SA LLC	Membership Interests	100% owned by Optio Rx, LLC
Rose Pharmacy SF LLC	Membership Interests	100% owned by Optio Rx, LLC
Baybridge Pharmacy, LLC	Membership Interests	100% owned by Optio Rx, LLC
Central Pharmacy, LLC	Membership Interests	100% owned by Optio Rx, LLC
Pro Pharmacy, LLC	Membership Interests	100% owned by Optio Rx, LLC
Healthy Choice Compounding LLC[2]	Membership Interests	100% owned by Optio Rx, LLC
Healthy Choice Compounding LLC[3]	Membership Interests	100% owned by Healthy Choice Compounding LLC[4]
Oakdell Compounding Pharmacy LLC	Membership Interests	100% owned by Optio Rx, LLC

[2] Healthy Choice Compounding LLC, a Delaware limited liability company.
[3] Healthy Choice Compounding LLC, a New York limited liability company.
[4] Healthy Choice Compounding LLC, a Delaware limited liability company.

Fill in this information to identify the case:

Debtor name Optio Rx, LLC

United States Bankruptcy Court for the: _____ District of Delaware (State)

Case number (If known): _____

☐ Check if this is an amended filing

Official Form 204

Chapter 11 or Chapter 9 Cases: List of Creditors Who Have the 30 Largest Unsecured Claims and Are Not Insiders

12/15

A list of creditors holding the 30 largest unsecured claims must be filed in a Chapter 11 or Chapter 9 case. Include claims which the debtor disputes. Do not include claims by any person or entity who is an *insider*, as defined in 11 U.S.C. § 101(31). Also, do not include claims by secured creditors, unless the unsecured claim resulting from inadequate collateral value places the creditor among the holders of the 30 largest unsecured claims.

	Name of creditor and complete mailing address, including zip code	Name, telephone number, and email address of creditor contact	Nature of the claim (for example, trade debts, bank loans, professional services, and government contracts)	Indicate if claim is contingent, unliquidated, or disputed	Amount of unsecured claim If the claim is fully unsecured, fill in only unsecured claim amount. If claim is partially secured, fill in total claim amount and deduction for value of collateral or setoff to calculate unsecured claim.		
					Total claim, if partially secured	Deduction for value of collateral or setoff	Unsecured Claim
1	**Aves Management LLC** 150 North Riverside Plaza Ste 5200 Chicago, IL 60606	P: 312-705-0754 F: finance@avescap.com	Subordinated Noteholders				**$73,809,453.52**
2	**Baybridge** 1981 Marcus Ave Ste C129 New Hyde Park, NY 11042	Attn: Greg Savino P: 888-927-3499 F: greg.savino@yahoo.com	Seller Note				**$13,160,000.00**
3	**Pro-Yuriy Davydov** [redacted]	P: F: [redacted]	Seller Note				**$3,810,000.00**
4	**SBH - Rob Hirsch** [redacted]	P: F: [redacted]	Seller Note				**$2,989,900.43**
5	**Healthy Choice** 150 W End Ave Apt 24L New York, NY 10023-5748	Attn: Phil Altman P: F: wholerx.com	Seller Note				**$2,653,285.10**
6	**Pharmcare** 16662 Pineridge Dr Granada Hills, CA 91344-1848	Attn: Ayk Dzhragatspanyan P: 818-419-2514 F:	Seller Note				**$2,643,864.00**
7	**Central-Yuriy Davydov** [redacted]	P: F: [redacted]	Seller Note				**$1,830,000.00**
8	**H&H** 16662 Pineridge Dr Granada Hills, CA 91344-1848	Attn: Ayk Dzhragatspanyan P: 818-419-2514 F:	Seller Note				**$1,519,005.70**

Debtor Optio Rx, LLC
Name

Case number (if known)

	Name of creditor and complete mailing address, including zip code	Name, telephone number, and email address of creditor contact	Nature of the claim (for example, trade debts, bank loans, professional services, and	Indicate if claim is contingent, unliquidated, or disputed	Amount of unsecured claim If the claim is fully unsecured, fill in only unsecured claim amount. If claim is partially secured, fill in total claim amount and deduction for value of collateral or setoff to calculate unsecured claim.		
					Total claim, if partially secured	Deduction for value of collateral or setoff	Unsecured claim
9	**Crestview-Bryan Henderson/Hal Densman** [redacted]	P: F:	Seller Note				**$654,324.00**
10	**Arcutis Biotherapeutics Inc** [redacted]	P: [redacted] F: information@arcutis.com	Trade Vendor				**$586,485.90**
11	**Rose SF-Trang TERI Hoang & Peter Chu (Thang Tat Chu)** [redacted]	P: [redacted] F:	Seller Note				**$514,884.23**
12	**ICS Direct** 12601 Collection Center Drive Chicago, IL 60693	P: F: titlecash@icsconnect.com	Trade Vendor				**$441,954.33**
13	**FFF Enterprises Inc** 44000 Winchester Road Temecula, CA 92590	P: 800-843-7477 F: 800-418-4333 fffinfo@fffenterprises.com; bwemple@fffenterprises.com	Trade Vendor				**$374,471.34**
14	**Mayne Pharma - 128B** PO Box 603644 Charlotte, NC 28260-3644	P: 919-922-0561 F: us.ar.remit@maynepharma.com	Trade Vendor				**$230,544.13**
15	**Troutman Pepper Hamilton Sanders LLP** 1313 Market Street, Suite 5100 Hercules Plaza Wilmington, DE 19801	P: 302-777-6500 F: kathleen.sawyer@troutman.com	Professional Fees	Disputed			**$222,676.20**
16	**Enovex** 16662 Pineridge Dr Granada Hills, CA 91344-1848	Attn: Ayk Dzhragatspanyan P: 818-419-2514 F:	Seller Note				**$181,301.04**
17	**ARL Bio Pharma, Inc.** 840 Research Parkway Oklahoma City, OK 73104	P: 717-829-6448 F: info@arlok.com	Trade Vendor				**$101,544.00**
18	**Virtus Pharmaceuticals LLC** PO Box 947177 Atlanta, GA 30394-7177	P: 267-938-4850 F: 813-283-1354 arcash@eversana.com	Trade Vendor				**$101,430.00**
19	**Oakdell-Jeff Carson** [redacted]	P: [redacted] F: [redacted]	Seller Note				**$78,590.77**
20	**Plante Moran PLLC - 1725** 16060 Collections Center Dr Chicago, IL 60693	P: 248-352-2500 F: 248-352-0018 tom.risi@plantemoran.com	Trade Vendor				**$55,000.00**

	Name of creditor and complete mailing address, including zip code	Name, telephone number, and email address of creditor contact	Nature of the claim (for example, trade debts, bank loans, professional services, and	Indicate if claim is contingent, unliquidated, or disputed	Amount of unsecured claim If the claim is fully unsecured, fill in only unsecured claim amount. If claim is partially secured, fill in total claim amount and deduction for value of collateral or setoff to calculate unsecured claim.		
					Total claim, if partially secured	Deduction for value of collateral or setoff	Unsecured claim
21	**INCYTE** 12601 Collection Center Drive Chicago, IL 60693	P: F: ir@incyte.com	Trade Vendor				**$44,417.52**
22	**BSD Construction, Inc.** 8369 Vickers Street #100 San Diego, CA 92111	P: 858-657-9186 F: 858-657-0914 info@bsdbuilders.com	Trade Vendor				**$34,670.74**
23	**Constangy, Brooks, Smith & Prophete, LLP - 7070** PO Box 102476 Atlanta, GA 30368-0476	P: 404-230-6002 F: nwasser@constangy.com	Trade Vendor				**$32,555.20**
24	**Forte Bio-Pharma LLC - 8744** PO Box 29650 Dept 880412 Phoenix, AZ 85038-9650	P: 833-336-7837 F: 833-336-7837 francisco.torres@fortebiopharma.com	Trade Vendor				**$29,152.06**
25	**Journey Medical Corporation - 5894** 9237 East Via De Ventura Suite 105	P: 973-349-7497 F: journeymedicalar@icsconnect.com	Trade Vendor				**$17,644.32**
26	**PAAS National LLC** 160 Business Park Circle Stoughton, WI 53589	P: 888-870-7227 F: info@paasnational.com	Trade Vendor	Disputed			**$17,089.00**
27	**Medisca Inc** 626 Tom Miller Road Plattsburgh, NY 12901	P: F:	Trade Vendor				**$13,819.53**
28	**FDS, Inc.** 5000 Birch Street, Suite 8500 Newport Beach, CA 92660	P: 949-757-0400 F: 949-757-0404 info@fdsinc.net	Trade Vendor				**$8,488.62**
29	**P.C.C.A., INC** 9901 South Wilcrest Dr Houston, TX 77099	P: 800-331-2498 F: accounting@pccarx.com	Trade Vendor				**$8,345.21**
30	**Amneal Pharmaceuticals** Lockbox #7979 PO Box 7247 Philadelphia, PA 19170-0001	P: 833-289-8559 F: 614-652-8349 accountsreceivable@amneal.com	Trade Vendor				**$7,040.00**

Fill in this information to identify the case:	
Debtor name	**Optio Rx, LLC**
United States Bankruptcy Court for the:	DISTRICT OF DELAWARE
Case number (if known)	

☐ Check if this is an amended filing

Official Form 202

Declaration Under Penalty of Perjury for Non-Individual Debtors 12/15

An individual who is authorized to act on behalf of a non-individual debtor, such as a corporation or partnership, must sign and submit this form for the schedules of assets and liabilities, any other document that requires a declaration that is not included in the document, and any amendments of those documents. This form must state the individual's position or relationship to the debtor, the identity of the document, and the date. Bankruptcy Rules 1008 and 9011.

WARNING – Bankruptcy fraud is a serious crime. Making a false statement, concealing property, or obtaining money or property by fraud in connection with a bankruptcy case can result in fines up to $500,000 or imprisonment for up to 20 years, or both. 18 U.S.C. §§ 152, 1341, 1519, and 3571.

Declaration and signature

I am the president, another officer, or an authorized agent of the corporation; a member or an authorized agent of the partnership; or another individual serving as a representative of the debtor in this case.

I have examined the information in the documents checked below and I have a reasonable belief that the information is true and correct:

- ☐ *Schedule A/B: Assets–Real and Personal Property* (Official Form 206A/B)
- ☐ *Schedule D: Creditors Who Have Claims Secured by Property* (Official Form 206D)
- ☐ *Schedule E/F: Creditors Who Have Unsecured Claims* (Official Form 206E/F)
- ☐ *Schedule G: Executory Contracts and Unexpired Leases* (Official Form 206G)
- ☐ *Schedule H: Codebtors* (Official Form 206H)
- ☐ *Summary of Assets and Liabilities for Non-Individuals* (Official Form 206Sum)
- ☐ Amended *Schedule* _____
- ■ *Chapter 11 or Chapter 9 Cases: List of Creditors Who Have the 20 Largest Unsecured Claims and Are Not Insiders* (Official Form 204)
- ■ Other document that requires a declaration **Debtors' Consolidated Corporate Ownership Statement and List of Equity Interest Holders Pursuant to Fed. R. Bankr. P. 1007(a)(1), 1007(a)(3), and 7007.1**

I declare under penalty of perjury that the foregoing is true and correct.

Executed on **June 7, 2024**

X **/s/ Leo LaFranco**
Signature of individual signing on behalf of debtor

Leo LaFranco
Printed name

Chief Financial Officer
Position or relationship to debtor

RESOLUTIONS OF THE GOVERNING BODIES OF
OPTIO RX, LLC,
BRAUN PHARMA, LLC
HCP PHARMACY LLC,
PET APOTHECARY LLC,
THE PET APOTHECARY, LLC,
CRESTVIEW HOLDINGS, LLC,
CRESTVIEW PHARMACY, LLC,
DR. IKE'S PHARMACARE LLC,
ENOVEX PHARMACY LLC,
H&H PHARMACY LLC,
SMC PHARMACY LLC,
SMC LYONS HOLDINGS LLC,
CONCIERGE PHARMACY LLC,
FIRSTCARE PHARMACY LLC,
EASYCARE PHARMACY LLC,
PRIMECARE PHARMACY LLC,
SBH MEDICAL LLC,
SBH MEDICAL, LTD.,
ROSE PHARMACY RM LLC,
ROSE PHARMACY SA LLC,
ROSE PHARMACY SF LLC,
BAYBRIDGE PHARMACY, LLC,
CENTRAL PHARMACY, LLC,
PRO PHARMACY, LLC,
HEALTHY CHOICE COMPOUNDING LLC,
HEALTHY CHOICE COMPOUNDING LLC, AND
OAKDELL COMPOUNDING PHARMACY LLC

June 7, 2024

WHEREAS, Pharmacy Management LLC ("**Pharmacy Manager**") is the sole manager of Optio Rx, LLC ("**Optio Manager**" or "**Optio Member,**" as applicable);

WHEREAS, Optio Manager is the sole manager of each of Braun Pharma, LLC, an Illinois limited liability company; HCP Pharmacy LLC, a Delaware limited liability company; Pet Apothecary LLC, a Delaware limited liability company ("**Pet Apothecary Member**"); The Pet Apothecary, LLC, a Wisconsin limited liability company; Crestview Holdings, LLC, a Delaware limited liability company ("**Crestview Member**"); Crestview Pharmacy, LLC, a Florida limited liability company; Dr. Ike's Pharmacare LLC, a Delaware limited liability company; Enovex Pharmacy LLC, a Delaware limited liability company; H&H Pharmacy LLC, a Delaware limited liability company; SMC Pharmacy LLC, a Delaware limited liability company; SMC Lyons Holdings LLC, a Delaware limited liability company ("**SMC Member**"); Concierge Pharmacy LLC, a California limited liability company; Firstcare Pharmacy LLC, a California limited liability company; Easycare Pharmacy LLC, a California limited liability company; Primecare Pharmacy LLC, a California limited liability company; SBH Medical LLC, a Delaware limited liability company ("**SBH Member**"); SBH Medical, Ltd., an Ohio limited liability company; Rose

Pharmacy RM LLC, a Delaware limited liability company; Rose Pharmacy SA LLC, a Delaware limited liability company; Rose Pharmacy SF LLC, a Delaware limited liability company; Baybridge Pharmacy, LLC, a Delaware limited liability company; Central Pharmacy, LLC, a Delaware limited liability company; Pro Pharmacy, LLC, a Delaware limited liability company; Healthy Choice Compounding LLC, a Delaware limited liability company ("**Healthy Choice Member**" and together with Optio Member, Pet Apothecary Member, Crestview Member, SMC Member and SBH Member, the "**Authorizing Members**"); Healthy Choice Compounding LLC, a New York limited liability company; and Oakdell Compounding Pharmacy LLC, a Texas limited liability company (collectively, the "**Subsidiaries**" and together with Optio Manager, the "**Companies**");

WHEREAS, the Optio Member is the sole member of Braun Pharma, LLC; HCP Pharmacy, LLC; Pet Apothecary Member; Crestview Member; Dr. Ike's Pharmacare LLC; Enovex Pharmacy LLC; H&H Pharmacy, LLC; SMC Pharmacy LLC; SMC Member; SBH Member; Rose Pharmacy RM LLC; Rose Pharmacy SA LLC; Rose Pharmacy SF LLC; Baybridge Pharmacy, LLC; Central Pharmacy, LLC; Pro Pharmacy, LLC; Healthy Choice Member; and Oakdell Compounding Pharmacy LLC;

WHEREAS, the Pet Apothecary Member is the sole member of The Pet Apothecary, LLC;

WHEREAS, the Crestview Member is the sole member of Crestview Pharmacy, LLC;

WHEREAS, the SMC Member is the sole member of each of Concierge Pharmacy, LLC, Firstcare Pharmacy, LLC, Easycare Pharmacy, LLC and Primecare Pharmacy, LLC;

WHEREAS, the SBH Member is the sole member of SBH Medical, Ltd.;

WHEREAS, the Healthy Choice Member is the sole member of Healthy Choice Compounding LLC;

WHEREAS, Pharmacy Manager, Optio Manager, and the Authorizing Members (collectively, the "**Governing Bodies**") have had the opportunity to consult with the management and the legal and financial advisors of such Company to fully consider, and has considered, each of the strategic alternatives available to such Company;

WHEREAS, each Governing Body desires to approve the following resolutions;

WHEREAS, Section 5.3 of the Operating Agreement of each Company provides that its Manager or Member, as applicable, may act by written consent in lieu of a meeting;

WHEREAS, Sections 18-301(d) and 18-404(d) of the Delaware Limited Liability Company Act; Sections 6.201 and 101.358 of the Texas Business Organizations Code; Sections 407(a) and 408(c) of the New York Limited Liability Law; Section 15-1(e) of the Illinois Limited Liability Company Act; Sections 605.04073(4) and (5) of the Florida Revised Limited Liability Company Act; Section 183.0407(4) of the Wisconsin Uniform Limited Liability Company Law; Section 1104.07(n)(1) of the California Revised Uniform Limited Liability Company Act; and Section 1706.30(D) of the Ohio Revised Limited Liability Company Act provide that members and managers may act by written consent in lieu of a meeting;

WHEREAS, the limited liability company acts of certain states under the laws of which certain Subsidiaries are formed require, or arguably require, member approval to file bankruptcy petitions;

I. CHAPTER 11 FILING

WHEREAS, the Governing Body of each Company, acting in its capacity as a member and/or manager, as applicable, has considered presentations by the management and the financial and legal advisors of such Company regarding the liabilities and liquidity situation of such Company, the strategic alternatives available to it and the effect of the foregoing on such Company's business, creditors, stakeholders and other parties in interest;

WHEREAS, the Governing Body of each Company has had the opportunity to consult with such Company's management and financial and legal advisors and fully consider each of the strategic alternatives available to such Company;

WHEREAS, the Governing Body of each Company, based on its review of all available alternatives and advice provided by such advisors and professionals, has determined that it is advisable and in the best interest of such Company and its stakeholders for such Company to take the actions specified in the following resolutions;

WHEREAS, the Governing Body of each Company has been presented with a proposed voluntary petition (the "**Chapter 11 Petition**") to be filed by such Company in the United States Bankruptcy Court for the District of Delaware (the "**Bankruptcy Court**") seeking relief under the provisions of Chapter 11 of title 11 of the United States Code (the "**Bankruptcy Code**"), in which the authority to operate as a debtor-in-possession will be sought;

WHEREAS, the Governing Body of each Company has had the opportunity to consult with the management and the legal and financial advisors of such Company regarding the material terms of the "first day" pleadings, applications, affidavits and other documents, in each case, in form and substance substantially similar to the form provided to the Governing Bodies as of the date hereof (collectively, the "**Chapter 11 Filings**") to be filed by such Company before the Bankruptcy Court in connection with the commencement of such Company's Chapter 11 case (the "**Bankruptcy Case**"); and

WHEREAS, the Governing Body of each Company, having considered the financial and operational aspects of such Company's business and the best course of action to maximize value, have determined that it is advisable and in the best interest of such Company, its creditors, stakeholders and other interested parties that the Chapter 11 Petition be filed by such Company seeking relief under the provisions of Chapter 11 of the Bankruptcy Code.

NOW, THEREFORE, BE IT RESOLVED, that in the judgment of the Governing Body of each Company, it is advisable and in the best interest of such Company, its creditors, stakeholders and other interested parties, that the Chapter 11 Petition and the Chapter 11 Filings be filed by such Company seeking relief under the provisions of Chapter 11 of the Bankruptcy Code, and the filing of such Chapter 11 Petition and Chapter 11 Filings is authorized hereby; and be it further

RESOLVED, that any officer of each Company or its sole member or sole manager, as applicable (each an "**Authorized Person**"), in each case, be, and each hereby is, authorized, empowered and directed, on behalf of and in the name of such Company, to execute and verify the Chapter 11 Petition and the Chapter 11 Filings in the name of such Company under Chapter 11 of the Bankruptcy Code and to cause the same to be filed in the Bankruptcy Court in such form and at such time as the Authorized Person(s) executing said Chapter 11 Petition and Chapter 11 Filings on behalf of such Company shall determine.

II. PLAN OF REORGANIZATION AND DISCLOSURE STATEMENT

WHEREAS, the Governing Body of each Company has had the opportunity to consult with the management and legal and financial advisors of such Company regarding the material terms of a proposed plan of reorganization (the "**Plan**") pursuant to which such Company would, among other things, implement a reorganization of such Company's liabilities and emerge from its Bankruptcy Case;

WHEREAS, the Governing Body of each Company has had the opportunity to consult with the management and the legal and financial advisors of such Company regarding the material terms of a proposed Disclosure Statement (the "**Disclosure Statement**") accompanying the Plan and the contents and disclosures thereof; and

WHEREAS, the Governing Body of each Company has determined that it is advisable and in the best interest of such Company, its creditors, stakeholders and other interested parties that such Company, in furtherance of a reorganization of such Company's liabilities and emergence from Chapter 11, file the Plan and Disclosure Statement with the Bankruptcy Court and to solicit acceptances and approvals thereof.

NOW, THEREFORE, BE IT RESOLVED, that the Governing Body of each Company adopts, ratifies, confirms and approves the form, terms and provisions of, and each of the transactions contemplated by the Plan and the Disclosure Statement, as each may be amended or modified from time to time; and be it further

RESOLVED, that each Company's advisors be, and each hereby is, authorized, empowered and directed, on behalf of an in the name of such Company, to prepare, finalize and file, as appropriate, procedures for the solicitation and tabulation of votes to accept or reject the Plan.

III. DIP FINANCING

WHEREAS, the Governing Body of each Company has determined that, in connection with the Bankruptcy Case, it is desirable and in the best interest of such Company, its creditors, stakeholders, and other interested parties to request that one or more potential financing sources provide such Company with post-petition debtor-in-possession financing, including, but not limited to, a multi-draw term loan facility of $10,000,000.00 (collectively "**DIP Financing**"), subject to exceptions and limitations to be set forth in any orders of the Bankruptcy Court concerning any of the DIP Financing (the "**DIP Financing Orders**");

WHEREAS, the Governing Body of each Company has been presented with and has reviewed the terms and provisions of a definitive senior secured super-priority debtor-in-possession credit agreement (the "**DIP Financing Agreement**") by and among such Company and certain of its affiliates, as debtors-in-possession, and Funds and vehicles managed by (i) MC Credit Partners LP and (ii) CION Investment Corporation, as First Out Holders under the Prepetition Credit Agreement, and Caprice Capital Partners, LLC (collectively, with the other lenders contemplated by the DIP Financing Agreement, the "**DIP Lenders**") pursuant to which the DIP Lenders have agreed to provide such Company with DIP Financing, which provides for the borrowing and reborrowing of loans, guaranteeing of obligations, granting of security and the pledging of collateral;

WHEREAS, in connection with the DIP Financing Agreement, the DIP Lenders require that each Company grant security interests in substantially all of its assets that now or hereafter come into the possession, custody or control of such Company, in order to secure the prompt and complete payment, observance, and performance of all obligations under the DIP Financing Agreement, subject to exceptions and limitations to be set forth in DIP Financing Orders and related documents contemplated thereunder (collectively, the "**DIP Documents**"); and

WHEREAS, the Governing Body of each Company has determined that it is in the best interests of such Company, its creditors, stakeholders, and other interested parties, for such Company to (i) consummate the transactions contemplated by the DIP Financing Agreement provided to the Governing Body of such Company, and (ii) empower, authorize and direct the Authorized Persons of such Company to take any and all actions as may be deemed appropriate to effect and perform the transactions contemplated thereby.

NOW, THEREFORE, BE IT RESOLVED, that the form, terms and provisions of the DIP Financing Agreement are hereby, in all respects, authorized, ratified, approved and adopted by the Governing Body of each Company on behalf of such Company; and it be further

RESOLVED, that each Company be, and hereby is, authorized to incur and to undertake any and all related transactions contemplated under the DIP Financing Agreement and the DIP Documents; and it be further

RESOLVED, that Optio Manager be, and hereby is, authorized to borrow and reborrow loans, guaranty obligations, grant security interests in collateral and pledge collateral pursuant to, and in accordance with, the DIP Documents; and it be further

RESOLVED, that each Company be, and hereby is, authorized to guaranty obligations, grant security interests in collateral and pledge collateral pursuant to, and in accordance with, the DIP Documents; and it be further

RESOLVED, that the Authorized Persons be, and each of them hereby is, empowered, authorized and directed, with full power of delegation, on behalf of and in the name of such Company, to cause such Company to negotiate, execute and deliver the DIP Financing Agreement and the related documents contemplated thereby, in such form and with such changes or amendments (substantial or otherwise) thereto as any one or more of such Authorized Persons may

deem necessary, desirable or appropriate, in order to consummate the transactions contemplated by the DIP Financing Agreement; and it be further

RESOLVED, that the Authorized Persons be, and each of them hereby is, empowered, authorized and directed, with full power of delegation, on behalf of and in the name of such Company, to take all such further actions which shall be necessary, proper or advisable to perform such Company's obligations under or in connection with the DIP Financing Agreement, the DIP Documents and the transactions contemplated therein, and to carry out fully the intent of the foregoing resolutions.

IV. RETENTION OF PROFESSIONALS

RESOLVED, that the Authorized Persons be, and each hereby is empowered, authorized and directed, on behalf of and in the name of such Company, to continue to retain and employ the law firm of Chipman Brown Cicero & Cole, LLP ("**CBCC**"), as general bankruptcy counsel, to represent and assist such Company in carrying out its duties under the Bankruptcy Code, and to take any and all actions to advance such Company's rights and obligations, including filing any motions, objections, replies, applications, or pleadings in the Bankruptcy Case and all other related matters in connection therewith, in such capacities and on such terms as the Authorized Persons of such Company, and each of them, may or shall approve and/or have previously approved; and be it further

RESOLVED, that the Authorized Persons be, and each hereby is empowered, authorized and directed, on behalf of and in the name of such Company, to continue to retain Paladin Management Group, LLC ("**Paladin**") to serve as financial advisor to such Company, and (iii) Stretto ("**Stretto**") to provide consulting services to such Company regarding noticing, claims management and reconciliation, plan solicitation, balloting, disbursements, and any other services agreed to by the parties; and be it further

RESOLVED, that the Authorized Persons be, and each hereby is, empowered, authorized and directed, on behalf of and in the name of such Company, to continue the employment and retention of professionals in the ordinary course as long as they deem appropriate and in the Bankruptcy Case to retain and employ other attorneys, accountants, and other professionals to assist in such Company's Bankruptcy Case on such terms as are deemed necessary, appropriate or advisable; and be it further

RESOLVED, that the Authorized Persons be, and each hereby is, authorized and directed, on behalf of and in the name of such Company, to execute any appropriate engagement letters and agreements and such other documents necessary to retain or continue to retain CBCC, Paladin, and Stretto, and any other or additional financial advisors, investment bankers, accountants, auditors, advisors, legal counsel, and other professionals not specifically identified herein (the "**Professionals**"), and to cause such Company to pay appropriate retainers to such Professionals prior to the filing of the Bankruptcy Case or after to the extent appropriate and permitted in the Bankruptcy Case, and to cause to be filed appropriate applications or motions seeking authority to retain and pay for the services of such Professionals; and be it further

RESOLVED, that the Authorized Persons be, and each hereby is, authorized and directed, on behalf of and in the name of such Company, to pay, or cause to be paid, all fees and expenses incurred by such Company in connection with services rendered by the Professionals and to make, or cause to be made, all payments as they, or any of them individually, shall determine to be necessary, appropriate or advisable, such payment to be conclusive evidence of their determination; and be it further

V. GENERAL

RESOLVED, that Jarlath Johnston is hereby authorized to execute these resolutions on behalf of Optio Rx, LLC in its capacity as Optio Manager and Optio Member;

RESOLVED, that the Authorized Persons be, and each hereby is, authorized, empowered and directed, on behalf of and in the name of such Company, to amend, supplement or otherwise modify from time to time the terms of any documents, certificates, instruments, agreements, financing statements, notices, undertakings or other writings referred to in the foregoing resolutions; and be it further

RESOLVED, that the Authorized Persons be, and each hereby is, authorized, empowered and directed, on behalf of and in the name of such Company, to take or cause to be taken any and all such further action and to execute, deliver, perform, verify and/or file, or cause to be executed, delivered, performed, verified and/or filed (or direct others to do so on its behalf as provided herein) all such further documents, agreements, instruments, financing statements, notices, undertakings, certificates, resolutions and other writings as they or any of them deem necessary, desirable or appropriate to effectuate the purpose and intent of any and all of the foregoing resolutions, the necessity, desirability, and appropriateness of which shall be conclusively evidenced by the action in support thereof, or the execution and delivery thereof, by such Authorized Persons (or such persons directed by such Authorized Persons); and be it further

RESOLVED, that all acts lawfully done or actions lawfully taken by any Authorized Person to seek relief on behalf of such Company under Chapter 11 of the Bankruptcy Code, or in connection with the Bankruptcy Case, or any matter related thereto, be, and hereby are, adopted, ratified, confirmed and approved in all respects as the acts and deeds of such Company in all respects by the Governing Body of such Company; and be it further

RESOLVED, that all acts lawfully done or actions lawfully taken by any Authorized Person, or by any employees or agents of such Company, on or before the date hereof in connection with the transactions contemplated by the foregoing resolutions be, and hereby are, authorized, adopted, ratified, confirmed and approved in all respects by the Governing Body of such Company; and be it further

RESOLVED, that the omission from these resolutions of any agreement, document or other arrangement contemplated by any of the agreements, instruments, filings or other documents described in the foregoing resolutions or any action to be taken in accordance with any requirement of any of the agreements, instruments, filings or other documents described in the foregoing resolutions shall in no manner derogate from the authority of the Authorized Persons to take all actions necessary, appropriate or advisable to consummate, effectuate, carry out or further the

transaction contemplated by, and the intent and purposes of, the foregoing resolutions, the necessity, appropriateness, and advisability, of which shall be conclusively evidenced by the execution and delivery thereof, or action in support thereof, by such Authorized Person; and be it further

RESOLVED, that the Governing Body of such Company has received sufficient notice of the actions and transactions relating to the matters contemplated by the foregoing resolutions, as may be required by the organizational documents of such Company, or hereby waive any right to have received such notice; and be it further

RESOLVED, that the Authorized Persons be, and each hereby is, authorized, empowered and directed, on behalf of and in the name of such Company, to execute, deliver, perform, verify and/or file, or cause to be executed, delivered, performed, verified and/or filed (or direct others to do so on their behalf as provided herein) all necessary documents, including, without limitation, all petitions, affidavits, statements, schedules, motions, lists, applications, pleadings, other papers, guarantees, reaffirmations, additional security documents, control agreements, waivers of or amendments to existing documents, and to negotiate the forms, terms and provisions of, and to execute and deliver any amendments, modifications, waivers or consent to any of the foregoing as may be approved by any Authorized Person, which amendments, modifications, waivers or consents may provide for consent payments, fees or other amounts payable or other modifications of or relief under such agreements or documents, the purpose of such amendments, modifications, waivers or consents being to facilitate consummation of the transactions contemplated by the foregoing resolutions or for any other purpose, and, in connection with the foregoing, to employ and retain all assistance by legal counsel, investment bankers, accountants, restructuring professionals or other professionals, and to take any and all action which such Authorized Person or Authorized Persons deem necessary, appropriate or advisable in connection with the Bankruptcy Case, and the DIP Financing, with a view to the successful prosecution of the Bankruptcy Case contemplated by the foregoing resolutions and the successful consummation of the transactions contemplated by the foregoing resolutions including, without limitation, any action necessary, appropriate, or advisable to maintain the ordinary course operation of such Company's business; and be it further

RESOLVED, that the Authorized Persons be, and each hereby is, authorized, empowered and directed, on behalf of and in the name of such Company, to execute, deliver and perform any and all special powers of attorney as such Authorized Person may deem necessary, appropriate or advisable to facilitate consummation of the transactions contemplated by the foregoing resolutions, pursuant to which such Authorized Person will make certain appointments of attorneys to facilitate consummation of the transactions contemplated by the foregoing resolutions as such Company's true and lawful attorneys and authorize each such attorney to execute and deliver any and all documents of whatsoever nature and description that may be necessary, appropriate or advisable to facilitate consummation of the transactions contemplated by the foregoing resolutions.

[Signature Page Follows]

IN WITNESS WHEREOF, the undersigned have executed this written consent as of the date first set forth above.

PHARMACY MANAGEMENT LLC,
in its capacity as manager of Optio Rx, LLC

By: its Board of Managers

Jarlath A. Johnston

Jarlath Johnston

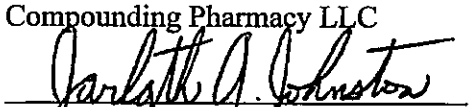
IN WITNESS WHEREOF, the undersigned has executed this written consent as of the date first set forth above.

OPTIO RX, LLC, in its capacity as Manager of each Subsidiary

By: Jarlath Johnston
Its: Authorized Signatory

IN WITNESS WHEREOF, the undersigned has executed this written consent as of the date first set forth above.

OPTIO RX, LLC, in its capacity as Sole Member of each of Braun Pharma, LLC; HCP Pharmacy LLC; Pet Apothecary LLC; Crestview Holdings, LLC; Dr. Ike's Pharmacare LLC; Enovex Pharmacy LLC; H&H Pharmacy LLC; SMC Pharmacy LLC; SMC Lyons Holdings LLC; SBH Medical LLC; Rose Pharmacy RM LLC; Rose Pharmacy SA LLC; Rose Pharmacy SF LLC; Baybridge Pharmacy, LLC; Central Pharmacy, LLC; Pro Pharmacy, LLC; Healthy Choice Compounding LLC; and Oakdell Compounding Pharmacy LLC



By: Jarlath Johnston
Its: Authorized Signatory

IN WITNESS WHEREOF, the undersigned has executed this written consent as of the date first set forth above.

PET APOTHECARY LLC, in its capacity as Sole Member of The Pet Apothecary, LLC

By: Optio Rx, LLC
Its: Manager

By: Jarlath Johnston
Its: Authorized Signatory

IN WITNESS WHEREOF, the undersigned has executed this written consent as of the date first set forth above.

CRESTVIEW HOLDINGS, LLC, in its capacity as Sole Member of Crestview Pharmacy, LLC

By: Optio Rx, LLC
Its: Manager

By: Jarlath Johnston
Its: Authorized Signatory

IN WITNESS WHEREOF, the undersigned has executed this written consent as of the date first set forth above.

SMC LYONS HOLDINGS LLC, in its capacity as Sole Member of Concierge Pharmacy, LLC; Firstcare Pharmacy, LLC; Easycare Pharmacy, LLC; and Primecare Pharmacy, LLC

By: Optio Rx, LLC
Its: Manager

By: Jarlath Johnston
Its: Authorized Signatory

IN WITNESS WHEREOF, the undersigned has executed this written consent as of the date first set forth above.

SBH Medical LLC, in its capacity as Sole Member of SBH Medical, Ltd.

By: Optio Rx, LLC
Its: Manager

By: Jarlath Johnston
Its: Authorized Signatory

IN WITNESS WHEREOF, the undersigned has executed this written consent as of the date first set forth above.

HEALTHY CHOICE COMPOUNDING LLC, in its capacity as Sole Member of Healthy Choice Compounding LLC

By: Optio Rx, LLC
Its: Manager

By: Jarlath Johnston
Its: Authorized Signatory

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: SBH MEDICAL LTD d/b/a OPTIORX - 290

NV Pharmacy or Outsourcing facility license # (if applicable): N/A

Physical Address: 7654 CROSSWOODS DR.

City: COLUMBUS State: OH Zip: 43235

Mailing Address (if different from physical address): (SAME AS ABOVE)

City: State: Zip:

Telephone: 614-847-6007 Toll Free # (NAC 639.708, NRS 639.23286): 866-724-6333

Fax: 614-847-6015 Contact Email: LICENSES@OPTIORX.COM

Website: https://sbhmed.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): DOUGLAS NAVARRO

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24452

Name of Designated Person(s) as defined by revised USP-797 guidelines: Jason Morrison CphT

Email of Designated Person(s): jmorrison@optiorx.com

Telephone of Designated Person(s): 614-847-6007

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ■ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 8/21/2024 next scheduled for 02/12/2024

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Weekly

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Please see included attachments of Cat 2 drugs prepared in the last year. We are also in the study phase for several Cat 3 drugs that will also be listed in the included attachment.

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma and (Eagle Analytical 11111 S. Wilcrest Dr, S1000 Houston TX 77099 800-745-8916)

Address: 840 Research Parkway Ste 546

City: Oklahoma City State: OK Zip: 73104

Telephone: 800-393-1595

13. What is your procedure for visual inspection of compounded sterile products?

Please see included SOP S-12.001.01 Sterile Visual Inspection of Ingredients and Compounded Sterile Preps.

14. How often do you perform glove fingertip and medial fill testing?

We perform these every 3 months on personnel compounding due to Cat 3 requirements. We perform them annually on pharmacists that oversee compounding process and are not directly involved in compounding.

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Please see included Policy P-2.001.01 Personnel Training and Evaluation. We also recently had our Sterile compounding staff complete an ACPE approved National Sterile training class (20 hour-RPH and 40 hour-Tech). Our plan is to have all employees complete this course as part of their training.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see included SOP S-7.001.01 Sterile Non HD cleaning and Disinfecting and S-800.005.01 Sterile HD Deactivating-Decontaminating-Cleaning-Disinfecting. We clean on a daily basis instead of weekly all items required under Cat 3. We also perform the monthly cleaning requirements as included in the SOP under the requirements of USP 797 and 800. We use Sterile Isopropyl 70% alcohol and Sterile RTU Peridox as our cleaning, disinfectant, sporicidal and decontamination agent.

17. Who performs the sterile compounding process at your facility?

The compounding is performed by our Certified Pharmacy Technicians.

18. Who is responsible and accountable for the sterile compounding process at your facility?

The supervising pharmacists are responsible and accountable for the process.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Please see included SOP S-19.001.01 Handling Storage Packaging Shipping and Transport for Compounded Preparation Delivery. We also ship cold chain products per policy P-19.003.01 Cold Chain Distribution. We have also included our package preparation procedure for packing our cooler totes.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Class II BSC.		
2. Are you complying with all USP 800 guidelines?	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	Yes	■ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

Medications found in table 1 are placed in yellow transport bags "Caution Chemotherapy Material". The bag contains the following statements: After Use, Dispose of in accordance with established procedures. Observe Safety precautions for handling and administration. We also place auxiliary labels on all prescription containers for table 1 and table 2 that read: Caution. Follow procedures for proper handling and disposal of hazardous drugs. Caution: Hazardous drug require thorough hand washing after handling.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Please see included Policy P-2.001.01 Personnel Training and Evaluation. We also perform additional training with regards to SOP S-800.003.01 Gown, Garb, Hand Hygiene as related to Hazardous and also perform annual Respiratory fit tests per SOP S-800.004.01

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Please see attached reference.

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

We complete these assessments every 3 months.

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

We complete this on a monthly basis.

5. What is the frequency for completing surface sampling?

We perform weekly surface samples of 30 sites within our 797, 800, and ante room. We also perform a surface sample in the PEC for any Cat 3 batches.

6. What is the frequency for using sporicidal agents?

We use these on a daily basis for cleaning and disinfecting.

For question 7 and 8 below, we use Cat 2 BUD dating from USP Table 13. In our Cat 3 medications we will conduct endotoxin and sterility testing and use BUD's supported by our stability indicating analytical study.

7. Is an endotoxin test performed for all products compounded from one or more nonsterile component? Yes ■ No

8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method? Yes ■ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Doug Navarro

Name of Person who Completed the Form

Pharmacist in Charge

Title

Signature (copies or stamps not accepted)

1/24/25

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

CATEGORY 2 COMPOUNDED PREPARATIONS

Description	DEA Schedule	Item Group	Dosage Form
Acetylcysteine 10% (PF) Ophthalmic Soln	0	13190	Solution
Acetylcysteine 5% Ophthalmic Soln	0	Opthalmic	Solution
Amphotericin B (Lipo) 1% Opth Soln	0	SBH	Solution
Amphotericin B Collo Opht 0.3% (dex) 3mg/Ml Ophtho Soln	0	13791	Solution
Atropine (cmpd) Pf 0.05% Ophtho Soln	0	18348	Solution
Atropine Sulfate Monohydrate PF 0.1% Stock Solution	0	SBH	Solution
Autologous Serum Eye Drops 30% Ophtho Soln	0	19551	Solution
Autologous Serum Eye Drops 50% Ophtho Soln	0	Solution	Solution
Autologous Serum Eye Drops 60% Ophtho Soln	0	Solution	Solution
Baclofen (Gablofen) 200mcg/Ml Injectable	0	SBH	Solution
Baclofen Injection (pf) 2250mcg/Ml Injectable	0	18489	Solution
Baclofen Injection (pf) 2500mcg/Ml Injectable	0	Injectable	Solution
Benzalkonium Chloride (inj) 1.33mg/Ml Liquid	0	SBH	Solution
Bimix 1 (papav/Phent) 24mg/1mg Injectable	0	Solution	Solution
Bimix 10 (papav/Phent) 30mg/5mg Injectable	0	Solution	Solution
Bimix 5 (papav/Phent) 30mg/4mg/Ml Injectable	0	Solution	Solution
Bimix 7 (papav/Phent) 36mg/2mg Injectable	0	Solution	Solution
Bladder Irr Amikacin (0.05%) 0.5mg/Ml Sterile Soln	0	Solution	Solution
Bladder Irr Lidocaine (1%) 10mg/ml Sterile Soln	0	Solution	Solution
Brilliant Blue G In Dextrose (pf) 0.25mg/Ml Injectable	0	Injectable	Solution
Buprenorphine W/Pres (5ml) 0.3mg/Ml Injectable	3	Injection	Solution
Buprenorphine W/Pres (5ml) 0.6mg/Ml Injectable	3	Injection	Solution
Cefazolin 33mg/ml Ophthalmic Solution	0	SBH	Solution
Cefazolin Inj Pf 10mg/ml Injectable	0	Injectable	Solution
Ceftazidime Hcl Fort Opth Pf 5% 50mg/Ml Ophtho Soln	0	10437	Solution
Ceftazidime Inj Pf 22.5mg/Ml Injectable	0	SBH	Solution
Chloramphenicol Ophthalmic 1% Soln	0	SBH	Solution
Cidofovir Intraocular 3.75mg/Ml Injectable	0	12663	Solution
Clindamycin (cmpd) 150mg/Ml Injectable	0	Injection	Solution
Clonidine Hcl (pf) 300mcg/Ml Injectable	0	17105	Solution
Clorpactin Irrigation 0.05% Solution	0	19213	Solution
Clorpactin Irrigation 0.1% Solution	0	19513	Solution
Cyclosporine (Aqueous, PF) 2% Ophth Suspension	0	sbh	Suspension
Desmopressin (0.1mg/ml) 0.01% Sterile Soln in VIAL	0	Injectable	Solution
Dexamethasone (PF) 24mg/mL Sterile Soln	0	Injection	Solution
Dexamethasone Sod Phos Cmpd (pf) 0.1% Ophtho Soln	0	SBH	Solution

Description	DEA Schedule	Item Group	Dosage Form
Doxycycline (PF) 0.1% (1mg/ml) Ophthalmic Solution	0	Solution	Solution
Edetate Ca Disodium (pf) 200mg/Ml Injectable	0	Injectable	Solution
Fentanyl Citrate Injection (pf) 50mcg/Ml Injectable	2	Injectable	Solution
Fentanyl Inj (pf) 75mcg/Ml Injectable	2	11707	Solution
Fentanyl Injection (pf) 200mcg/Ml Injectable	2	19683	Solution
Fentanyl Injection (pf) 25mcg/Ml Injectable	2	Injectable	Solution
Fentanyl/Baclofen (pf) 520mcg/2300mcg/Ml Injectable	2	Injectable	Solution
Fentanyl/Baclofen (pf) 700mcg/500mcg/Ml Injectable	2	19523	Solution
Fentanyl/Bupivacaine (pf) 1000mcg/12.5mg/Ml Injectable	2	20369	Solution
Fentanyl/Bupivacaine (pf) 1000mcg/12mg/Ml Injectable	2	Injectable	Solution
Fentanyl/Bupivacaine (pf) 1000mcg/18mg/Ml Injectable	2	Injectable	Solution
Fentanyl/Bupivacaine (pf) 1000mcg/22mg/Ml Injectable	2	Injectable	Solution
Fentanyl/Bupivacaine (pf) 1000mcg/33mg/Ml Injectable	2	SBH	Solution
Fentanyl/Bupivacaine (pf) 1000mcg/9mg/Ml Injectable	2	Injectable	Solution
Fentanyl/Bupivacaine (pf) 500mcg/18mg/Ml Injectable	2	SBH	Solution
Fentanyl/Bupivacaine (pf) 500mcg/40mg/Ml Injectable	2	Injectable	Solution
Fentanyl/Bupivacaine (pf) 50mcg/30mg/Ml (40ml) Injectable	2	SBH	Solution
Fentanyl/Bupivacaine Hcl (pf) 100mcg/20mg/Ml Injectable	2	Injectable	Solution
Fentanyl/Bupivacaine Hcl (pf) 500mcg/11mg/Ml Injectable	2	SBH	Solution
Fentanyl/Bupivacaine Hcl (pf) 500mcg/12.5mg/Ml Injectable	2	19390	Solution
Fentanyl/Bupivacaine Hcl (pf) 50mcg/15mg/Ml Injectable	2	SBH	Solution
Fentanyl/Bupivacaine HCl (pf) 50mcg/30mg/ml	2	19390	Solution
Fentanyl/Bupivacaine Hcl (pf) 50mcg/30mg/Ml Injectable	2	20244	Solution
Fentanyl/Bupivacaine Hcl Inj (pf) 250mcg/Ml/10mg/Ml Injectable	2	SBH	Solution
Fentanyl/Bupivacaine Hcl Inj (pf) 250mcg/Ml/3.7mg/Ml Injectable	2	SBH	Solution
Fentanyl/Bupivacaine Hcl Inj (pf) 250mcg/Ml/9mg/Ml Injectable	2	SBH	Solution
Fentanyl/Bupivacaine/Baclofen (pf) 1000mcg/12mg/70mcg/Ml Injectable	2	Injectable	Solution
Gablofen (baclofen) 2000 Mcg/Ml Solution (Baclofen)	0	SBH	Solution
Gablofen (baclofen) 2000 Mcg/Ml Solution: Baclofen	0	Injectable	Solution
Gablofen (baclofen) 400mcg/Ml (40ml) Solution	0	18928	Solution
Gablofen (baclofen) 500mcg/Ml Solution: Baclofen	0	9871	Solution
Gablofen (baclofen) Pfs 500mcg/Ml Solution	0	Injectable	Solution
Gablofen (PF) 125mcg/Ml Injectable	0	12132	Solution
Gablofen 250mcg/Ml (PF) Solution	0	19377	Solution
Glycerin 60%/Lidocaine W/Epi 1% 2:1 Injectable	0	Injectable	Solution
Hydromorphone (pf) 2.5mg/Ml Injectable	2	1161	Solution

Description	DEA Schedule	Item Group	Dosage Form
Hydromorphone (pf) 4mg/Ml Injectable	2	2497	Solution
Hydromorphone Hcl (PF) 0.5mg/Ml Injectable	2	2965	Solution
Hydromorphone Hcl (PF) 0.75mg/Ml Injectable	2	SBH	Solution
Hydromorphone Hcl (pf) 1.2mg/Ml Injectable	2	SBH	Solution
Hydromorphone Hcl (pf) 1.8mg/Ml Injectable	2	SBH	Solution
Hydromorphone hcl (pf) 11mg/ml	2	Injection	Solution
Hydromorphone Hcl (pf) 15mg/Ml Injectable	2	Injectable	Solution
Hydromorphone Hcl (pf) 8mg/Ml Injectable	2	15398	Solution
Hydromorphone Hcl (pf) 9mg/Ml Injectable	2	Injectable	Solution
Hydromorphone Hcl 20mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Baclofen (pf) 0.9mg/500mcg/Ml Injectable	2	17934	Solution
Hydromorphone/Baclofen (pf) 10mg/1021mcg/Ml Injectable	2	15923	Solution
Hydromorphone/Baclofen (pf) 10mg/50mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Baclofen (pf) 1mg/10mcg/Ml Injectable	2	20370	Solution
Hydromorphone/Baclofen (pf) 1mg/25mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Baclofen (pf) 25mg/1888mcg/Ml Injectable	2	15996	Solution
Hydromorphone/Baclofen (pf) 2mg/15mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Baclofen (pf) 2mg/20mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Baclofen/Clonidine (pf) 15mg/50mcg/15mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Baclofen/Clonidine (pf) 30mg/100mcg/15mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Baclofen/Clonidine (pf) 30mg/100mcg/30mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine (pf) 0.25mg/40mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 10mg/10mg/Ml Injectable	2	Injection	Solution
Hydromorphone/Bupivacaine (pf) 10mg/40mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 10mg/7.2mg/Ml Injectable	2	15325	Solution
Hydromorphone/Bupivacaine (pf) 12mg/12mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 14mg/9mg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine (pf) 15mg/10mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 15mg/20mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 16mg/20mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 1mg/6mg/Ml Injectable	2	sbh	Solution
Hydromorphone/Bupivacaine (pf) 25mg/13mg/Ml Injectable	2	injectable	Solution
Hydromorphone/Bupivacaine (pf) 25mg/5.4mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 25mg/6mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 2mg/10mg/Ml Injectable	2	17650	Solution
Hydromorphone/Bupivacaine (pf) 2mg/8mg inj.	2	SBH	Solution

Description	DEA Schedule	Item Group	Dosage Form
Hydromorphone/Bupivacaine (pf) 4mg/10mg/Ml Injectable	2	2990	Solution
Hydromorphone/Bupivacaine (pf) 4mg/16mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 4mg/20mg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine (pf) 4mg/4mg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine (pf) 4mg/6mg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine (pf) 5mg/10mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 5mg/5mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine (pf) 8mg/8mg/Ml Injectable	2	16431	Solution
Hydromorphone/Bupivacaine 10mg/12mg/Ml Injectable	2	15862	Solution
Hydromorphone/Bupivacaine 30mg/20mg/ml injectable	2	injectable	Solution
Hydromorphone/Bupivacaine Hcl (pf) 1mg/40mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine Hcl (pf) 3mg/6mg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine pf 1mg/10mg/ml Injectable	2	17913	Solution
Hydromorphone/Bupivacaine/Baclofen (pf) 15mg/15mg/15mcg/Ml Injectable	2	Injection	Solution
Hydromorphone/Bupivacaine/Baclofen (pf) 15mg/6mg/30mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine/Baclofen (pf) 2mg/8mg/400mcg/Ml	2	Injectable	Solution
Hydromorphone/Bupivacaine/Baclofen (pf) 4mg/20mg/40mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine/Baclofen (pf) 8mg/20mg/80mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 10mg/10mg/530mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 10mg/15mg/150mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 15mg/14mg/800mcg/Ml Injectable	2	sbh	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 15mg/7mg/120mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 1mg/10mg/30mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 2mg/15mg/60mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 40mg/5mg/800mcg/Ml Injectable	2	1887	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 5mg/2.5mg/40mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 5mg/2mg/15mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 7.5mg/5mg/375mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Bupivacaine/Clonidine (pf) 7mg/2mg/35mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 1.5mg/10mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 1.5mg/17mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 1.5mg/20mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 10mg/250mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Clonidine (pf) 10mg/50mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 12mg/18mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 12mg/30mcg/Ml Injectable	2	Injectable	Solution

Description	DEA Schedule	Item Group	Dosage Form
Hydromorphone/Clonidine (pf) 2mg/200mcg/Ml Injectable	2	SBH	Solution
Hydromorphone/Clonidine (pf) 30mg/350mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 3mg/35mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 3mg/8mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 5mg/425mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 8mg/20mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Clonidine (pf) 8mg/40mcg/Ml Injectable	2	Injectable	Solution
Hydromorphone/Fentanyl (pf) 4mg/110mcg/Ml	2	Injectable	Solution
Hydromorphone/Fentanyl (pf) 4mg/130mcg/Ml	2	SBH	Solution
Hydromorphone/Fentanyl (pf) 6mg/200mcg/Ml	2	Injectable	Solution
Hydromorphone/Morphine (pf) 2mg/3mg Injectable	2	Injectable	Solution
Lidocaine HCL 1mg/ml Aliquot (pf)	0	Injection	Solution
LIDOCAINE/EPINEPHRNE 1%/1:100,000	0		Solution
Methylprednisolone Ace Pf 1% Ophtho Susp	0	14442	Suspension
Mitomycin 0.2mg/Ml Injectable	0	Injectable	Solution
Mitomycin 0.4mg/Ml Injectable: Mitomycin	0	10176	Solution
Morphine 1mg/ml Inj (PF)	2	14903	Solution
Morphine Inj (pf) 0.5 Mg/Ml Injectable	2	Injectable	Solution
Morphine Inj (pf) 1.5mg/Ml Injectable	2	Injectable	Solution
Morphine Inj (pf) 12mg/Ml Injectable	2	2263	Solution
Morphine Inj (pf) 1mg/Ml Injectable	2	840	Solution
Morphine Inj (pf) 30mg/Ml Injectable	2	1255	Solution
Morphine//Baclofen/Clonidine (pf) 15mg/10mcg/440mcg/Ml Injectable	2	Injectable	Solution
Morphine/Baclofen (pf) 10mg/500mcg/Ml Injectable	2	2414	Solution
Morphine/Baclofen (pf) 12mg/15mcg/Ml Injectable	2	19366	Solution
Morphine/Baclofen (pf) 12mg/40mcg/Ml Injectable	2	19366	Solution
Morphine/Baclofen (pf) 20mg/100mcg/Ml Injectable	2	Injectable	Solution
Morphine/Baclofen (pf) 2mg/15mcg/ml Injectable	2	Injectable	Solution
Morphine/Baclofen (pf) 2mg/30mcg/Ml Injectable	2	Injectable	Solution
Morphine/Baclofen (pf) 3mg/20mcg/ml Injectable	2	Injectable	Solution
Morphine/Baclofen (PF) 6mg/15mcg/ML inj	2	SBH	Solution
Morphine/Baclofen (PF) 6mg/18mcg/ML inj	2	SBH	Solution
Morphine/Baclofen (pf) 6mg/35mcg/Ml Injectable	2	SBH	Solution
Morphine/Buipivacaine (pf) 3mg/0.5mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 5mg/40mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 0.75mg/4mg/Ml Injectable	2	Injectable	Solution

Description	DEA Schedule	Item Group	Dosage Form
Morphine/Bupivacaine (pf) 10mg/12mg/Ml Injectable	2	16148	Solution
Morphine/Bupivacaine (pf) 10mg/17mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 10mg/30mg/Ml Injectable	2	20432	Solution
Morphine/Bupivacaine (pf) 10mg/6mg/Ml Injectable	2	15825	Solution
Morphine/Bupivacaine (pf) 13mg/20mg/Ml Injectable	2	SBH	Solution
Morphine/Bupivacaine (pf) 15mg/10mg/Ml Injectable	2	5973	Solution
Morphine/Bupivacaine (pf) 15mg/15mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 15mg/5mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 15mg/8mg/Ml Injectable	2	SBH	Solution
Morphine/Bupivacaine (pf) 1mg/10mg Injectable	2	SBH	Solution
Morphine/Bupivacaine (pf) 20mg/10mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 20mg/15mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 20mg/20mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 20mg/25mg/Ml Injectable	2	5499	Solution
Morphine/Bupivacaine (pf) 20mg/5mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 25mg/12mg/Ml Injectable	2	SBH	Solution
Morphine/Bupivacaine (pf) 25mg/15mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 25mg/5mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 2mg/5mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 2mg/9mg/Ml Injectable	2	19823	Solution
Morphine/Bupivacaine (pf) 3mg/10mg/Ml Injectable	2	SBH	Solution
Morphine/Bupivacaine (pf) 3mg/12mg/Ml Injectable	2	18010	Solution
Morphine/Bupivacaine (pf) 4mg/10mg/Ml Injectable	2	20427	Solution
Morphine/Bupivacaine (pf) 4mg/5mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 5mg/13mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 5mg/14mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 5mg/20mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 6mg/10mg/Ml Injectable	2	18631	Solution
Morphine/Bupivacaine (pf) 6mg/15mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 6mg/17mg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine (pf) 6mg/6mg/Ml Injectable	2	SBH	Solution
Morphine/Bupivacaine 2.5mg/30mg/ml (PF) Injectable Solution	2	Injection	Solution
Morphine/Bupivacaine 30mg/20mg/ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine/Baclofen (pf) 6mg/10mg/10mcgMl Injectable	2	SBH	Solution
Morphine/Bupivacaine/Baclofen (pf) 8mg/14mg/15mcgMl Injectable	2	SBH	Solution
Morphine/Bupivacaine/Clonidine (pf) 12mg/15mg/150mcg/Ml Injectable	2	SBH	Solution

Description	DEA Schedule	Item Group	Dosage Form
Morphine/Bupivacaine/Clonidine (pf) 25mg/8mg/1000mcg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine/Clonidine (pf) 3mg/10mg/22mcg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine/Clonidine (pf) 3mg/10mg/25mcg/Ml Injectable	2	Injectable	Solution
Morphine/Bupivacaine/Clonidine (pf) 3mg/10mg/30mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 10mg/450mcg/Ml Injectable	2	Injection	Solution
Morphine/Clonidine (pf) 10mg/600mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 10mg/60mcg/ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 10mg/800mcg/Ml Injectable	2	10669	Solution
Morphine/Clonidine (pf) 20mg/125mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 20mg/25mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 25mg/150mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 2mg/1000mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 2mg/400mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 3mg/400mcg/Ml Injectable	2	SBH	Solution
Morphine/Clonidine (pf) 5mg/400mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 6mg/50mcg/Ml Injectable	2	SBH	Solution
Morphine/Clonidine (pf) 6mg/60mcg/Ml Injectable	2	Injectable	Solution
Morphine/Clonidine (pf) 7mg/85mcg/Ml Injectabl	2	Injectable	Solution
Morphine/Clonidine (pf) 8mg/100mcg/Ml Injectabl	2	Injectable	Solution
Morphine/Fentanyl/Bupivacaine (pf) 15mg/100mcg/17mg/ml	2	Injectable	Solution
Morphine/Fentanyl/Bupivacaine (pf) 15mg/150mcg/17mg/ml	2	Injectable	Solution
Morphine/Fentanyl/Bupivacaine (pf) 15mg/200mcg/17mg/ml	2	Injectable	Solution
Morphine/Fentanyl/Bupivacaine (pf) 15mg/300mcg/17mg/ml	2	Injectable	Solution
Morphine/Fentanyl/Bupivacaine (pf) 15mg/350mcg/17mg/ml	2	Injectable	Solution
Morphine/Hydromorphone (pf) 10mg/2mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 12mg/7mg/Ml Injectable	2	Injectable	Solution
Morphine/Hydromorphone (pf) 15mg/5mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 17mg/5mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 1mg/3mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 20mg/5mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 3mg/1mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 5mg/2mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 5mg/4mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 6mg/6mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone (pf) 8mg/4mg/Ml Injectable	2	SBH	Solution
Morphine/Hydromorphone/Baclofen (pf) 2mg/6mg/30mcg/Ml Injectable	2	Injectable	Solution

Description	DEA Schedule	Item Group	Dosage Form
Morphine/Hydromorphone/Clonidine (pf) 15mg/5mg/25mcgMl Injectable	2	Injectable	Solution
Naltrexone 0.4mg/ml (PF) Ophthalmic Solution	0	SBH	Solution
Papaverine/Phentolamine/Pge1 30mg/2mg/20mcg/Ml Injectable	0	Injectable	Solution
Papaverine/Phentolamine/Pge1 30mg/2mg/30mcg/Ml Injectable	0	Injectable	Solution
Papaverine/Phentolamine/Pge1 30mg/2mg/60mcg/Ml Injectable	0	Injectable	Solution
Papaverine/Phentolamine/Pge1 30mg/3mg/20mcg/Ml Injectable	0	Injectable	Solution
Papaverine/Phentolamine/ProstaglandinE1/Atropine/Lidocaine 28.8mg/2mg/20mcg/0.15mg/6.67mg Injection	0	SBH	Solution
Papaverine/Phentolamine/ProstaglandinE1/Lidocaine 30mg/1mg/10mcg/8mcg/mL Injection	0	Injection	Solution
Phenol (10ml) 6% Injectable	0	991	Solution
Platelet Rich Plasma (prp) Eye Drops Ophtho Soln	0	Solution	Solution
Prostaglandin E1 10mcg/Ml Injectable	0	Solution	Solution
Prostaglandin E1 30mcg/Ml Injectable	0	10171	Solution
Prostaglandin E1 60mcg/Ml	0	Injection	Solution
Quadmix 1 (pap/Phent/Pge1/Atropine) 12mg/1mg/10mcg/0.15mg Injectable	0	Solution	Solution
Quadmix 2 (pap/Phent/Pge1/Lido) 10mg/0.5mg/30mcg/6.67mg Injectable	0	Solution	Solution
Quadmix 8 (pap/Phent/Pge1/Lido) 36mg/2mg/30mcg/6.67mg Injectable	0	Solution	Solution
Sbh Amikacin Sterile (25mg/Ml) 2.5% Injectable	0	SBH	Solution
Sbh Gel 30% Injectable	0	SBH	Gel
Sodium Hydroxide 20% (w/V)/Water For Injection	0	C10076	Solution
Super Trimix 11 (pap/Phent/Pge1) 30mg/1mg/20mcg	0	Solution	Solution
Super Trimix 13 (pap/Phent/Pge1) 36mg/2mg/30mcg Injectable	0	Solution	Solution
Super Trimix 8 (pap/Phent/Pge1) 36mg/1.2mg/30mcg Injectable	0	Solution	Solution
Tacrolimus Alcohol Stock 0.2% Solution	0	SOLUTION	Solution
Tacrolimus Aqueous (pf) (purilens) 0.02% Ophtho Soln	0	Opht Solution	Solution
Tacrolimus Aqueous (pf) (purilens) 0.03% Ophtho Soln	0	19800	Solution
Tobramycin Fortified 13.6mg/ml Ophtho Soln	0	Ophthalmic Solution	Solution
Tobramycin Fortified 15mg/Ml Ophtho Soln	0	SBH	Solution
Trimix 1 (pap/Phen/Pge1) 23.4mg/1mg/10mcg Injectable	0	Solution	Solution
Trimix 11 (pap/Phen/Pge1) 15mg/0.5mg/10mcg Injectable	0	Solution	Solution
Trimix 12 (pap/Phen/Pge1) 15mg/0.5mg/30mcg Injectable	0	Solution	Solution
Trimix 13 (pap/Phen/Pge1) 15mg/0.5mg/5mcg Injectable	0	Solution	Solution
Trimix 2 (pap/Phen/Pge1) 22.5mg/1mg/25mcg Injectable	0	Solution	Solution
Trimix 3 (pap/Phen/Pge1) 17.65mg/0.59mg/5.9mcg Injectable	0	Solution	Solution
Trimix 4 (pap/Phen/Pge1) 12mg/1mg/10mcg Injectable	0	Solution	Solution
Trimix 7 (pap/Phent/Pge1) 16.7mg/0.56mg/5.6mcg Injectable	0	Solution	Solution
Trimix 8 (pap/Phen/Pge1) 8.825mg/0.3mg/2.95mcg Injectable	0	Solution	Solution

Description	DEA Schedule	Item Group	Dosage Form
Vancomycin Hcl Pf 10mg/Ml Injectable	0	8555	Solution
Vancomycin Hcl Fort Pf 2.5% 25mg/Ml Ophtho Soln	0	Solution	Solution
Vancomycin Hcl Fort Pf 5% 50mg/Ml Ophtho Soln	0	849	Solution
Vancomycin Hcl W/BAk 14mg/Ml Ophtho Soln	0	SBH	Solution
Voriconazole (1%) 10mg/Ml Ophtho Soln	0	SBH	Solution

CATEGORY 3 PROPOSED COMPOUNDED PREPARATIONS

Medication	Category	Strength	Dosage Form	Package Size
Glutathione	CSP #3	200 mg/mL	Injectable	10mL Vial
Methylcobalamin	CSP #3	1 mg/mL	Injectable	10mL Vial
	CSP #3	5 mg/mL	Injectable	10mL Vial
	CSP #3	10 mg/mL	Injectable	10mL Vial
Nicotinamide Adenine Dinucleotide Plus (NAD+)	CSP #3	200 mg/mL	Injectable	10mL Vial
Semaglutide	CSP #3	1 mg/mL	Injectable	1mL (2mL Amber Vial)
	CSP #3	1 mg/mL	Injectable	2.5mL (2mL Amber Vial)
	CSP #3	5 mg/mL	Injectable	1mL (2mL Amber Vial)
	CSP #3	5 mg/mL	Injectable	2.5mL Vial (2mL Amber Vial)
Semaglutide / B3	CSP #3	1/2 mg/mL	Injectable	1mL (2mL Amber Vial)
	CSP #3	1/2 mg/mL	Injectable	2.5mL (2mL Amber Vial)
	CSP #3	5/2 mg/mL	Injectable	1mL (2mL Amber Vial)
	CSP #3	5/2 mg/mL	Injectable	2.5mL Vial (2mL Amber Vial)
Sermorelin Acetate	CSP #3	2 mg/mL	Injectable	5mL Vial (10mL Amber Vial)
	CSP #3	2 mg/mL	Injectable	10mL Vial (10mL Amber Vial)
Tirzepatide	CSP #3	10 mg/mL	Injectable	1mL Vial (2mL Amber Vial)
	CSP #3	10 mg/mL	Injectable	4mL Vial (5mL Amber Vial)
Tirzepatide / B3	CSP #3	10/2 mg/mL	Injectable	1mL Vial (2mL Amber Vial)
	CSP #3	10/2 mg/mL	Injectable	4mL Vial (5mL Amber Vial)
	CSP #3	20/2 mg/mL	Injectable	3mL Vial (5mL Amber Vial)

Section Name: Release Inspections and Testing	SOP Name: Visual Inspection of Ingredients and Compounded Sterile Preparations
SOP: S-12.001.01	Last Revision/Review: 10/31/2024
Accreditation Standards: TCRX5-G, TCRX6-H, TCRX-L, DRX7-8J.01, DRX7-8L, DRX7-8M, DRX7-N	

Policy

All pre-release inspection checks are performed by an employee who has passed the Pre-Release Inspection – Compounded Sterile Preparations competency and as permitted by the state board of pharmacy laws and regulations.

Upon completion of a compounded sterile preparation (CSP), the CSP must be visually inspected to determine if the physical appearance of the CSP is what is expected before release and dispensing.

Pre-release visual inspections include the following checking activities:

- Compounding record (CR) matches the prescription/medication order.
- Label matches the prescription/medication order.
- CSP was compounded according to the CR (e.g., ingredients, strengths, quantities, equipment, etc.).
- Presence of particulates, precipitation, or other foreign matter.
- Presence of cloudiness or color change when compared to the expected color.
- Total volume of the CSP.
- Quantity of CSP(s) prepared.
- Container-closure integrity (e.g., checking for leakage, cracks in container, or improper seals).
- Beyond-use date (BUD).
- Storage requirements.
- Special handling and warning statements (e.g., hazardous).
- Additional statements required by laws and regulations (e.g., compounded preparation).

Finished CSPs dispensed the same day of preparation and finished CSPs stored internally and dispensed other than the day of preparation must be visually inspected immediately before being released or dispensed to ensure the CSP does not exhibit any defects, such as precipitation, cloudiness, or leakage, which could have developed during storage.

At the time of a visual inspection, if the CSP exhibits signs of a defect(s), the CSP must be immediately discarded or marked and segregated from acceptable CSPs to prevent it from being released or dispensed.

Defects must be investigated to determine the root cause, and a corrective action plan must be implemented. Defects are documented electronically or using the Adverse Event/Risk Event Report form and reviewed by the designated person(s).

Definitions

None.

Procedures

Visual Inspection for Particulates and Precipitation

- Hold the CSP container under a light source, preferably over a contrasting background.
- Invert and move the container slowly from one side of the contrasting background to the other.
- Observe for particulates, precipitation, and other unexpected matter.

Visual Inspection for Clarity or Color Change

- Compare the color and clarity to that described in the CR to determine if the CSP is consistent with the expected results.

Visual Inspection of the Label

- Check the CSP label against the prescription/medication order to ensure:
- Correct patient.
- Correct prescription number or other identification number.
- Correct active ingredients, strength/concentration, and dose.
- Correct route of administration.
- Correct total volume.
- Correct quantity of CSP(s) being dispensed.
- Correct BUD and storage instructions.
- Correct instructions for use.
- Legible printing.
- Special handling and warning statements, if applicable.
- Compounding statement as required by applicable laws and regulations.

Visual Inspection of Container-Closure Integrity

- Squeeze the container and inspect for leaks.
- Inspect seals and closure mechanisms to ensure they are intact.
- Ensure tubing clamps are completely closed, if applicable.

Any CSPs that fail any pre-release inspections are placed in the quarantine area and clearly marked indicating why.

Any CSPs that fail any pre-release inspection are documented electronically or using the Adverse Event/Risk Event Report form.

All pre-release checks are documented on the CR.

When the CSP release occurs at any time other than the day the CSP is prepared, a visual inspection must be conducted immediately before it is released or dispensed to ensure the CSP does not exhibit signs of a defect(s) such as:

- Precipitation, particulates, or other foreign matter.
- Changes in clarity or color.
- Loose container closures or container leakage.

At a minimum, the pre-release inspection, conducted after the CSP process is completed, will be documented on the CR, indicating the pharmacist that performed the check and the date/time checked.

USP <797> References

Section 12: Release Inspections and Testing.

Section 12.1: Visual Inspection.

Other USP References

USP <1163> Quality Assurance in Pharmaceutical Compounding.

Reference Documents

Pre-Release Inspection – Compounded Sterile Preparations Competency

Inventory Handling, Storage, Labeling, Transport, and Disposal – Non-Hazardous Compounding SOP

Inventory Handling, Storage, Labeling, Transport, and Disposal – Hazardous Compounding SOP

Adverse Event/Risk Event Report Form

Equipment and Materials

Light-contrasting background (white and black), preferred

This document has:

- ❑ been further customized as in _____
- ❑ NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
01/12/2024	S-12.001.01	New release-new Format/USP Standards update 11/2023	N/A	Kelly Klotz
10/31/2024	S-12.001.01	Annual review.	N/A	Mike Blaine

Section Name: Personnel Training and Evaluation	Policy Name: Competency Requirements
Policy: P-2.001.01	Last Revision/Review: 10/31/2024
Accreditation Standards: DRX4-7A, C, DRX 4-14B, TCRX3-A, B, E, F, H, TCRX5-G, I	

Policy

The pharmacy will have an ongoing process to assess the knowledge and competence of personnel in job-related areas deemed important to the organization. These include skills and knowledge necessary to perform specific tasks such as preparing compounded preparations, oversight of compounding, and operating various types of equipment.

Definitions

Competency Assessment: The assessment of someone's capabilities against the requirements of their job. Competency can be determined through observation, demonstration, or testing (e.g., verbal, written).

Designated Person: One or more individuals assigned to be responsible and accountable for specific aspects of the performance and operation of the facility and personnel for the preparation of compounded preparations.

Observer: The person who assesses competency using a facility-approved competency assessment tool, based on adopted policies, SOPs, and industry-recognized best practices. The observer has been deemed competent by the designated person. In facilities that have only one compounder, the compounder must obtain and maintain training and demonstrated competency by a third party per this policy.

Procedures

USP <797> Related Requirements

Before beginning to prepare compounded sterile preparations (CSPs) independently, all compounding personnel involved in or having direct oversight of preparing and dispensing must complete training and be able to demonstrate knowledge of principles and proficiency of skills for performing sterile manipulations and achieving and maintaining appropriate environmental conditions.

Competency must be demonstrated every 12 months in at least the following:

- Hand hygiene.
- Garbing.
- Cleaning and disinfection.
- Calculations, measuring, and mixing.
- Aseptic technique.
- Achieving and/or maintaining sterility and apyrogenicity if compounding with non-sterile components.

- Use of equipment.
- Documentation of the compounding process (e.g., master formulation and compounding records).
- Principles of high-efficiency particulate air (HEPA)-filtered unidirectional airflow within the ISO Class 5 area.
- Proper use of primary engineering controls (PECs).
- Principles of movement of materials and personnel within the compounding area.

All compounding personnel involved in or having direct oversight of CSPs must complete written or electronic testing every 12 months in appropriate sterile compounding principles and practices.

Any other personnel handling CSPs and/or accessing the compounding area must complete training and demonstrate competency in maintaining the quality of the environment in which they are performing their assigned task.

The designated person(s) must oversee the training of personnel and ensure that any person who enters the sterile compounding area maintains the quality of the environment.

If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of USP <797>.

All compounding personnel must be visually observed initially, every six months for Category 1 and Category 2 CSPs, and every three months for Category 3 CSPs while performing hand hygiene and garbing procedures. The visual audit must be documented, and the documentation is maintained to provide a record of personnel competency.

Initial gloved fingertip and thumb sampling evaluates a compounder's competency in correctly performing hand hygiene and garbing.

Before being allowed to independently compound, all compounders must successfully complete an initial competency evaluation, including visual observation and gloved fingertip and thumb sampling (GFT) on both hands, no fewer than three separate times. The three successful completions must be in succession. Failure of any of the three initial GFT samples requires repeat testing until personnel successfully complete three GFT samples in a row. Each fingertip and thumb evaluation must occur after performing a separate and complete hand hygiene and full garbing procedure.

Personnel who have direct oversight of compounding personnel, but do not compound, must complete a gown, garb, and hand hygiene competency evaluation every 12 months. The competency evaluation should correspond to the type of garbing activities of the personnel they oversee. Personnel who have direct oversight of compounding personnel must not compound until they have completed the compounding competencies (e.g., gowning, garbing, and hand hygiene; media-fill testing including post-GFT sampling; and surface sampling) at the same interval required for compounding personnel.

After the initial competency evaluation, compounding personnel must successfully complete GFT on both hands after completing the media-fill test at least every six months for Category 1 and Category 2 CSPs and at least every three months for Category 3 CSPs.

Initial GFT must be performed on donned sterile gloves in a classified area or segregated compounding area (SCA).

Subsequent GFT must be performed on donned sterile gloves inside of an ISO Class 5 PEC. If conducting GFT in a compounding aseptic isolator (CAI), compounding aseptic containment isolator

(CACI), or a pharmaceutical isolator, samples must be taken from sterile gloves placed over the gloves attached to the restricted-access barrier system (RABS) sleeves.

Successful completion of the initial GFT is defined as zero colony-forming units (CFU) on all samples.

Successful completion of the subsequent GFT after media-fill testing is defined as less than three CFUs (total from both hands).

Failure is indicated by observed, improper hand hygiene and garbing procedures and/or GFT results that exceed the action levels.

Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must, at a minimum, include the name of the person evaluated; the evaluation date/time; media and components used, including manufacturer name, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; the results; and identification of the observer and the person who reads and documents the results.

All compounding personnel must perform media-fill testing to assess their sterile technique and related practices initially, every six months for Category 1 and Category 2 CSPs, and every three months for Category 3 CSPs.

Personnel compounding Category 1, Category 2, and Category 3 CSPs must perform an aseptic manipulation competency evaluation that consists of media-fill testing, followed by GFT of both hands, and then surface sampling of the direct compounding area to assess aseptic technique and related practices.

When performing a media-fill test, simulate the most difficult and challenging compounding procedures and processing conditions encountered by the person replacing all the components used in the CSPs with soybean-casein digest media.

If using commercial sterile microbial growth media, a certificate of analysis (COA) must be obtained from the supplier stating that the lot of the growth media will support the growth of microorganisms.

Store microbial growth media in accordance with manufacturer instructions and initiate the media-fill test before the expiration date of the media.

If preparing sterile microbial growth media in-house for sterile-to-sterile media-fill testing, the growth promotion capability of the media must be demonstrated for each batch and documented as described in Sterility Tests ⟨71⟩, Culture Media, and Incubation Temperatures, Growth Promotion Test of Aerobes, Anaerobes, and Fungi.

Failure is indicated by visible turbidity or other visual manifestations of growth in the media in one or more container-closure unit(s) on or before the end of the incubation period.

Results of the evaluation and corrective actions, in the event of failure, must be documented and the documentation maintained to provide a record and long-term assessment of personnel competency. Documentation must, at a minimum, include the name of the person evaluated; the evaluation date/time; media and components used, including manufacturer name, expiration date, and lot number; starting temperature for each interval of incubation; dates of incubation; the results; and the identification of the observer and the person who reads and documents the results.

USP <795> Related Requirements

All personnel involved in or having direct oversight of the preparation and handling of compounded non-sterile preparations (CNSPs) must be initially trained, demonstrate competency, and undergo refresher training every 12 months.

Training and competency of personnel must be documented.

A designated person must oversee a training program that describes the required training, the frequency of training, and the process for evaluating the competency of personnel involved in non-sterile compounding and handling of CNSPs.

This program must equip personnel with the appropriate knowledge and training in the required skills necessary to perform their assigned tasks.

Before preparing CNSPs independently, all compounding personnel must complete training and be able to demonstrate proficiency in the principles and hands-on skills of non-sterile manipulations for the type of compounding they will be performing.

Proficiency must be demonstrated every 12 months in at least the following core competencies:

- Hand hygiene.
- Garbing.
- Cleaning and sanitizing.
- Handling and transporting components and CNSPs.
- Measuring and mixing.
- Proper use of equipment and devices selected to compound CNSPs.
- Documentation of the compounding process (e.g., master formulation records and compounding records).

Steps in the training procedure must include the following:

- Read and understand USP <795>, other applicable standards, and other relevant literature.
- Understand and interpret safety data sheets (SDSs) and, if applicable, COAs.
- Read and understand procedures related to their compounding duties.

Training and observation may be performed by the designated person(s) or an assigned trainer, but personnel must be observed and guided throughout the training process.

Personnel will then be expected to repeat the procedures independently but under the direct supervision of the designated person(s) and/or trainer.

Personnel will be permitted to perform the procedure without direct supervision only after independently demonstrating understanding and competency.

Upon completion of the training program, the designated person(s) and/or trainer must document that the person has been trained and successfully completed competency assessments.

In addition to the initial and annual competency training and evaluation described, a designated person should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed.

SOPs must describe procedures for monitoring and observing compounding activities and personnel.

If the facility has only one person in the compounding operation, that person must document that they have obtained training and demonstrated competency, and they must comply with the other requirements of this chapter.

General Requirements

Personnel who prepare compounded preparations do so only after successfully completing the required competencies.

Pharmacy personnel that do not prepare compounded preparations but have direct oversight of compounding are required to successfully complete the applicable trainings and assessments as outlined in USP <797>.

Performing a self-assessment alone is not an acceptable means of documenting competence.

Personnel competency assessment occurs via a trained and competent observer who has mastered the applicable competencies listed below.

Personnel that fail to demonstrate knowledge or competency assessments are immediately reinstructed and reevaluated by the observer.

To support a culture of continuous improvement, all personnel are expected to observe coworker behavior and offer insights in enhancing that behavior as appropriate.

All training and competency assessment documents are kept by the pharmacy per pharmacy records retention requirements.

The pharmacy provides a comprehensive orientation, training, and assessment program for each employee specific to their role.

The orientation and training program must include, but not be limited to:

- Completion of items required trainings and competencies as outlined by USP standards.
- Review and understand all pharmacy policies and SOPs.
- Review of operating principles of the pharmacy, equipment, and maintenance procedures.
- Understanding all pharmacy paper and electronic forms and documentation.
- Review of the pharmacy's Performance Improvement Program and any ongoing quality improvement projects.

Orientation and training consist of didactic training (written information, web-based information, and/or video training) in addition to hands-on practical training and mentorship by observers.

Personnel receive additional or new orientation and training when new processes are introduced that impact their job.

Personnel receive additional or new orientation and training when new equipment is introduced to the pharmacy.

Personnel are required to demonstrate knowledge and skill in selected tasks before they are allowed to independently perform those tasks in the course of their job.

If an employee fails an assessment, the observer, or designee, will retrain, reassess the employee, and document these activities.

Each pharmacy position is assessed initially and at a frequency as outlined in the USP Standards.

USP <795> References

Section 2: Personal Training and Evaluation.

USP <797> References

Section 2: Personal Training and Evaluation.

- Section 2.1: Demonstrating Knowledge and Competency of Core Skills.
- Section 2.2: Demonstrating Competency in Garbing and Hand Hygiene.
- Section 2.3: Competency Testing in Aseptic Manipulation.

USP <800> References

Section 9: Personnel Training.

Reference Documents, as applicable per location

Bubble Point Filter Integrity Test Competency

Sterilization by Filtration – Sterile Compounding

Terminal Sterilization by Dry Heat – Sterile Compounding

Terminal Sterilization by Steam – Sterile Compounding

Master Formulation Record Generation and Editing

Pre-Release Inspection – Compounded Sterile Preparations

Bacterial Endotoxin Testing – Sterile Compounding

Sterility Testing – Sterile Compounding

Pre-Release Inspection – Compounded Non-Sterile Preparations

Method Suitability Testing – Sterile Compounding

Shipping Temperature-Controlled Items

Aseptic Technique – Sterile Non-Hazardous Compounding

Annual Test on USP <797> and Aseptic Technique Including Pharmaceutical Math

Annual Test on USP <795>, SDSs, COAs, SOPs, and Pharmaceutical Math

Principals of HEPA and Unidirectional ISO Class 5 Air

Liquid and Semisolid Dosage Form Preparations – Non-Sterile Non-Hazardous Compounding

Solid Dosage Form Preparations – Non-Sterile Non-Hazardous Compounding

General Equipment Skills Competency

IV and SubQ Infusion Pump Cleaning and Testing

Enteral Pump Cleaning and Testing

Balance Calibration and Cleaning – Sterile Compounding

Gown, Garb, and Hand Hygiene – Sterile Non-Hazardous Compounding

Gown, Garb, and Hand Hygiene – Non-Sterile Non-Hazardous Compounding

PEC Use – Laminar Airflow Workbench (LAFW) – Sterile Non-Hazardous Compounding

PEC Use – Biological Safety Cabinet (BSC) – Sterile Non-Hazard Compounding

PEC Use – Containment Ventilated Enclosure (CVE)-Biological Safety Cabinet (BSC) – Non-Sterile Non-Hazardous Compounding

PEC Use – Compounding Aseptic Isolator (CAI)-Compounding Aseptic Containment Isolator (CACI) – Sterile Non-Hazardous Compounding

Surface Sampling – Sterile Compounding

Viable Air Sampling – Sterile Compounding

General Pharmacy Area Cleaning and Disinfecting/Sanitizing – Sterile Non-Hazardous Compounding

PEC Cleaning and Disinfecting – Sterile Non-Hazardous

SEC Cleaning and Disinfecting – Sterile Non-Hazardous

PEC Cleaning and Sanitizing – Non-Sterile Non-Hazardous

SEC Cleaning and Sanitizing – Non-Sterile Non-Hazardous

General Pharmacy Area Cleaning and Disinfecting/Sanitizing – Non-Sterile Non-Hazardous Compounding

Ampules, Vials, Cassettes, Elastomerics, ACDs, and Pools – Sterile Non-Hazardous Compounding

Compounding Equipment – Non-Sterile Compounding

Spill Management – Hazardous Compounding

Gown, Garb, and Hand Hygiene – Sterile Hazardous Compounding

Gown, Garb, and Hand Hygiene – Non-Sterile Hazardous Compounding

C-PEC Deactivating, Decontaminating, Cleaning, and Disinfecting – Sterile Hazardous Compounding

C-SEC Deactivating, Decontaminating, Cleaning, and Disinfecting – Sterile Hazardous Compounding

Hazardous Materials Disposal

C-PEC Deactivating, Decontaminating, Cleaning, and Sanitizing – Non-Sterile Hazardous Compounding

C-SEC Deactivating, Decontaminating, Cleaning, and Sanitizing – Non-Sterile Hazardous Compounding

Liquid and Semisolid Dosage Form Preparations – Non-Sterile Hazardous Compounding

Solid Dosage Form Preparations – Non-Sterile Hazardous Compounding

Aseptic Technique – Sterile Hazardous Compounding

Annual Test on USP <800>

C-PEC Use – Biological Safety Cabinet – Sterile Hazardous Compounding

C-PEC Use – Compounding Aseptic Containment Isolator (CACI) – Sterile Hazardous Compounding

C-PEC Use – Containment Ventilated Enclosure (CVE)-Biological Safety Cabinet (BSC) – Non-Sterile Hazardous Compounding

General Pharmacy Area Decontaminating, Cleaning, and Disinfecting/Sanitizing – Sterile Hazardous

General Pharmacy Area Decontaminating, Cleaning, and Disinfecting/Sanitizing – Non-Sterile Hazardous

Ampules, Vials, Cassettes, Elastomerics – Sterile Hazardous Compounding

Compounding Ingredient Receipt, Evaluation, Handling, Storage, and Selection – Sterile Hazardous

Compounding Ingredient Receipt, Evaluation, Handling, Storage, and Selection – Non-Sterile Hazardous

Compounding Ingredient Receipt, Evaluation, Handling, Storage, and Selection – Sterile Non-Hazardous

Compounding Ingredient Receipt, Evaluation, Handling, Storage, and Selection – Non-Sterile Non-Hazardous

Automated Compounding Device (ACD) Use – Sterile Compounding

Competency Assessment Template

Competency Assessment Plan of Correction Template

This document has:

- ☐ been further customized as in
- ☐ NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
10/20/2023	P-2.001.01	Initial release.	N/A	Kelly Klotz
10/31/2024	P-2.001.01	Annual review.	N/A	Mike Blaine

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Statement of Continuing Pharmacy Education Credit

Douglas James Navarro

Has successfully completed the 20.0-hour (CEUs: 2) ACPE-provider accredited course

National Sterile Compounding Training - October 2024

Activity Date:	Tuesday October 1, 2024
ACPE UAN:	0156-9999-23-065-B07-P
Activity Type:	Application
Date Issued:	Monday October 28, 2024

CE Administrator's Authorized Signature

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Statement of Continuing Pharmacy Education Credit

Brooklyn Granato

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

National Sterile Compounding Training - October 2024

Activity Date:	Tuesday October 1, 2024
ACPE UAN:	0156-9999-23-066-B07-T
Activity Type:	Application
Date Issued:	Tuesday November 5, 2024

CE Administrator's Authorized Signature

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Statement of Continuing Pharmacy Education Credit

Brooklyn Granato

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

National Sterile Compounding Training - August 2024

Activity Date:	Thursday August 1, 2024
ACPE UAN:	0156-9999-23-066-B07-T
Activity Type:	Application
Date Issued:	Tuesday November 5, 2024

CE Administrator's Authorized Signature

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Statement of Continuing Pharmacy Education Credit

Jason Morrison

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

National Sterile Compounding Training - October 2024

Activity Date:	Tuesday October 1, 2024
ACPE UAN:	0156-9999-23-066-B07-T
Activity Type:	Application
Date Issued:	Wednesday October 30, 2024

CE Administrator's Authorized Signature

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Statement of Continuing Pharmacy Education Credit

Jason Morrison

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

National Sterile Compounding Training - August 2024

Activity Date:	Thursday August 1, 2024
ACPE UAN:	0156-9999-23-066-B07-T
Activity Type:	Application
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Statement of Continuing Pharmacy Education Credit

Nader Wahba

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

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Statement of Continuing Pharmacy Education Credit

Nader Wahba

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

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Statement of Continuing Pharmacy Education Credit

Alyssa Turner

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

National Sterile Compounding Training - October 2024

Activity Date:	Tuesday October 1, 2024
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Activity Type:	Application
Date Issued:	Wednesday October 30, 2024

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Statement of Continuing Pharmacy Education Credit

Alyssa Turner

Has successfully completed the 40.0-hour (CEUs: 4) ACPE-provider accredited course

National Sterile Compounding Training - August 2024

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Section Name: Cleaning, Sanitizing, Disinfecting, and Applying Sporicidal Agents	SOP Name: Cleaning and Disinfecting – Sterile Non-Hazardous Compounding
SOP: S-7.001.01	Last Revision/Review: 10/31/2024
Accreditation Standards: TCRX 3-B, TCRX6-C, TCRX6-E, TCRX6-L, TCRX6-M, TCRX6-O, DRX4-7C, DRX4-14F, DRX7-8F, DRX7-8G, DRX7-8N, DRX7-8P, DRX7-9A	

Policy

Various cleaning and disinfecting activities and tasks are performed to maintain the sterile compounding area in compliance with USP <797> and other state and federal laws and regulations. These activities must be completed according to a specified schedule and process to minimize the chance of microbial contamination of compounded sterile preparations (CSPs).

Personnel who perform cleaning and disinfecting activities in the cleanroom suite must be trained and competent in appropriate procedures to protect the environment from microbial contamination.

Pharmacy personnel are responsible for completing these tasks and activities according to a specified schedule and process.

Personnel performing these activities must wear appropriate PPE (e.g., resistant to the cleaning agents used; eye, face, and respiratory protection as warranted by the activity being performed) in accordance with USP <797>.

The designated person and pharmacist-in-charge are responsible for supervising and guaranteeing these tasks and activities are completed properly.

Definitions

Cleaning: The process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically using water with detergents or enzymatic agents.
Cleaning Agent: An agent, usually containing a surfactant, used for the removal of substances such as dirt, microbes, and chemicals from surfaces.
Disinfectant or Disinfecting Agent: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that are also effective against bacterial and fungal spores.
Disinfection: The process of inhibiting or destroying microorganisms on surfaces.
Dwell Time: The amount of time a sanitizer or disinfectant must be in a liquid state and in contact with an object or surface to achieve its reported degree of antimicrobial action. Also known as contact time.
Sporicidal Agent: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Sterile isopropyl alcohol (sIPA): A powerful disinfectant that works by removing water from microbes, leading to cell wall disruption as it evaporates; sIPA is not sporicidal and has no detergent properties. It contains, by volume, 70% USP-grade isopropyl alcohol and 30% USP-purified water that comes in sterile wipes, trigger spray bottles, squeeze bottles, gallon sizes, etc.

Procedures

USP <797> describes three steps in the cleaning and disinfection of sterile compounding areas and their contents:

- Cleaning: The process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically using a cleaning agent.
- Disinfecting: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria.
- Sporicidal Treatment: The use of a disinfectant capable of destroying bacterial and fungal spores.

Cleaning and disinfecting activities occur in three contexts regarding the creation of CSPs:

- Treatment of drugs, supplies, and other items coming into the sterile compounding facility for the compounding of CSPs.
- Treatment of gloved hands, objects, and work surfaces within the PEC during sterile compounding.
- Treatment of the sterile compounding facilities, equipment, and furnishings within the sterile compounding area. This is the primary focus of this document.

Responsibilities

- The designated person and PIC are responsible for ensuring that:
    - All processes concerned with cleaning and disinfecting the classified areas comply with this SOP.
    - Routine daily, weekly (Category 3 only), and monthly cleaning/disinfecting processes actually achieve a dwell time appropriate for the agents used.
- Cleaning and disinfecting activities must only be performed by adequately trained personnel who have passed competency assessments and gowning, garbing, and hand hygiene per policy.
- All cleaning personnel (e.g., outside vendors, housekeeping/janitorial department) must adhere to all cleaning policies and procedures.
- Cleaning and disinfecting activities must be documented properly and promptly using the appropriate cleaning and maintenance logs or compliance software.
    - "N/A" should be used when, for instance, the compounding facility does not undergo the daily regimen or during weekends and holidays rather than leaving the entry blank.
    - These records must be reviewed at least monthly by the designated person for accuracy and completeness. This review must be documented.

Choice of Agents

- The pharmacy may choose from a wide variety of commercially available cleaning, disinfecting, and sporicidal agents or an EPA-registered, one-step disinfectant cleaner, taking into consideration compatibility, effectiveness, and the potential of leaving a residue.
- There are many commercially available EPA-registered, one-step products that not only clean, disinfect, and are sporicidal, but also combine one or more traits to be effective at decontamination:
    - Chlorine-containing agents (e.g., sodium hypochlorite).
    - Accelerated hydrogen peroxide products that include surfactants, wetting agents, and chelating agents.
- All peroxide-based agents and neutral or acidic chlorine agents may be used on stainless steel without the need for a follow-up rinsing step. If sodium hypochlorite is used on stainless steel, it must be neutralized with one-percent sodium thiosulfate or, preferably, followed with an agent to remove the sodium hypochlorite (e.g., isopropyl alcohol, water for irrigation, germicidal detergent) to prevent corrosion.
- Rotation of disinfectants is not required by USP <797>, not advised by USP <1072>, nor recommended by many microbiologists.
    - https://www.pharmaceuticalonline.com/doc/should-you-rotate-disinfectants-industry-experts-weigh-in-0001
    - If a pharmacy, nonetheless, elects to rotate disinfectants, it should select agents with differing mechanisms of action.
- While sIPA is a very useful disinfectant for treating items entering the sterile compounding facility or during sterile compounding, the following limitations apply:
    - sIPA is not sporicidal.
    - sIPA is not a good cleaning agent or solvent.
    - While dwell time is not as important for sIPA because of its mechanism of action of desiccating microbes, enough must be used to wet all treated surfaces.
    - sIPA must be allowed to air dry to be effective.
- USP <797> only requires the use of sterile IPA:
    - Within the PEC.

- On objects brought into the PEC.
- Sterile IPA, sporicidal disinfectant, or an EPA-registered disinfectant is used as a pre-treatment for items being brought into the sterile compounding facility.
- Non-sterile IPA may be used for general facility cleaning.
- Some cleaning/disinfecting agents leave residues. Although these residues might have antimicrobial activity themselves, their potential to become airborne particulates means that a pharmacy should either:
  - Use an agent leaving no or very little residue visible on windows or smooth surfaces.
  - Use a secondary agent (e.g., distilled water, sterile water for injection (SWI), sterile water for irrigation (SW Irrig), sIPA) as follows:
    - PEC interior: SWI, SW Irrig, sIPA.
    - SEC and other areas and objects: Distilled water, SWI, SW Irrig, sIPA, IPA.
- Although there is no accepted standard for what an acceptable degree of residue is, the following resource provides valuable information on this topic:
- https://www.cleanroomtechnology.com/news/article_page/Challenging_disinfectant_residue_as_per_GMP_Annex_1/160751.
- The beyond-use dates of cleaning and disinfecting agents, including the agents prepared by the pharmacy, must be documented on the container of the agent and be based either on manufacturer instructions or documented stability information. Once opened, sterile cleaning and disinfection supplies (e.g., containers of sterile wipes, bottles of 70% sIPA) may be used for the period specified by the manufacturer.
- If applicable, secondary containers such as spray or pour bottles must bear labels containing but not limited to:
  - Name.
  - Strength.
  - Lot number.
  - Transfer date.
  - Beyond-use date.
  - Manufacturer or source.
- A best-practice recommendation is to purchase ready-to-use products that are small enough to not require repackaging.
- Low-lint wipes and cleaning, disinfecting, and sporicidal agents must be sterile for use within the PEC and should be sterile in classified areas outside the PEC.

Means of Application

- Mops should consist of stainless steel or other impermeable substances such as plastic. Wooden handles, even if thoroughly painted, are not to be used.
- Mops and other tools used to clean the sterile compounding areas (e.g., PEC, SEC) must be dedicated for use in their respective areas, replaced should they become damaged, and removed only for disposal.
- Reusable cleaning tools, including mop handles/tools, must be cleaned and disinfected before and after each use.
- Mop heads must be non-shedding and should be disposable.
- A best-practice recommendation is to use a microfiber cleaning tool/system.
- Mops should be hung from the anteroom wall, if possible. Buckets, if used, should be hung and inverted to allow for drying.
- It is essentially impossible to apply enough of most agents to such surfaces as floors, walls, and ceilings using only a spray bottle. The act of pouring or squirting of agents on surface or mop head may be considered.
- Spray bottles may be practical and recommended to apply an agent to furnishings such as work surfaces, sinks, or equipment.
- Spray bottles should not be used to treat the interior of PECs because of the potential for wetting the HEPA filter; if used, it must be done with the utmost caution.
- All wipes used in the sterile compounding facility must be low-lint and *must* be sterile for use within the PEC, and *should* be sterile when used in the SEC.

- Dedicated scrub brushes should be used to clean objects and areas such as exposed sink plumbing, wheels, door hinges, and the junctions of floors, walls, and ceilings.
- Disposable cleaning supplies, when used, must be discarded after each cleaning activity.

Application Strategy

- If cleaning and disinfecting are performed as separate steps, cleaning must be performed first. Use of an EPA-registered, one-step disinfectant cleaner eliminates the need for two steps.
- Because a cleaning and disinfecting agent(s) can only work if present in a liquid state, the pharmacy must determine the dwell time of the agents it uses and ensure, through observation of cleaning and disinfecting activities, that a sheen from the agent is visible on surfaces and objects for the specified dwell time.
- The ability of an agent to dissolve residue is also dependent on being in a liquid state for enough time.
- Even slight degrees of texture on ceilings, walls, and floors will significantly increase the amount of cleaning/disinfecting agent needed.
- For daily floor cleaning and disinfecting, one mop head may be used to treat the anteroom and buffer room floor if the employee begins in the buffer room and works outward into the anteroom.
- For the monthly cleaning of ceilings and walls, one mop head may be used to clean first the ceiling and then the walls, with a different mop head used to clean the floors.
- Mop heads are replaced when visibly soiled, torn, damaged, or at the end of each day's cleaning activities.
- Manufacturer instructions should be consulted prior to the use of equipment/tools and agents to assess whether they are appropriate for various surfaces.
- When applying cleaning and disinfecting agents, use a slow, uniform motion and overlapping strokes that slightly overlap by at least 25 percent.
- Personnel performing cleaning must follow the same garbing and hand hygiene process as used before compounding.
- For the monthly cleaning of walls, ceilings, and surfaces under the hinged or removable work surface of the PEC, personnel should wear face and eye protection (e.g., face shield and goggles) to prevent any splashing onto the face or into the eyes. Such protection is required if called for in the product's safety data sheet.
- A best-practice recommendation is to place a dedicated, easy-to-clean metal or plastic step stool or ladder within the anteroom for use in reaching the ceiling, shelving, and the tops of the PECs.
- Steps for PEC cleaning, disinfecting, and applying sporicidal disinfectants:
    - Remove visible particles, debris, or residue with an appropriate solution (e.g., SWI or SW Irrig) using sterile, low-lint wipes.
    - Using sterile, low-lint wipes, apply a sterile cleaning agent followed by a sterile disinfecting agent, or apply an EPA-registered (or equivalent), one-step disinfectant cleaner to the equipment and all interior surfaces of the PEC. When applying a sporicidal agent is required, after cleaning and disinfecting, use sterile low-lint wipes to apply the sterile sporicidal disinfectant. **Note:** If the sporicidal disinfectant is an EPA-registered (or equivalent), one-step disinfectant sporicidal cleaner, separate cleaning and disinfecting steps are not required.
    - Ensure the contact time specified by the manufacturer is achieved.
    - Using sterile low-lint wipes, apply sterile 70% IPA to equipment and all interior surfaces in the PEC.
    - Allow the surface to dry completely before beginning compounding.

Direction of Application

- Cleaning must be performed working in the direction from the cleanest to the dirtiest areas.
- Ceilings start at the wall opposite the room entry door and end at the door.
- Floors should be mopped using slightly overlapping (by at least 25 percent) broad strokes whenever possible, moving from the least accessible and presumably "cleanest" area of the buffer room and working toward the entrance to the buffer room and then onto the anteroom. Repeat the process in the anteroom, moving toward and ending at the exit to the anteroom.
- For walls, including doors, windows, and door frames, start at the wall opposite the room-entry door. Mop top to bottom, ending at the door.

- For work surfaces, carts, and stools, start at the top and work downward.
- For PECs with horizontal airflow, cleaning and disinfecting proceeds in the following order:
    - Interior ceiling: moving left to right, back to front.
    - HEPA grill: moving left to right, top to bottom.
    - Bar and individual hooks, if applicable.
    - Interior sides of the PEC: moving top to bottom, back to front.
    - Work surface: moving left to right, back to front.
- For PECs with vertical airflow, cleaning and disinfecting proceeds in the following order:
    - Interior ceiling: moving left to right, back to front.
    - Bar and individual hooks, if applicable.
    - Back wall: moving left to right, top to bottom.
    - Interior sides of the PEC: moving top to bottom, back to front.
    - Work surface: moving left to right, back to front.
    - Interior sash/visor: moving left to right, top to bottom.

Treatment Frequency and Locations

- Cleaning and disinfection of the buffer room, work surfaces, or equipment outside of the PEC must not occur at the same time as compounding activities. The interiors of PECs not involved in compounding may be cleaned and disinfected at any time.
- If compounding is not performed daily, cleaning and disinfecting must be completed before initiating compounding.
- Cleaning and disinfecting of the PEC must occur:
    - At the beginning of every shift.
    - Before each batch.
    - Approximately every 30 minutes, unless the compounding process takes longer than 30 minutes, in which case the compounding must not be disrupted. The work surface of the PEC must be cleaned and disinfected immediately after the compounding process is completed.
    - After spills.
- If a PEC is not running, its interior surfaces must be cleaned and disinfected before use. This should be done only after an acceptable "purge time," as defined by the manufacturer, that allows all air to be replaced with ISO Class 5 air.
- It is preferable to perform daily, weekly, and monthly cleaning and disinfection at the end of the workday to encourage the use of enough agent(s) to reach an adequate dwell time on surfaces.
- The interior of the PEC to be used and equipment inside of the PEC must be cleaned and disinfected daily, preferably in the morning or immediately prior to compounding, and when surface contamination is known or suspected. The PEC must also be cleaned and disinfected anytime a spill occurs, before and after certification, and any time voluntary interruptions occur.
- Care must be taken to clean and disinfect all exterior surfaces of PECs, stools, carts, and other equipment within sterile compounding areas.
- The table below summarizes what surfaces and objects must be treated and how often they are treated with cleaning, disinfecting, and sporicidal agents. Tasks are performed in the order shown.

		Cleaning and Disinfecting			Applying Sporicidal Disinfectant	
Order	Sterile Non-Hazardous	Every Compounding Day/Shift	Between Batches or Every 30 mins[1]	Monthly	Weekly	Monthly
1	PEC interior	x	x		Category 3	Category 1 and/or 2
2	Equipment inside of PEC	x	x		Category 3	Category 1 and/or 2
3	PEC work tray/surface	x	x			All categories
4	PEC underneath work tray/surface			x		All categories
5	Work surfaces outside of PEC	x			Category 3	Category 1 and/or 2
6	Ceiling			x		All categories
7	Walls			x		All categories
8	PEC exterior			x	Category 3	Category 1 and/or 2
9	Equipment outside of PEC			x		All categories
10	Pass-through	x			Category 3	Category 1 and/or 2
11	Storage shelving and bins/totes			x		All categories
12	Sink	x				All categories
13	Floor	x			Category 3	Category 1 and/or 2
14	Refrigerator/freezer			x		All categories

[1] At least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted, and the work surface of the PEC must be disinfected immediately after compounding.

- As described above, the use of an EPA-registered, one-step disinfecting/cleaning agent with sporicidal activity allows the pharmacy to use only one agent for all tasks.
- If tacky mats are used outside of the entrance to the anteroom, they should be changed any day compounding occurs or the anteroom has been entered. The used layer should be carefully folded up from the edges and disposed of. Permanent tacky mats should be treated as per the manufacturer's instructions any day compounding occurs or the anteroom has been entered.
    - A best-practice recommendation is for the tacky mat to be placed vertically with the door so as to increase the number of steps taken to cross it (it should not look like a welcome mat).
- The liners of garbage containers in any classified area should be sealed before removal and promptly disposed of.
- "Daily" cleaning is not required if no compounding or other activity takes place that day, unless required by state law.
    - However, a best-practice recommendation is that the "daily" regimen should be performed no less often than weekly.
- If the air supply to the SEC is interrupted for more than 12 hours for any reason, a complete monthly cleaning cycle must be performed prior to reuse. If interrupted for more than 24 hours, a "triple clean" must be performed.

Triple Cleaning

- Triple cleaning is a process used when:
  - Classified areas have been exposed to significant amounts of unclassified air (e.g., during the removal or addition of PECs to the area, the repair of ceiling tiles or equipment, etc.).
  - SEC airflow has been interrupted for a significant period of time.
  - Viable air and surface sampling results exceed alert levels or show an unfavorable trend.
- Triple cleaning is essentially a repetition of routine monthly cleaning performed three times in immediate succession. Special care is taken to use generous amounts of cleaning/disinfecting agents and pay special attention to hard-to-reach areas such as wheels, crevices, and the junctions of floors, walls, and ceilings.
- If viable air or surface sampling has identified specific microbes, ensure that selected disinfectants are effective against them.
- Each treatment should be allowed to dry before the application of the next agent.

Objects Entering the SEC

- All items crossing into the clean side of the anteroom, entering a classified air area via pass-through, or brought into the SCA must be wiped with a low-lint wipe heavily saturated with one of the following agents by gloved personnel:
  - Sporicidal agent: Of sufficient quantity to reach all surfaces and remain in a liquid state for the agent's dwell time.
  - EPA-registered disinfectant: Of sufficient quantity to reach all surfaces and remain in a liquid state for the agent's dwell time.
  - sIPA: Of sufficient quantity to reach all surfaces and is allowed to fully dry.
  - Alternatively, these agents may be thoroughly sprayed onto objects to ensure coverage of all surfaces and then wiped off with a low-lint wipe after the agent's dwell time has passed or, in the case of sIPA, is allowed to air dry.
    The wiping procedure should not compromise the packaging integrity or render the product label unreadable.
- Cardboard of any kind should not enter the sterile compounding facility, if possible; corrugated or unsealed cardboard must never enter a classified area.
- Any objects brought into the sterile compounding facility by non-employees (e.g., equipment and carts used by certification technicians) must be subjected to the same cleaning and disinfecting regimen as anything used in compounding or cleaning/disinfecting activities.
- The diagram above summarizes for the SEC what surfaces and objects must be treated and how often they are to be treated with cleaning, disinfecting, and sporicidal agents. Tasks are performed in the order shown.

Objects Entering the PEC

- All items brought into a PEC must be thoroughly wiped with a sIPA-saturated, low-lint wipe just prior to their introduction into a PEC. The wiping procedure must not render the product label unreadable.
- The sIPA on these items must be allowed to dry prior to use.
- Sterile items enclosed in sealed packaging or containers may be removed as they are introduced into a PEC without further treatment.
- The diagram above summarizes for a PEC what surfaces and objects must be treated and how often they are to be treated with cleaning, disinfecting, and sporicidal agents. Tasks are performed in the order shown.

USP <797> References

Section 4: Facilities and Engineering Controls.

- Section 4.4: Water Sources.

Section 7: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in Compounding Areas.

- Section 7.1: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants.
  - Section 7.1.1: Agents.
  - Section 7.1.2: Supplies.

- Section 7.2: Procedures for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA in the PEC.

Section 8: Introducing Items into the SEC and PEC.

- Section 8.1: Introducing Items into the SEC.
- Section 8.2: Introducing Items into the PEC.
- Section 8.3: Use of Sterile 70% IPA on Critical Sites within the PEC.

Reference Documents

PEC Cleaning and Disinfecting – Sterile Non-Hazardous Compounding Competency.
SEC Cleaning and Disinfecting – Sterile Non-Hazardous Compounding Competency.
PEC Cleaning and Maintenance Log – Sterile Non-Hazardous Compounding Area.
SEC Cleaning and Maintenance Log – Sterile Non-Hazardous Compounding Area.
Gown, Garb, and Hand Hygiene – Sterile Non-Hazardous Compounding SOP.

Equipment and Materials

Approved EPA-registered (or equivalent), one-step disinfectant cleaner.
Approved EPA-registered (or equivalent) sporicidal agent.
Sterile 70% isopropyl alcohol (sIPA).
SWI or SW Irrig.
Disposable low-lint wipes.
Mops and buckets or microfiber cleaning tool/system.
PPE.

This document has:

- ❑ been further customized as in
- ❑ NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
02/20/2024	S-7.001.01	New format and ref to new USP Standards effective 11/1/2023	N/A	Kelly Klotz
10/31/2024	S-7.001.01	Annual review.	N/A	Mike Blaine

Section Name: Cleaning, Sanitizing, Disinfecting, and Applying Sporicidal Agents	SOP Name: Deactivating, Decontaminating, Cleaning, and Disinfecting – Sterile Hazardous Compounding
SOP: S-800.005.01	Last Revision/Review: 10/31/2024
Accreditation Standards: TCRX 3-B, TCRX3-E, TCRX6-C, TCRX6-E, TCRX6-L, TCRX6-M, TCRX6-N, TCRX6-O, DRX4-7C, DRX4-14F, DRX7-8F, DRX7-8G, DRX7-8N, DRX7-8O, DRX7-8O.01, DRX7-8P, DRX7-9A	

Policy

Deactivating, decontaminating, cleaning, and disinfecting activities and tasks must be performed to maintain the hazardous sterile compounding area in compliance with USP <797>, USP <800>, and other state and federal laws and regulations. These activities must be completed according to a specified schedule and process to minimize the chance of microbial contamination of compounded sterile preparations (CSPs) and exposure of personnel and the environment to hazardous drugs (HDs).

Personnel who perform deactivating, decontaminating, cleaning, and disinfecting activities in HD handling areas must be trained and competent in appropriate procedures to protect themselves and the environment from HD and microbial contamination.

Personnel performing these activities must wear appropriate PPE (e.g., resistant and impermeable to the cleaning agents used; eye, face, and respiratory protection as warranted by the activity being performed) in accordance with USP <797> and USP <800>.

Pharmacy personnel are responsible for completing these tasks and activities according to a specified schedule and process.

The designated person and Pharmacist in Charge are responsible for supervising and guaranteeing these tasks and activities are completed properly.

Definitions

Cleaning: The process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically using water with detergents or enzymatic agents.
Cleaning Agent: An agent, usually containing a surfactant, used for the removal of substances such as dirt, microbes, and chemicals from surfaces.
Deactivating Agent: An agent that transforms a HD into a less-hazardous substance.
Deactivation: Treatment of a HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less-hazardous agent, rendering it chemically inert.
Decontaminating Agent: A substance that inactivates, neutralizes, or removes HD contaminants on surfaces, usually by chemical means.
Decontamination: The inactivation, neutralization, or removal of HD contamination on surfaces, usually by chemical means.
Disinfectant or Disinfecting Agent: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria. Sporicidal disinfectants are considered a special class of disinfectants that also are effective against bacterial and fungal spores.
Disinfection: The process of inhibiting or destroying microorganisms on surfaces.
Dwell Time: The amount of time a sanitizer or disinfectant must be in a liquid state and in contact with an object or surface to achieve its reported degree of antimicrobial action. Also known as contact time.
Sporicidal Agent: A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Sterile isopropyl alcohol (sIPA): A powerful disinfectant that works by removing water from microbes, leading to cell wall disruption as it evaporates; sIPA is not sporicidal and has no detergent properties. It contains, by volume, 70% USP-grade isopropyl alcohol and 30% USP-purified water that comes in sterile wipes, trigger spray bottles, squeeze bottles, gallon sizes, etc.

Procedures

USP <797> describes three steps in the cleaning and disinfection of sterile compounding areas and their contents:

- Cleaning: The process of removing substances (e.g., organic and inorganic material) from objects and surfaces, normally accomplished manually or mechanically using a cleaning agent.
- Disinfecting: A chemical or physical agent used on inanimate surfaces and objects to destroy fungi, viruses, and bacteria.
- Sporicidal Treatment: The use of disinfectant capable of destroying bacterial and fungal spores.

USP <800> discusses cleaning and disinfection but also introduces two new and somewhat overlapping terms:

- Deactivation: Treatment of a HD contaminant on surfaces with a chemical, heat, ultraviolet light, or another agent to transform the HD into a less-hazardous agent, rendering it chemically inert.
- Decontamination: The inactivation, neutralization, or removal of HD contamination on surfaces, usually by chemical means.

Deactivating, decontaminating, cleaning, and disinfecting activities occur in four contexts regarding the compounding and handling of HD-CSPs.

- Treatment of drugs, supplies, and other items coming into the sterile compounding facility for the compounding of HD-CSPs.
- Treatment of gloved hands, objects, and work surfaces within the C-PEC during HD sterile compounding.
- Treatment of the sterile compounding facilities, equipment, and furnishings within the HD sterile compounding area. This is the primary focus of this document.
- Decontamination of objects and surfaces containing HD residue. This is another major focus of this document.

Responsibilities

- The designated person and PIC are responsible for ensuring that:
    - All processes concerned with deactivating, decontaminating, cleaning, and disinfecting the classified areas comply with this SOP.
    - Routine daily, weekly (Category 3 only), and monthly deactivating, decontaminating, cleaning, and disinfecting processes actually achieve a dwell time appropriate for the agents used.
- Deactivating, decontaminating, cleaning, and disinfecting activities must only be performed by adequately trained personnel who have passed a competency assessments for PEC and SEC DDCD procedures and gowning, garbing, and hand hygiene per policy.
- All cleaning personnel (e.g., outside vendors, housekeeping/janitorial department) must adhere to all cleaning policies and procedures.
- Deactivating, decontaminating, cleaning, and disinfecting activities must be documented properly and promptly by using the appropriate cleaning and maintenance logs or compliance software.
    - "N/A" should be used when, for instance, the compounding facility does not undergo the daily regimen or during weekends and holidays, rather than leaving the entry blank.
    - These records must be reviewed at least monthly by the designated person for accuracy and completeness. This review must be documented.

Choice of Agents

- The pharmacy may choose from a wide variety of commercially available deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents, or an EPA-registered, one-step disinfectant cleaner, taking into consideration the appropriateness for the type of HD contaminants, compatibility, effectiveness, and the potential of leaving a residue.
- Although a "universal decontaminating agent" does not exist, two types of products have the ability to deactivate many chemical substances, including HDs:
    - Oxidizing agents.
    - Agents with high or low pH values (pH <3 or >12).

- Although the deactivation of HDs is an appealing goal, the act of physical cleaning and decontaminating should be the primary means of protecting against HD contamination.
- There are many commercially available EPA-registered, one-step agents that not only clean, disinfect, and are sporicidal, but also combine one or more traits to be effective at decontamination:
    - Chlorine-containing products (e.g., sodium hypochlorite).
    - Accelerated hydrogen peroxide products that include surfactants, wetting agents, and chelating agents.
- Detailed information on this topic may be found at: https://ordspub.epa.gov/ords/pesticides/f?p=PPLS:1
- All peroxide-based agents and neutral or acidic chlorine agents may be used on stainless steel without the need for a follow-up rinsing step. If sodium hypochlorite is used on stainless steel, it must be neutralized with one-percent sodium thiosulfate or, preferably, followed with an agent to remove the sodium hypochlorite (e.g., isopropyl alcohol, water for irrigation, germicidal detergent) to prevent corrosion.
- The pharmacy should consult pharmaceutical literature to determine what type of decontaminating agent is most effective against the HDs handled by the pharmacy.
- Rotation of disinfectants is not required by USP <797>, not advised by USP <1072>, nor recommended by many microbiologists.
    - https://www.pharmaceuticalonline.com/doc/should-you-rotate-disinfectants-industry-experts-weigh-in-0001
    - If a pharmacy, nonetheless, elects to rotate disinfectants, it should select agents with differing mechanisms of action.
- While sIPA is a very useful disinfectant for treating items entering the sterile compounding facility or during sterile compounding, the following limitations apply:
    - sIPA is not sporicidal.
    - sIPA is not a good cleaning agent or solvent.
    - sIPA is not an effective deactivator of HDs.
    - While dwell time is not as important for sIPA because of its mechanism of action of desiccating microbes, enough must be used to actually wet all treated surfaces.
    - sIPA must be allowed to fully air dry to be effective.
- USP <797> only requires the use of sterile IPA:
    - Within the C-PEC.
    - On objects brought into the C-PEC.
- Sterile IPA, sporicidal disinfectant, or an EPA-registered disinfectant is used as a pre-treatment for items being brought into the sterile compounding facility.
- Non-sterile IPA may be used for general facility cleaning.
- Some cleaning/disinfecting agents leave residues. Although these residues might have antimicrobial activity themselves, their potential to become airborne particulates means that a pharmacy should either:
    - Use an agent leaving no or very little residue as visible on windows or smooth surfaces.
    - Use a secondary agent (e.g., distilled water, sterile water for injection (SWI), sterile water for irrigation (SW Irrig), sIPA) as follows:
        - C-PEC interior: SWI, SW Irrig, sIPA.
          C-SEC and other areas and objects: Distilled water, SWI, SW Irrig, sIPA, IPA.
- Although there is no accepted standard for what an acceptable degree of residue is, the following resource provides valuable information on this topic: https://www.cleanroomtechnology.com/news/article_page/Challenging_disinfectant_residue_as_per_GMP_Annex_1/160751
- The beyond-use dates of deactivating, decontaminating, cleaning, and disinfecting agents, including the agents prepared by the pharmacy, must be documented on the container of the agent and be based either on manufacturer instructions or documented stability information. Once opened, sterile cleaning and disinfection supplies (e.g., containers of sterile wipes, bottles of 70% sIPA) may be used for the period specified by the manufacturer.
- If applicable, secondary containers such as spray or pour bottles must bear labels containing but not limited to:
    - Name.
    - Strength.

    - Lot number.
    - Transfer date.
    - Beyond-use date.
    - Manufacturer or source.
- A best-practice recommendation is to purchase ready-to-use products that are small enough to not require repackaging.
- Low-lint wipes and deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents must be sterile for use within the C-PEC and should be sterile in classified areas outside the C-PEC.

Means of Application

- Mops should consist of stainless steel or other impermeable substances such as plastic. Wooden handles, even if thoroughly painted, are not to be used.
- Mops and other tools used to clean the sterile hazardous compounding areas (e.g., C-PEC, C-SEC) should be dedicated for use in their respective areas, replaced should they become damaged, and removed only for disposal. The mop handle/tool must be cleaned and disinfected prior to being used in the C-PEC.
- Reusable cleaning tools, including mop handles/tools, must be deactivated, decontaminated, cleaned, and disinfected before and after each use.
- Mop heads must be non-shedding and should be disposable.
- A best-practice recommendation is to use a microfiber cleaning tool/system.
- Mops should be hung from the C-SEC wall, if possible. Buckets, if used, should be hung and inverted to allow for drying.
- It is essentially impossible to apply enough of most agents to such surfaces as floors, ceilings, and walls using only a spray bottle. The act of pouring or squirting of agents on surface or mop head may be considered.
- Spray bottles may be practical and recommended to apply an agent to furnishings such as sinks or equipment.
- Spray bottles should not be used to treat the interior of C-PECs because of the potential for wetting the HEPA filter and generating airborne HD particles.
- Additionally, spray bottles should not be used to apply liquids to flat surfaces such as work surfaces, floors, walls, or HD-receiving or storage areas because of their potential to aerosolize particulates.
- All wipes used in the sterile compounding facility must be low-lint and *must* be sterile for use within the C-PEC and *should* be sterile when used in the C-SEC.
- Used wipes are disposed of as trace or bulk hazardous waste depending on the degree of HD contamination.
- Dedicated scrub brushes should be used to clean objects and areas such as exposed sink plumbing, wheels, door hinges, and the junctions of floors, walls, and ceilings.
- Disposable cleaning supplies, when used, must be discarded after each cleaning activity in accordance with EPA regulations as trace or bulk hazardous waste depending on the level of contamination.

Application Strategy

- If cleaning and disinfecting are performed as separate steps, cleaning must be performed first. The use of an EPA-registered, one-step disinfectant cleaner eliminates the need for two steps.
- Because a decontaminating, cleaning, and disinfecting agent(s) can only work if present in a liquid state, the pharmacy must determine the dwell time of the agents it uses and ensure, through observation of decontaminating, cleaning, and disinfecting activities, that a sheen from the agent is visible on surfaces and objects for the specified dwell time.
- The designated person is responsible for ensuring that routine daily, weekly (Category 3 only), and monthly deactivating, decontaminating, cleaning, and disinfecting processes actually achieve a dwell time appropriate for the agents used.
- The ability of an agent to dissolve residue is also dependent on the agent being in a liquid state for enough time.
- The dwell time required for a decontaminating agent to deactivate HD residues is seldom known, or would require extensive and expensive chemical testing. This time must furthermore be assumed to vary

for different HDs, if effective at all. A reasonable best-practice recommendation is to assume that the deactivation dwell time is equal to its microbial dwell time.

- Even slight degrees of texture on ceilings, walls, and floors will significantly increase the amount of deactivating, decontaminating, cleaning, and disinfecting agent needed.
- For daily floor cleaning and disinfecting, a separate mop head must be used to treat the anteroom and C-SEC floors.
- For the monthly cleaning of ceilings and walls, one mop head may be used to clean first the ceiling and then the walls. However, a new mop head is required for each room.
- Mop heads are replaced when visibly soiled, torn, damaged, or at the end of each cleaning activity. They are disposed of as trace hazardous waste unless known to be significantly contaminated, in which case they are disposed of as bulk hazardous waste.
- Manufacturer instructions should be consulted prior to the use of equipment/tools and agents to assess whether they are appropriate for various surfaces.
- When applying deactivating, decontaminating, cleaning, and disinfecting agents, use a slow, uniform motion and overlapping strokes that slightly overlap by at least 25 percent.
- Personnel performing cleaning must follow the same garbing and hand hygiene process as used before compounding.
- For the monthly cleaning of walls, ceilings, and surfaces under the hinged or removable work surface of the C-PEC, personnel should wear face and eye protection (e.g., face shield and goggles) to prevent any splashing onto the face or into the eyes. Such protection is required if called for in the product's safety data sheet.
- Respirators or powered air-purifying respirators may be used for additional protection at the pharmacy's discretion.
- A best-practice recommendation is to place a dedicated, easy-to-clean metal or plastic step stool or ladder within the anteroom for use in reaching ceilings, shelving, and the tops of the C-PECs.
- Steps for C-PEC deactivating, decontaminating, cleaning, disinfecting, and applying sporicidal disinfectants:
    - Remove visible particles, debris, or residue with an appropriate solution (e.g., SWI or SW Irrig) using sterile, low-lint wipes.
    - Using sterile, low-lint wipes, apply a sterile deactivating/decontaminating agent, followed by a cleaning agent and then a sterile disinfecting agent, or apply an EPA-registered (or equivalent), one-step decontaminating disinfectant cleaner to equipment and all interior surfaces of the C-PEC. When applying a sporicidal agent is required, use sterile, low-lint wipes to apply the sterile sporicidal disinfectant after decontaminating, cleaning, and disinfecting. **Note:** If the sporicidal disinfectant is an EPA-registered (or equivalent), one-step decontaminating disinfectant sporicidal cleaner, separate decontaminating, cleaning, and disinfecting steps are not required.
    - Ensure the contact time specified by the manufacturer is achieved.
    - Using sterile, low-lint wipes, apply sterile 70% IPA to equipment and all interior surfaces in the C-PEC.
    - Allow the surface to dry completely before beginning compounding.

Direction of Application

- Deactivating, decontaminating, cleaning, and disinfecting must be performed working in the direction from the cleanest to the dirtiest areas.
- Ceilings start at the wall opposite the room-entry door and end at the door.
- Floors should be mopped using slightly overlapping (by at least 25 percent), broad strokes whenever possible, moving from the least accessible and therefore presumably "cleanest" area of the buffer room and working toward the entrance to the buffer room and then onto the anteroom. Repeat the process in the anteroom, using a new mop head, moving toward and ending at the main entrance to the anteroom.
- For walls, including doors, windows, and door frames, start at the wall opposite the room-entry door. Mop top to bottom, ending at the door.
- For work surfaces, carts, and stools, start at the top and work downward.
- For C-PECs with vertical airflow, deactivating, decontaminating, cleaning, and disinfecting proceeds in the following order:
    - Interior ceiling: moving left to right, back to front.

- Bar and individual hooks, if applicable.
- Back wall: moving left to right, top to bottom.
- Interior sides of the PEC: moving top to bottom, back to front.
- Work surface: moving left to right, back to front.
  Interior sash/visor: moving left to right, top to bottom.

Treatment Frequency and Locations

- Deactivating, decontaminating, cleaning, and disinfection of the buffer room, work surfaces, or equipment outside of the C-PEC must not occur at the same time as compounding activities. The interiors of C-PECs not involved in compounding may be deactivated, decontaminated, cleaned, and disinfected at any time.
- If compounding is not performed daily, deactivating, decontaminating, cleaning, and disinfecting must be completed before initiating compounding.
- Cleaning and disinfecting of the C-PEC must occur:
  - At the beginning of every shift.
  - Before each batch.
  - Every 30 minutes, unless the compounding process takes longer than 30 minutes, in which case the compounding must not be disrupted. The work surface of the PEC must be cleaned and disinfected immediately after the compounding process is completed.
  - After spills.
- If a C-PEC is not running for any reason, its interior surfaces must be deactivated, decontaminated, cleaned, and disinfected prior to use. This should be done only after an acceptable "purge time," as defined by the manufacturer, that allows all air to be replaced with ISO Class 5 air.
- It is preferable to perform daily, weekly, and monthly deactivating, decontaminating, cleaning, and disinfection at the end of the workday to encourage the use of enough agent(s) to reach an adequate dwell time on surfaces.
- The interior of the C-PEC to be used and equipment inside of the C-PEC must be deactivated, decontaminated, cleaned, and disinfected daily, preferably in the morning or immediately prior to compounding, and when surface contamination is known or suspected. The C-PEC must also be deactivated, decontaminated, cleaned, and disinfected anytime a spill occurs, before and after certification, any time voluntary interruptions occur, and if the ventilation tool is moved.
- Care must be taken to deactivate, decontaminate, clean, and disinfect all exterior surfaces of C-PECs, stools, carts, and other equipment within the sterile hazardous compounding areas.
- The table below summarizes what surfaces and objects must be treated, and how often they are treated with deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents. Tasks are performed in the order shown.

		Deactivating, Decontaminating, Cleaning, and Disinfecting			Applying Sporicidal Disinfectant	
Order	Sterile Hazardous	Every Compounding Day/Shift	Between Batches or Every 30 mins[1]	Monthly	Weekly	Monthly
1	C-PEC interior	x	x		Category 3	Category 1 and/or 2
2	Equipment inside of C-PEC	x	x		Category 3	Category 1 and/or 2
3	C-PEC work tray/surface	x	x			All categories
4	C-PEC underneath work tray/surface			x		All categories
5	Work surfaces outside of C-PEC	x			Category 3	Category 1 and/or 2
6	Ceiling			x		All categories
7	Walls			x		All categories
8	C-PEC exterior			x	Category 3	Category 1 and/or 2
9	Equipment outside of C-PEC			x		All categories
10	Pass-through	x			Category 3	Category 1 and/or 2
11	Storage shelving and bins/totes			x		All categories
12	Sink	x				All categories
13	Floor	x			Category 3	Category 1 and/or 2
14	Refrigerator/freezer			x		All categories

[1] At least every 30 minutes if the compounding process takes 30 minutes or less. If the compounding process takes more than 30 minutes, compounding must not be disrupted, and the work surface of the C-PEC must be disinfected immediately after compounding.

- As described above, the use of an EPA-registered, one-step deactivating, decontaminating, cleaning, and disinfecting agent with sporicidal activity allows the pharmacy to use only one agent for all tasks.
- If a refrigerator must be placed in the C-SEC for HD storage, it should receive very thorough treatment at least monthly, including the cleaning and disinfecting of coils and the motor, if present and visible. Briefly unplug the refrigerator during treatment to avoid potential electrical shock.
- If tacky mats are used outside of the entrance to the anteroom, they should be changed any day compounding occurs or the anteroom has been entered. The used layer should be carefully folded up from the edges and disposed of. Permanent tacky mats should be treated as per the manufacturer's instructions any day compounding occurs or the anteroom has been entered.
    - A best-practice recommendation is for the tacky mat to be placed vertically with the door so as to increase the number of steps taken to cross it (it should not look like a welcome mat).
- The liners of garbage containers in any classified area should be sealed before removal and promptly disposed of. New liners should be placed in the garbage container slowly without whipping the liner about in the air.
- "Daily" cleaning is not required if no compounding or other activity is to take place that day, unless required by state law.

- However, a best-practice recommendation is that the "daily" regimen should be performed no less often than weekly.
- If the air supply to the C-SEC is interrupted for more than 12 hours for any reason, a complete monthly cleaning cycle must be performed prior to reuse. If interrupted for more than 24 hours minutes, a "triple clean" must be performed.
- If, however, a significant amount of unclassified air has entered the C-SEC during even a short interruption of airflow, a complete monthly cleaning cycle should be performed.

Triple Cleaning

- Triple cleaning is a process used when:
  - Classified areas have been exposed to significant amounts of unclassified air (e.g., during the removal or addition of C-PECs to the area, the repair of ceiling tiles, ungarbed persons, etc.).
  - C-SEC airflow has been interrupted for a significant period of time.
    Viable air and surface sampling results exceed alert levels or show an unfavorable trend.
- Triple cleaning is essentially a repetition of routine monthly cleaning performed three times in immediate succession. Special care is taken to use generous amounts of cleaning/disinfecting agents and pay special attention to hard-to-reach areas such as wheels, crevices, and the junctions of floors, walls, and ceilings.
- If viable air or surface sampling has identified specific microbes, ensure that selected disinfectants are effective against them.
- Each treatment should be allowed to dry before the application of the next agent.

Objects Entering the C-SEC

- All items crossing into the clean side of the anteroom, entering a classified air area via pass-through, or brought into the C-SCA must be wiped with a low-lint wipe heavily saturated with one of the following agents by gloved personnel:
  - Sporicidal agent: Of sufficient quantity to reach all surfaces and remain in a liquid state for the agent's dwell time.
  - EPA-registered disinfectant: Of sufficient quantity to reach all surfaces and remain in a liquid state for the agent's dwell time.
  - sIPA: Of sufficient quantity to reach all surfaces and is allowed to fully dry.
  - Alternatively, these agents may be thoroughly sprayed onto objects to ensure coverage of all surfaces and wiped off with a low-lint wipe after the agent's dwell time has passed, or in the case of sIPA, is allowed to air dry.
    The wiping procedure should not compromise the packaging integrity or render the product label unreadable.
- Cardboard of any kind should not enter the sterile compounding facility if possible; corrugated or unsealed cardboard must never enter a classified area.
- Any objects brought into the sterile hazardous compounding facility by non-employees (e.g., equipment and carts used by certification technicians) must be subjected to the same cleaning and disinfecting regimen as anything used in compounding or cleaning/disinfecting activities.
- The table above summarizes for the C-SEC what surfaces and objects must be treated and how often they are to be treated with deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents. Tasks are performed in the order shown.

Objects Entering the C-PEC

- All items brought into a C-PEC must be thoroughly wiped with a sIPA-saturated, low-lint wipe just prior to their introduction into a C-PEC. The wiping procedure must not render the product label unreadable.
- The sIPA on these items must be allowed to dry prior to use.
- Sterile items enclosed in sealed packaging or containers may be removed as they are introduced into a C-PEC without further treatment.
- The table above summarizes for a C-PEC what surfaces and objects must be treated and how often they are to be treated with deactivating, decontaminating, cleaning, disinfecting, and sporicidal agents. Tasks are performed in the order shown.

Objects Leaving the C-PEC

- Finished hazardous CSPs must be wiped just prior to removing them from the C-PEC with a wipe saturated with a decontaminating/cleaning agent to remove any hazardous residue.
- The decontaminating/cleaning agent should not be sprayed on the CSPs to avoid aerosolizing any HD residue.

Objects Leaving the C-SEC

- Any objects brought into the sterile hazardous compounding area by non-employees (e.g., equipment and carts used by certification technicians) must be subjected to the same deactivating, decontaminating, cleaning, and disinfecting protocols prior to leaving the C-SEC area as anything used in hazardous compounding activities.

USP <797> References

Section 4: Facilities and Engineering Controls.
- Section 4.4: Water Sources.

Section 7: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants in Compounding Areas.
- Section 7.1: Cleaning, Disinfecting, and Applying Sporicidal Disinfectants.
  - Section 7.1.1: Agents.
  - Section 7.1.2: Supplies.
- Section 7.2: Procedures for Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA in the PEC.

Section 8: Introducing Items into the SEC and PEC.
- Section 8.1: Introducing Items into the SEC.
- Section 8.2: Introducing Items into the PEC.
- Section 8.3: Use of Sterile 70% IPA on Critical Sites within the PEC.

USP <800> References

Section 15: Deactivating, Decontaminating, Cleaning, and Disinfecting.
- Section 15.1: Deactivation.
- Section 15.2: Decontamination.
- Section 15.3: Cleaning.
- Section 15.4: Disinfection.

Reference Documents

C-PEC Deactivating, Decontaminating, Cleaning, and Disinfecting – Sterile Hazardous Compounding Competency
C-SEC Deactivating, Decontaminating, Cleaning, and Disinfecting – Sterile Hazardous Compounding Competency.
C-PEC Cleaning and Maintenance Log – Sterile Hazardous Compounding Area.
C-SEC Cleaning and Maintenance Log – Sterile Hazardous Compounding Area.
Gown, Garb, and Hand Hygiene – Sterile Hazardous Compounding SOP.

Equipment and Materials

Approved EPA-registered (or equivalent), one-step deactivating and decontaminating disinfectant cleaner.
Approved EPA-registered (or equivalent) sporicidal agent.
Sterile 70% isopropyl alcohol (sIPA).
SWI or SW Irrig.
Disposable low-lint wipes.
Mops and buckets or microfiber cleaning tool/system.
Scrub brushes.
PPE

This document has:

- ❑ been further customized as in: _____
- ❑ NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
02/20/2024	S-800.005.01	New format and ref to new USP Standards effective 11/1/2023	N/A	Kelly Klotz
10/31/2024	S-800.005.01	Annual review.	N/A	Mike Blaine

Section Name: Handling, Storage, Packaging, Shipping, and Transport	SOP Name: Compounded Preparation Delivery
SOP: S-19.001.01	Last Revision/Review: 10/31/2024
Accreditation Standards: TCRX6-D, DRX7-9B	

Policy

Packaging materials must protect prescription medications and compounded preparations from damage, leakage, contamination, degradation, and absorption while preventing inadvertent exposure to transport personnel. The pharmacy must select appropriate shipping containers and packaging materials based on the prescription medication and/or compounded preparation specifications, information from vendors, and the mode of transport.

Alternative modes of transport and/or special packaging (e.g., tamper-evident closures) may be needed to protect the quality of compounded preparations and prescription medications. Light-resistant packaging materials must be used if the compounded preparation is sensitive to light. In some cases, the compounded preparation or prescription medication must be packaged in a particular container (e.g., a cooler) to protect it from temperature fluctuations.

After compounding, and before releasing and dispensing, the compounded preparation must be visually inspected to determine whether the physical appearance of the compounded preparation is as expected (e.g., color, no cracks in container, improper seals, appropriate storage temperature, the label is legible, no evidence of inappropriate visible particulates or other foreign matter, or other defects).

The pharmacy uses a national third-party shipper (e.g., FedEx, UPS, USPS). Shipping lanes may be tested via internal studies for the environmental extremes experienced by transported pharmaceuticals. Testing takes into consideration the product's start temperature, and various ambient temperatures experienced by the package in transit to keep the pharmaceutical at the temperature described by the manufacturer, USP, and/or other applicable regulatory requirements. A best-practice recommendation is to conduct the test during the hottest and coldest times of the year for all the various storage temperatures (e.g., controlled room temperature, refrigerated, frozen) that the pharmacy is shipping under.

The pharmacy will communicate expected turnaround and update patient or designee if there will be delays. Delays may consist of out of stock issues, weather or other unplanned events out of control of the pharmacy. The patient may not agree to the expected turnaround date and will need to contact the provider to arrange for an alternative pharmacy. If a shipment is lost, damaged or in any other way adulterated, the product will be replaced as quickly as possible.

Definitions

PMS-Pharmacy Management System (I.e. PionerRx).

Procedures

When a compounded preparation will not be released or dispensed on the day of preparation:

- The compounded preparation(s) will be moved to the appropriate storage area necessary to maintain the compounded preparation at the correct storage temperature and conditions (e.g., protected from light).
- A visual inspection according to Visual Inspection of Ingredients and Compounded Sterile Preparations or Visual Inspection of Ingredients and Compounded Non-Sterile Preparations SOPs must be conducted immediately before it is released or dispensed to make sure the compounded preparation does not exhibit any defects, such as a cracked container, discoloration, precipitation, cloudiness, or leakage, which could develop during storage.
- Following the final release check and documentation on the compounding record, the compounded preparation may be placed in the appropriate shipping/delivery container. All controlled temperature items are packaged according to Cold Chain Distribution Policy.

When a compounded preparation will be released and dispensed on the same day of preparation:

- A visual inspection according to Visual Inspection of Ingredients and Compounded Sterile Preparations or Visual Inspection of Ingredients and Compounded Non-Sterile Preparations SOPs must be conducted immediately before it is released or dispensed to make sure the compounded preparation does not exhibit any defects, such as a cracked container, discoloration, precipitation, cloudiness, or leakage, which could develop prior to packaging.
    - Following the final release check and documentation on the compounding record, the compounded preparation may be placed in the appropriate shipping/delivery container. All controlled temperature items are packaged according to Cold Chain Distribution Policy.

Pharmacy personnel must select modes of transport that are expected to deliver properly packed compounded preparations and prescription medications in undamaged, stable conditions while maintaining sterility, if applicable. Inappropriate modes of transport can adversely affect the quality of compounded preparations and prescription medications. For example, preparation-specific considerations should be given to undue exposure to heat, cold, or light. Pharmacy shall ensure the preparations are shipped in a manner to maintain their integrity.

Package containers will protect pharmacy personnel and their representatives (e.g., local couriers) who handle and transport prescription medications and compounded preparations.

When shipping or transporting compounded preparations and prescription medications that require special handling (e.g., refrigerate upon arrival, handle with care, chemotherapy-special handling), pharmacy personnel shall include specific handling instructions on the exterior of the packaging container.

Containers used for delivery will be properly labeled with the beneficiary to whom it is to be delivered, instructions on what must be done upon receipt (e.g., refrigerate upon arrival), and marked for the number of shipping containers (e.g., 1 of 2, 2 of 2).

Delivery Container Care

- Delivery personnel will return any shipping-related materials to the pharmacy.
- Upon receipt, any materials that are not reusable will be discarded.
- Upon receipt, any reusable materials will be cleaned inside and out with an appropriate cleaning and disinfecting agent, taking care to keep the surface of the item being cleaned wet long enough to meet the dwell time of the product used.
- Any returned materials in disrepair will be discarded.

The pharmacist intervenes, when necessary, to ensure that appropriate conditions are achieved or maintained during the delivery process.

When it is known that a compounded preparation has been exposed to temperatures either below or above the storage temperature limits for the compounded preparation, the designated person(s) must determine (e.g., by consulting literature or analytical testing) whether the compounded preparation is expected to retain its integrity or quality. If the designated person cannot determine, due to one or more temperature excursion(s), that the compounded preparation will retain its integrity or quality through its BUD, it must be discarded. The review and investigation is documented using the Adverse Event/Risk Event Report Form.

In the event that a patient reports any abnormal physical changes or signs of instability of their compounded preparation such as grittiness, crystallization, abnormal odor or changes in color a review and investigation is documented. The review may include but is not limited to shipping duration, temperature exposures, storage of compounded medication and dating. The pharmacist will inform the patient to stop taking and to notify their healthcare provider as needed. The pharmacy may replace the compounded prescription if indicated and will be determined on a case by case basis.

Unsuccessful Delivery

- When the pharmacy attempts, but is unable, to deliver a compounded preparation or prescription medication, the following will be followed:
    - If by the pharmacy's own delivery personnel or an approved common carrier, the compounded preparation(s) may be returned if:
        - The delivery remains in its original packaging for transport, including, when applicable, original sealed and tamper-evident packaging.
        - The delivery is returned within the validated window for cold chain, when applicable.
        - The delivery is not past the BUD for compounded preparations or the expiration date for non-compounded prescription medications.
        - The return delivery is approved by a pharmacist at the site.
        - The return delivery is permissible by state law.

Documentation
The delivery ticket, signed by the beneficiary or designee, or the delivery ticket affixed with the shipping tracking number of a national third-party shipper (e.g., FedEx, UPS, USPS) and the ability to capture the signature obtained by the national third-party shipper will be proof of delivery.

For shipments performed by a national third-party shipper (e.g., FedEx, UPS, USPS), the pharmacy may release the national third-party shipper from the obligation of obtaining a patient's signature when permissible by laws and regulations of the applicable regulatory jurisdiction and payer, if applicable.

For shipments performed by a national third-party shipper (e.g., FedEx, UPS, USPS), the tracking info is integrated with the PMS and auto-populates delivery and tracking information.

For shipments performed by pharmacy personnel or local couriers, proof of delivery will include the signature of the beneficiary and the date of receipt. When this is not feasible, the person authorized to receive the delivery will sign their name, relationship to the beneficiary, and the date of receipt. A copy of the form will be left with the beneficiary.

USP <795> References

Section 13: CNSP Packaging and Transporting.

- Section 13.1: Packaging of CNSPs.
- Section 13.2: Transporting of CNSPs.

USP <797> References

Section 19: CSP Handling, Storage, Packaging, Shipping, and Transport.

- Section 19.1: Handling and Storing CSPs.
- Section 19.2: Packaging of CSPs.
- Section 19.3: Shipping and Transporting CSPs.

Reference Documents

Cold Chain Distribution
Visual Inspection of Ingredients and Compounded Sterile Preparations
Visual Inspection of Ingredients and Compounded Non-Sterile Preparations
Adverse Event/Risk Event Report Form

Equipment and Materials

Materials will vary and may include the following:
Reusable thermal coolers (e.g., plastic Igloo cooler).
Thermal shipping cooler (e.g., Styrofoam inserts or cooler in a corrugated shipping container).
Foam or gel ice packs in the appropriate size(s) based on the third-party vendor or internal validation study.
Corrugated shipping containers or similar containers.
Bubble wrap or similar material.
Temperature-sensing devices (e.g., strips, data recorders).
Tamper-evident tape.
Shipping label.
Special handling labels (e.g., refrigerate upon arrival, handle with care, chemotherapy-special handling).

Cleaning and sanitizing/disinfecting agents for reusable containers.

This document has:

- been further customized as in
- NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
11/29/2023	S-19.001.01	Initial release for new formatting, review & USP Standards update.	N/A	Kelly Klotz
10/31/2024	S-19.001.01	Annual review.	N/A	Mike Blaine

Section Name: Handling, Storage, Packaging, Shipping, and Transport	Policy Name: Cold Chain Distribution
Policy: P-19.003.01	Last Revision/Review: 10/31/2024
Accreditation Standards: TCRX6-D, DRX7-8F, DRX7-9B	

Policy

The pharmacy uses a shipping system that has been either validated by a third party or by internal studies for the environmental extremes experienced by transported pharmaceuticals. The validation takes into consideration the initial product's start temperature, types of insulation/packaging used, and various ambient temperatures experienced by the package in transit to keep the pharmaceutical at the temperature described by the manufacturer, USP, and/or other applicable regulatory requirements.

Shipping methods are tested initially and periodically thereafter to ensure compounded preparations and prescription medications stay within specified temperature requirements. A best-practice recommendation is to conduct the test during the hottest and coldest times of the year for all the various storage temperatures (e.g., controlled room temperature, refrigerated, frozen) that the pharmacy ships under.

When it is known that a compounded preparation has been exposed to temperatures either below or above the storage temperature limits for the compounded preparation, the designated person(s) must determine (e.g., by consulting literature or analytical testing) whether the compounded preparation is expected to retain its integrity and quality. If the designated person cannot determine—due to one or more temperature excursion(s)—that the compounded preparation will retain its integrity or quality through its BUD, it must be discarded. The review and investigation are documented using the Adverse Event/Risk Event Report Form.

Any pharmaceutical required to be maintained at refrigerated temperature, unless otherwise specified by the manufacturer, will be maintained between 2°C and 8°C (36°F and 46°F) during storage and transport.

Any pharmaceutical required to be maintained at controlled room temperature, unless otherwise specified by the manufacturer, will be maintained as follows:

- Storage: Between 20°C and 25°C (68°F and 77°F), allowing excursions from 15°C to 30°C (59°F to 86°F), provided the mean kinetic temperature does not exceed 25°C (77°F) and the excursion is no longer than 24 hours.
- Transport: Between 20°C and 25°C (68°F and 77°F), allowing excursions from 15°C to 30°C (59°F to 86°F). Provided the mean kinetic temperature does not exceed 25°C (77°F), transient spikes up to 40°C (104°F) are permitted as long as they do not exceed 24 hours. Spikes above 40°C (104°F) may be permitted only if the manufacturer so instructs.

Any pharmaceutical required to be maintained at frozen temperature, unless otherwise specified by the manufacturer, will be maintained between -25°C and -10°C (-13°F and 14°F).

Definitions

Ambient Temperature: The air temperature of an environment (e.g., the temperature conditions the shipping container is exposed to, including the temperature in the delivery vehicle, delivery hub, and at the residence of the patient prior to opening the package).
Ambient Temperature Profile: A range of temperatures a shipment may encounter. These profiles should adequately capture the expected summer and winter extreme conditions specific to your distribution channels. Typically, there are multiple ambient temperature profiles. One example includes profiles for less than 4°C (25°F), 4°C to 7°C (25°F to 45°F), 8°C to 21°C (46°F to 70°F), 22°C to 32°C (71°F to 90°F), and greater than 32°C (90°F).
Pack-Out Procedure: A detailed set of packing instructions based on the container size and the ambient temperature profile the container will encounter.

Procedures

Materials and packing methods used in the transport of pharmaceuticals will be appropriate to keep products at the correct temperature while in transit. Documentation of cold chain distribution will be tested/recorded using the Internal Study- Distributed Pharmaceutical Temperature Data Form.

Container sizes shall be tested against applicable ambient temperature profiles the product will encounter. The specific ambient temperature profiles will be described in the pack-out procedure. If the pharmacy adopts different packaging, packing materials, or methods of delivery or expands its service area thus requiring transport time that exceeds the current known information, the pharmacy, prior to shipping, shall perform updated studies that will take into consideration the new materials, methods, or transportation time.

Validation methods include:

- May use distribution processes validated by other reputable sources as long as the pharmacy retains the records of the validation process and results. Some reputable sources accepted include:
  - ASTM: American Society for Testing and Materials.
  - FDA: U.S. Food and Drug Administration.
  - ISO: International Organization for Standardization.
  - ISPE: International Society of Pharmaceutical Engineers.
  - ISTA: International Safe Transit Association.
  - PDA: Parenteral Drug Association.
  - WHO: World Health Organization.
- May use a distribution system that is internally studied as follows:
  - The pharmacy will conduct tests to test the packaging product or product's ability to maintain the appropriate temperature range.
  - The pharmacy will follow the packaging manufacturer's guidelines and packaging instructions for each box/container size to create the selected number of "test packages."
  - The pharmacy will place a digital temperature-data-logging device inside each "test package."
  - As medications have different appropriate temperature ranges, the pharmacy must test each box at the temperature profiles pharmaceuticals are shipped (e.g., controlled room temperature, refrigerated, frozen).
  - The pharmacy will ship the test packages per their normal shipping routine to preselected locations and/or back to the pharmacy. These shipments must occur within the ambient temperature profiles selected for the pack-out.
  - Once the "test package" reaches its intended location, it will be opened and the temperature device downloaded.
    - If the temperatures are within the appropriate ranges, then the packaging will be considered successful, and the pharmacy will move forward using this pack-out.
    - If temperatures are outside the appropriate ranges, the designated person(s) must be notified to determine the outcome of the test, implement corrective actions, and retest as appropriate.
  - The pharmacy may document all internal validation studies on the Internal Study-Distributed Pharmaceutical Temperature Data form.

- The pharmacy will summarize the study results, relevant ambient temperature profiles, and pack-out definitions.
- Any system selected to be used by the pharmacy will be taught to the appropriate staff.
- Any validated system will have the appropriate pack-out per box/container size and ambient temperature profile displayed in the shipping area.

- All staff will be trained on the transit time limits each package/container is approved at for each ambient temperature profile.
- If a package is not delivered within the validated window, the designated person(s) must determine (e.g., by consulting literature or analytical testing) whether the pharmaceutical or compounded preparation is expected to retain its integrity and quality. If this cannot be determined, the product must be discarded.
- All shipping containers must be clearly labeled with storage instructions to ensure that proper storage conditions occur after the shipment is received (e.g., refrigerate upon arrival).

Concerns/complaints related to the transportation of pharmaceuticals are to be reported electronically or using the Complaint/Grievance/Concern Report Form.

Delivery issues resulting in the discarding of pharmaceuticals or compounded preparations are documented using the Adverse Event/Risk Event Report Form and reported to the Operations team. Quality assurance or the Compliance Officer may be informed as needed.

USP References

USP <659> Packaging and Storage Requirements.

Reference Documents

Validated Distributed Pharmaceutical Temperature Summary
Internal Study - Distributed Pharmaceutical Temperature Data
Adverse Event/Risk Event Report
Complaint/Grievance/Concern Report
Compounded Preparation Delivery

Equipment and Materials

Materials may include, but not limited to the following:
Reusable thermal coolers (e.g., plastic Igloo cooler).
Thermal shipping cooler (e.g., Styrofoam inserts or cooler in a corrugated shipping container).
Foam or gel ice packs in the appropriate size(s) based on the third-party vendor or internal validation study.
Corrugated shipping containers or similar containers.
Bubble wrap or similar material.
Temperature-sensing device(s) (e.g., strips, electronic data loggers, or data recorders).

This document has:

- ☐ been further customized as in _____
- ☐ NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
11/29/2023	P-19.003.01	Initial release with new formatting, review & USP standards release.	N/A	Kelly Klotz
10/31/2024	P-19.003.01	Annual review.	N/A	Mike Blaine

Frozen Shipping Procedure

Items Needed:

1. Frozen shipping container
2. Two ice packs
3. Tape
4. Frozen Labels
5. Shipping Label

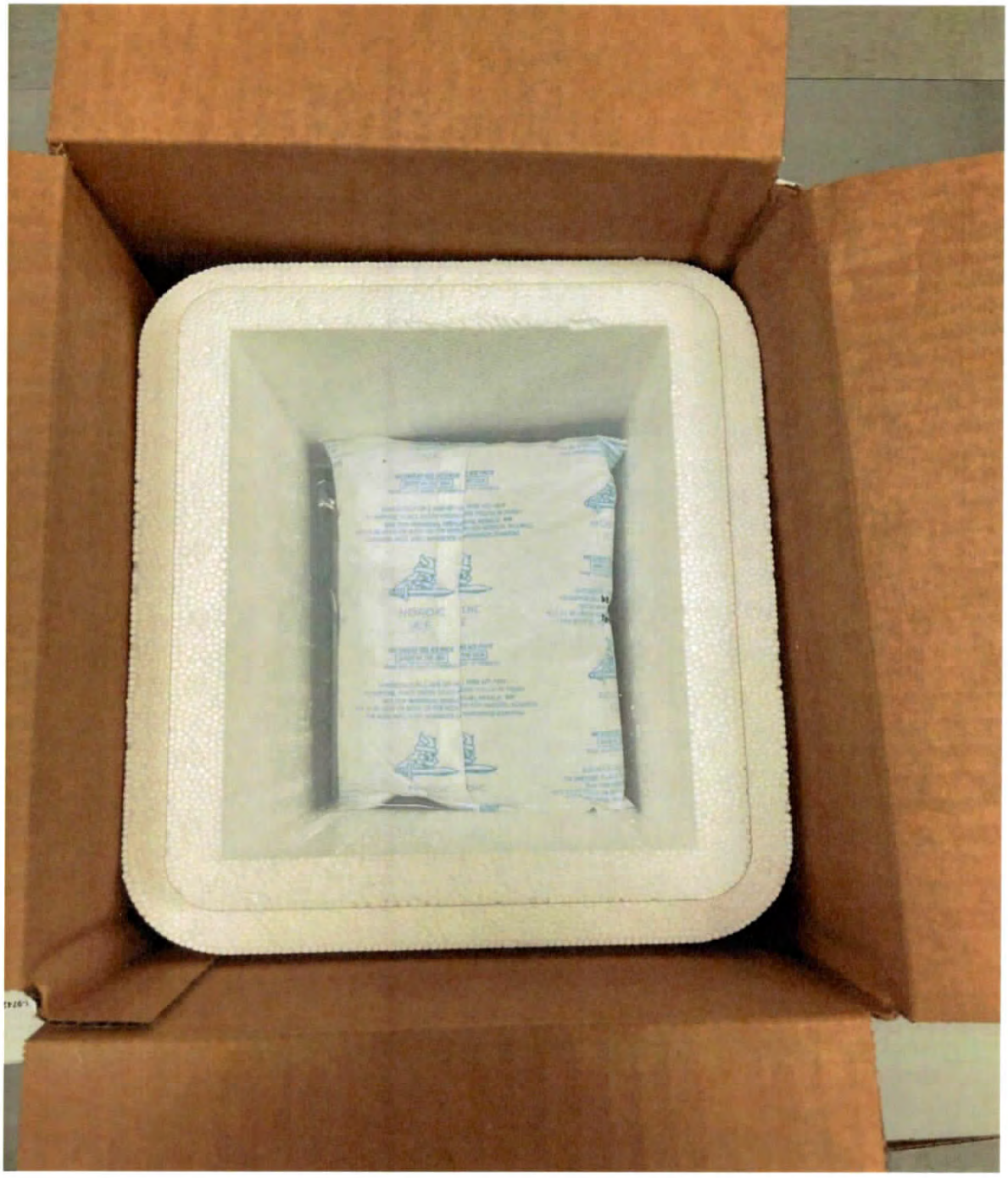
Procedure:

1. Scan your shipping label through the UPS platform, grab a frozen shipping container
2. Grab two ice packs, place one ice pack at the bottom of the shipping container
3. Place another ice pack on top of the frozen item, to create a sandwich
4. Add bubble wrap on top of the ice pack
5. Place lid back on top of shipping container and add the receipt on top
6. Seal the package with tape, place shipping label on the side stating, "shipping from" and add a frozen label onto the box for visibility

Images:

1. 

2. 

3. 

4. 

5.


SBH Medical, LTD
7854 Crosswoods Dr
Columbus, OH 43235-4621
Phone: (866) 724-8333
Fax: (614) 847-9015
Veterinary Compounding Medications
Not an FDA approved or tested drug. Caution: Federal law restricts this drug to use by or on the order of a licensed veterinarian.
Dec 17 2024 10:28AM
Shipping
120.00

6.


FREEZE
UPON
ARRIVAL
VASILIOS GIATIS
(614) 847-6007
SBH MEDICAL
1 LBS
1 OF 1
OH 449 9-03
UPS NEXT DAY AIR
TRACKING #: 1Z 441 47F 01 4836 6158
1
BILLING: P/P
REF 1:55888
SHIP T

Section Name: Personal Hygiene and Garbing	SOP Name: Gown, Garb, and Hand Hygiene – Sterile Hazardous Compounding
SOP: S-800.003.01	Last Revision/Review: 10/31/2024
Accreditation Standards: TCRX3-E, TCRX6-N, DRX7-6B, DRX7-8O.01	

Policy

Proper gowning, garbing, and hand hygiene and personal protective equipment (PPE) will be used to protect hazardous sterile compounded preparations (CSPs) from microbial contamination, and personnel from hazardous drug (HD) contamination.

Definitions

Anteroom: A transition area to ensure proper air classification and pressure relationships are maintained between classified and unclassified areas. The anteroom is where personnel perform hand hygiene and garbing procedures, component staging, and other activities that potentially generate higher levels of particulates. Anterooms providing access to positive-pressure buffer rooms must meet at least ISO Class 8 classifications. Anterooms providing access to negative-pressure buffer rooms must meet at least ISO Class 7 classifications.

Buffer Room: An ISO Class 7 or cleaner room with fixed walls and doors where primary engineering controls (PECs) that generate and maintain an ISO Class 5 environment are physically located. The buffer room may only be accessed through the anteroom or another buffer room.

Containment Primary Engineering Control (C-PEC): A ventilated device designed and operated to minimize worker and environmental exposures to HDs by controlling emissions of airborne contaminants through the following:

- The full or partial enclosure of a potential containment source.
- The use of airflow capture velocities to trap and remove airborne contaminants near their point of generation.
- The use of air pressure relationships that define the direction of airflow into the cabinet.
- The use of HEPA filtration on all potentially contaminated exhaust streams.

Containment Secondary Engineering Control (C-SEC): A room with fixed walls under negative pressure in which the C-PEC is placed. The room incorporates specific design and operational parameters required to contain the potential hazard within the compounding room.

Containment Segregated Compounding Area (C-SCA): A type of C-SEC with nominal requirements for airflow and room pressurization as they pertain to HD compounding. A designated, unclassified space, area, or room with a defined perimeter that contains a C-PEC and is suitable for preparations of Category 1 CSPs only.

Personal Protective Equipment (PPE): Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposure.

Pharmaceutical Isolator: An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air operated at a continuously higher pressure than its surrounding environment and is decontaminated using an automated system. It uses only decontaminated interfaces or rapid transfer ports for materials transfer.

Note: A compounding aseptic isolator (CAI) or compounding aseptic containment isolator (CACI) is not a pharmaceutical isolator.

Powered Air-Purifying Respirator (PAPR): A device that forces filtered, purified air into an enclosed space around the user's face. Most PAPRs can be fitted with activated charcoal cartridges when there is the potential for exposure to HD vapors and gases.

Restricted-Access Barrier System (RABS): An enclosure that provides HEPA-filtered ISO Class 5 unidirectional air that allows for the ingress and/or egress of material through defined openings that have been designed and validated to preclude the transfer of contamination, and that generally are not to be opened during operations. Examples of RABS include CAIs and CACIs.

Sterile Compounding Facility (SCF): Room(s) or areas devoted exclusively to sterile compounding, consisting of either a cleanroom suite or a C-SCA.

Procedures

Preparation

- Personnel who have passed competency testing concerning gowning, garbing, and hand hygiene (see Gown, Garb, and Hand Hygiene – Sterile Hazardous Compounding Competency), or are being trained in this regard, may enter the hazardous SCF. Other personnel or visitors (e.g., auditors, inspectors, regulators, surveyors, and student observers) must comply with gowning, garbing, and hand hygiene SOPs, but they do not need to prove competency in order to enter the hazardous SCF.
    - Prior to entering the anteroom or C-SCA, personnel must remove:
        - Personal outer garments such as bandanas, coats, hats, jackets, sweaters, vests, etc.
        - Cosmetics, as applicable.
        - All hand, wrist, and other exposed jewelry, including piercings that may compromise the effectiveness of PPE or otherwise increase the risk of contamination of the HD-CSP. Cover any jewelry that cannot be removed.
        - Earbuds, headphones, or headsets, as applicable.
    - Additionally:
        - Fingernails must be kept clean and closely trimmed.
        - Nail polish, artificial nails, or extenders must not be worn.
        - Eyeglasses are washed with water and soap, preferably using disinfectant soap, and dried with a low-lint wipe.
        - Personnel with rashes, sunburns, recent tattoos, oozing sores, and/or eye, skin, or respiratory infections must report these conditions to the designated person for assessment.
        - Chewing gum, lozenges, etc., must not be used while in the cleanroom suite or C-SCA.
    - The designated person may permit accommodations concerning these issues as long as the quality of the HD-CSP and environment are not compromised. Examples include canes, crutches, or wheelchairs needed by employees with disabilities, clothing requirements for various religions, and/or the use of throat lozenges for medical purposes. Accommodations must be documented.
    - Garb and PPE used during the compounding of CSPs containing HDs must serve the dual purpose of protecting the preparation from microbial contamination by personnel and protecting personnel from chemical contamination by the HD.
    - Additional garbing requirements for Category 3 CSPs must be continuously met for all personnel regardless of whether Category 3 CSPs are compounded on a given day:
        - No exposed skin is allowed in the buffer room (face and neck must be covered).
        - All garb must be sterile.
        - Garb must not be reused

Hand Hygiene

- Hands and forearms up to the elbows are thoroughly washed prior to donning a gown using liquid soap from a non-refillable container for at least 30 seconds, using a timing device if available.
- Use a disposable nail pick under warm running water to remove debris from underneath fingernails.
- Scrub brushes must not be used because of their potential for causing skin irritation and the shedding of skin particles.
- Rinse hands and forearms over the sink with hands facing upward so the water flows away from the fingertips down to the elbows.
- Dry hands and forearms using disposable low-lint wipes. Hand dryers must not be used.
- Allow hands to air dry without waving them.
- Hand hygiene must be repeated whenever an employee leaves and reenters the SCF.

Gloves

- Two pairs of chemotherapy-rated gloves must be used when compounding HD-CSPs.
- At least the outer gloves used for sterile compounding must be sterile.
- A best-practice recommendation is for both pairs of gloves to be sterile to avoid confusion and the need for two types of gloves.
- Gloves used for the compounding of HDs must meet the requirements of the American Society for Testing and Materials (ASTM) standard D6978 or its successor.
- Gloves must be powder-free because powder can absorb HDs and contaminate the compounding environment.
- Inner gloves are donned after the first gown and after applying the manufacturer's recommended quantity of an alcohol-based hand sanitizer on the hands and rubbing the hands together, covering all surfaces of hands and fingers, until hands are dry. Do not wave hands.
- Outer gloves are donned; this may occur on the clean side of the anteroom, upon entering the buffer room, or on the clean side of the C-SCA, but not in the C-PEC.
    - They must be pulled up over the cuff of the gown.
- Gloved hands are disinfected by applying sIPA and allowing them to air dry:
    - Prior to compounding the first preparation.
    - Between preparations.
    - Frequently, during the compounding process.
    - Whenever hands are removed from the direct compounding area (DCA).
    - Whenever non-sterile surfaces or objects are touched.
- sIPA is allowed to dry by holding hands still without waving them.
- If using a RABS such as a CACI:
    - Disposable gloves should be worn directly on the hands as per the manufacturer's recommendations.
    - Sterile gloves as described above must be placed over the permanent gloves attached to the RABS sleeve.
    - The integrity of the RABS sleeves and gloves must be checked prior to performing any compounding of HD-CSPs.
    - The sleeves and gloves of the RABS must be replaced according to the manufacturer's guidelines or immediately upon detecting defects such as punctures, tears, holes, etc.
- All gloves must be inspected for holes, punctures, or tears and must be replaced immediately if such defects are detected, and gloves must be replaced:
    - When visibly soiled.
    - Every 30 minutes unless the manufacturer's instructions allow for a longer period of use.
    - When personnel leave the C-SEC buffer room or C-SCA.
    - When cross-contamination between preparations is suspected.
- Outer gloves are removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or are contained in a sealable disposal bag within the C-PEC and disposed of with other materials from the preparation at the end of the compounding process after wiping the HD-CSP container with a decontaminating agent.
- A best-practice recommendation is to wipe the outer gloves down with a decontaminating agent prior to wiping the HD-CSP container to avoid transfer from the contaminated gloves.
- Gloves are disposed of as trace or bulk waste[1] depending upon the level of suspected or known contamination by HDs upon them.
- The inner gloves remain on after the outer gloves are removed. The inner gloves are used to affix labels and place compounded HDs in a zip-lock bag for transport.

Note: Transport bags must never be placed in the DCA during compounding to avoid contamination of the bag's outer surface.

- Inner gloves used within a RABS are removed and disposed of as regular waste.
- Outer gloves used over the permanent gloves of a RABS are disposed of with other materials from the preparation at the end of the compounding process.
    - They are treated as trace or bulk waste[1] depending upon the level of suspected or known contamination by HDs.
- When removing gloves, the contaminated glove fingers must only touch the contaminated outer surface of the gloves, never the inner surface. If the inner gloves become contaminated, both pairs of gloves must be changed.
- Inner gloves are removed after leaving the C-SEC buffer room on the clean side of the anteroom or prior to leaving the C-SCA.
- Hands must be washed with suitable liquid soap and water after removing gloves.

Gowns

- One sterile gown must be worn whenever personnel are within the C-SEC buffer room or C-SCA, including during the compounding of HD-CSPs.
- Gowns for all categories of CSPs must:
    - Be sterile.
    - Be low lint.
    - Be long sleeved.
    - Have cuffs that fit snugly around the wrist.
    - Have an enclosed neck.
    - Be large enough to fully cover the back.
- Additional requirements if any Category 3 compounding occurs in the buffer room:
    - All exposed skin, including the face and neck, must be covered.
    - All low-lint garb must be sterile.
- Additionally, gowns used must:
    - Be disposable.
    - Resist permeation by HDs.
    - Close in the back.
    - Lack seams or closures that could retain HDs.
    - Be made of polyethylene-coated polypropylene or other laminate materials.
    - Not made of cloth.
- Coverall ("bunny suit") systems may be used if they meet all criteria for garb described in this document.
- Gowns should be donned so as to avoid personal contamination and without touching the floor on the clean side of the anteroom, or prior to crossing the line of demarcation inside the C-SCA.
- Gowns are removed while on the contaminated side of the line of demarcation at the entrance to the C-SEC buffer room or C-SCA.
    - It should be removed slowly and carefully, rolling the gown from inside out into a ball prior to placing it in a disposal container.
- Inner gowns are removed after leaving the C-SEC buffer room on the clean side of the anteroom or prior to leaving the C-SCA.
- Gowns are disposed of as trace or bulk waste[1], unless significantly contaminated by HDs.

Sleeve Coverings

- Sleeve covers, if used:
    - Must be disposable.
    - Resist permeation by HDs.
    - Are made of polyethylene-coated polypropylene or other laminate materials.
    - Should be sterile for Category 1 and 2 CSPs and must be sterile for Category 3 CSPs.
- Sleeve covers are donned after gowns but before gloves.

- Sleeve coverings must be replaced:
  - When visibly soiled, torn, or otherwise damaged.
  - When personnel leave the C-SEC buffer room or C-SCA.
  - When cross-contamination between preparations is suspected.
- Sleeve covers are removed and discarded immediately into a waste container approved for trace contaminated waste inside the C-PEC or are contained in a sealable disposal bag within the C-PEC and disposed of with other materials from the preparation at the end of the compounding process.
- Sleeve covers are disposed of as trace or bulk waste[1] depending on the presence of significant HD contamination.

Respiratory Protection

- Face masks ("surgical masks") or other acceptable masks (e.g., N95) must be worn whenever employees are on the clean side of the anteroom, within the C-SEC buffer room, or within the C-SCA.
- Surgical masks do not provide respiratory protection from drug exposure and must not be used when respiratory protection from HD exposure is required.
- N95 respirators provide additional respiratory protection should this be desired against airborne particles. N95 respirators offer no protection against gases and vapors (refer to the CDC's Respiratory Protection Information Trusted Source). If used, N95 respirators follow the same protocols as face masks ("surgical masks").
- N95 masks, if used, must be fit tested to comply with OSHA respiratory standard 29 CFR 1910.34.
- A full facepiece, chemical cartridge-type respirator or PAPR should be worn when there is a risk of HD respiratory exposure, including when:
  - Attending to HD spills larger than what can be contained with a spill kit.
  - Deactivating, decontaminating, and cleaning underneath the work surface of a C-PEC.
  - There is known or suspected airborne exposure to powders, gases, or vapors.
- Nose and mouth coverings are donned on the dirty side of the anteroom or upon entering the C-SCA.
- Face masks should be worn with the outside folds in the material facing down.
- Nose and mouth coverings must be replaced:
  - If visibly soiled, torn, or otherwise damaged.
  - Each time personnel leave the C-SEC buffer room or C-SCA.
- Nose and mouth coverings are removed after leaving the C-SEC buffer room and after crossing into the clean side of the anteroom or before leaving the C-SCA.
- Nose and mouth coverings are disposed of as trace or bulk waste depending on the presence or absence of significant HD contamination.
- Chemical cartridge-type respirators and PAPRs must be deactivated, decontaminated, cleaned, and disinfected after each use.
- The manufacturer's instructions are followed for deactivating, decontaminating, cleaning, and disinfecting the respirator. When manufacturer instructions are not available, deactivating, decontaminating, cleaning, and disinfecting will be conducted as follows:
  - While wearing a clean pair of ASTM D6978-rated gloves along with other appropriate PPE, remove filters, cartridges, or canisters. Disassemble facepieces by removing speaking diaphragms, demand and pressure-demand valve assemblies, hoses, or any other components.
  - Wipe the components using a low-lint wipe saturated with an EPA-registered, one-step deactivating, decontaminating, cleaning, and disinfecting agent approved by the manufacturer. Follow the manufacturer's instructions for the dwell time of the deactivating, decontaminating, cleaning, and disinfecting agent.
  - Thoroughly rinse the components with sterile water for injection or sterile water for irrigation. Drain.
  - Dry components with low-lint wipes.

- Reassemble the facepiece, replacing filters, cartridges, and canisters when necessary.

Eye Protection

- Eye protection is not required during the compounding of HD-CSPs, however Recommended and encouraged for compounder safety. Safety Data Sheets will be referenced as needed.
- Eye protection is strongly recommended when cleaning any surface higher than eye level (e.g., upper walls and ceilings).
- Eye protection is required when performing major cleaning of a C-PEC such as removing the work surface tray.
- If used, eye protection must provide complete protection. Devices capable of such protection include:
  - Wrap-around goggles.
  - Full-facepiece respirators.
  - PAPR units.
- Must be deactivated, decontaminated, cleaned, and disinfected before being reused.
- The manufacturer's instructions are followed for deactivating, decontaminating, cleaning, and disinfecting goggles. When the manufacturer's instructions for deactivating, decontaminating, cleaning, and disinfecting goggles are not available, deactivating, decontaminating, cleaning, and disinfecting will be conducted as follows:
  - While wearing a clean pair of ASTM D6978-rated gloves along with other appropriate PPE, carefully wipe the inside of the goggles, followed by the outside of the goggles using a low-lint clean wipe saturated with a mild soap solution.
  - Carefully wipe the outside of the goggles using a low-lint wipe saturated with an EPA-registered, one-step deactivating, decontaminating, cleaning, and disinfecting agent.
  - Wipe the outside of the goggles with sIPA to remove the residue.
  - Allow to fully dry (air dry or dry with a low-lint wipe).

Head and Facial Hair Coverings

- Head and facial hair coverings must be worn whenever personnel are on the clean side of the anteroom, C-SEC buffer room, or C-SCA.
- These items must:
  - Be low lint.
  - Be disposable.
  - Fully cover all hair and ears.
- Head and facial hair coverings are donned on the dirty side of the anteroom, or upon entering the C-SCA.
- These items must cover all head or facial hair, which should be confirmed by the use of a mirror or coworker.
- Head and facial hair coverings must be replaced:
  - If visibly soiled, torn, or otherwise damaged.
  - Each time personnel leave the C-SEC buffer room or C-SCA.
- Head and facial hair coverings are removed after leaving the C-SEC buffer room after crossing into the dirty side of the anteroom or before leaving the C-SCA.
- Head and facial hair coverings are disposed of as trace or bulk waste[1] depending on the presence or absence of significant HD contamination.

Foot Coverings

- Foot coverings with the characteristics described below must be worn:
  - On the clean side of the anteroom.
  - In the C-SEC buffer room.
  - In the C-SCA.

- Foot coverings may be accomplished in the following ways:
  - Dedicated shoes.
  - Disposable shoe covers.
- Dedicated shoes, if used:
  - Must be easily cleaned.
  - Must be nonporous.
  - Must be smooth and free of holes.
  - Should be white or black to make soiling more visible.
  - Should be cleaned and disinfected periodically, preferably with an EPA-registered, one-step cleaning and disinfecting agent.
- Shoe covers:
  - Must be low lint.
  - Must be disposable.
- Shoe covers that are part of a coverall ("bunny suit') system:
  - Must be low lint.
  - Must be disposable.
- A set of disposable outer shoe covers must be donned prior to entering the C-SEC buffer room or C-SCA in addition to any primary foot covering with the traits described above. These shoe covers may be donned at the same time as the primary foot coverings.
- Outer disposable shoe covers must be replaced:
  - If visibly soiled, torn, or otherwise damaged.
  - Each time personnel leave the C-SEC buffer room or C-SCA.
- Dedicated shoes must be replaced if unfit for use or unable to be cleaned.
- Shoe covers that are part of a coverall ("bunny suit") system must be replaced if visibly soiled, torn, or otherwise damaged.
- Outer shoe covers must be removed when stepping over the line of demarcation that separates the contaminated and uncontaminated areas of the C-SEC buffer room or C-SCA.
- Outer disposable shoe covers are treated as trace or bulk waste[1] based on the presence or absence of significant HD contamination.
- Inner disposable shoe covers or dedicated shoes are removed when stepping over the line of demarcation into the dirty side of the anteroom or C-SCA.
- Inner shoe covers, if applicable, are disposed of as regular waste.
- Dedicated shoes, if used, should be placed on the clean side of the line of demarcation near the entrance to the anteroom or C-SCA to be convenient for personnel.

Surgical Scrubs

- A best-practice recommendation is for personnel to wear surgical scrubs beneath required gowns.
- Scrubs should be worn at least during compounding and cleaning activities within the sterile compounding suite of the SCA.
- A freshly laundered pair of scrubs should be worn each workday. Under no circumstances should potentially contaminated surgical scrubs be taken home to be laundered.
- Scrubs are preferably liquid resistant.
- Replace scrubs when worn or torn.

Storage of Garb

- Reasonable quantities for the number of compounders (i.e., 7-day, 30-day) supply of disposable garb and PPE may be stored in the anteroom or C-SCA, away from any sink, and stored so as not to collect dust and in a manner that minimizes the potential for contamination.
- A reasonable supply of sterile gloves may be stored in the C-SEC buffer room or C-SCA.

- Reusable personal protective eye and respiratory equipment (e.g., goggles, full-facepiece respirators, and PAPR units) may be stored in the C-SEC buffer room or C-SCA unless removal for other uses or cleaning and decontamination is required.
- Dedicated shoes, if used, should be placed on the clean side of the line of demarcation near the entrance to the anteroom or C-SCA to be convenient for personnel.

[1] PPE used during the cleaning of a hazardous chemical spill needs to be disposed of as bulk waste.

Gown, Garb and Hand Hygiene Sequence of Events Based on Location of the Sink and LOD

Sink on the Clean Side of the LOD in the Anteroom	Sink on the Dirty Side of the LOD in the Anteroom	Sink Outside of the Anteroom or C-SCA
Donning		
Don head covering, facial hair covering, and face mask on dirty side of anteroom.	Don head covering, facial hair covering, and face mask on dirty side of anteroom.	Clean debris from under fingernails using warm running water and a disposable nail cleaner.
Don dedicated cleanroom shoes plus one pair of shoe covers or two pairs of shoe covers as stepping over LOD into clean side of anteroom.	Clean debris from under fingernails using warm running water and a disposable nail cleaner.	Wash hands and forearms up to elbows for at least 30 seconds with soap and water.
Clean debris from under fingernails using warm running water and a disposable nail cleaner.	Wash hands and forearms up to elbows for at least 30 seconds with soap and water.	Enter dirty side of anteroom or C-SCA and apply manufacturer's recommended amount of alcohol-based hand sanitizer, rub hands together, covering all surfaces of hands and fingers, and allow to air dry.
Wash hands and forearms up to elbows for at least 30 seconds with soap and water.	Don dedicated cleanroom shoes plus one pair of shoe covers or two pairs of shoe covers as stepping over LOD into clean side of anteroom.	Don head covering, facial hair covering, and face mask on dirty side of anteroom or C-SCA.
Don inner gown on clean side of anteroom.	Apply alcohol-based hand sanitizer, rub hands together, covering all surfaces of hands and fingers, and allow to air dry on clean side of anteroom	Don dedicated cleanroom shoes plus one pair of shoe covers, or two pairs of shoe covers as stepping over LOD into clean side of anteroom for C-SEC or across threshold into C-SCA.
Apply alcohol-based hand sanitizer, rub hands together, covering all surfaces of hands and fingers, and allow to air dry on clean side of anteroom.	Don gown on clean side of anteroom.	Apply manufacturer's recommended amount of alcohol-based hand sanitizer, rub hands together, covering all surfaces of hands and fingers, and allow to air dry upon entering the clean side of anteroom or C-SCA.
Don first pair of chemo ASTM-rated gloves on clean side of anteroom.	Apply alcohol-based hand sanitizer, rub hands together, covering all surfaces of hands and fingers, and allow to air dry on clean side of anteroom.	Don gown on clean side of anteroom or C-SCA.
Don, as applicable, sleeve covers on clean side of anteroom.	Don first pair of chemo ASTM-rated gloves on clean side of anteroom.	Apply alcohol-based hand sanitizer, rub hands together, covering all surfaces of hands and fingers, and allow to air dry on clean side of anteroom or C-SCA.
Don 2nd pair of chemo ASTM-rated sterile gloves on clean side of anteroom or upon entering the C-SEC buffer room.	Don, as applicable, sleeve covers on clean side of anteroom.	Don first pair of chemo ASTM-rated gloves on clean side of anteroom or C-SCA.
	Don second pair of chemo ASTM-rated sterile gloves on clean side of anteroom or upon entering C-SEC buffer room.	Don, as applicable, sleeve covers on clean side of anteroom or C-SCA.
		Don second pair of chemo ASTM-rated sterile gloves on clean side of anteroom or upon entering C-SEC buffer room or C-SCA.

Sink on the Clean Side of the LOD in the Anteroom	Sink on the Dirty Side of the LOD in the Anteroom	Sink Outside of the Anteroom or C-SCA
Doffing		
Remove and dispose of outer pair of gloves in the C-PEC.	Remove and dispose of outer pair of gloves in the C-PEC.	Remove and dispose of the outer pair of gloves in the C-PEC.
Remove and dispose of sleeve covers in the C-PEC.	Remove and dispose of sleeve covers in the C-PEC.	Remove and dispose of sleeve covers in the C-PEC.
Remove and dispose of gown while on contaminated side of LOD for C-SEC buffer room.	Remove and dispose of gown while on contaminated side of LOD of C-SEC buffer room.	Remove and dispose of gown while on contaminated side of C-SEC or C-SCA.
Remove and dispose of outer shoe covers while stepping over LOD from contaminated side into uncontaminated side of C-SEC buffer room.	Remove and dispose of outer shoe covers while stepping over LOD from contaminated side into uncontaminated side of C-SEC buffer room.	Remove and dispose of outer shoe covers while stepping over LOD from contaminated side into uncontaminated side of C-SEC or C-SCA.
Remove and dispose of inner pair of gloves in clean side of anteroom after leaving C-SEC buffer room.	Remove and dispose of inner pair of gloves in clean side of anteroom after leaving C-SEC buffer room.	Remove and dispose of inner pair of gloves in clean side of anteroom or C-SCA after leaving C-SEC buffer room.
Wash hands using soap and water for 30 seconds and dry thoroughly.	Remove dedicated shoes or inner shoe covers as stepping over LOD into dirty side of anteroom.	Remove dedicated shoes or inner shoe covers as stepping over LOD into dirty side of anteroom or C-SCA.
Remove dedicated shoes or inner shoe covers as stepping over LOD into dirty side of anteroom.	Remove and dispose of head covering, facial hair covering, and face mask on dirty side of anteroom.	Remove and dispose of head covering, facial hair covering, and face mask on dirty side of anteroom or C-SCA.
Remove and dispose of head covering, facial hair covering, and face mask on the dirty side of anteroom.	Wash hands using soap and water for 30 seconds and dry thoroughly.	Wash hands using soap and water for 30 seconds and dry thoroughly.

USP <797> References

- Section 2: Personnel Training and Evaluation.
  - Section 2.1: Demonstrating Knowledge and Competency of Core Skills.
  - Section 2.2: Demonstrating Competency in Garbing and Hand Hygiene.
- Section 3: Personal Hygiene and Garbing.
  - Section 3.1: Personnel Preparation.
  - Section 3.2: Hand Hygiene.
    - Box 3: Hand Washing Procedures.
    - Box 4: Hand Sanitizing Procedures.
  - Section 3.3: Garbing Requirements.
- Section 4: Facilities and Engineering Controls.
  - Section 4.4: Water Source.

USP <800> References

- Section 5: Facilities and Engineering Controls.
  - Section 5.3: Compounding.
  - Section 5.3.2: Sterile Compounding.
- Section 7: Personal Protective Equipment.
  - Section 7.1: Gloves.
  - Section 7.2: Gowns.
  - Section 7.3: Head, Hair, Shoe, and Sleeve Covers.
  - Section 7.4: Eye and Face Protection.
  - Section 7.5: Respiratory Protection.
  - Section 7.6: Disposal of Used Personal Protective Equipment.
- Section 9: Personnel Training.
- Section 13: Compounding.

Reference Documents

Gown, Garb, and Hand Hygiene – Sterile Hazardous Compounding Competency

The Respiratory Protection Information Trusted Source.
https://www.cdc.gov/niosh/npptl/topics/respirators/disp_part/respsource.html

Equipment and Materials

- Liquid soap and water,
- Alcohol-based hand sanitizer.
- Disposable nail picks.
- Disposable low-lint wipes/towelettes.
- Sterile gloves, ASTM D6978-rated, powder-free, in a variety of sizes.
- Sterile gloves, powder-free in a variety of sizes.
- Gowns or coveralls ("bunny suit") in a variety of sizes.
- HD-resistant gowns made of polyethylene-coated polypropylene or other laminate material, in a variety of sizes.
- Disposable HD-resistant sleeve coverings, optional.
- Dedicated shoes and/or disposable shoe covers.
- Head and face coverings (e.g., bouffant, N95 mask, beard cover, face shield).
- Eye protection (e.g., wrap-around goggles).
- Respiratory protection (e.g., full-facepiece cartridge-type respirator, PAPR).
- Sterile 70% isopropyl alcohol (sIPA).

This document has:

- ☐ been further customized as in _____
- ☐ NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
01/30/2024	S-800.003.01	New format, new official USP Standards 11/1/2023	N/A	Kelly Klotz
10/31/2024	S-800.003.01	Annual review.	N/A	Mike Blaine

Section Name: Personal Hygiene and Garbing	Policy Name: Respiratory Protection
Policy: S-800.004.001	Last Revision/Review: 10/31/2024
Accreditation Standards: TCRX-3-E, DRX7-6B	

Policy

Proper respiratory protection will be used to protect from hazardous chemicals during compounding and cleaning procedures, where applicable. Some pharmacy members may routinely handle, or work in the vicinity of, chemicals classified as hazardous drugs by the National Institute for Occupational Safety and Health (NIOSH) guidelines.

Definitions

NIOSH: National Institute for Occupational Safety and Health
Personal Protective Equipment (PPE): Items such as gloves, gowns, respirators, goggles, face shields, and others that protect individual workers from hazardous physical or chemical exposure.
Powered Air-Purifying Respirator (PAPR): A device that forces filtered, purified air into an enclosed space around the user's face. Most PAPRs can be fitted with activated charcoal cartridges when there is the potential for exposure to HD vapors and gases.

Procedures

1. Who policy and procedure applies to
    a. Personal Respiratory Protection—in the form of a respirator--is required for pharmacy team members who compound with hazardous chemicals and/or who clean the hazardous compounding designated areas as a part of their job responsibilities.
    b. A respirator may also be necessary for duties performed in the non-hazardous compounding areas.
    c. Pharmacy team members classified as at-risk for exposure are: All Pharmacists, as well as any Pharmacy Technicians who may enter, or clean the negative pressure lab. In addition, the Pharmacist in Charge may designate other team members to be classified as "at risk." For example, team members who may receive hazardous chemicals upon delivery.
    d. The pharmacy will make training available to all employees classified as "at risk" for exposure to hazardous drugs. Training will take place at orientation and annually.
2. Steps to ensure employee safety and correct respirator selection.
    a. Upon new hire or job change, if an employee will work with hazardous chemicals, they will complete a medical evaluation per OSHA standards to ensure they are medically capable to wear a respirator.
    b. If medical evaluation indicated employee has the ability to wear a respirator, the PIC or designated person will conduct a respirator fit test to determine best size and fit. This will be completed prior to handling or exposure to any hazardous materials.
    c. The type of hazardous materials that an employee may be exposed to determines what type of respirator is appropriate.
        i. N-95 is indicated to reduce exposure to particles and liquid or non-oil based particles from sprays that do not emit oil aerosols or vapors. Do not use N-95s for gases and vapors and oil aerosols.
        ii. Powered air-purifying respirators (PAPR) may be indicated when a higher level or eye and face protection may be required due to potential sprays, splashes, vapors or gases.
        iii. Surgical masks-do NOT provide respiratory protection from drug exposure and MUST NOT be used when respiratory protection from HD exposure is required.

3. Respirator fit test procedure.
    a. When to complete
        i. Upon new hire or job change to handle hazardous materials.
        ii. The fit test will be repeated on an annual basis.
        iii. A fit test may need to be repeated in the event facial structure has changed. For example, significant weight loss or gain, any injury or surgery that may have changed the structure of the face for a respirator to be well-fitted.
    b. A respirator is intended to provide a good seal. Facial hair, such as a beard or sideburns may prevent a good seal. Shaving may need to take place to ensure respiratory protection.
    c. Complete fit test with all PPE (goggles) or personal items (glasses) that will be worn at the same time to ensure that equipment is compatible and does not reduce the effectiveness of the respirator.
    d. Follow instructions of Fit test Kit to complete Fit Test
    e. Document results on Qualitative Respirator Fit Test Record form
        i. Documentation includes employee name, employee signature, respirator make/model, style and size and affirmative pass or fail.
        ii. If an employee fails, do not use that make/ model or size. Repeat testing procedure until correct make/model or size is determined.
4. Storage
    a. Store per manufacturer's recommendations. This is generally, room temperature in less than 80% relative humidity. Shelf-life is typically 3-5 years from date of manufacture.
    b. Do not use past expiration date.
    c. Do not use if damaged (during delivery, while wearing or during storage).

References / Resources

OSHA respiratory standard 29 CFR 1910.34
USP <800> Section 7.5: Respiratory Protection
Fit Test FAQs | NPPTL | NIOSH | CDC
Tips for Managing Respirator Fit Testing Programs (3m.com)
My 3M N95 Respirator Use and Care Information | Worker Health and Safety | 3M US
OSHA 3384 SMALL ENTITY FOR RESPIRATORY PROTECTION STANDARD REV 9.28.11:Layout 1 (fit.edu)

Reference Documents

Qualitative Respirator Fit Test Record form
Gown, Garb and Hand Hygiene Non-Sterile Hazardous Compounding SOP
Gown, Garb and Hand Hygiene Sterile Hazardous Compounding SOP
Qualitative Respirator Fit Test Record Form

This document has:
- ☐ been further customized as in
- ☐ NOT been further customized

Major Change Summary

Date	Revision Number	Reason for Change	Section(s) Affected	Approver(s)
12/05/2023	S-800.004.01	Initial release	N/A	Kelly Klotz
10/31/2024	S-800.004.01	Annual review.	N/A	Mike Blaine

State of Ohio Board of Pharmacy

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(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 021260150

Sbh Medical Ltd

7654 Crosswoods Dr
Columbus, OH 43235-4621
Franklin County

Terminal - Pharmacy - Category 3

TDDD Inspection Guide Updated 5/2/2024

May 22, 2024

License 021260150 - Sbh Medical Ltd

Full

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Completed by Alex Seminara
Start 5/22/2024 11:00 AM
End 5/22/2024 2:11 PM

Organization

Name
Sbh Medical Ltd

License Type
Terminal - Pharmacy - Category 3

Category

License Number
021260150

Business Type
FL - Fluid Therapy

DEA Number
BS7232046

Responsible Person
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Hours of Operation

Contact

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Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Douglas Navarro, R.Ph.			03323838		dnavarro@optiorx.com

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Compliance Specialist Alex Seminara

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description

Observation
Category 3 - Fluid Therapy Pharmacy. Sterile and Non Sterile Compounding Present. Hazardous Compounding Included

4) Have there been any changes in the TDDD's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

5) *Does the TDDD have a valid registration issued by the Drug Enforcement Administration?

Yes

Observation
BS7232046

6) Is the Responsible Person present during the inspection?

Yes

7) How often is the Responsible Person at the TDDD?

Observation
Full Time

9) Does the TDDD ensure all individuals are acting within their scope of practice?

Yes

37.1) Definitions – pharmacy compounding (OAC 4729:7-2-01)

1) Does the pharmacy compound?

Yes: Non-sterile Compounding

Yes: Sterile Compounding

Yes: Hazardous Compounding

37.2) Sterile compounding exemptions (OAC 4729:7-2-02)

1) Does the pharmacy compound non-hazardous, conventionally manufactured sterile products in accordance with the directions contained in approved labeling provided by the product's manufacturer?

Yes

2) Do the conventionally manufactured non-hazardous sterile products compounded in accordance with the manufacturer approved labeling meet the requirements of the rule to be exempted from OAC 4729:7-2 Pharmacy Compounding?

No

37.3) Drugs compounded in a pharmacy (OAC 4729:7-2-03)

1) Does the pharmacy compound non-sterile drug products?

Yes: The pharmacy prepares non-hazardous, conventionally manufactured non-sterile products in accordance with the directions contained in the approved labeling provided by the product's manufacturer (e.g., reconstitution) and these products are exempt from USP<795>

Yes: The pharmacy compounds non-sterile drug products and must be in compliance with USP<795>

2) Does the pharmacy compound sterile drug products?

Yes: Pharmacy compounds sterile drug preparations and must comply with USP<797>

3) Does the pharmacy compound antineoplastic hazardous drug preparations listed in table 1 of the NIOSH list?

Yes.

4) Does the pharmacy compound non-antineoplastic hazardous drugs listed in NIOSH table 1, and/or compounds with hazardous drug preparations listed in NIOSH table 2 or 3?

Yes.

5) How does the pharmacy comply with OAC 4729:7-2-03 for non-antineoplastic compounded hazardous drug preparations listed in NIOSH table 1 and/or for compounded hazardous drug products listed in NIOSH table 2 or 3?

Pharmacy states it complies with USP 800

8) Do only appropriate personnel engage in compounding at a pharmacy?

Yes: Pharmacist

Yes: Certified certified pharmacy technician, registered pharmacy technician, or pharmacy technician trainee under the personal supervision of a pharmacist

9) Is a pharmacist responsible for compounded drug preparations?

Yes: A pharmacist conducts the final check of a compounded drug preparation

Yes: A pharmacist is responsible for dispensing compounded drug preparations

Yes: A pharmacist maintains all compounding records

Yes: A pharmacist is responsible for the proper maintenance, cleanliness and use of all equipment used in compounding

10) Are drugs compounded pursuant to a patient specific prescription issued by a licensed health professional authorized to prescribe drugs?

Yes.

14) Do compounded drugs labeled for outpatients include the additional labeling requirements of the rule?

Yes: Contains the statement "compounded drug" or similar statement

Yes: Contains the name and address of the pharmacy as it appears on the TDDD license

Yes: Contains the full name of the patient, or if an animal, the last name of the owner, the animal name and species.

Yes: Contains the directions for use of the drug

Yes: Contains the date of dispensing

Yes: Contains any cautions required by federal law

Yes: Contains the serial number of the prescription

Yes: Contain the proprietary name, if any, or the generic name and the name of the distributor or national drug code of the drug dispensed, and the strength, if more than one strength of the drug is marketed. The dispensing pharmacist may omit the name and strength of the drug only if the prescriber specifically requests omission and such request is documented

Yes: Contain the quantity of the drug dispensed

16) Does the pharmacy maintain a system for the safe disposal of drug waste?

Yes

17) Does the pharmacy comply with the drug database reporting requirements for compounded drugs?

Yes: OARRS reportable compounded patient specific drugs are reported to OARRS within 24-hours of being dispensed

18) Does the pharmacy report to the board within 72-hours upon discovery any product quality issue attributed to a compounded drug preparation dispensed by the pharmacy?

No: The pharmacy has not experienced any reportable product quality issues, but understands the reporting requirements.

19) Does the pharmacy report to the board within 72-hours of receipt any warning letters, injunctions, or decrees issued in relation to the pharmacy by the FDA?

No: The pharmacy has not received a warning letter, injunction or decree from the FDA, but understands the reporting requirement.

37.4) Record keeping (OAC 4729:7-2-04)

1) Do records of drugs compounded in a pharmacy include all of the required elements?

Yes: Includes the patient name

Yes: Includes the drug name, strength or activity, and dosage form

Yes: Includes the assigned internal identification number (e.g., prescription, order, lot number)

Yes: Includes the date and time of preparation

Yes: Includes the name of each ingredient

Yes: Includes the vendor, lot number, and expiration date for each ingredient for compounded drug preparations prepared for more than one patient and for any sterile compounded product prepared from nonsterile ingredients

Yes: Includes the weight or volume of each ingredient

Yes: Includes the total quantity compounded

Yes: Includes the disposition of unused controlled substances drug(s), and amount

Yes: Includes the assigned beyond-use date

Yes: Inlcudes the positive identification of the pharmacy personnel responsible for preparing the compounded drug preparation

Yes: Includes the positive identification of the pharmacist conducting the final check of the compounded preparation

Yes: Includes the positive identification of the pharmacist who dispensed the compounded drug preparation

Yes: Includes records that are compliant to USP 795, 797 and 800 requirements

2) Compounding records are readily retrievable and uniformly maintained for at least 3 years.

Yes, records are readily retrievable

Yes; records are uniformly maintained

Yes; records are maintained for at least 3 years

3) Are all records maintained for at least 3 years?

Yes: Records are kept on-site for 3 years

37.5) Drugs compounded for veterinarian office use (OAC 4729:7-2-05)

1) Does the pharmacy compound drugs intended for animal use by licensed veterinarians?

Yes: Ohio licensed pharmacy

2) Does the pharmacy compound non-patient specific drugs pursuant to a request made by a veterinarian for direct administration to patients in the course of the veterinarian's practice?

Yes

3) Does the pharmacy only provide non-commercially available non-patient specific compounded drugs to veterinarians for the permitted reasons?

Yes: To treat an emergency situation

Yes: For an unanticipated procedure or treatment for which a time delay would negatively affect a patient outcome

Yes: For diagnostic purposes

4) Are only limited quantities of non-patient specific compounded drugs provided to veterinarians in compliance with the rule?

Yes: The quantity supplied is sufficient for that veterinarian's office use consistent with the beyond use date of the preparation

Yes: The quantity supplied is reasonable considering the intended use of the compounded preparation and nature of the veterinarian's practice

Yes: The pharmacist who provides the veterinarian with the compounded drug exercised professional judgement as to whether the quantity of the drug supplied was appropriate

6) Does pharmacy sell compounded drugs to another pharmacy or facility registered as a drug distributor?

No

8) Reminder: Pharmacy sale of a non-patient specific compounded drug preparation is an occasional sale pursuant to OAC 4729:5-3-09 Occasional sale and drug transfers.

37.6.1) Introduction and Scope

3) Does the facility compound CNSPs (compounded nonsterile products)?

Yes: Solid oral preparations

Yes: Liquid oral preparations

Yes: Rectal preparations

Yes: Vaginal preparations

Yes: Topical preparations (i.e., creams, gels, and ointments)

Yes: Nasal and sinus preparations intended for local application (i.e., nasal sprays and nasal irrigations)

Yes: Otic preparations (excluding use in perforated ear drums)

4) Does the facility perform any practies that are not considered compounding, and are therefore not subject to the requirements of USP 795?

No: The facility does not perform any practices not subject to the requirements of USP 795.

5) Are compounding leadership and all personnel involved in preparing, storing, transporting, packaging, and dispensing CNSPs responsible for compliance with USP 795?

Yes: Compounding personnel are responsible for ensuring that the applicable practices and quality standards in USP 795 are continually and consistently applied to their operations.

Yes: Compounding personnel proactively identify and remedy potential problems within their operations.

Yes: Personnel engaged in compounding and dispensing of CNSPs comply withy laws and regulations of the applicable regulatory jurisdiction.

6) Has the facility appointed a designated person?

Yes

Observation
Alyssa Turner

7) What activities is the designated person responsible for?

Oversees a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs

Selecting components

Monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed

Ensuring that standard operating procedures (SOPs) are fully implemented.

Ensuring that follow-up is carried out if problems, deviations, or errors are identified

Establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs

37.6.2) Personnel Training and Evaluation

1) Do all personnel who compound or have direct oversight of compounding receive initial training before being allowed to perform their job functions independently?

Yes

2) Has the designated person created and implemented a training program that equips personnel with knowledge and training in the required skills necessary to perform their assigned tasks?

Yes: Frequency of training is described

Yes: Process for evaluating the competency of personnel is described

Yes: Equips personnel with the skills to perform their assigned tasks.

3) Do personnel who compound or have direct oversight with compounding personnel complete training initially and at least every 12 months?

Yes

4) Do SOPs describe training requirements for personnel who do not compound and only perform functions such as in-process checks, final verification, or dispensing?

Yes

5) Does facility training demonstrate knowledge and competency initially and at least annually in the core competencies?

Yes: Hand hygiene

Yes: Garbing

Yes: Cleaning and sanitizing

Yes: Handling and transporting components and CNSPs

Yes: Mixing and measuring

Yes: Proper use of equipment and devices selected to compound CNSPs

Yes: Documentation of the compounding process

6) Do training procedures include a review of appropriate written materials?

Yes: USP 795

Yes: Staff understand and interpret safety data sheets (SDSs)

Yes: Staff understandi certificates of analysis (CofA)

Yes: Staff read and understand procedures related to their compounding duties

7) Does the training process document personnel have been trained and successfully completed competency assessments?

Yes: Personnel are observed and guided throughout the training process.

Yes: Personnel are expected to repeat procedures independently under direct supervision.

Yes: Personnel are permitted to perform the procedure without direct supervision only after independently demonstrating understanding and competency.

Yes: Upon completion of the training program the designated person or assigned trainer documents personnel have been successfully trained and completed competency assessments.

8) Does the designated person monitor and observe compounding activities?

Yes: Routinely monitors and observes compounding activities

Yes: Takes immediate corrective action if deficient practices are observed.

9) Does the facility have SOPs that describe the procedures for monitoring and observing compounding activities and personnel?

Yes

37.6.3) Personal Hygiene and Garbing

1) Does the facility require that individuals entering the compounding area maintain appropriate personal hygiene?

Yes: Individuals are trained to report conditions that present a personal risk of potential contamination to the compounding environment and CNSP to the designated person.

Yes: The designated person evaluates whether individuals should be excluded from working in the compounding area until personal conditions resolve.

2) Do personnel remove items that are not easily cleanable and that might interfere with garbing prior to entering the compounding area?

Yes: Personnel remove outer garments (e.g., bandanas, coats, hats and jackets) prior to engaging in compounding.

Yes: Personnel remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing or hand hygiene (e.g., watches, rings) prior to engaging in compounding.

Yes: Personnel remove earbuds/headphones prior to engaging in compounding.

3) Does the designated person permit accommodations for personal items provided that the quality of the environment and CNSP are not affected?

No accommodations for personal items are provided.

4) Do compounding staff perform appropriate hand hygiene procedures when entering the compounding area?

Yes: Personnel wash hands with soap and water for at least 30 seconds

Yes: Personnel dry hands completely with disposable towels or wipers

Yes: Personnel don gloves

5) Does the facility wipe or replace other items before beginning to compound a CNSP that has different components?

Yes

6) Do compounding personnel inspect gloves for holes, punctures or tears?

Yes: Gloves are replaced immediately if defects are detected.

7) Are gloves worn for all compounding activities?

Yes

8) Is other garb appropriate for the type of compounding performed?

Yes: Garb protects personnel from chemical exposures

Yes: Garb prevents CNSP contamination

Yes: Garbing requirements are determined by the facility and documented in the SOPs.

Yes: Frequency of changing garbing is determined by the facility and documented in the facility's SOPs.

9) Is garbing replaced immediately if it becomes visibly soiled or if its integrity is compromised?

Yes

10) Is garb stored in a manner that minimizes contamination?

Yes

11) Is garb removed and discarded when leaving the compounding area?

Yes: All garb, except gowns (as applicable), are removed and discarded when leaving the compounding area.

Yes: Unsoiled/undamaged gowns remain in the compounding area for reuse during the same shift.

12) Do facility SOPs describe cleaning and sanitization procedures for reusing goggles, respirators, and other reusable equipment?

Yes

13) Is appropriate PPE worn and disposed of in accordance with USP 800 for hazardous drug compounding?

Yes

37.6.4) Buildings and Facilities

1) COMPOUNDING AREA: Is there a designated area for nonsterile compounding?

Yes: The method of designation is described in the facility's SOPs.

Yes: Other activities are not occurring in the compounding area at the same time as compounding.

2) Is the compounding area suitable?

Yes: The compounding area is well lit, clean, orderly, and sanitary condition

Yes: The compounding area is in a good state of repair.

Yes: The compounding area is not carpeted.

4) STORAGE AREA: Are temperatures monitored and recorded in the compounding area?

Yes: Temperature readings are documented on a log.

Yes: Temperatures are monitored with a continuous recording device.

Yes: Temperatures are stored in the continuous temperature device and are retrievable.

5) Is temperature monitoring equipment calibrated or verified for accuracy?

Yes: As recommended by the manufacturer

Yes: Every 12 months if not specified by the manufacturer.

6) Does the facility have a process to evaluate CNSPs exposed to temperature excursions?

Yes

7) Are all CNSPS, components, equipment and containers stored off the floor?

Yes

8) WATER SOURCES: Does the facility have an easily accessible sink with hot and cold water?

Yes

9) Is the sink empty of all items unrelated to compounding?

Yes

10) Is the sink cleaned when visibly soiled before being used to clean compounding equipment?

Yes

11) Are plumbing systems free of defects that may contribute to CNSP contamination?

Yes

12) Is purified water used for rinsing equipment and utensils?

No

37.6.5) Cleaning and Sanitizing

1) Are work surfaces cleaned at appropriate intervals?

Yes: Beginning and end of each shift

Yes: After spill/splash contamination is known or suspected

Yes: Between compounding CNSPs with different components

2) Are floors cleaned at appropriate intervals?

Yes: On days compounding occurs

Yes: After spills

Yes: When surface contamination is known or suspected

3) Are walls cleaned at appropriate intervals?

Yes: When visibly soiled

Yes: After spills

Yes: When surface contamination is known or suspected

4) Are ceilings cleaned at appropriate intervals?

Yes: When visibly soiled

Yes: When surface contamination is known or suspected

5) Is storage shelving cleaned at appropriate intervals?

Yes: at least every 3 months

Yes: After spills

Yes: When surface contamination is known or suspected

6) Are surfaces resistant to damage caused by cleaning and sanitizing agents?

Yes

7) Are floors in the compounding area easily cleanable?

Yes: Floors are non-porous.

Yes: Floors are not particle generating.

8) Are appropriate cleaning and sanitizing agents used?

Yes

37.6.6.1) Equipment

1) Is the equipment used in the compounding process suitable?

Yes: Equipment surfaces are not reactive, additive or sorptive.

Yes: Equipment surfaces do not alter the quality of the CNSP.

Yes: Disposable or dedicated equipment is used to reduce the chance of bioburden and cross contamination.

2) Is the equipment used in compounding stored in a manner that minimizes the risk of contamination?

Yes. Equipment is stored in a manner that minimizes contamination risk.

Yes: Equipment is located to facilitate use, maintenance and cleaning.

3) Is equipment used in compounding or testing of compounded preparations properly inspected and maintained?

Yes: Inspected prior to use

Yes: Equipment is verified for accuracy as recommended by the manufacturer or at least every 12-months.

Yes: Equipment is cleaned after compounding

4) Are activities that generate airborne chemical particles performed in a closed-system processing device?

Yes: There is a process in place to identify components that could generate airborne chemical particles.

Yes: Particle generating components are manipulated in a closed system processing device

Yes: Facility SOPs document the assessment of particle generating components.

5) Are CVSs and/or BSCs certified at least every 12-months?

Yes: The CVE or BSC is certified according to manufacturer specifications.

6) CVE: Is the CVE cleaned and sanitized according to minimum USP frequencies?

Yes: Beginning and end of each shift on days when compounding occurs

Yes: After spills/surface contamination is known or suspected

Yes: The horizontal work surface of the CVE is cleaned between compounding CNSPs with different components.

8) Are other devices and equipment used in compounding cleaned according to USP minimum frequencies?

Yes: Before their first use

Yes: According to manufacturer recommendations

Yes: Cleaned between compounding CNSPs with different components, if no manufacturer recommendation is available

37.6.6.2) Components

1) Does the facility have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP?

Yes

2) Are SDSs readily accessible to all personnel working with components?

Yes

3) Is the designated person responsible for component selection?

Yes

4) API COMPONENT SELECTION: Do APIs used in compounding comply with USP 795?

Yes: Components comply with USP monographs, if one exists.

Yes: Components have a COA that includes specifications and test results showing the API meets expected quality.

Yes: Components are manufactured at an FDA-registered facility.

5) COMPONENTS OTHER THAN APIs: Do other components used in compounding comply with USP 795?

Yes: Components are accompanied by a COA that verifies the component meets the criteria in the USP/NF, if one exists.

Yes: Components are manufactured in an FDA-registered facility.

Yes: If a component cannot be obtained form an FDA-registered facility, the designated person selects a component for suitable for the intended use.

6) WATER: Is purified water or better quality used for compounding nonsterile drug preparations?

Yes

7) COMPONENT RECEIPT: Is the COA of non-conventionally manufactured products reviewed?

Yes: Review documents the receipt date, quantity received, and supplier name.

Yes: Review documents the lot number and expiration date.

Yes: Review documents the results of any in-house or third-party testing performed.

8) COMPONENT RECEIPT: Does the facility has a process to identify and label components that lack a vendor expiration date?

Yes: Marks components with the date of receipt.

Yes: Assigns a BUD of not more than 3 years from the date of receipt.

Yes: APIs and added substances that are used in sterile compounding are assigned a BUD of not more than 1-year from the date of receipt.

Yes: APIs and added substances known to be susceptible to degradation are assigned a 1-year expiration date.

9) COMPONENT RECEIPT: Are components found to of unacceptable quality are promptly rejected?

Yes: labeled as rejected and segregated from active stock

Yes: Other lots of rejected components from the same vendor are examined

10) COMPONENT EVALUATION: Are components visually inspected prior to use?

Yes

11) COMPONENT EVALUATION: Is a process in place to ensure components are of the correct identity and were properly stored prior to each use?

Yes

12) COMPONENT HANDLING: Are components handled in accordance with manufacturer instructions and/or pre applicable laws and regulations?

Yes

13) COMPONENT HANDLING: Are components removed from the original container discarded if not used?

Yes

14) COMPONENT SPILL AND DISPOSAL: Does the facility maintain current chemical hazard and disposal information?

Yes

15) COMPONENT SPILL AND DISPOSAL: Is the facility prepared to handle a nonhazardous component spill?

Yes: The management and documentation of nonhazardous component spills and disposal is described in the facility SOPs.

Yes: Spill kit is readily accessible in the compounding area.

Yes: Personnel required to remediate spills receive training in spill management of chemicals used and stored in the compounding facility.

Yes: Spill training is conducted and documented at least every 12 months for all personnel required to clean up spills.

16) COMPONENT SPILL AND DISPOSAL: Is component waste disposed of in accordance with laws and regulations?

Yes

37.6.7) Master Formulation and Compounding Records

1) MASTER FORMULAS: Does the facility have a master formula for each unique formulation of a CNSP?

Yes: Changes and alterations are approved and documented

Yes: SOPs describe how master formulas are created, altered and approved

2) MASTER FORMULAS: Do master formulas contain all required elements?

Yes: Contain the name, strength or activity, and dosage form

Yes: Contain the identities and amounts of all components

Yes: Contain the relevant characteristics of components (e.g., particle size, salt form, purity grade, solubility, etc.), if appliable

Yes: Contain the container closure system

Yes: Contain complete instructions for preparing the CNSP

Yes: Contain the equipment and supplies needed

Yes: Contain a description of the compounding process

Yes: Contain a physical description of the final CNSP

Yes: Contain beyond-use date and storage requirements

Yes: Contain a reference source for assigned BUD

Yes: Contain calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s), where appliable

Yes: Contain labeling requirements (e.g. shake well)

Yes: Contain quality control (QC) procedures (e.g., pH testing, visual inspection, etc.) and expected results

Yes: Contain other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature, etc.)

3) COMPOUNDING RECORDS: Does the facility create a compounding record for each CNSP?

Yes

4) COMP0OUNDING RECORDS: Do compounding records contain all the required elements?

Yes: Contain the name, strength or activity, and dosage form

Yes: Contain the date (or date and time) of preparation

Yes: Contain an assigned internal identification number (Rx number or lot number)

Yes: Contain a method to identify individuals involved in the compounding process

Yes: Contain a method to identify the individual(s) verifying the final CNSP

Yes: Include the name, vendor or manufacturer, lot number, and expiration date of each component

Yes: Include the weight or measurement of each component

Yes: Include the total quantity of CNSP compounded

Yes: Contain the assigned beyond-use date

Yes: Contain the storage requirements of the CNSP

Yes: Contain calculations to determine and verify quantities and/or concentrations of components and strength or activity of the API(s), where applicable

Yes: Contain a physical description of the final CNSP

Yes: Contain the results of quality control procedures (e.g., pH testing, visual inspection, etc.)

Yes: Contain a reference to the master formula record for the CNSP

37.6.8) Release Inspections and Testing

1) Are all release inspections included in the facility's documentation?

Yes

2) Do visual inspections confirm the CNSP is ready for releasing and dispensing?

Yes

3) Are CNSPs not dispensed or released on day of preparation visually inspected before being dispensed?

Yes

37.6.9) Labeling

2) Do prepared CNSP contain a label with the minimum required information in USP 795?

Yes: Contain the assigned internal identification number

Yes: Contain the active ingredients and their amounts, activities, or concentrations

Yes: Contain the storage conditions, if other than controlled room temperature

Yes: Contain the beyond use date

Yes: Contain the dosage form

Yes: Contain the total amount or volume, if it is not obvious from the container

Observation
(Lot number, Rx number, etc.)

3) Do labels on dispensed CNSPs contain all information required by USP 795?

Yes: Contain the route of administration

Yes: Indicate the preparation was compounded

Yes: Include any applicable special handling instructions

Yes: Iclude any applicable warning statements

Yes: Contain the compounding facility name and contact information if the CNSP is sent outside the facility or healthcare system in which it was compounded

4) Do facility SOPs describe labeling procedures?

Yes: Labeling procedures are defined in facility SOPs.

Yes: Procedures include processes to prevent labeling errors.

Yes: CNSP label verification includes confirmation of the prescription or medication order.

Yes: CNSP label verification includes confirmation of the master formula record and compounding record.

37.6.10.1) Terminology and Parameters

2) Does the facility consider parameters which may affect CNSP quality when assigning a BUD?

Yes: Include a review of chemical and physical stability properties of the API

Yes: Include a review of the chemical and physical stability of any added substances in the preparation

Yes: Include a review of the compatibility of the container closure system with the finished preparation

Yes: Include a review of the degradation of the container closure system which can lead to a reduction of the integrity of the CNSP

Yes: Include a review of the potential for microbial proliferation in the CNSP

Yes: Include a review for significant deviations from essential compounding steps and procedures which may impact the stability of the formulation?

37.6.10.2) Establishing a BUD

4) Does the facility assign BUDs in accordance with USP 795?

Yes, non-preserved aqueous dosage forms in the absence of a USP/NF monograph or CNSP specific stability information are assigned a BUD of 14 days refrigerated.

Yes, preserved aqueous dosage forms in the absence of a USP/NF monograph or CNSP specific stability information are assigned a 35-day BUD.

Yes, non-aqueous oral liquids in the absence of a USP/NF monograph or CNSP specific stability information are assigned a 90 day BUD.

Yes, other non-aqueous dosage forms in the absence of a USP/NF monograph or CNSP specific stability information are assigned a 180 day BUD.

Yes, in the absence of specific storage conditions, CNSPs are protected from moisture, freezing, and excessive heat, and where necessary, from light.

37.6.10.3) CNSPs Requiring a Shorter BUD

1) Does the facility have a process to determine if data shows a CNSP requires a shorter BUD?

Yes, processes are in place to determine if a shorter BUD is required for a compounded CNSP.

2) Are assigned BUDs shorter than the shortest remaining expiration date of any commercially available starting components?

Yes.

3) Are BUDs shorter than the shortest BUD of any of the individual compounded components?

Yes.

37.6.10.4) Extending BUDs for CNSPs

1) Are all CNSPs with a USP-NF monograph assigned a BUD that does not exceed the BUD specified in the monograph?

Yes:

37.6.11) SOPs

1) Does the facility have SOPs on all aspects of the compounding operation?

Yes.

2) Are all personnel who conduct or oversee compounding activities trained in the facility SOPs?

Yes. SOP training is on file.

3) Is an employee designated to ensure facility SOPs are fully implemented?

Yes, one (or more) person(s) are designated to ensure the facility SOPs are fully implemented.

37.6.12) Quality Assurance and Quality Control

2) Are QA and QC programs formally established?

Yes, QA and QC programs are documented in the facility's SOPs.

Yes,. QA and QC programs ensure all aspects of CNSP compounding are conducted in accordance with USP 795.

Yes, QA and QC programs ensure all aspects of CNSP compounding are conducted in accordance with state and federal laws.

3) Are QA and QC programs complete?

Yes, programs establish a system to ensure adherence to procedures.

Yes, programs establish a system to prevent and detect errors and other quality problems.

Yes, programs establish a system to evaluate complaints and adverse events.

Yes, programs establish a system for appropriate investigations and corrective actions.

4) Do facility SOPs describe each aspect of the QA program?

Yes, SOPs describe the roles, duties, and training of personnel responsible for each aspect of the QA program.

Yes, the designated person responsible for the QA program has training, experience, and authority to perform QA duties.

5) Is the QA and QC program reviewed annually by the designated person?

Yes, the results of the review is documented.

Yes, appropriate action is taken if needed.

6) RECALL PROCEDURES: Does the facility have recall procedures in place?

Yes, there is a procedure to determine if a recall must be initiated.

Yes, procedures include immediate notification to prescribers if a compounded product fails specifications and may result in patient harm.

Yes, procedures include the recall of any unused dispensed CNSPs.

Yes, procedures include the quarantine of any remaining stock in the facility.

Yes, procedures include the investigation of other lots for recall.

Yes, other lots are recalled if necessary.

7) RECALL PROCEDURES: Do SOPs for recalls of dispensed CNSPs contain all elements required by USP 795?

Yes, SOPs describe procedures to determine the severity of the problem and the urgency for implementation and completion of a recall.

Yes, SOPs describe procedures to determine the distribution on any affected CNSP, including the data and quantity of distribution.

Yes, SOPs describe procedures to identify patients who have received the CNSP.

Yes, SOPs describe methods for disposal and documentation of the recalled CNSP.

Yes, SOPs describe procedures for investigation and documentation of the recall.

8) RECALL PROCEDURES: Do SOPs for recalls require documentation and notification to the appropriate regulatory bodies?

Yes, the facility has a policy to report recalls to the appropriate regulatory body, but no recalls have occurred.

9) COMPLAINT HANDLING: Does the facility have a SOP for handling complaints?

Yes, there is an SOP for complaint handling.

10) COMPLAINT HANDLING: Are complaints reviewed to identify potential quality problems?

Yes, the designated person reviews all complaints to determine if there is a quality problem with the CNSP.

Yes, nnvestigations identify the root cause of the problem.

Yes, investigations consider if the quality problem extends to other CNSPs.

Yes, corrective actions are taken for all potentially affected CNSPs.

Yes, the complaint is evaluated to determine if a recall of potentially affected CNSPs is required.

Yes, the complaint is evaluated to determine if the facility should cease some or all non-sterile compounding processes until the problem has been identified and corrected.

11) COMPLAINT HANDLING: Are records of complaints readily retrievable and complete?

Yes, a record of each complaint is maintained in a readily retrievable format.

Yes, records contain the name of the complainant or other unique identifier.

Yes, records contain the date the complaint was received.

Yes, records identify the nature of the complaint.

Yes, records contain the response to the complaint.

Yes, records include the name and strength of the CNSP involved in the complaint.

Yes, records include the CNSP internal identification number (Rx number or lot number).

12) COMPLAINT HANDLING: Do complaint records include the findings of investigation?

Yes, records include the findings of the investigation.

Yes, records document post investigation follow up.

Yes, records are readily retrievable.

Yes, records are evaluated for possible trends.

13) COMPLAINT HANDLING: Are CNSPs returned in connection with a complaint quarantined and destroyed?

Yes, CNSPs returned in conjunction with a complaint are quarantined.

Yes, CNSPs returned in conjunction with a complaint are destroyed after completion of the investigation.

14) ADVERSE EVENT REPORTING: Are adverse events properly reported?

Yes, there is a policy to report adverse events which reveal CNSP quality problems to those patients and prescribers potentially affected, but no such events have occurred.

37.6.13) CNSP Packaging and Transporting

1) Do facility SOPs include CNSP packaging requirements?

Yes, packing materials maintain the physical and chemical integrity of the CNSP.

Yes, packing materials maintain the stability of the CNSP.

Yes, packing materials protect from damage, leakage, contamination and degradation.

Yes, packing materials protect personnel from exposure.

2) Do SOPs describe CNSP transport?

Yes, SOPs describe the mode of CNSP transportation.

Yes, SOPs describe CNSP special handling instructions.

Yes, SOPs instruct when temperature monitoring devices are needed.

37.6.14) Documentation

1) Does the facility maintain written or electronic documentation demonstrating compliance with USP 795?

Yes, the facility maintains documentation of personnel training, competency assessments, and qualification records including corrective actions for any failures.

Yes, the facility maintains equipment records (e.g., calibration, verification, maintenance reports).

Yes, the facility maintains COAs and all documentation required for components not conventionally manufactured.

Yes, the facility maintains records of receipt for all components.

Yes, the facility maintains all SOPs, master formula records, and compounding records.

Yes, the facility maintains all release inspection and testing records.

Yes, the facility maintains all information related to complaints and adverse events including corrective actions taken.

Yes, the facility maintains results of all investigations and corrective actions.

Yes, the facility maintains all records of cleaning and sanitizing the designated compounding area.

Yes, the facility maintains all temperature logs.

Yes, the facility maintains records of all accommodations to personnel compounding CNSPs.

Yes, the facility maintains records of all required routine reviews (e.g., yearly review of QA and QC programs, yearly review of chemical hazard and disposal information, etc.)

2) Does the facility maintain required documentation in a readily retrievable manner for at least 2 years?

Yes, records are legible.

Yes, records are stored in a manner that prevents deterioration or loss.

Yes, all compounding records are readily retrievable for at least 2 years (3 for Ohio).

37.7.1.1) Scope/Administration/Immediate Use CSPs/Prep per Approved Labeling/ CSP Categories

13) PROPRIETARY BAG AND VIAL SYSTEMS: Does the facility prepare proprietary bag and vial systems which are exempt from USP 797?

No.

37.7.2.1) Knowledge and Competency of Core Skills

1) Does the designated person ensure personnel who compound are initially and annually trained and qualified to sterile compound?

Yes. The designated person creates and implements a training program for personnel.

Yes. The designated person ensures compounders are trained and qualified before being able to perform their job functions independently.

Yes. The designated person ensures personnel who have direct oversight over compounding are trained and qualified before being able to perform their job functions independently.

Yes. The designated person ensures personnel who perform restocking or cleaning and disinfection duties are trained and qualified before being able to perform their job functions independently.

Yes. Training and observation is performed by the designated person or an assigned trainer.

Yes. Training is completed initially and at least every 12 months in appropriate sterile compounding practices. .

Yes. Personnel who perform only restocking or cleaning and disinfecting duties outside the PEC complete ongoing training according to facility SOPs

Yes. Personnel who compound only immediate use CSPs are trained according to facility SOPs. q

2) Does the facility have a written training program?

Yes. the program describes the required training.

Yes. The program describes the frequency of training.

Yes. The program describes the process for evaluating the performance of individuals who compound.

Yes. The program describes the process for evaluating the performance of individuals who have direct oversight of compounding personnel.

Yes. The program describes the process for evaluating the performance of individuals who perform in-process checks.

Yes. The program describes the process for evaluating the performance of individuals who perform final verification.

Yes. The program describes the process for evaluating the performance of individuals who perform the final dispensing of CSPs.

Yes. The program equips personnel with appropriate knowledge and skills to perform their assigned tasks.

Yes. SOPS specify the training required for each task.

Yes. Training and evaluation are documented.

3) Does initial training for compounding personnel and those with oversight of compounding personnel include all required elements in USP 797?

Yes. Knowledge of principals and competency of skills is assessed for hand hygiene.

Yes. Knowledge of principals and competency of skills is assessed for garbing.

Yes. Knowledge of principals and competency of skills is assessed for cleaning and disinfection.

Yes. Knowledge of principals and competency of skills is assessed for calculations, measuring, and mixing.

Yes. Knowledge of principals and competency of skills is assessed for aseptic technique.

Yes. Knowledge of principals and competency of skills is assessed for achieving and maintaining sterility (and apyrogenicity if applicable).

Yes. Knowledge of principals and competency of skills is assessed for use of equipment.

Yes. Knowledge of principals and competency of skills is assessed for documentation of the compounding process.

Yes. Knowledge of principals and competency of skills is assessed for principals of HEPA filtered unidirectional airflow within the ISO Class 5 area.

Yes. Knowledge of principals and competency of skills is assessed for proper use of PECs.

Yes. Knowledge of principals and competency of skills is assessed for principals of movement of materials and personnel within the compounding area.

4) Does the facility conduct initial training competencies for persons ancillary staff according to facility SOPs?

Yes. There are SOPS and initial training for personnel who restock and disinfect the compounding area.

Yes. There are SOPs and initial training for personnel who perform in-process checks or final verification of CSPs.

Yes. There are SOPs and initial training for personnel who only compound immediate use CSPs.

Yes. There are SOPs and initial training for other personnel (E.g., maintenance, certifiers, contractors, inspectors, surveyors).

5) Does the facility conduct ongoing training and competency evaluations according to facility SOPs?

Yes. Compounders complete ongoing training and competency evaluations in the principals of sterile compounding every 12 months

Yes. Compounders complete ongoing garbing and media fill competencies with gloved fingertip sampling and surface sampling every 6 months for category I & II compounding.

Yes. The designated person and personnel with direct oversight of compounding personnel complete training in sterile compounding principals, practices, garbing, and media fill testing with gloved fingertip testing and surface sampling at least every 12 months.

Yes. Personnel who restock or clean and disinfect the compounding area complete ongoing training and competencies according to facility SOPs.

Yes. Personnel who perform in-process checks or final verification of CSPs complete ongoing training and competencies according to facility SOPs

Yes. Personnel who only compound immediate use CSPs complete ongoing training and competencies according to facility SOPs.

Yes. Ancillary personnel (e.g., maintenance, certifiers, contractors, inspectors, surveyors) complete ongoing training and competencies according to facility SOPs

37.7.2.2) Garbing and Hand Hygiene

1) Is an initial garbing competency completed no fewer than 3 separate times prior to compounding Category I, II, or III CSPs?

Yes. Personnel successfully complete three initial garbing competencies in succession prior to compounding category I, II, or III CSPs.

Yes. Failure of any 3 initial garbing competency evaluations requires repeat testing until personnel successfully complete 3 evaluations in a row.

Yes. Garbing competency evaluations consist of visual observation and gloved fingertip and thumb sampling of both hands.

Yes. Each of the 3 initial competency evaluations occurs after performing a separate and complete hand hygiene and full garbing procedure.

Yes. All garbing competencies are completed with gloved fingertip and thumb sampling after garbing.

Yes. All garbing competencies are a documented visual audit.

Yes. All gloved fingertip and thumb sampling occurs after garbing but before applying sterile 70% IPA to gloves.

Yes. Gloved fingertip sampling is performed on donned sterile gloves on both hands in a classified area or segregated compounding area.

2) Are failed glove fingertip tests are properly identified and recorded?

Yes. Failure is indicated by visual observation of improper hand hygiene and garbing procedures.

Yes. Failure is indicated by gloved fingertip and thumb sampling results that exceed allowable action levels.

Yes. Results of failed evaluations and corrective actions are documented and maintained.

Yes. Documentation includes the name of the person evaluated.

Yes. Documentation includes the date and time of the evaluation.

Yes. Documentation includes the media and components used, including manufacturer, expiration date, and lot number .

Yes. Documentation contains the starting temperature for each interval of incubation and the dates of incubation.

Yes. Documentation contains the results of incubation.

Yes. Documentation contains the identification of the observer.

Yes. Documentation contains the identification of the person reading and documenting the results.

NOTE: Identification of the CFUs tis not required for glove fingertip testing.

3) Are repeat garbing competencies completed in accordance with USP 797?

Yes. Garbing competencies are repeated every 6 months for personnel who compound Category I and Category II CSPs.

Yes. Personnel who have direct oversight of compounding personnel but do not compound complete garbing competencies every 12-months.

Yes. Evaluations for personnel who have direct oversight of compounding personnel but do not compound correspond to the type of garbing activities of the personnel they oversee.

Yes. Personnel who have direct oversight of compounding who occasionally compound complete garbing competencies at the same interval as required for the category of CSP they compound.

4) Does the facility employ accurate gloved fingertip and thumb sampling procedures?

Yes. One sampling media device is used per hand containing general microbial growth agar that supports both bacterial and fungal growth.

Yes. Each media device is labeled with a personal identifier, right or left hand, and the date and time of sampling.

Yes. Sterile 70% IPS is not applied to gloves before touching the media device.

Yes. Samples are collected from all gloved fingertips and thumbs from both hands.

Yes. Collection includes rolling the fingertip pads and thumb pad over the surface area.

Yes. Samples are incubated at 30-35 C for no less than 48-hours and then at 20-25 C for no less than 5 additional days.

Yes. All samples (sample temperatures) are incubated in an incubator.

Yes. Sample plates are inverted.

Yes. Documentation includes the number of CFU per hand. (each hand)

Yes. CFU action levels are determined by counting the total number of CFU from both hands.

37.7.2.3) Aseptic Manipulation

1) Do personnel successfully complete an aseptic manipulation competency evaluation before beginning to compound or before overseeing compounding?

Yes. Aseptic manipulation competencies are completed by personnel prior to compounding Category I, II, or III CPS.

Yes. Aseptic manipulation competencies are completed by personnel who have direct oversight of compounding personnel.

Yes. The aseptic manipulation consists of a visual observation.

Yes. The aseptic manipulation consists of media fill testing followed by a gloved fingertip and thumb sampling on both hands, and surface sampling of the direct compounding area.

2) Do aseptic manipulation competencies occur at appropriate intervals?

Yes. Aseptic manipulation competencies occur every 6 months for personnel compounding category I and II CSPs.

Yes. Aseptic manipulation competencies occur every 12 months for personnel who have direct oversight of compounding.

Yes. Evaluations for personnel with direct oversight of compounding corresponds to the type of activities overseen, but does not require the same quantities.

Yes. People who have direct oversight of compounding do not compound unless they have completed aseptic compounding competencies at the same intervals and level of difficulty of compounding personnel.

3) Do media fill tests simulate the most difficult and challenging aseptic compounding procedures encountered by the compounder?

Yes. Simulations capture elements that could potentially affect the sterility of the CSP.

Yes. Simulations include the length of time needed to complete compounding.

Yes. Simulations include the number of aseptic additions or transfers.

Yes. Simulations include the number, type and complexity of manipulations.

Yes. Simulations include the number of personnel in the buffer room or SCA.

4) Is sterile microbial growth media appropriately handled and stored?

Yes. A CofA is obtained from the supplier stating the lot will support the growth of microorganisms.

Yes. Media is stored in accordance with manufacturer specifications.

Yes. Media is used discarded if expired.

Yes. If prepared inhouse the growth promotion capability of the media is demonstrated for each batch and documented per USP 71.

5) Does the facility document the results of a media fill test?

Yes. Failure is indicated by visible turbidity or other visual signs of growth in any container.

Yes. Failure is identified on or before the end of the incubation period.

Note: Microbial identification of the CFU is not required for media fill testing.

6) Is gloved fingertip and thumb sampling performed after media fill testing?

Yes. Gloved fingertip and thumb sampling is performed on both hands after media fill testing.

Yes. Sampling occurs in the ISO Class 5 PEC.

Yes. Gloved fingertip and thumb sampling in a CAI or CACI is performed on the sterile gloves placed over the gloves attached to the RABS or pharmaceutical isolator sleeves.

Yes. Successful completion of the sampling is defined as equal to or less than 3 CFU total for both hands.

Note: Microbial identification of the CFU is not required for gloved fingertip and thumb testing.

7) Does the facility correctly assess media fill competencies for pass/fail?

Yes. Surface sampling of the direct compounding area is completed with media fill testing.

Yes. A failure in the media fill, gloved fingertip and thumb sampling, or surface sampling constitutes an overall failure of the aseptic manipulation competency.

8) Are media fill competencies accurately documented?

Yes. Competencies record the name of the person evaluated.

Yes. Competencies record the evaluation date and time.

Yes. Competencies record the media components used, including their manufacturer and supplier.

Yes. Competencies record the expiration date and lot numbers.

Yes. Competencies record the starting temperature for each interval of incubation.

Yes. Competencies record the date of incubation.

Yes. Competencies record the results.

Yes. Competencies record the name or other identification of the obsrever.

Yes. Competencies record the name or other identification of he person who reads and documents the results.

9) Are media fill testing procedures compliant with USP 797?

Yes. For sterile to sterile manipulations the media is transferred into container closure systems commonly used by the facility, and media is not further diluted unless specified by the manufacturer.

Yes. For nonsterile to sterile compounding nonsterile soybean-casein digest is dissolved in nonbacteriosttic water to make a 3% solution.

Yes. for nonsterile to sterile compounding at least one container is prepared as a positive control.

Yes. When compounding is complete, a gloved fingertip and thumb sample is performed on each hand.

Yes. When compounding is complete, a surface sample is collected from the direct compounding area inside the PEC.

Yes. Direct surface samples and glove samples are taken prior to disinfecting.

Yes. Samples are handled to avoid contamination and are stored inverted.

Yes. Final containers are incubated at 20-25 C and 30-35 C for a minimum of 7 days each.

Yes. All incubation occurs in an incubator.

Yes. The order of incubation is described in the facility SOPs.

Yes. Failure is indicated by visible turbidity or other visual manifestations of growth in the media on or before day 14.

37.7.3) Personal Hygiene and Garbing

1) Are individuals with a higher risk of contaminating CSPs and the compounding environment evaluated by the designated person prior to entering a compounding area?

Yes. Individuals with conditions such as rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections report them to the designated person.

Yes. Individuals with conditions such as rashes, recent tattoos, oozing sores, conjunctivitis, or active respiratory infections are restricted from compounding areas.

2) Does the facility adhere to the minimum requirements for staff to enter a compounding area?

Yes. No food, including mints/gum are permitted in compounding areas.

Yes. Staff remove all personal outer garments prior to entering compounding areas.

Yes. Staff remove all cosmetics prior to entering compounding areas.

Yes. Staff remove all hand, wrist and other exposed jewelry that could interfere with the effectiveness of garbing, or otherwise increase the risk of contamination of the CSP.

Yes. Staff cover any jewelry that cannot be removed.

Yes. Staff to not ware earbuds or headphones.

Yes. Staff do not bring electronic devices that are not necessary for compounding or other required tasks into the compounding area.

Yes. Staff nails are clean, neatly trimmed and free of nail products (e.g., polish, artificial nails, extenders, etc.).

Yes. Staff wipe eye glasses if worn.

Yes. Any accommodations to personal preparations granted by the designated person are documented.

3) Do staff entering compounding areas where category I, II, or III CSPs are prepared complete hand washing?

Yes. Hands and forearms up to the elbows are washed with soap and water for at least 30 seconds.

Yes. Brushes are not used for hand hygiene.

Yes. Hand dryers are not used.

Yes. Disposable soap containers are not refilled to topped off.

Yes. Personnel clean underneath fingernails with warm running water and a disposable nail cleaner.

Yes. Personnel dry hands and forearms up to the elbows completely with low-lint disposable towels or wipers.

Yes. Personnel apply an alcohol-based hand rub to dry skin.

Yes. Personnel apply hand rub to one hand and rub hands together, covering all surfaces of hands and fingers, until hands are dry.

Yes. Hands are allowed to thoroughly dry before donning sterile gloves.

Yes. The order of handwashing and garbing is determined by the placement of the sink and is documented in the facility's SOPs.

Yes. Hands are sanitized with alcohol-based hand rub before donning sterile gloves. .

Yes. Sterile gloves are donned in a classified room or SCA.

4) For Category I and II CSPs do staff don and doff garb in specified areas in the specified order?

Yes. Garbing order reduces the risk of contamination.

Yes. Garb is donned in a classified area before entering the buffer room.

Yes. If hand hygiene is completed outside of a classified area, alcohol-based hand rub is used prior to donning garb.

Yes. Skin is not exposed inside the ISO 5 Class PEC.

Yes. Garb is not donned and doffed at the same time.

5) Does the facility follow the minimum garbing requirements for category I & 2 CSPs?

YEs. Personnel wear low lint garments with sleeves that fit snugly around the wrists and an enclosed neck.

Yes. Personnel wear low-lint covers for shoes.

Yes. Personnel wear low-lint head covers that cover the hair and ears.

Yes. If applicable, covers for facial hair are worn.

Yes. Low lint face masks are worn.

Yes. Sterile powder-free gloves are worn.

6) Is garb stored, replaced, disinfected and reused in a manner that prevents contamination?

Yes. Garb is replaced immediately if visibly soiled.

Yes. Garb is stored in a manner that minimizes contamination (e.g. away from sinks).

Yes. For Category I & II CSPs, gowns are reused during the same shift by the same person.

Yes. Gowns which are reused are stored in a classified area or adjacent to, or within the SCA in a manner that prevents contamination.

Yes. When exiting the compounding area all garb except for gowns is discarded.

Yes. .Facility SOPs describe disinfection procedures for reusing goggles, respirators, and other reusable equipment.

9) Are gloves inspected and changed at appropriate intervals?

Yes. Gloves are sterile and powder free.

Yes. Application of sterile 70% IPA occurs immediately before compounding.

Yes. Application of sterile 70% IPA occurs regularly throughout the compounding process.

Yes. Gloves are inspected for holes, punctures, and tears, and replaced immediately if defects are detected.

37.7.4) Facilities and Engineering Controls

4) Does the facility monitor and document appropriate temperature and humidity of the cleanroom suite?

Yes. The cleanroom suite is maintained at 20C (68F) or cooler.

Yes. The relative humidity of the cleanroom suite is maintained at 60% or below.

Yes. Temperature and humidity are monitored in each room of the cleanroom suite each day that compounding is performed by a manual or continuous recording device.

Yes. The results of temperature and humidity readings are documented at least once daily or retrievable from a continuous recording device.

Yes. Temperature and humidity readings are reviewed according to facility SOPs.

Yes. Temperature and humidity are controlled through a HVAC system.

Yes. Free standing air conditioners, humidifiers, and dehumidifiers are not used in the classified area or the SCA.

Yes. Monitoring devices are verified for accuracy at least every 12 months, or as required by the manufacturer.

Yes. The designated person ensures areas related to CSP preparation meet air quality and temperature standards.

5) Is the cleanroom suite design 797 compliant?

Yes. The anteroom and buffer room are separated from the surrounding unclassified areas by fixed walls and doors.

Yes. Controls are in place to minimize the flow of lower-quality air into the more controlled areas.

Yes. Classified rooms have a pressure differential monitoring system.

Yes. HEPA filtered air is introduced through the ceiling of anteroom and buffer room.

Yes. Air returns are low on the walls in the anteroom and buffer room.

Yes. There is a line of demarcation to separate the clean side and the dirty side of the anteroom.

Yes. The anteroom is entered through the dirty side and the clean side is the area closest to the buffer room.

Yes. There is a dirty anteroom which leads to a separate clean anteroom, which leads to the buffer room.

Yes. Tacky mats are NOT placed in ISO classified areas.

7) Are PECs used in sterile compounding certified to meet ISO Class 5 or better conditions?

Yes. The PECs are certified to meet ISO Class 5 or better conditions.

Yes. PECS are certified under dynamic operating conditions.

Yes. PECS are designed to minimize the risk of contamination during compounding.

Yes. Unidirectional air flow is maintained in the PEC.

Yes. HEPA filtered air is supplied by the PEC.

Yes. Air velocities are sufficient to sweep particles away from the critical sites and maintain unidirectional airflow during operations.

Yes. Proper design, control and use minimizesturbulence and creation of eddies or stagnant air in the PEC.

8) Identify the type of PECs the facility maintains.

Laminar Airflow Workbench

Class II Biological Safety Cabinet.

9) Are Laminar Airflow systems appropriately placed?

Yes. LAFS are located outside of traffic patterns.

Yes. LAFS are located away from room air currents that could disrupt airflow within the PEC.

Yes. If used to prepare Category II and III CSPs, the LAFs are located in a cleanroom suite with an ISO 7 or better buffer room and an ISO 8 or better anteroom.

Yes. Dynamic airflow smoke pattern tests are performed in the PEC initially and at least every 6 months.

14) Do ISO 7 Class rooms meet air change requirements?

Yes. A minimum of 30 ACPH of HEPA filtered air is supplied.

Yes. The total HEPA filtered ACPGH maintains ISO Class 7 during dynamic operating conditions.

Yes. At least 15 ACPH comes from the HVAC through HEPA filters located in the ceiling.

Yes. HEPA filtered air from the PEC increases the total ACPH to 30.

Yes. ACPH from the HVAC, PEC and the total ACPH are documented on certification reports.

15) Do ISO Class 8 rooms meet air exchange requirements?

Yes. A total of 20 ACPH of HEPA filtered air is supplied to ISO Class 8 rooms.

Yes. The HEPA filtered air exchange rate maintains ISO Class 8 conditions under dynamic operating conditions.

Yes. At least 15 ACPH of the total air exchange is supplied through the HVAC system.

Yes. The total ACPH is documented on the certification report.

16) Are pressure differentials continuously monitored, recorded, and sufficient to minimize airflow from areas with lower air-quality to areas of higher air quality?

Yes. A minimum differential positive pressure of 0.02 inch water column between adjacent ISO-classified areas.

Yes. The pressure differential between the anteroom and the unclassified space is not less than 0.02 inch water column.

Yes. Pressure differentials are continuously monitored.

Yes. Results from pressure monitoring devices are reviewed and documented at least daily on days when compounding occurs.

18) Is the cleanroom suite constructed of smooth, impervious surfaces, free from cracks, crevices and non-shedding materials for easy cleaning and disinfection?

Yes. Surfaces are resistant to damage by cleaning agents (e.g., rust, cleaning tools).

Yes. Junctures between the ceiling and walls and between walls and floors are sealed.

Yes. Ceiling panels are caulked around each panel.

Yes. Walls are constructed or covered with a durable material (e.g., epoxy painted, heavy-gauge polymer).

Yes. Wall panels are joined together and sealed.

Yes. Floors include coving to the side wall, or the juncture between the floor and the wall is caulked.

Yes. Classified areas minimize dust-collecting overhangs.

Yes. Dust collecting overhangs are easily cleanable.

Yes. The exterior lens surfaces of ceiling light fixtures are smooth, flush mounted, and sealed.

Yes. Other penetrations thorough ceilings or walls are sealed.

20) Are water sources restricted to authorized areas?

Yes. Surfaces of sinks are cleaned and disinfected daily each day of use.

Yes. A sporicidal agent is applied to sinks at least monthly.

Yes. In a cleanroom suite, the sink is inside the anteroom.

Yes. In a cleanroom suite, the sink is outside the anetroom.

Yes. If the sink is outside the anteroom it minimizes the risk of bringing contaminants into the anteroom.

Yes. The buffer room does not contained plumbed water sources.

Yes. The anteroom does not contain floor drains.

21) Are materials in the classified area or SCA appropriate?

Yes. Only furniture and equipment necessary for compounding are in the classified area or SCA.

Yes. Materials are low shedding and easily cleaned and disinfected.

Yes. The quantity, location, design, and instillation of equipment and materials does not impact environmental air quality.

Yes. No shipping cartons or corrugated or uncoated cardboard are allowed in classified areas or the SCA.

Yes. Carts used to transport components/equipment are nonporous and have easily cleanable casters/wheels.

Yes. Carts are not moved from the dirty to the clean side of the anteroom unless cleaned and disinfected.

22) Are equipment and materials in the PEC cleaned, disinfected and verified prior to entering the PEC?

Yes. Only equipment necessary for compounding is permitted in the PEC.

Yes. Placement of equipment is initially verified by dynamic airflow smoke pattern tests.

Yes. Dynamic airflow smoke pattern tests are repeated if equipment is placed in a different location.

Yes. Equipment is not moved/removed except for servicing, cleaning, calibration or other maintenance.

Yes. Equipment is cleaned and wiped with sterile 70% IPA or a suitable disinfectant before being returned to the classified area or SCA.

Yes. Materials exposed to patient care areas/treatment areas do not enter anterooms, buffer rooms or SCAs unless they are cleaned and disinfected.

Yes. If the designated person permits accommodations, they are documented.

37.7.5) Certification and Recertification

1) Are compounding areas initially and annually certified?

Yes. Airflow testing is performed to determine air velocity, air exchange rates, and pressure differentials.

Yes.. Airflow testing documents ACPH from HVAC, from the PEC, and total ACPH.

Yes. HEPA filter integrity testing is performed.

Yes. Total particle count testing is performed under dynamic operating conditions.

Yes. Dynamic airflow smoke pattern testing is performed for each PEC during dynamic operating conditions demonstrating unidirectional airflow and sweeping action away form the preparation.

2) Are classified areas recertified if there are changes to the area?

Yes. Classified areas are recertified if there is a redesign.

Yes. Classified areas are recertified if there is construction.

Yes. Classified areas are recertified if there is replacement or relocation of any PEC.

Yes. Classified areas are recertified if there is a change in room configuration which may affect airflow or air quality.

3) Does the designated person review certification reports to ensure proper documentation and corrective action is taken if needed?

Yes. The designated person reviews certification and recertification reports.

Yes. The designated person ensures the number of personnel present in each PEC and SEC during total particle count tests and dynamic airflow smoke pattern tests is documented.

Yes. A corrective action plan is implemented and documented in response to any out-of-range results.

Yes. Data collected from actions taken is reviewed to confirm effectiveness.

4) Are airborne particle counts conducted in all classified areas during dynamic operating conditions at least every 6 months?

Yes. Counts are taken in all classified areas during dynamic operating conditions.

Yes. Counts are taken at least every 6 months.

Yes. Measurements are taken in each PEC at locations where there is greatest risk to the exposed CSPs, containers, and closures.

Yes. When sampling care is taken to avoid disturbing unidirectional airflow in the PEC.

Yes. Sampling locations and procedures are described in the facility SOPs.

Yes. Measurements in other classified areas (not PECs) are taken in areas that reflect the quality of room air.

5) Does the facility investigate causes and take corrective action if air sampling results exceed the ISO criteria for the area sampled?

Yes. If particle counts exceed USP criteria an investigation is completed.

Yes. Corrective action is taken and documented if particle counts exceed USP criteria.

Yes. Data collected in response to corrective action confirms the corrective actions were effective.

Yes. The extent of the investigation is consistent with the deviation.

Yes. The corrective action includes an evaluation of trends.

37.7.6.1) General Monitoring Requirements

1) Does the facility have SOPs for microbiological air and surface monitoring?

Yes. Procedures are documented.

Yes. Test results are documented.

Yes. Corrective actions are documented.

Yes. Records are maintained in a manner that prevents deterioration and loss.

Yes. Records are maintained for 3 years.

Observation

USP 797 requirement is 2 years- Ohio requirement is 3-years.

2) Does the microbiological air and surface monitoring program include a documented review of air and surface sampling trends.

Yes. The program includes viable impact volumetric airborne particulate sampling.

Yes. The program includes surface sampling.

Yes. The program includes an evaluation of samples to detect contaminants.

Yes. The data is used to assess contamination risks (e.g., route, cleaning agents, etc.)

Yes. The results are reviewed in conjunction with personnel data.

Yes. The results of the review are documented.

Yes. Corrective actions are taken to maintain environmental quality.

Yes. Data following corrective actions is reviewed to confirm the effectiveness of corrections made.

3) Is air and surface sampling conducted in all classified areas during dynamic operating conditions?

Yes. Sampling is conducted in all classified areas.

Yes. Sampling is conducted under dynamic operating conditions.

Yes. Sampling is performed in conjunction with the certification of new facilities and equipment.

Yes. Sampling is conducted after any servicing of facilities or equipment.

Yes. Sampling is conducted in response to identified problems.

Yes. Sampling is conducted in response to identified trends.

Yes. Sampling is conducted in response to changes that could impact the sterile compounding environment.

4) Is the microbiological air and surface sampling program clearly defined in the facilities SOPs?

Yes. SOPs include a diagram of sampling locations.

Yes. SOPs include procedures for collecting samples.

Yes. SOPs include sampling frequency.

Yes. SOPs include the size of samples (e.g., surface area, volume of air).

Yes. SOPs include the time of day for sampling in relation to compounding activities.

Yes. SOPs include action levels that trigger corrective action.

Yes. Sampling locations include areas of highest possible risk of CSP contamination.

Yes. All samples are obtained during dynamic operating conditions.

Yes.. Surface sampling is performed at the end of compounding activity or a shift, but before areas are cleaned and disinfected.

Yes. The program minimizes risk that the sampling will contribute to CSP contamination.

Yes. Impact samplers area serviced and calibrated as recommended by the manufacturer.

37.7.6.2) Monitoring Air Quality for Viable Airborne Particles

1) Is volumetric active air sampling measured at the correct time and locations?

Yes. Sampling is conducted in each classified area.

Yes. Sampling is conducted during dynamic operating conditions.

Yes. For Category I & II CSPs sampling is completed every 6 months.

2) Are air sampling procedures appropriate?

Yes. A general microbiological growth media supporting the growth of bacteria and fungi is sued (e.g.,TSA).

Yes.. CofAs verify growth promotion, pH, and sterilization requirements.

Yes. Manufacturer directions are followed for operation of the impaction air sampler.

Yes. At least one cubic meter or 1000L of air is sampled at each location.

Yes. At the end of sampling, plates are inverted.

Yes. Plates are incubated at 30-35C for not less than 48 hours and CFUs are recorded if present.

Yes. Plates are then incubated at 20-25C fort not less than 5 additional days.

Yes. The total number of CFUs from both incubation times are recorded on a form which documents the sample type, location and date.

Yes. Two sampling media devices are collected for each sample location and incubated concurrently at separate temperatures.

Yes. If two media devices are used, the fungal media device (E.g., MEA/SDA) is incubated at 20-25C for no less than 5 days.

Observation

The facility is using an alternative sampling method, where two media devices are sampled simultaneously and incubated at separate temperatures/times. All other requirements are the same.

(TSA would be incubated for 48 hours at 30-35C)

3) Is the data evaluation and action plan for viable airborne particle testing appropriate?

Yes. Counts are examined in relation to previous data.

Yes. If two sampling media devices are collected, all recovered growth on each sample is documented, and action levels are applied to each device separately.

Yes. If action levels are exceeded corrective action is taken.

Yes. If corrective action is taken data is collected to confirm actions were effective.

Yes. Action plans are dependent on the CFU count and microorganism recovered.

Yes. The extend of evaluation is consistent with the deviation and includes an evaluation of trends.

Yes. Corrective acdtion plans are documented and include resampling of failed areas.

Yes. An attempt is made to identify any microorganisms recovered to the genus level.

37.7.6.3) Monitoring Surfaces for Viable Particles

1) Is surface sampling conducted at the proper time and in the proper locations?

Yes. Sampling occurs in each classified room, in each ISO 5 PEC, and in each pass-through chamber connecting classified areas.

Yes. Surface sampling in the DCA is conducted in conjunction with media-fill testing.

Yes. For Category I & II CSPs sampling is conducted at least monthly.

2) Is proper equipment used during surface sampling?

Yes. COAs from the manufacturer verify sampling media devices meet growth promotion, pH, and sterilization requirements.

Yes. Media contain general microbial growth media (e.g., TSA) supplemented with neutralizing additives (lecithin adn polysorbate 80).

Yes. Media has a raised convex surface.

Yes. Sterile swabs wetted with sterile water or a sterile neutralizing buffer are used to sample irregular surfaces and/or difficult-to-reach locations.

Yes. The incubator temperature is monitored manually or by a continuous recording device during incubation.

Yes. The incubator is located outside the sterile compounding area.

3) Are surface sampling procedures appropriate?

Yes. Using a rolling motion media is firmly pressed to the sampling surface.

Yes. After sampling the surface is cleaned and disinfected.

Yes. Media devices are covered and inverted.

Yes. Media is incubated at 30-35C for not less than 48 hours and the total number of CFU is recorded on the environmental sampling form.

Yes. Media is then incubated at 20-25C for no less than 5 additional days, and the total number of CFU is recorded on the environmental sampling form.

Yes. The total number of CFU is counted on each device and recorded separately.

Yes. All sampling results are recorded on an environmental sampling form and contain the type of sample, the sate and sample location.

4) Is the data evaluation and action plan for viable surface sampling appropriate?

Yes. CFU counts are examined in relation to previous data.

Yes. If action levels are exceeded the cause is investigated and corrective action is taken.

Yes. Data collected from corrective action is reviewed.

Yes. Corrective action plans are dependent upon the CFU count and microorganism recovered.

Yes. The investigation is consistent with the deviation and includes an evaluation of trends.

Yes. The corrective action plan is documented.

Yes. If action levels are exceeded, an attempt is made to identify microorganisms to the genus level.

37.7.7) Cleaning, Disinfecting, and Applying Sporicidal Disinfectants and Sterile 70% IPA

1) Is 70% sterile IPA applied after cleaning and disinfecting?

Yes. Sterile IPA is applied in the PEC after cleaning and disinfecting.

Yes. Sterile IPA is applied immediately before initiating compounding.

Yes. Sterile IPA is applied to the horizontal work surface and any removable work trays in the PEC every 30 minutes during compounding.

Yes. IF compounding takes more than 30 minutes, the work surface of the PEC is cleaned immediately after compounding.

Yes. Sterile IPA is allowed to dry.

3) Are surfaces cleaned and disinfected according to USP 797?

Yes. Surfaces are cleaned with a cleaning agent containing a surfactant prior to disinfecting.

Yes. Surfaces are disinfected with an EPA-registered disinfectant after cleaning.

Yes. Surfaces are cleaned and disinfected with an EPA approved one-step cleaner and disinfectant.

Yes. A sporicidal disinfectant is also applied.

Yes. Surfaces are cleaned and disinfected with an EPA approved one-step cleaner, disinfectant, sporicidal agent.

Yes. Cleaning and disinfecting is performed by trained and garbed personnel.

Yes. The facility has cleaning SOPs.

Yes. Cleaning is performed in the direction of cleanest to dirtiest.

Yes. Floor mops used in the buffer and anteroom are used in that order.

Yes. Manufacturer's directions or published data are used to establish the minimum contact time for each cleaning/disinfecting agent.

4) Are the minimum cleaning frequencies met?

Yes. PECs and equipment inside the PEC are cleaned and disinfected daily when compounding occurs.

Yes. PECs and equipment inside the PEC is cleaned and disinfected when contamination is known or suspected.

Yes. A sporicidal agent is applied to PECs and equipment inside the PEC monthly for Category I and II CSP compounding.

Yes. The work surface of removable work trays in the PEC is cleaned and disinfected daily when compounding occurs.

Yes. All surfaces and the area underneath the work tray are cleaned and disinfected monthly.

Yes. A sporicidal is applied to all work surfaces of the PEC tray monthly.

Yes. A sporicidal is applied to all surfaces and the area underneath the work tray monthly.

Yes. Passthrough chambers are cleaned and disinfected daily when compounding occurs.

Yes. A sporicidal agent is applied to passthrough chambers monthly for category I and category II CSPs.

Yes. Worksurfaces outside the PEC are cleaned and disinfected daily when compounding occurs.

Yes. A sporicidal agent is applied to work surfaces outside the PEC monthly for category I and II CSPs.

Yes. Floors are cleaned and disinfected daily on days compounding occurs.

Yes. A sporicidal agent is applied to floors monthly for category I and II compounding.

Yes. Walls, doors, door frames, ceilings, storage shelving, bins and equipment outside the PEC is cleaned and disinfected monthly.

Yes. A sporicidal agent is applied to walls, doors, door frames, ceilings, storage shelving, bins, and equipment outside the PEC monthly.

5) Are sterile cleaning and disinfecting agents used in the PEC?

Yes Cleaning, disinfecting, and sporicidal agents used within the PEC are sterile.

Yes. When diluting concentrated agents used in the PEC, sterile water is used.

6) Are cleaning and disinfecting supplies appropriate for use in classified areas?

Yes. All supplies are low-lint.

Yes. All supplies used in the PEC are sterile (except tool handles).

Yes. All tool handles/holders are cleaned and disinfected prior to use in a PEC.

Yes. Disposable wipers, sponges, pads, and mop heads are discarded after each use.

Yes. Reusable cleaning tools are made of cleanable materials.

Yes. Reusable cleaning tools are cleaned and disinfected before and after each use.

Yes. Reusable cleaning tools are dedicated to use in the classified areas or SCA, and are not removed except for disposal.

Yes. Reusable cleaning tools are discarded based on the condition of the tool.

Yes. Once opened cleaning and disinfecting supplies are used/reused according to the manufacturer specifications or facility SOPs.

7) Do procedures for cleaning and disinfecting the PEC comply with USP 797?

Yes. Visible particles, debris or residue is removed with an appropriate solution (e.g. sterile water) and low lint wipes.

Yes. Sterile cleaning agents are applied using a sterile low-lint wipe, followed by an EPA-registered disinfectant to all interior surfaces of the PEC and equipment within. .

Yes. An EPA registered on-step disinfectant-cleaner is applied to all interior surfaces of the PEC and equipment within.

Yes. Contact time specified by the manufacturer is achieved.

Yes. Sterile 70% IPA is applied to the PEC and equipment within after cleaning and disinfecting with a sterile low-lint wiper.

Yes. Surfaces are allowed to completely dry before compounding begins.

8) Do procedures for applying a sporicidal disinfectant in the PEC comply with USP 797?

Yes. Visible particles, debris, and residue is removed with an appropriate sterile solution and sterile low-lint wipers.

Yes. After cleaning and disinfecting a sporicidal disinfectant is applied using a sterile low-lint wiper to all surfaces of the PEC and the area under the work tray.

Yes. The sporicidal used is a one-step disinfectant sporicidal cleanser applied with sterile low-lint wipes.

Yes. The contact time specified by the manufacturer is achieved.

Yes. Using a sterile low-lint wiper sterile 70% IPA is applied to all interior surfaces, including underneath the work tray.

Yes. Surfaces are allowed to dry completely before beginning compounding.

37.7.8) Introducing items into the SEC and PEC

1) Are items introduced into the SCA, the clean side of the anteroom or placed in a passthrough wiped with an appropriate solution?

Yes. Items are wiped with sterile 70% IPA and allowed to dry.

Yes. Items are wiped with low-lint wipers by gloved personnel.

Yes. Wiping procedures do not compromise package integrity or render labels unreadable.

2) Are items introduced into the PEC wiped with sterile 70% IPA?

Yes. Sterile 70% IPA and sterile low-lint wipers are used to wipe all items just before introduction into the PEC.

Yes. The sterile 70% IPA is allowed to dry before items are introduced into the PEC.

Yes. The overwrap covering sterile supplies is removed as supplies are introduced into the PEC without wiping the individual sterile supply items.

Yes. Wiping procedures do not render product labels unreadable.

3) Are critical sites wiped with sterile 70% IPA in the PEC prior to use.

Yes. Vial stoppers, ampule necks, and IV bag septums are wiped with sterile 79% IPA in the PEC.

Yes. Sterile 70% IPA is allowed to dry before use.

37.7.9) Equipment, Supplies, and Components

1) Does the facility compound with conventionally manufactured sterile products when available and appropriate for the intended CSP?

Yes.

5) Are components inspected upon receipt?

Yes. External packaging is examined.

Yes. The labeling and condition of components is examined.

Yes. Components of unacceptable quality are rejected, labeled as such, and segregated from active drug stock.

Yes. If a component is rejected, other lots from the same vendor are examined for defects.

Yes. The date of receipt by the compounding facility is clearly marked on each API or added substance package that lacks a vendor expiration date.

Yes. Packages of components that lack a vendor's expiration date are assigned an expiration date that does not exceed 1-year from the date of receipt.

6) Are components evaluated before use?

Yes. All components are reinspected before use to ensure the correct identity, quantity, expiration date and storage conditions.

Yes. All component packages are inspected to detect container breaks, looseness of the cap/closure.

Yes. All component packages are inspected to detect deviations from the expected aroma, appearance, texture, etc. that might have occurred during storage.

Yes. Sterile container closures are visually inspected.

Yes. Components found to be of unacceptable quality are rejected, labeled as such, and segregated from active drug stock.

Yes. All lots of a rejected component are inspected for safe use.

7) Are components appropriately stored?

Yes. Components are stored in closed containers.

Yes. Components are stored under appropriate temperature, humidity, and lighting per manufacturer specifications.

Yes.. Temperatures are monitored in component storage areas daily when the facility is open or by a continuous temperature monitoring device.

Yes. Results of temperature readings are documented on a temperature log or stored in the continuous monitoring device.

Yes. Temperatures stored in a continuous monitoring device are retrievable.

Yes. Temperature monitoring equipment is calibrated or verified for accuracy as recommended by the manufacturer, or every 12 months.

37.7.11) Master Formulation and Compounding Records

1) Does the facility have a master formulas for CSP preparation?

Yes. The facility has master formulas for all CSPs prepared from nonsterile ingredients.

Yes. The facility has master formulas for all CSPs prepared for more than one patient.

Yes. Changes to master formulas are approved and documented.

3) Does the facility generate compounding records for each CSP?

Yes. Compounding records are created for all category I, II & III CSPs.

Yes. A compounding record is created for all immediate use CSPs prepared for more than one patient.

Yes. The compounding record documents the compounding process.

Yes. Compounding records are stored electronically. (e.g., ACD workflow or similar equipment)

Yes. The master formula record serves as the basis for preparing a compounding record.

4) Do compounding records contain the required information?

Yes. Compounding records contain the name, strength or activity, and dosage form of the CSP

Yes. Compounding records contain the date and time of preparation.

Yes. Compounding records contain the assigned internal identification number.

Yes. Compounding records contain a method to identify the individuals involved in the compounding process and the individuals verifying the final CSP.

Yes. Compounding records contain the name of each component.

Yes. Compounding records contain the vendor, lot number and expiration date for each component for CSPs prepared for more than one patient and for CSPs prepared from nonsterile ingredients.

Yes. Compounding records contain the weight or volume of each component.

Yes. Compounding records contain the strength or activity of each component.

Yes. Compounding records contain the total quantity compounded.

Yes. Compounding records contain the final yield (quantity, containers, number of units).

Yes. Compounding records contain the assigned BUD and storage requirements.

Yes. Compounding records contain the results of QC procedures (e.g., visual inspection, filter integrity testing, pH testing, etc.)

Yes. If applicable, compounding records contain the master formula reference for the CSP.

Yes. If applicable, compounding records contain calculations made to determine and verify the quantities and or concentrations of componenets.

37.7.12) Release Inspections and Testing

2) Are CSPs visually inspected at the completion of compounding, before release and dispensing?

Yes. The physical appearance is inspected.

Yes. The CSP labeling is inspected to ensure it matches the prescription and medication order.

Yes. Inspection includes a visual inspection of container closure integrity.

Yes. CPSs found unacceptable are rejected, labeled as such, and segregated from active drug stock.

3) Are CSPs prepared in advance of need reinspected prior to dispensing?

Yes. A visual inspection is conducted to identify CSP defects that developed during storage.

Yes. CSPs found unacceptable are rejected, labeled as such, and segregated from active drug stock.

Yes. Defects that indicate sterility or stability problems are investigated to determine the cause.

37.7.13) Labeling

2) To labels on the immediate container of the CSP contain the minimum required information?

Yes. Labels contain the assigned internal identification number.

Yes. Labels contain the active ingredients and their amounts, activities, or concentrations.

Yes. Labels contain the storage conditions if other than controlled room temperature.

Yes. Labels contain the BUD.

Yes. Labels contain the dosage form.

Yes. Labels contain the total amount or volume if it's not obvious from the container.

Yes. When space permits single-dose containers are labeled as such.

Yes. A statement if the CSP is a multidose container.

3) Are CSPs labeled with the following information if applicable?

Yes. Route of administration.

Yes. Special handling instructions.

Yes. Warning statements.

Yes. Compounding facility name and contact information if the CSP is sent outside the facility or healthcare system where it was compounded.

Yes. A statement that the preparation was compounded

4) Do SOPs describe labeling procedures?

Yes. SOPs describe verification of the CSP label to the prescription or medication order.

Yes. SOPs describe verification of the CSP label to the master formula record if required.

Yes. SOPs describe verification of the CSP label to the compounding record if required.

37.7.14.2) Establishing a BUD for a CSP- All Categories

1) Are shorter BUDs assigned when the stability of the CSP or its components is less than the USP allowed BUDs based on category?

Yes. BUDs do not exceed the shortest remaining expiration date of any commercially available starting components.

Yes. BUDs do not exceed the shortest BUD of any individual compounded components used.

2) Are CSP storage times within the original BUD placed on the CSP for it's labeled storage condition?

Yes. The storage time of a CSP does not exceed the original BUD placed on the CSP for its original storage condition.

Yes. BUDs are not additive.

Yes. Once a CSP is stored under a condition which requires a shorter BUD, the CSP is used within the time frame for that storage condition.

3) Does the facility correctly assign BUDs for Category I CSPs?

Yes. Category I CSPs stored at a controlled room temperature as assigned a BUD of not more than 12 hours.

Yes. Category I CSPs stored at a refrigerated temperature are assigned a BUD of not more than 24 hours.

Reminder: Category I CSPs may be prepared in an SCA or Cleanroom suite.

4) Does the facility correctly assign BUDs for Category II CSPs?

Yes. Aseptically processed CSPs prepared from only sterile starting components which are not sterility tested are assigned BUDs based on storage conditions: Controlled room Temp = 4 days, Refrigerator = 10 days, Freezer = 45 days.

Reminder: A shorter BUD must be assigned when the physical and chemical stability of the CSP is less than the USP BUD limits.

Reminder: All terminally sterilized Category II CSPs which are sterility tested also require an endotoxin test to use the extended BUDs in this section.

Reminder: The maximum batch size for all CSPs requiring sterility testing must be limited to 250 final yield units.

37.7.15) Use of Conventionally Manufactured Products as Components

1) Are conventionally manufactured single dose containers used within the allowable period after puncture?

Yes. Single dose containers are punctured/entered only in ISO Class 5 or cleaner air.

Yes. Single dose containers are used for up to 12 hours after initial entry.

Yes. Single dose containers are stored according to package labeling for up to 12-hours after puncture.

Yes. Single-dose ampules are not stored after opening.

2) Are conventionally manufactured multiple dose containers used within the allowable period after puncture?

Yes. After initial entry multiple dose containers are not used for more than 28 days.

Yes. After initial entry multiple dose containers are used according to manufacturer labeling.

37.7.16) Use of CSPs as Components

1) Does the facility use CSPs as components of final CSPs?

No.

37.7.17) SOPs

1) Does the facility have properly developed SOPs?

Yes. There are SOPs for compounding processes and support activities.

Yes. SOPs include the types of CSPs that are prepared.

Yes. The designated person ensures SOPS are appropriate and implemented.

Yes. The designated person ensures personnel are competent in all procedures related to their job function.

Yes. The designated person follows up on corrective actions taken when problems are identified.

Yes. Corrective actions are documented.

2) Are personnel who perform, oversee, or support compounding activities trained to recognize and report problems?

Yes. Potential problems, deviations, failures, and errors are reported to the designated person./

3) Are SOPs reviewed initially and every 12 months by the designated person?

Yes. Review of SOPs is documented by the designated person.

Yes. Changes or alterations to SOPs are made only by the designated person.

Yes. Changes to SOPs are documented.

Yes. Revisions to SOPs are communicated to all personnel involved in the process or procedure.

Yes. Personnel document acknowledgement of SOP changes.

37.7.18) Quality Assurance and Quality Control

1) Does the facility have a formal, written QA and QC program?

Yes. The program establishes a system of adherence to procedures.

Yes. The program establishes a system to prevent and detect errors and other quality problems.

Yes. The program establishes a system to evaluate complaints and adverse events.

Yes. The program establishes a system for investigations and corrective actions.

2) Do SOPs describe the roles, duties, and training of personnel involved in the QA program, and are they reviewed annually?

Yes. The designated person(s) responsible for the QA program have training, experience, responsibility, and authority to perform these duties.

Yes. SOPs are reviewed at least once every 12 months by the designated person.

Yes. Review of SOPs is documented.

4) Do SOPs for out-of-specification dispensed CSPs contain the required elements?

Yes. There is a procedure to determine the severity of the problem and the urgency for implementation and completion of the recall.

Yes. There is a procedure to determine the distribution of affected CSPs, including date and quantity distributed.

Yes. There is a procedure to identify patients who have received the CSP.

Yes./ There is a procedure for disposal and documentation of the recalled CSP.

Yes. There is a procedure to investigate and document the reason for the failure.

5) Are recalls documented and reported to the appropriate regulatory authorities?

Yes. Recalls are documented.

Yes,. Recalls are reported to the appropriate regulatory body.

6) Do facility SOPs for complaint handling include an investigative process?

Yes. Complaints are reviewed by a designated person(s).

Yes. If a potential CSP quality problem is identified an investigation is initiated and completed.

Yes. Investigations consider whether the problem extends to other CSPs.

Yes. Corrective action is implemented for all potentially affected CSPs.

Yes. Recalls are considered based on the investigation.

Yes. The facility evaluates whether or not to cease sterile compounding until underlying problems are identified and corrected.

7) Do records of complaints contain the required information in a readily retrievable manner?

Yes. Records contain the name or unique identifier of the complainant.

Yes. Records contain the date the complaint was received.

Yes. Records contain the nature of the complaint.

Yes. Records contain the response to the complaint.

Yes. Records contain the name and strength of the CSP and it's assigned internal identification number.

Yes. Records include the findings of the investigation.

Yes. Records include any investigation follow up.

Yes. Records are readily retrievable for review and evaluation of possible trends.

Yes. Records are retained for the required time.

Yes. Returned CSPs are quarantined until they are destroyed.

Yes. CSPs are not destroyed until after the completion of the investigation.

8) Does the facility report adverse events to the appropriate people/organizations?

Yes. Adverse events are reported according to the facility SOPs.

Yes. Adverse events are reported to regulatory authorities if applicable.

Yes. Affected patients are informed of adverse events if applicable.

Yes. Prescribers are informed of adverse events if applicable.

37.7.19) CSP Handling, Storage, Packaging, Shipping, and Transport

1) Are staff trained according to SOPs for handling, storage, packaging, shipping and transport of CSPs?

Yes. There are SOPs for handling, storage, packaging, shipping and transport of CSPs.

Yes. Staff training is documented.

2) Are processes in place to ensure CSP quality is maintained during storage at the compounding facility?

Yes. A controlled temperature is established and monitored.

Yes. Temperature monitoring is conducted daily manually or by a continuous recording device.

Yes. The results of temperature readings are documented in a temperature log or stored in the continuous monitoring device.

Yes. Data from continuous recording devices is retrievable.

Yes. Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer.

3) Does the facility evaluate CSPs if/when storage temperature excursions occur?

No. There have been no temperature excursions documented.

4) Are packaging materials sufficient to protect a CSP during shipping and transport?

Yes. Packaging materials protect the CSP from damage, leakage, contamination, degradation, and adsorption.

Yes. Packaging materials protect transport personnel.

Yes. Packaging materials and shipping containers are based on product specifications, information from vendors, and mode of transport.

Yes. Alternative modes of transport and/or packaging are used if needed to protect the quality of the CSP. .

5) Do modes of CSP transportation delivery CSPs in an undamaged, sterile and stable condition?

Yes. Specific handling instructions are included on the exterior of shipping containers when necessary.

37.7.20) Documentation

1) Does the facility maintain required compounding documentation?

Yes. There is documentation of personnel training, competency assessments, and qualification records, including corrective actions for any failures.

Yes. There are certification reports, including corrective actions for any failures.

Yes. There are environmental air and surface monitoring procedures and results.

Yes. There are equipment records (e.g., calibration, verification, and maintenance reports).

Yes. There are records for component receipt.

Yes. There are records for SOPs, MFRs (if required) and CRs (if required).

Yes. There are records for release and inspection testing.

Yes. There are records of complaints and adverse events, including corrective actions.

Yes. There are records of investigative results and corrective actions.

2) Are records properly maintained?

Yes. Records are stored in a manner that prevents their deterioration.

Yes. Records are stored in a manner that prevents their loss.

Yes. Records are readily retrievable for at least 2 years (3 for Ohio) after preparation.

48) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation

The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

49) Inspection Affirmation

1) Inspection Affirmation

Observation
As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Douglas Navarro, R.Ph. _____

(signature)

eLicense Ohio
Professional Licensure

License Look Up

2/18/2025 4:33 PM

SBH MEDICAL LTD

License Number	021260150
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 3
License Issue Date	04/17/2001
License Expiration Date	03/31/2027
License Effective Date	04/01/2025
Street Address	7654 Crosswoods Dr
City	Columbus
State	OH
Zipcode	43235-4621
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
DOUGLAS NAVARRO	03323838	Active	Fri Feb 24 00:00:00 GMT 2023	

Current date & time: **2/18/2025 4:33 PM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
BS7232046	02-29-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-13-2025

SBH MEDICAL LTD
DBA OPTIORX - 290
7654 CROSSWOODS DR
COLUMBUS, OH 43235

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
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SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-13-2025

SBH MEDICAL LTD
DBA OPTIORX - 290
7654 CROSSWOODS DR
COLUMBUS, OH 43235

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Form DEA-223 (9/2016)

4LLL

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☐ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: AMRx

Physical Address: 2925 Country Club Rd. Suite #103

City: Denton State: TX Zip: 76210

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (888) 853-1836 Toll Free # (NAC 639.708, NRS 639.23286): (888) 853-1836

Fax: (888) 853-1836 Contact Email: info@AllMyRxs.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Jonathan Hamer

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24134

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jonathan Hamer	NV Pharmacist Registration #: 24134
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): The Pharmacy Authority LLC

Corporation/Organization Name: AMRx LLC

Mailing Address: 2925 Country Club Rd. Suite #103

City: Denton State: TX Zip: 76210

Telephone: (888) 853-1836 Email: info@AllMyRxs.com

Contact Person Name: Jonathan Hamer

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager & PIC (title) for AMRx (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jonathan Hamer

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

4/15/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jonathan Hamer hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager & Pharmacist in Charge (title) for AMRx (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

NOTARY PUBLIC STATE OF TEXAS
CLAUDIA ROMANO
Notary Public, State of Texas
Comm. Expires 02-26-2029
Notary ID 132265537

SUBSCRIBED AND SWORN TO
Before me, a notary public this 16th day of April, 20 25

Notary Public

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Hamer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

Date 4/15/25

Board Use Only	Date Received: 4/21/25	Amount: $500 ck 1016

AMRx - List of Officers

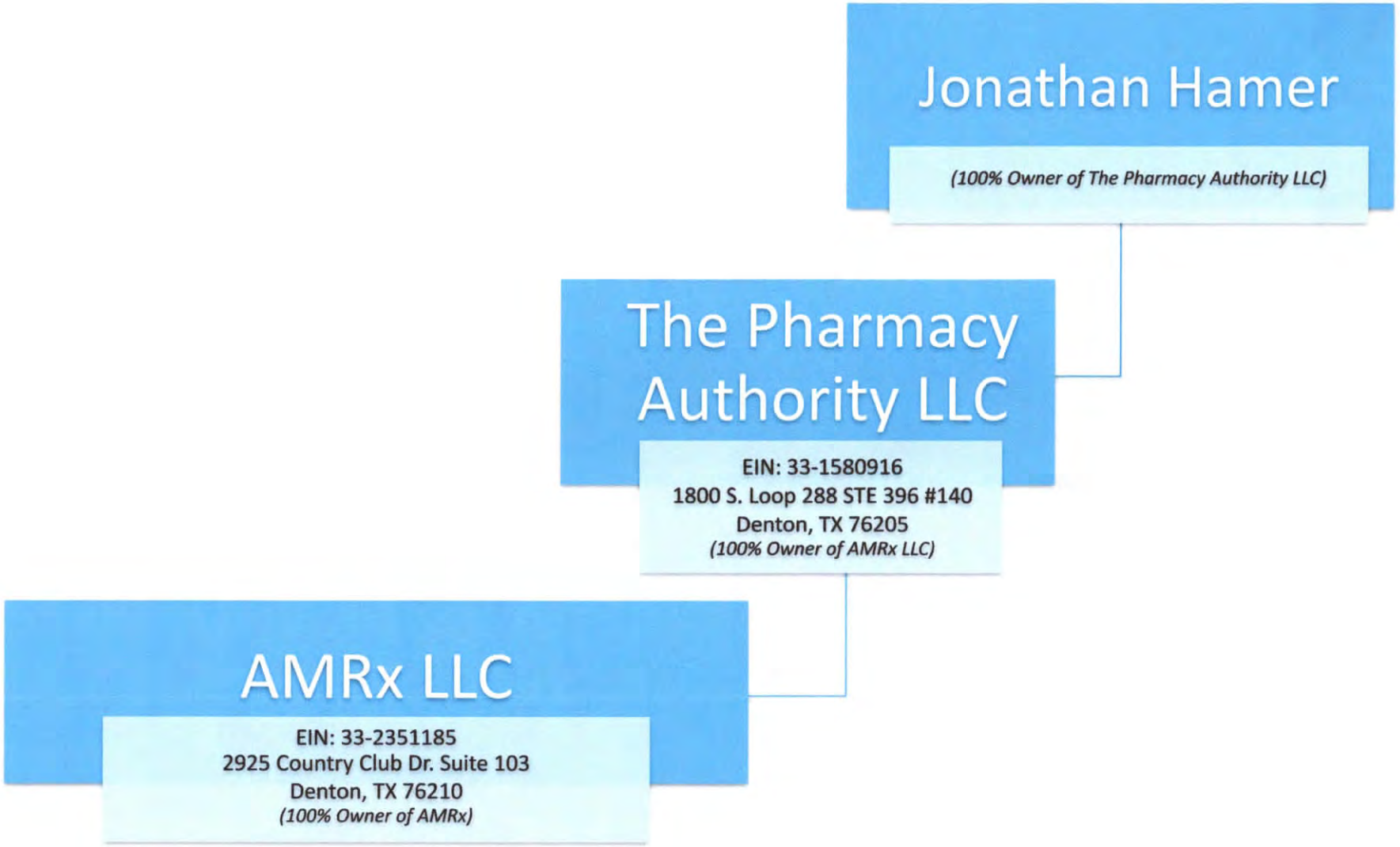
Jonathan Hamer - Manager/Officer

AMRx - List of Stockholder with ownership

AMRx LLC owns 100% of AMRx

The Pharmacy Authority LLC owns 100% of AMRx LLC

Jonathan Hamer owns 100% The Pharmacy Authority LLC


Jonathan Hamer
(100% Owner of The Pharmacy Authority LLC)
The Pharmacy Authority LLC
EIN: 33-1580916
1800 S. Loop 288 STE 396 #140
Denton, TX 76205
(100% Owner of AMRx LLC)
AMRx LLC
EIN: 33-2351185
2925 Country Club Dr. Suite 103
Denton, TX 76210
(100% Owner of AMRx)

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for AMRx LLC (file number 805754207), a Domestic Limited Liability Company (LLC), was filed in this office on October 21, 2024.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on March 29, 2025.

Jane Nelson
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Jonathan Hamer

Pharmacy/Wholesaler License # (if applicable) _____

Physical Address 2925 Country Club Rd Suite #103

City Denton State TX Zip 76210

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (888)853-1836 Website NA

Licensing Company Email Info@AllMyRxs.com

Section 2: Personal Information

First Jonathan Middle _____ Last Hamer

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Denton State TX Zip [redacted]

Telephone [redacted] Email info@AllMyRxs.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University Of Maryland, Baltimore		08/2006-05/2010	
Address	**City**	**State**	**Zip**
620 W Lexington St	Baltimore	MD	21201
Diploma/Degree obtained, if any			
PharmD			
School Name		**From - To (MM/YY – MM/YY)**	
University Of Baltimore			
Address	**City**	**State**	**Zip**
1420 N. Charles St	Baltimore	MD	21201
Diploma/Degree obtained, if any			
MBA			
School Name		**From - To (MM/YY – MM/YY)**	
University of California, San Diego		09/2000-06/2005	
Address	**City**	**State**	**Zip**
9500 Gilman Dr.	LA Jolla	CA	92093
Diploma/Degree obtained, if any			
Bachelor of Science			
School Name		**From - To (MM/YY – MM/YY)**	
Oak Park High School		09/1996-06/2000	
Address	**City**	**State**	**Zip**
899 Kanan Rd	Oak Park	CA	91377
Diploma/Degree obtained, if any			
Diploma			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/20 Current	[redacted]	Denton	TX	[redacted]
From - To (MM/YY – MM/YY)		City	State	
06/19- 12/20		Oak Pointy	TX	
From - To (MM/YY – MM/YY)		City	State	
07/11- 06/19		Frisco	TX	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
CUE HEALTH			10/22- 07/24
Business Address	**City**	**State**	**Zip**
4980 Carroll Canyon Rd	San Diego	CA	92121
Phone	**Title**		**Number of Employed Hours**
1833-283-8378	Senior Program Manager		4,000
Description of Duties			
Acquired and started up mail order pharmacy			

Business Name			From - To (MM/YY – MM/YY)
AIS Healthcare			10/22
Business Address	**City**	**State**	**Zip**
18451 Dallas Parkway	Dallas	TX	75287
Phone	**Title**		**Number of Employed Hours**
877-443-4006	PIC, Director and Senior Director of Innocations		10,000
Description of Duties			
Started and ran sterile compounding pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Jonathan Hamer, **certify that as the designated representative for**

AMRx,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JH I am at least 21 years of age;
3. JH I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JH I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JH I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JH I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JH I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jonathan Hamer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/16/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan, Hamer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/16/25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Denton

I, JONATHAN HAMER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/16/25

Date

Subscribed and Sworn to before me this 16 day of April 2025.

Notary Public Signature

CLAUDIA ROMANO
Notary Public, State of Texas
Comm. Expires 02-26-2029
Notary ID 132265537

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site AMRx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 2925 Country Club Rd Suite #103

City Denton State TX Zip 76210

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 888-853-1836 Website NA

Licensing Company Email info@AllMyRxs.com

Section 2: Personal Information

First Jonathan Middle Alan Last Hamer

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Denton State TX Zip [redacted]

Telephone [redacted] Email info@AllMyRxs.com

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University Of Maryland, Baltimore		08/2006-05/2010	
Address	**City**	**State**	**Zip**
620 W Lexington St	Baltimore	MD	21201
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University Of Baltimore			
Address	**City**	**State**	**Zip**
1420 N. Charles St	Baltimore	MD	21201
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
University of California, San Diego		09/2000-06/2005	
Address	**City**	**State**	**Zip**
9500 Gilman Dr.	LA Jolla	CA	92093
Diploma/Degree obtained, if any			
Bachelor of Science			

School Name		From - To (MM/YY – MM/YY)	
Oak Park High School		09/1996-06/2000	
Address	**City**	**State**	**Zip**
899 Kanan Rd	Oak Park	CA	91377
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/20 Current	[redacted]	Denton	TX	[redacted]
06/19- 12/20		Oak Pointy	TX	
07/11- 06/19		Frisco	TX	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AMRx LLC			12/01/2024- Current
Business Address	**City**	**State**	**Zip**
2925 Country Club Rd. Suite #103	Denton	TX	76210
Phone	**Title**		
888-853-1836	Manager/PIC		
Description of Duties			
Startup Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
White Label Pharmacy LLC			02/24 - 10/2024
Business Address	**City**	**State**	**Zip**
2925 Country Club Rd Suite 103	Denton	TX	76210
Phone	**Title**		
940-334-3404	Manager/ PIC		
Description of Duties			
Startup Pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JONATHAN HAMER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/16/25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Denton

I, JONATHAN HAMER, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/16/25

Date

Subscribed and Sworn to before me this 16th day of April 2025

Notary Public Signature

CLAUDIA ROMANO
Notary Public, State of Texas
Comm. Expires 02-26-2029
Notary ID 132265537

(Seal)

Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *AMRX*

License Number:

Class of License: *A*

Inspection Information

Type: *Compliance*

Purpose: *Pre-Inspection*

Date: *04/10/2025*

Arrival Time: *10:15 AM*

Departure Time: *11:00 AM*

Action Taken: *Pre-Inspection*

General Comments:

Pre-Inspection Checklist

Verify Owner/Owner's Representative ID — *Not Applicable*

Name	Title
:	:

Verify PIC ID — *Yes*

Name	Title
: *Jonathan Hamer*	: *PIC/Owner*

1. The prescription department has adequate space for the size and scope of the pharmaceutical services provided by the pharmacy. — *Yes*

2. Fixtures (i.e. shelving, countertops, etc.) for the storage of drugs, equipment, and supplies necessary to operate a pharmacy are installed. — *Yes*

3. Electrical supply exists. — *Yes*

4. A sink with hot and cold running water available exclusive of the restroom facilities. — *Yes*

5. Pharmacy arranged in an orderly fashion and kept clean. — *Yes*

6. The prescription department is complete and contains the following required equipment and supplies including, but not limited to: — *Yes*

6a. data processing system including a printer or comparable equipment; — *Yes*

6b. refrigerator to be maintained within a range compatible with the proper storage of drugs requiring refrigeration; — *Yes*

6c. adequate supply of child-resistant, light-resistant, tight, and, if applicable, glass containers; — *Yes*

6d. adequate supply of prescription labels with name, address, and telephone number of the pharmacy; — *Yes*

6e. appropriate equipment necessary for the proper preparation of prescription drug orders;	*Yes*
6f. metric-apothecary weight and measure conversion charts;	*Yes*
6g. if the pharmacy serves the public, the word "pharmacy" or similar word or symbol, as determined by the board, is displayed in a prominent place on the front of the pharmacy.	*Yes*
7. A reference library is on site and current:	*Yes*
7a. Texas Pharmacy Laws and Regulations (publication year: _____)	*Yes*
Publication Year : *2025*	
7b. Drug Interactions Reference (publication year: _____)	*Yes*
Publication Year : *Online*	
7c. General Information Reference (publication year: _____)	*Yes*
Publication Year : *Online*	
7d. Chapter 795 of the USP/NF concerning Pharmacy Compounding Non-Sterile Preparations (if the pharmacy is compounding non-sterile preparations)	*Yes*
7e. General reference text on veterinary drugs (if the pharmacy dispenses veterinary prescriptions)	*Yes*
7f. Basic Antidote Information and telephone number of the nearest Regional Poison Control Center.	*Yes*
8.If the pharmacy is compounding sterile preparations, the following references are also required:	*Not Applicable*
8a. United States Pharmacopeia/National Formulary or USP Pharmacist's Pharmacopeia containing USP Chapter 797, Pharmaceutical Compounding Sterile Preparations	*Not Applicable*
8b. Chapter 71 of the USP/NF concerning Sterility Tests	*Not Applicable*
8c. Chapter 85 of the USP/NF concerning Bacterial Endotoxins Test	*Not Applicable*
8d. Chapter 1163 of the USP/NF concerning Quality Assurance in Pharmaceutical Compounding	*Not Applicable*
8e. Handbook on Injectable Drugs (publication year: _____)	*Not Applicable*
Publication Year :	
8f. Specialty reference text appropriate for the scope of pharmacy services provided by the pharmacy (e.g., if the pharmacy prepares hazardous drugs, a reference text on the preparation of hazardous drugs)	*Not Applicable*
9. Security Requirements can be met to assure the pharmacy will be locked by key, combination, or other mechanical or electronic means to prohibit unauthorized access when a pharmacist is not on-site.	*Yes*

10. Pharmacy has basic alarm system with the off-site monitoring and perimeter and motion sensors. (Alarm must be activated). *If your city requires an alarm permit, provide a copy of the permit.	*Yes*
11. Written policies and procedures/SOPs for the pharmacy's security system that meet the requirements of Rule 291.33(b)(2)(E)	*Yes*
12. An area suitable for confidential patient counseling, if the pharmacy serves the general public	*Yes*
13. If compounding sterile preparations, the pharmacy has controlled area that meets the requirements in Rule 291.133 (d)(6)(A) if the pharmacy is compounding low-risk and medium-risk preparations or Rule291.133(d)(6)(B) if high-risk preparations are being compounded.	*Not Applicable*
14. Certified primary engineering control device (e.g., laminar airflow work benches, biological safety cabinets, compounding aseptic isolators, and compounding aseptic containment isolators).	*Not Applicable*
15. Certified clean room(s) (e.g. ante area, buffer area).	*Not Applicable*

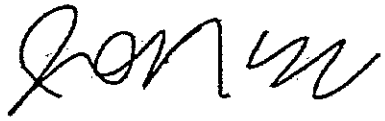
Discussion Items

The requirements of TSBP Rule 291.11 and Section 565.0591 of the Pharmacy Act regarding the operation of a pharmacy within 6 months of becoming licensed.	*Yes*
Corresponding Responsibility and the Red Flags checklist using references from the DEA RPh Manual, the Texas Controlled Substances Act, and TSBP Rules 291.29 and 291.34 (b).	*Yes*
Pharmacy will need to conduct an opening inventory on the first day of business.	*Yes*
Pharmacy will need to report all controlled substances to the PMP as required.	*Yes*

Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



Jonathan Hamer PIC 49333



Terri Burrows

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacist License # 49333

License Information

License Status Active
License # 49333
Expiration Date 12/31/2026
Date License Issued 09/10/2010

Pharmacist Details

School Graduated UNIVERSITY OF MARYLAND
Graduation Year 2010
Degree at time of licensure Pharm D
License Method Exam
Preceptor Yes
Prior Disciplinary Order(s)* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

HAMER, JONATHAN ALAN

Names

Last Name HAMER
First Name JONATHAN
Middle Name ALAN
Other Name
Certificate Name HAMER, JONATHAN ALAN

More Pharmacist Details

Specialty Board Certification ¥
BPS CERT STERILE COMP PHARM (BCSCP)
BPS CERT PHARMACOTHERAPY SPEC (BCPS)

¥ Data regarding Specialty Board Certification is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder for clarification.

Remedial Plans and Drug Therapy Management

Remedial plans (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 35706

AMRX

License Information

License Status Active
License # 35706
Expiration Date 04/30/2027
Date License Issued 04/14/2025

Address

2925 COUNTRY CLUB RD STE 103
DENTON, TX 76210
County DENTON
Phone (888) 853-1836

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Pharmacy
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
HAMER, JONATHAN ALAN

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	Yes
Translating services (Listed Below If Available)	

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3404702 35706 AMRX 2025-04 04-2030.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	Yes
Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	Yes
24 Hour Service	No
Closed Door	No
Compounding, Office Use	No
Home Delivery	No
Infusion	No
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No
In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No

Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
HAMER, JONATHAN ALAN	49333	09/10/2010	12/31/2026	PIC	Active

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Texas Registered Technicians/Trainees Employment information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status

Page 0 of 0 20 No records to view

Texas Remote Pharmacy information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner information

Owner Name	Owner Title	Address	City	State	Zipcode
AMRX LLC	OWNER	,			
HAMER, JONATHAN ALAN	OFFICER	,			

Page 1 of 1 20 View 1 - 2 of 2

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

4MMM

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04130		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: CareFirst Specialty Pharmacy LLC

Physical Address: 400 Fellowship Rd, Ste 100

City: Mount Laurel State: NJ Zip: 08054

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 856-267-0528 Toll Free # (NAC 639.708, NRS 639.23286): 844-822-7379

Fax: 800-786-1405 Contact Email: [redacted]

Website: www.cfspharmacy.pharmacy

Nevada Business License # (if applicable) NV20201892768

Supervising/Managing Pharmacist Name (NRS 639.220): Sundeep Thakrar

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21153

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Sundeep Thakrar	NV Pharmacist Registration #: 21153
Name: Michael Vuong	NV Pharmacist Registration #: 21839
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation N/A

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): Fagron Holdings USA LLC

Corporation/Organization Name: CareFirst Specialty Pharmacy LLC

Mailing Address: 400 Fellowship Rd, St 100

City: Mount Laurel State: NJ Zip: 08554

Telephone [redacted] Email: info@cfspharmacy.com

Contact Person Name: Sundeep Thakrar

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership N/A

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner N/A

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Sundeep Thakrar (title) for Pharmacist in Charge (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Sundeep Thakrar

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

2-24-2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Sundeep Thakrar hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for CareFirst Specialty Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 25 day of February, 2025

Notary Public

JESSICA N MULLENAX
Notary Public, State of New Jersey
My Commission Expires Dec 5, 2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sundeep Thakrar

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

2-24-2025

Date

Board Use Only	Date Received: 3/25/25	Amount: $500-CK 1622

RE: Carefirst Specialty Pharmacy, LLC

Regarding the explanation of disciplinary actions taken against CareFirst Specialty Pharmacy, please review the following information as well as the previously disclosed documentation of all disciplinary and preliminary disciplinary findings.

- The New Jersey Board of Pharmacy inspection conducted a routine inspection of the facility on March 26, 2019. As a result, the NJBOP cited CareFirst Specialty Pharmacy for three deficiencies. All deficiencies were immediately rectified. Please see attached information regarding full explanations and final disciplinary documents.
- On May 16, 2022, the New Jersey Board of Pharmacy conducted an inspection as a result of the change of location for CareFirst Specialty Pharmacy. The inspection resulted in preliminary findings that are still being reviewed by the New Jersey Board of Pharmacy. There has been no finalized disciplinary action currently. CareFirst Specialty Pharmacy has previously disclosed these preliminary findings, and corresponding documents are attached for review.
- CareFirst Specialty Pharmacy was inspected by the FDA beginning on November 15, 2022, and ending on November 30, 2022. As a result of the inspection, the FDA issued an FDA 483 letter noting 1 observation to be addressed. After addressing the concerns outlined in the observation, the FDA issued an EIR and Closeout letter with no disciplinary actions issued. All the previously disclosed documents regarding the inspection results as well as the closeout letter issued from the FDA are attached for review.

For full explanation of all disciplinary actions, please review the previously disclosed documentation.

Sincerely,

[redacted]

Sundeep Thakrar

Manager, Pharmacist in Charge

CareFirstRx Specialty Pharmacy

Re: New Jersey Board of Pharmacy Citations

On 1/27/2020, we proactively notified all boards of pharmacy (in which we were licensed at the time), a notice of disciplinary action issued by our home state board of pharmacy. This was a result of an on-site inspection conducted March 26, 2019 at CareFirst Specialty Pharmacy located at 2200 Garry Rd, Cinnaminson, NJ. Three citations were issued as a result of this inspection and all correspondence to and from the NJ Board of Pharmacy relating to the citations were included with these notices. Also included, were statements of corrective actions implemented to meet the board's requirements. A copy of the notice along with all applicable correspondence with the board is attached.

Please note all citations have been resolved and closed with the NJ Board of Pharmacy. A summary of citations and event history is provided below:

***CITE #1: N.J.A.C. 13:39-6.7 (b)*- Pharmacy Technician registrations were not conspicuously displayed in the pharmacy in view of the public.** Notified via certified letter issued by the NJ Board of Pharmacy on 9/13/2019.

We did not contest this citation. Payment was made for the applicable fine on 10/11/2019. Corrective action was immediately performed to meet the board's requirements. The pharmacy technician registrations that were in obstructed view have been relocated to be in clear view of the public.

***CITE #2: N.J.A.C. 13:39-5.8(a)1*- The pharmacy failed to maintain a current pharmacy reference library. The reference for the General Practice of Pharmacy, The Pharmacological Basis of Therapeutics, was published more then ten (10) years ago. The pharmacy had the 11th edition, which was published in 2006.** Notified via certified letter issued by the NJ Board of Pharmacy on 9/13/2019.

We did not contest this citation. Payment was made for the applicable fine on 10/11/2019. Corrective action was immediately performed to meet the board's requirements. The pharmacy library has been updated to include the newest edition of the Pharmacological Basis of Therapeutics.

***CITE #3: N.J.A.C. 13:39-6.15(d) and N.J.A.C. 13:39-11A.14(a)*- Pharmacists failed to provide immediate supervision to pharmacy technicians engaged in non-sterile compounding.** Notified via certified letter issued by the NJ Board of Pharmacy on 9/13/2019.

We did contest this citation with regards to removing this citation for reasons detailed in our original notice and attached here.

Per a certified letter sent to us on our about 11/21/2019, the board denied mitigation for this citation. Subsequently, the applicable fine was paid on 12/06/2019. In addition, corrective actions were implemented to meet the board's requirement. Processes were updated to ensure a pharmacist is stationed and always present in the non sterile lab for immediate personal supervision of pharmacy technicians engaged in non-sterile compounding at all times. Prior to the inspection, our pharmacists would be present and provide supervision while rotating in/out of the laboratory. This has been updated so that a pharmacist is assigned a physical station in the lab and present at all times during compounding.

Sundeep Thakrar, RPh

Pharmacist In Charge

CareFirst Rx
Specialty Pharmacy
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379 | Fax: 844-922-7379

January 22, 2020

Re: CareFirst Specialty Pharmacy
Non- Resident Pharmacy Permit

To Whom It May Concern,

Please accept this as written notification of disciplinary action taken by the New Jersey Board of Pharmacy for NJ Pharmacy Permit Registration #28RS00740200. This is the result of three citations issued by the NJ Board of Pharmacy a result of an on-site inspection. We have attached a list of the closed citations.

In addition, we have included all associated documentation and correspondence with the New Jersey Board of Pharmacy starting with the board's initial letter dated 9/13/2019 up to our certification letter dated 12/2/2019.

If you have any questions, please feel free to contact me at [redacted] or email info@cfspharmacy.com.

Sincerely,

Sundeep Thakrar
Pharmacist-In-Charge

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy (973) 504-6450 • Enforcement Bureau (973) 504-6300

Date: 03/26/2019
File number: E-65414-19

286

Board of Pharmacy Inspection Report

Pharmacist Specialty Pharmacy LLC Pharmacy trade name Corporation name (if not the same) Owner (as identified on the occasion of this inspection) 3260 East 1st Ave Unit 1 Street address Hialeah FL 33013 City State ZIP code	(Paste pharmacy label here)

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

Name of permit holder | 25EC02740200 Certificate number | 11/30/2019 Expiration date

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

D1569200 Certificate number | 10/31/2019 Expiration date

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

BS9792042 Certificate number | 8/31/2021 Expiration date

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): Sundeep Thakrar
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☑ Yes ☐ No)

25EL02571800 Permit number | 04/30/2021 Expiration date | 40+ Hours worked per week

1. Is the registered pharmacist-in-charge's current renewal on display? ☑ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3] [Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1) Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☐ Yes ☑ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
Sundeep Thakrar	RPIC	25EL02571800	☑ Yes ☐ No	40+
			☐ Yes ☐ No	
See Personnel IDs forms			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.8(a)8 and 13:39-5.6]

1. Is there a sink with hot and cold running water?	☑ Yes	☐ No
2. Is there a satisfactory counting tray or device?	☑ Yes	☐ No

IV. Miscellaneous requirements

1. [16 C.F.R. 1700.14/15] Is a representative inventory of safety closures present?	☑ Yes	☐ No
2. Are prescriptions being dispensed in containers with an appropriate safety closure?	☑ Yes	☐ No
3. [N.J.A.C. 13:39-5.8(c)] Is the dispensing area in a clean, orderly and sanitary condition?	☑ Yes	☐ No
4. [N.J.S.A. 45:14-48a(10)] [N.J.A.C. 13:39-5.8(a)1] Is the pharmacy library satisfactory?	☐ Yes	☑ No
5. [N.J.A.C. 13:45H-5.7] Has the required biennial C.D.S. inventory been conducted?	☑ Yes	☐ No
6. [N.J.A.C. 13:45H-5.5] Has the C.D.S. inventory been properly documented?	☑ Yes	☐ No

Sundeep Thakrar
Print the name of the registered pharmacist who was present for the survey

[redacted]
Signature of the registered pharmacist who was present for the survey

Signature of the Enforcement Bureau representative

Form EB-02 (10/12)

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

Pharmacy: Carrwist Discount Pharmacy
Street Address: 2200 Kennedy Rd Suite 1
City, State, ZIP: Jamesburg, NJ 08777

Date: 03/26/2019

Jennifer Hinrichs
Inspector

Initials of Registered Pharmacist	Quantity or Commercial Package Size	Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Deficiencies [13:39-7.18] [13:39-6.2(f)7] Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
		Totals from above										
		Collective Totals from other pages										
		Composite Total on this page										

The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.

COMMENTS: No deficiencies noted

I hereby acknowledge and attest to the accuracy of the inventory deficiencies reported above.

Sundeep Thakrar
PRINTED NAME OF PHARMACIST

[redacted]
SIGNATURE OF PHARMACIST

EB-23A (1/05)

Date: 03/26/2019
Time entered: 9:05 am
Time departed: 3:45 pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: Wayne Specialty Pharmacy

Address: 3307 Hamburg Rd. Suite 1, Wyckoff, NJ 07477

Name and registration number of pharmacist-in-charge:

Sudeep Sharma RPH0257500

(If pharmacist-in-charge not present, give name and # of R.P. on duty)

The following deficiencies have been noted: Since it's a home infusion

① [13:39 6.7(B)] - Not viewed a written or visual warning that is prominently displayed in the pharmacy in view of the public. (obstructed in back of store)

② [13:39-5.5(a)1]. The Pharmacy is not using primary sources (Physician Office) to document & verify with the (4th Edition).

③ [13:39 6.15(d)(e)]. The Pharmacist is employing four (4) technicians but only three (3) technicians on duty at the time of the inspection Activity.

Additional deficiencies may be cited by the Investigator or the Board of Pharmacy subsequent to the inspection activity upon further investigation of documents & records provided.

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS: The above noted deficiencies will be remedied immediately and all corrective actions if necessary will be done and completed with my supervision

(Signature of pharmacist identified above)

EB-33

3/07

PRM-2019-09035

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 13, 2019

Sundeep Thakrar, RPIC
Carefirst Specialty Pharmacy, LLC
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077

Re: Inspection #8-6514-18-286
Date of Inspection: 3/26/19

Dear Sundeep Thakrar:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation of further disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

> **PAY A PENALTY IN THE AMOUNT OF $2,000.00** and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a re-inspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the re-inspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the

Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification **MUST** be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/rh
(8/19)

ATTACHMENT A

3. **Carefirst Specialty Pharmacy, LLC, Permit #28RS00740200** – 2200 Garry Road, Suite 1, Cinnaminson, NJ 08077
Pharmacist-In-Charge: Sundeep Thakrar
Bureau File #8-6514-18-286, **Period:** 3/26/19
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18 and a Memorandum dated March 12, 2018 from Anthony Rubinaccio, Executive Director, Board of Pharmacy, to Cyndy M. Gohl, Chief, Enforcement Bureau, requesting an inspection of the subject pharmacy in connection with an application for **Remodeling**. A routine inspection of the subject pharmacy was also conducted.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-6.7(b)	Pharmacy technician registrations were not conspicuously displayed in the pharmacy in view of the public. They were displayed in the back of the office in a manner that obstructs the view. Sixteen (16) technician registrations were displayed in this manner.	**$800.00**
N.J.A.C.13:39-5.8(a)1	The pharmacy failed to maintain a current pharmacy reference library. The reference for the General Practice of Pharmacy, The Pharmacological Basis of Therapeutics, was published more than ten (10) years ago. The pharmacy had the 11th edition, which was published in 2006.	**$200.00**
N.J.A.C.13:39-6.15(d) **N.J.A.C.13:39-11A.14(a)**	Pharmacists failed to provide immediate personal supervision to pharmacy technicians engaged in non-sterile compounding in the compounding laboratory. Pharmacists utilize cameras to supervise technicians. Pharmacists were rotating in the laboratory when the technicians required an in-progress check from the pharmacist. Mr. Thakrar verbalized that the pharmacists spend half their time in the lab and the other half performing verification outside of the lab.	**$500.00**
	It should be noted that a Verified Pharmacy Program inspection was conducted at the pharmacy by the National Association of Boards of Pharmacy on September 14, 2018.	
TOTAL: $1,500.00		

CERTIFICATION

I, Sundeep Thakrar, hereby acknowledge that I have read and reviewed the Board's letter dated September 13, 2019 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[ ] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $2,000.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action**, as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[✓] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

OCT 11 2019

[redacted]
(Signature)

Dated: 10/8/2019

Sundeep Thakrar
(Print Name)

Ref: Sundeep Thakrar, RPIC
Carefirst Specialty Pharmacy
(28RS00740200)
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Inspection #8-6514-18-286
AR/rh
(8/19)

10/11/19 Paid $1,000.00

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

September 26, 2019

Anthony Rubinaccio
Division of Consumer Affairs
New Jersey State Board of Pharmacy
124 Halsey Street
Newark, NJ 07102

OCT 07 2019

Re: Inspection #8-6514-18-286
Date of Inspection 3/26/2019

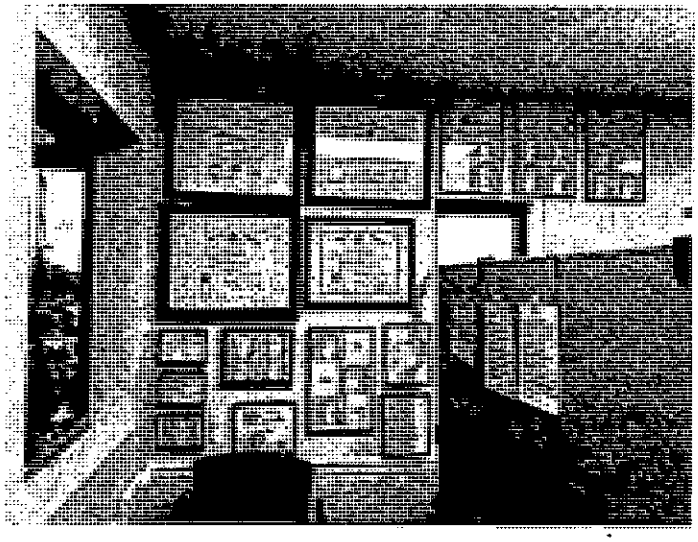
Dear Mr. Rubinaccio,

I am submitting a written statement and explanation to the board in response to your letter dated 9/13/2019 regarding the inspection findings. We would like to submit, for the Board's consideration, detailed explanations (and supporting documentation) that CareFirst Specialty Pharmacy demonstrated compliance with **N.J.A.C.13:39-6.15 (d) (e)** and **N.J.A.C.13:39-6.15(d), N.J.A.C.13:39-11A.14 (a).**

*Please note, I am not contesting CITE **N.J.A.C.13:39-6.7(b)** or CITE **N.J.A.C.13:39-5.8(a)1.** I have provided details regarding corrective actions implemented for these citations.*

In reference to CITE N.J.A.C.13:39-6.7(b):

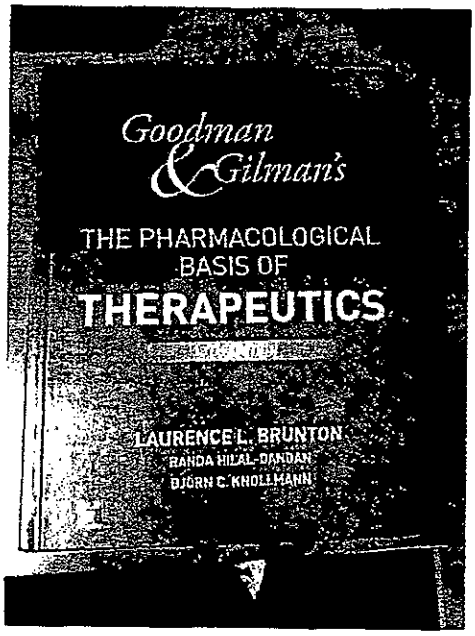
I do not contest this finding. The Pharmacy Technician Registrations have since been relocated so that they are now in public view next to our Pharmacist licenses. I have attached a photo indicating the new location below:



2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

In reference to CITE N.J.A.C.13:39-5.18(a)1:

I do not contest this finding. Our reference library has been updated to include current versions of *General Practice of Pharmacy*, and *The Pharmacological Basis of Therapeutics McGraw-Hill Education / Medical; 13 edition (December 5, 2017).* I have attached a photo for your review below:





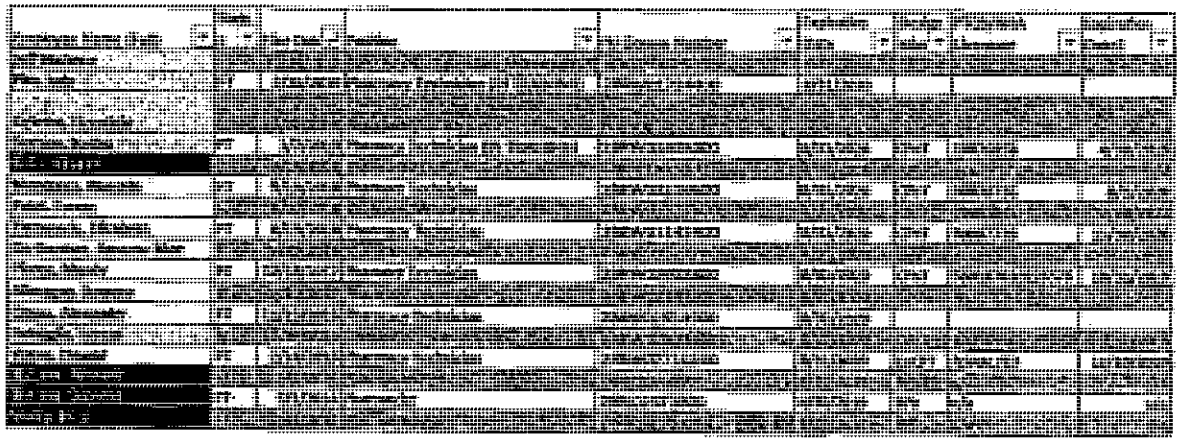
In reference to CITE N.J.A.C.13:39-6.15(d)(e):

I find that we were not in violation of this statute. As documented in the citation details, it is correct that we staffed 4 pharmacists and 9 supportive personnel (pharmacy technicians) on the date of the inspection. However, of the 9 technicians, one was a registered technician in training. It is our understanding that under regulation 13:39-6.15(d), a pharmacy technician in training shall be excluded from the 2:1 ratio provided that the training period does not exceed 210 days and the pharmacy technician is registered. At the time of the inspection, the technician did meet these criteria. I have attached a list of Pharmacy Technicians on staff on the date of the inspection along with their technician registration information and date of hire:

OCT 17 2019

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

Employee List
3/26/2019



[redacted] 4 RPh

Technicians

[redacted] Technician in Training (<210 days) or Non Tech Employee

Ratio 4 RPh: 8 Technicians = 1:2

In reference to CITE N.J.A.C. 13:39-6.15(d) and N.J.A.C. 13.39 - 11A.14(a)

Our pharmacists provide immediate personal supervision of technicians that are conducting Non-Sterile Compounding. I have referenced our procedures below to demonstrate that we meet this requirement. Our process for allowing non-sterile compounding technicians to compound is as follows:

1. We conduct training and routinely evaluate Pharmacy Technician competency of non-sterile compounding by:
    a. Having the Pharmacy Technician observe compounding of a given dosage form with a PIC assigned Compounding Trainer.
    b. Having the Pharmacy Technician independently perform compounding of a given dosage form with direct, personal supervision of a Pharmacist. Documentation of training and competency assessment is recorded in our Training Compliance System called Pestle.
    c. Only if performed correctly and having demonstrated proficiency, the technician is permitted to perform applicable compounding activities. Note: Every preparation must meet certain quality checks that require documentation on the batch record that is reviewed by a Pharmacist. Additionally, the Technician in Training will have a random preparation(s) sent to an outside laboratory for testing during the training period.

CareFirstRx Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

d. This training is performed initially, before the technician is permitted to compound a given dosage form, and at least every 12 months thereafter in which the Technician's competency is evaluated. All such training and competency evaluations are documented in our Training Compliance System called Pestle. Only a fully trained Compounding Pharmacist can conduct annual competencies. An example of documentation is attached.

2. ONLY AFTER training and competencies have been successfully completed by the technician, he or she is permitted to perform nonsterile compounding under Pharmacist supervision. Our Pharmacist supervision includes:
   a. Per 13:39-11A.14, "...the checking of each ingredient used and lot number, the quantity of each ingredient whether weighed, measured, or counted, and the finished label."
   b. The supervision and checking of each of these items occurs during the appropriate step of the compounding process and is documented in EVERY batch record.
   c. The pharmacist checks that proper equipment and setup is followed and the technician wears proper garbing.
   d. The pharmacist will randomly observe the compounding technicians' technique in performing non-sterile compounding and conducts quality checks in the lab throughout the day.
   e. Upon completion, the pharmacist will check the final preparation, review the final batch record, review and confirm that all of the quality checks were conducted and documented prior to dispensing.
   f. The Pharmacist will double check calculations for the compounded preparation prior to dispensing to confirm accuracy.

Our process was assessed by our consultant, Denise M. Frank, BPharm, RPh, FACA, who found it to be compliant.

It was noted on the citation that cameras are used to supervise technicians. However, we use the cameras for ***training purposes only*** and not for actual RPh verification checks which are done in person. As noted in the Attachment A of the CITE, Pharmacists were rotating in the lab and conducting in-progress checks. Additionally, as noted on the CITE, Pharmacists spend approximately half of their time in the lab supervising the technicians during the compounding process.

We have included payment in the amount of $1000.00 for CITES N.J.A.C.13:39-6.7(b) and N.J.A.C.13:39-5.8(a)1. We will await your response regarding the other 2 citations and will follow up accordingly. Please contact me for any additional information or documentation.

Sincerely,

Sundeep Thakrar, RPh
Pharmacist in Charge

CareFirst Rx
Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

October 21, 2019

Anthony Rubinaccio
Division of Consumer Affairs
New Jersey State Board of Pharmacy
124 Halsey Street
Newark, NJ 07102

Re: Inspection #8-6514-18-286
Date of Inspection 3/26/2019

Dear Mr. Rubinaccio,

I recently submitted a written statement dated 9/26/2019 in response to the Board's findings regarding our above referenced inspection. I would like to submit for your consideration, this addendum to our initial response in reference to **CITE N.J.A.C. 13:39-6.15(d)** and **N.JA.C. 13.39-11A.14(a):**

As noted previously, every batch made is physically supervised and verified by a pharmacist during key identified steps in the compounding process. This supervision and verification is documented along with any applicable notes by a pharmacist during the compounding process for every batch. Batch logs/records were provided on the date of the inspection for the inspector's review. I have included a sample batch record to show the documentation of the pharmacist direct supervision conducting in-process quality checks that are performed for each compounded preparation.

It is important to note that many other measures are taken in addition to the direct pharmacist supervision of our compounding technicians to ensure accuracy of our non-sterile compounded medications at CareFirst Specialty Pharmacy:

- All scales are fully integrated with the laboratory compounding software to document all actions performed on the scale.
- All scales have tolerances set to ensure accuracy of all measurements.
- All scales all locked until a calibration is first performed and recorded in the laboratory software.
- All ingredients used to compound including actives, in-actives, and flavors are barcoded, verified and signed and approved by a pharmacist prior to placement into inventory for use in compounding.

I appreciate your consideration in this matter and if there are any additional questions regarding our submitted materials, please do not hesitate to contact me.

Sincerely, [redacted]

Sunny Thakrar, Pharmacist In Charge
Cellular: 609-706-9247
Email: sthakrar@cfspharmacy.com

OCT 29 2019

enc/st

PHM-2019-09035

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 21, 2019

Sunny Thakrar, RPIC
CareFirst Specialty Pharmacy
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077

Re: Inspection #8-6514-18-286
Date of Inspection: 3/26/19

Dear Mr. Thakrar:

The New Jersey State Board of Pharmacy, at the November 13, 2019 meeting, reviewed correspondence submitted requesting mitigation relating to the above-referenced inspection.

The Board moved to deny mitigation of N.J.A.C.13:39-6.15(d) and N.J.A.C.13:39-11A.14(a). The Board also moved to remove N.J.A.C.13:39-6.15(d)(e).

We are in receipt of your check in the amount of $1,000.00. Please complete the attached **Certification** form and submit the balance of **$500.00** for fines incurred to the Board within fifteen (15) days receipt of this letter.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/rh
(7/19)

CERTIFICATION

I, SUNDEEP 'Sunny' THAKRAR, hereby acknowledge that I have read and reviewed the Board's letter dated November 21, 2019 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check:

[✓] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $500.00** (to be paid upon signing of this Certification).

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[redacted]
(Signature)

Dated: 12/2/209

SUNDEEP THAKRAR
(Print Name)

Ref: Sundeep Thakrar, RPIC
CareFirst Specialty Pharmacy
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
(28RS00740200)
Inspection #8-6514-18-286

AR/rh
(7/19)

DEC 06 2019

August, 1 2023

Nebraska Board of Pharmacy,

Regarding Relocation Inspection for CareFirst Specialty Pharmacy

NJ Registration Number: 28RS00740200
Date of Inspection: 05/16/2022
Performed By: New Jersey Board of Pharmacy

Please note that the final inspection findings are preliminary and still being reviewed by the New Jersey Board of Pharmacy. Current there are no disciplinary actions finalized by the New Jersey Board of Pharmacy regarding recent inspection. We understand that we are required to keep the Board apprised of any disciplinary action. Please note our remarks below regarding each item:

(1) 13:39-5.11(d) 4 - The pharmacy failed to contain verbiage in the temperature monitoring policies and procedures for calibration of thermometers at intervals consistent with the manufacturer's recommendations.

We have a complete temperature/humidity/differential pressure monitoring system installed by Aegis Scientific for the compounding spaces, drug storage areas, and refrigerators. The installed system will provide us with all data and alerts for temperature/humidity/differential pressure in the areas. The probes used for monitoring are NIST certified and are also monitored by the system to alert us when the annual replacement is due and automatically send us new NIST-certified probes. The system will alert us 6 weeks before the annual replacement. Although we have a Temperature/Humidity/Differential pressure monitoring SOP including any temperature excursion, it did not specifically reference the annual probe updates. Attached is our current annual NIST certification of the probes and annual probe contract with Aegis where you will see that we had the calibrations and monitoring in place. These measures were in place prior to the relocation and inspection. We have updated our SOP to reflect that the probes will be changed annually per the manufacturer.

(2) 13:39-5.3 (c) - The pharmacy failed to have exterior signage visible noting the presence of a pharmacy.

Our sign is placed to be viewed from the entrance of the building, but the board requires the sign to be viewed from a public roadway, conspicuously identifying the pharmacy. However, due to the location of the pharmacy in the business park, there is no direct entrance access from Fellowship Road. In addition, the local municipal ordinance does not allow a sign at the easement of our entrance road to our pharmacy.
The board investigator has confirmed this and requested we file for a waiver which will be acceptable.

(3) 13:39-6.10 (a) Pharmacy technicians Abigail Gadiano, Donald Vuong, and Valeria Torres Reyes failed to notify the Board of Pharmacy within thirty (30) days of the change of address.

We are working with the technicians to confirm if they had previously made the changes on the board's website/made notification of their address change if applicable and if any corrections are needed.

CareFirst Specialty Pharmacy
400 Fellowship Road, Suite 100
Mount Laurel, NJ 08054
Tel: (844) 822-7379 | Fax: (844) 922-7379

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: 07-Nov-2022
File number: 5-12214-22-515

Board of Pharmacy Inspection Report

Pharmacy trade name: Pinebrook Specialty Pharmacy 1	(Paste pharmacy label here)
Corporation name (if not the same):	
Owner (as identified on the occasion of this inspection):	
Street address: 440 Fellowship Rd Suite 104	
City: Mount Laurel State: NJ ZIP code: 08054	

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

Name of permit holder: _____ Certificate number: 25ES00744300 Expiration date: 06/30/2023

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

Certificate number: DI5900300 Expiration date: 01/31/2023

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

Certificate number: AC5893242 Expiration date: 03/31/2024

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): Sundeep Thakur
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☑ Yes ☐ No)

Permit number: 25RI03571800 Expiration date: 04/30/2023 Hours worked per week: 40

1. Is the registered pharmacist-in-charge's current renewal on display? ☑ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
[Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☑ Yes ☐ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
Sundeep Thakur	RPIC	25RI03571800	☑ Yes ☐ No	40
			☐ Yes ☐ No	
			☐ Yes ☐ No	
See Personnel ID forms			☐ Yes ☐ No	
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.8(a)8 and 13:39-5.6]

1. Is there a sink with hot and cold running water? ☑ Yes ☐ No
2. Is there a satisfactory counting tray or device? ☑ Yes ☐ No

IV. Miscellaneous requirements

1. [16 C.F.R.-1700.14/15] Is a representative inventory of safety closures present? ☑ Yes ☐ No
2. Are prescriptions being dispensed in containers with an appropriate safety closure? ☑ Yes ☐ No
3. [N.J.A.C. 13:39-5.8(c)] Is the dispensing area in a clean, orderly and sanitary condition? ☑ Yes ☐ No
4. [N.J.S.A. 45:14-48a(10)] [N.J.A.C. 13:39-5.8(a)1] Is the pharmacy library satisfactory? ☑ Yes ☐ No
5. [N.J.A.C. 13:45H-5.7] Has the required biennial C.D.S. inventory been conducted? ☑ Yes ☐ No
6. [N.J.A.C. 13:45H-5.5] Has the C.D.S. inventory been properly documented? ☑ Yes ☐ No

Sundeep Thakur — Print the name of the registered pharmacist who was present for the survey
X — Signature of the registered pharmacist who was present for the survey
Signature of the Enforcement Bureau representative

Form EB-02 (10/12)

New Jersey Office of the Attorney General
Division of Consumer Affairs
Board of Pharmacy
Inventory Quality Assurance Examination

Pharmacy: Rite Aid Pharmacy Date: 5/16/12
Street Address: 900 Fellowship Rd, Ste 100
City, State, ZIP: Mt. Laurel, N.J. 08054
Fields/Hueller
Inspector

The medications that were present for the filling of prescriptions have been examined for their compliance to the regulatory standards for quality assurance. The medications that were selected to be examined could potentially have been dispensed, and did not include any segments of the inventory that may already have been separated for future return to their respective manufacturers, or had been placed aside for proper disposal. The medications that were found to be in violation of the regulatory disciplines were segregated by the inspector, and then recorded below. The line entries are categorized by the deficiency for which the medication had been set apart, along with the appropriate regulatory cite. It is requested that you accept your option to compare each package of medication that has been separated as deficient against its collateral entry and, if you concur, place your initials in the left-hand column. The inspector will delete any deficiencies for which there are plausible explanations.

Initials of Registered Pharmacist	Quantity or Commercial Package Size	Name and Potency of Item	Manufacturer / Distributor	Lot Number	Expiration Date	Deficiencies [13:39-7.18] [13:39-6.2(f)7] Expired (1 day - 4 months)	Expired (4 months - 1 year)	Expired (more than 1 year)	Misbranded	"Sample" Medications (13:39-7.18)	Improperly Stored (13:39-6.2(f)7 and 8)	Other (See comments)
1.												
2.												
3.												
4.												
5.												
6.												
7.												
8.												
9.												
10.												
11.												
12.												
13.												
14.												
15.												
16.												
17.												
18.												
19.												
20.												
		Totals from above										
		Collective Totals from other pages										
		Composite Total on this page										

COMMENTS: No deficiencies noted.

I hereby acknowledge and attest to the accuracy of the inventory deficiencies reported above.

Suzanne Thomas
PRINTED NAME OF PHARMACIST

[redacted]
SIGNATURE OF PHARMACIST

EB-23A (1/05)

Date: 05/16/2022
Time entered: 09:15 AM
Time departed: 2:15 PM

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

page 1 of 1

Report of Inspection

Name of Pharmacy: CareFirst Specialty Pharmacy
Address: 400 Fellowship Rd, Ste 100, Mt. Laurel, N.J. 08054
Name and registration number of pharmacist-in-charge:
Sandeep Thakral, 18RS 03571500
(If the Pharmacist-in-Charge is not present, give the name and registration number of the Registered Pharmacist (R.P.) on duty.)

The following deficiencies have been noted: Rebecca Lux / Kristine.
Additional deficiencies may be cited by the Board Office or Pharmacy Inspector upon further examination if necessary pursuant to law.

1) ~~(13:39-5.11(d)4)~~ (13:39-5.11(d)4) – The pharmacy failed to ensure that use of the computer maintains patient and prescriber confidentiality. Pharmacists do not have their own unique user name and password.

2) (13:39-5.3(c)) – The pharmacy failed to have a current display of the pharmacy's pharmacist-in-charge.

3) (13:39-6.10(a) – Pharmacists Jessica Cano, Edward Godiano, Donald Hung, and Valeria Torres Reyes failed to notify the Board of Pharmacy within thirty (30) days of a change of address.

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS: Thank you. I will review the details of the report of inspection and make any changes and updates as required.

(Signature of the Pharmacist identified above)

EB-33

April 28, 2022

TO WHOMSOEVER IT MAY CONCERN

SUBJECT: Installation of Aegis Scientific Monitoring System

Aegis Scientific has completed the installation of the complete monitoring solution that includes temperature, relative humidity and differential pressure sensors for CareFirst Specialty Pharmacy located at 400 Fellowship Road Suite 100 Mount Laurel, NJ 08054. The system also includes the cloud software, web and tablet based alerting system. The sensor probes are NIST certified and the NIST traceable certificates are available online for download.

In additional, as per our contract Aegis will NIST certify the probes annually. The cloud portal will send you alerts 6 weeks prior to expiration of the certificate. If you have any questions please send email to support@aegisfridge.com or call us at 1-800-796-2344.

Sincerely yours,

Ashok Sabata

CFO/CTO Aegis Scientific

1 Ivybrook Blvd , Suite 145R, Ivyland, PA 18974 | T: 215-281-9180 | www.aegisfridge.com

400 Fellowship Rd, Ste 100
Mount Laurel, NJ 08054
P: 844-822-7379
F: 844-922-7379
Email: info@cfspharmacy.com

RE: CareFirst Specialty Pharmacy

Included in the following is the previously disclosed FDA 483. We would like to inform you that the FDA has officially closed the inspection and no warnings or citations were issued.

Sincerely,

Sundeep "Sunny" Thakrar

Pharmacist in Charge

TISS TRENK ISABEL SIDDIQI & SHAHDANIAN P.C.
ATTORNEYS AT LAW

290 W Mt Pleasant Ave Suite 2365 Livingston NJ 07039

Satish V. Poondi, Esq.
[redacted]

December 4, 2022

VIA E-MAIL (ORAPHARM1_RESPONSES@fda.hhs.gov) & (lisa.harlan@fda.hhs.gov)
Lisa Harlan, Program Division Director
Food and Drug Administration, New Jersey Office
10 Waterview Boulevard, 3rd Floor
Parsippany, New Jersey 07054

Re: CareFirst Specialty Pharmacy LLC; FEI No.: 3012258924
Response to 483

Dear Director Harlan:

Please be advised that I represent the above referenced pharmacy. Please accept this submission in response to the 483 issued to CareFirst Specialty Pharmacy LLC ("CareFirst Specialty Pharmacy"), located at 400 Fellowship Road, Ste. 100, Mount Laurel, New Jersey. A copy of the form FDA 483 is attached, as Exhibit A.

The dates of inspection were November 15, 2022 (***beginning at approximately 10:30, and approximately 90 minutes after the pharmacy's operations for the day commenced***), November 16, 2022, November 17, 2022, November 21, 2022, November 23, 2022, and November 30, 2022. During the inspection, CareFirst Specialty Pharmacy engaged cooperatively and constructively with FDA. We would like to assure FDA that CareFirst Specialty Pharmacy is committed to providing patients with the highest quality non-sterile compounded medications prepared in compliance with all applicable standards and that, as demonstrated herein, the pharmacy takes its professional responsibilities very seriously.

For the reasons set forth below, the pharmacy respectfully disputes portions of the FDA's factual and/or legal findings.

Please note that CareFirst Specialty Pharmacy makes this submission without conceding the relevancy, materiality, existence, or admissibility of any document or document request, and without prejudice as to its rights to further contest the FDA's findings. In producing or making available for inspection documents in connection with this action, CareFirst Specialty Pharmacy reserved, and continues to reserve, all claims of privilege and other such protections and further hereby expressly reserves the right to demand the return of all copies of, and object to the use of, any documents or information subject to a claim of privilege or other such protections that are inadvertently disclosed.

Additionally, insofar as the information contained in the enclosed documents includes protected health information, we request the FDA to maintain the same as confidential documents. The records are being produced pursuant to your representations and the HIPAA exception found at 45 C.F.R. 164.512 (b)(1).

Please also be advised that CareFirst Specialty Pharmacy reserves the right to supplement this response and/or submit additional information as it pertains to this matter and the 483 that has been issued. This letter does not waive any rights CareFirst Specialty Pharmacy may assert under applicable law. Furthermore, this submission should not be construed as a waiver of CareFirst Specialty Pharmacy's rights.

As an initial matter, we also note that the pharmacy fully and voluntarily cooperated with FDA throughout the course of this matter. In addition to responding to multiple requests for documentation, the pharmacy and its staff were also made available for multiple interviews. The pharmacy did not refuse to provide any information.

The Form 483 observation attempts to hold CareFirst Specialty Pharmacy to cGMP standards with which, as a matter of law, CareFirst Specialty Pharmacy is not required to comply. See 21 U.S.C. § 353a(a)(1)-(2). CareFirst Specialty Pharmacy objects to the observation in the Form 483 which inappropriately applies cGMP standards. While CareFirst Specialty Pharmacy is addressing all of FDA's inspectional findings, its cooperation with FDA should not be construed as CareFirst Specialty Pharmacy agreeing that it is required to comply with cGMP.

CareFirst Specialty Pharmacy is not a manufacturer. CareFirst Specialty Pharmacy is a retail pharmacy licensed by the New Jersey Board of Pharmacy that compounds non-sterile medications pursuant to patient specific prescriptions for humans and compounds non-sterile medications for veterinary use. Furthermore, CareFirst Specialty Pharmacy holds an unrestricted license which is in good standing.

To this end, we note that the category of establishment FDA lists on the Form 483 - "Producer of Non-Sterile Drug Products" - is not a category recognized in any statute, rule, or guidance. Similarly, FDA also has not published any regulations or even non-binding agency guidance that would provide inspection standards. Congress passed Section 503A, which, along with its exemption from cGMP, applies to this Pharmacy.

FDA's Observation ignores the fact that this pharmacy - which complies with the requirements set forth in Section 503A - is exempt from cGMP regulations. Pharmacies operating under Section 503A of the FDCA are exempt from cGMP in accordance with the Drug Quality and Security Act. Specifically, on November 27, 2013, President Obama signed into law the Drug Quality and Security Act ("DQSA"), Pub. L. No. 113-54. Title I of the DQSA, the Compounding Quality Act, eliminated certain unconstitutional advertising provisions from Section 503A, thus effectively re-enacting those provisions and allowing Section 503A unequivocally to go into effect. The statutory provisions, however, do not

expand FDA's inspection authority or alter in any way applicable standards for compounding pharmacies that comply with FDCA Section 503A.

A critical aspect of Section 503A is the explicit recognition that pharmacies acting in compliance with Section 503A are exempt from certain provisions of the FDCA. In light of this Congressional mandate, FDA must adhere to Section 503A and cannot impose more stringent standards on CareFirst Specialty Pharmacy, such as the cGMP. Section 503 A provides:

> Sections 501(a)(2)(B), 502(f)(l) and 505 shall not apply to a drug product if the drug product is compounded for an identified individual patient based on the receipt of a valid prescription order or a notation, approved by the prescribing practitioner....[1]

FDA's non-binding guidance, published July 2, 2014,[2] is completely consistent with the statute. It reiterates that drugs compounded in compliance with Section 503A will be exempt from certain sections of the FDCA including cGMP requirements (Section 503(a)(2)(B)); labeling with adequate directions for use (Section 502(1)(1)); and new drug requirements (Section 505)). Guidance at 2.

The Form 483 also appears to improperly hold CareFirst Specialty Pharmacy to standards outside applicable State and federal law to determine if its compounds are prepared under insanitary conditions and are therefore adulterated under Section 501(a)(2)(A) of the Federal Food, Drug, and Cosmetic Act ("Section 501(a)(2)(A)"). CareFirst Specialty Pharmacy is entitled to Section 503A's exemption from cGMP as a pharmacy acting within its requirements, and therefore FDA should only hold CareFirst Specialty Pharmacy to State law standards when evaluating the conditions under which CareFirst Specialty Pharmacy's compounds are prepared. As such, to the extent it is doing so, FDA cannot use Section 501(a)(2)(A) to apply cGMP or some other standards outside of State law to evaluate CareFirst Specialty Pharmacy.

Preparation of this Response to FDA's observation does not constitute an admission or agreement by this Pharmacy to the alleged deficiency or conclusions set forth in FDA's Observation. None of the actions that may be taken by this Pharmacy pursuant to its response should be considered an admission that an Observation existed or that additional measures should have been in place at the time of the inspection. Without conceding that any of the Observations are applicable, set forth below is Pharmacy's Response to the single observation. CareFirst Specialty Pharmacy respectfully requests that if FDA posts the Form 483 issued to

---

[1] Section 503A(b) further provides that a drug may be compounded if the pharmacist uses bulk substances that (1) comply with the standards of an applicable United States Pharmacopeia ("USP.,) or National Formulary ("NF") Monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are substances that are components of approved drug products; or (3) if neither of the above, then the drug appears on a shortage list developed by the FDA through regulations.

[2] Final Guidance; Pharmacy Compounding of Human Drug Products under Section 503A of the Federal Food, Drug, and Cosmetic Act; Availability; 79 Fed. Reg. 37742 (July 2. 2014).

this Pharmacy, then FDA shall post this Response along with it, and also provide this Response when FDA provides the Observation to third parties.

Notwithstanding the inappropriate application of federal manufacturing regulations to a retail pharmacy, we would like to assure FDA that CareFirst Specialty Pharmacy is committed to providing patients with the highest quality compounded medications prepared in compliance with all applicable standards and that, as demonstrated herein, the pharmacy takes its professional responsibilities very seriously.

To that end, patient safety is CareFirst Specialty Pharmacy's primary concern, and the pharmacy strives to provide the highest quality preparations and services. CareFirst Specialty Pharmacy has an impeccable safety record concerning the compounded medications that it prepares according to the applicable standards.

Its quality assurance and standard operating procedures ("SOPs") follow demonstrated pharmacy best practices and are designed to produce high-quality compounded non-sterile preparations. CareFirst Specialty Pharmacy's practices are based upon New Jersey Board of Pharmacy requirements and other standards applicable to retail pharmacies so that its patients can continue to access high-quality compounded medications to meet their individual medical needs.

Moreover, the Form 483 and FDA's observation is on its face incorrect. There is a material error of fact and the observation premised on this error should be withdrawn or amended to reflect the actual facts.

In light of the above, without waiving its right to contest FDA's application of cGMPs, CareFirst Specialty Pharmacy provides the following responses to the Observation set forth in the 483.

OBSERVATION 1

Non-microbial contamination was observed in your production area.

Specifically, unidentified residue buildup was observed during the walkthrough conducted on 11/15/2022 in both corners of the back wall of Bench 101 which was used to produce drug products.

RESPONSE

We acknowledge your observation but disagree with your conclusion, both factually and as a matter of law. As stated, CareFirst Specialty Pharmacy is a registered pharmacy practicing under the authority of the New Jersey Board of Pharmacy (NJBOP), complying with both NJBOP and USP General Chapter <795>- *Pharmaceutical Compounding – Nonsterile Preparations*, guidance for Environmental Quality and Control of our compounding rooms.

FDA's Observation is factually incorrect. The residue identified was created in the normal and routine course of the compounding process and contained within the Controlled Ventilated Enclosure (CVE), commonly referred to as a "powder hood," identified and marked as "Bench 101." Note that Bench 101 is located in CareFirst Specialty Pharmacy's Non-Hazardous Non-Sterile (Non-USP 800) compounding room. The investigators observed compounding activities in multiple benches during their inspection of the compounding room and Bench 101 was observed to contain powder and residue. The powder and any residues were created by the normal daily use of the CVE. The compounds made that day at that particular bench used the same active ingredient from the same lot number.

The walk-through by the FDA inspectors occurred during the compounding day, not at the beginning of the compounding day; the CVE was in-use and not terminally cleaned. Upon the identification of this condition of the CVE, once the compounding was completed for that particular and the CVE was no longer being used for compounding, the trained staff cleaned the CVE pursuant to its policies and procedures and removed any residues of the active pharmaceutical ingredients (API) or other components being prepared within. Attached as Exhibit B are photo(s) of "Bench 101" post-cleaning to demonstrate the usual end-of-day condition of the device.

In closing, we respectfully submit this response to explain and distinguish CareFirst Specialty Pharmacy's operational processes and to clarify what may have been misinterpreted by the FDA field investigator who visited the pharmacy.

CareFirst Specialty Pharmacy emphasizes that it takes patient safety and its professional responsibilities very seriously. CareFirst Specialty Pharmacy shares FDA's goal of ensuring that patients in need of custom compounded medications receive quality preparations. To that end, and although it is not required to do so, CareFirst Specialty Pharmacy has voluntarily taken corrective measures identified herein.

We respectfully submit that these measures more than adequately address FDA's observations, and otherwise should exceed FDA's expectations in this matter. We look forward to discussing this matter with you.

In the interim, please do not hesitate to contact me should you have any questions.

Very truly yours,

SATISH V. POONDI

SVP/js
Enclosures
cc: CareFirst Specialty Pharmacy LLC

Exhibit A

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
10 Waterview Blvd., 3rd Floor Parsippany, NJ 07054 [redacted]	11/15/2022-11/30/2022* FEI NUMBER 3012258924

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Sundeep Thakrar, Pharmacist-in-Charge

FIRM NAME	STREET ADDRESS
CareFirst Specialty Pharmacy LLC	400 Fellowship Road, Suite 100
CITY, STATE, ZIP CODE, COUNTRY Mount Laurel, NJ 08054	TYPE ESTABLISHMENT INSPECTED Producer of non-sterile drug products

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Non-microbial contamination was observed in your production area.

Specifically, unidentified residue buildup was observed during the walkthrough conducted on 11/15/2022 in both corners of the back wall of Bench 101 which was used to produce drug products.

*DATES OF INSPECTION

11/15/2022(Tue), 11/16/2022(Wed), 11/17/2022(Thu), 11/21/2022(Mon), 11/23/2022(Wed), 11/30/2022(Wed)

X Kristina L Conroy Investigator Signed By: Kristina L. Conroy -S Date Signed: 11-30-2022 11:25:45

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	DATE ISSUED
	Christina K Theodorou, Investigator Kristina L Conroy, Investigator X [signature]	11/30/2022

FORM FDA 483 (09/08) PREVIOUS EDITION OBSOLETE **INSPECTIONAL OBSERVATIONS** PAGE 1 of 1 PAGES

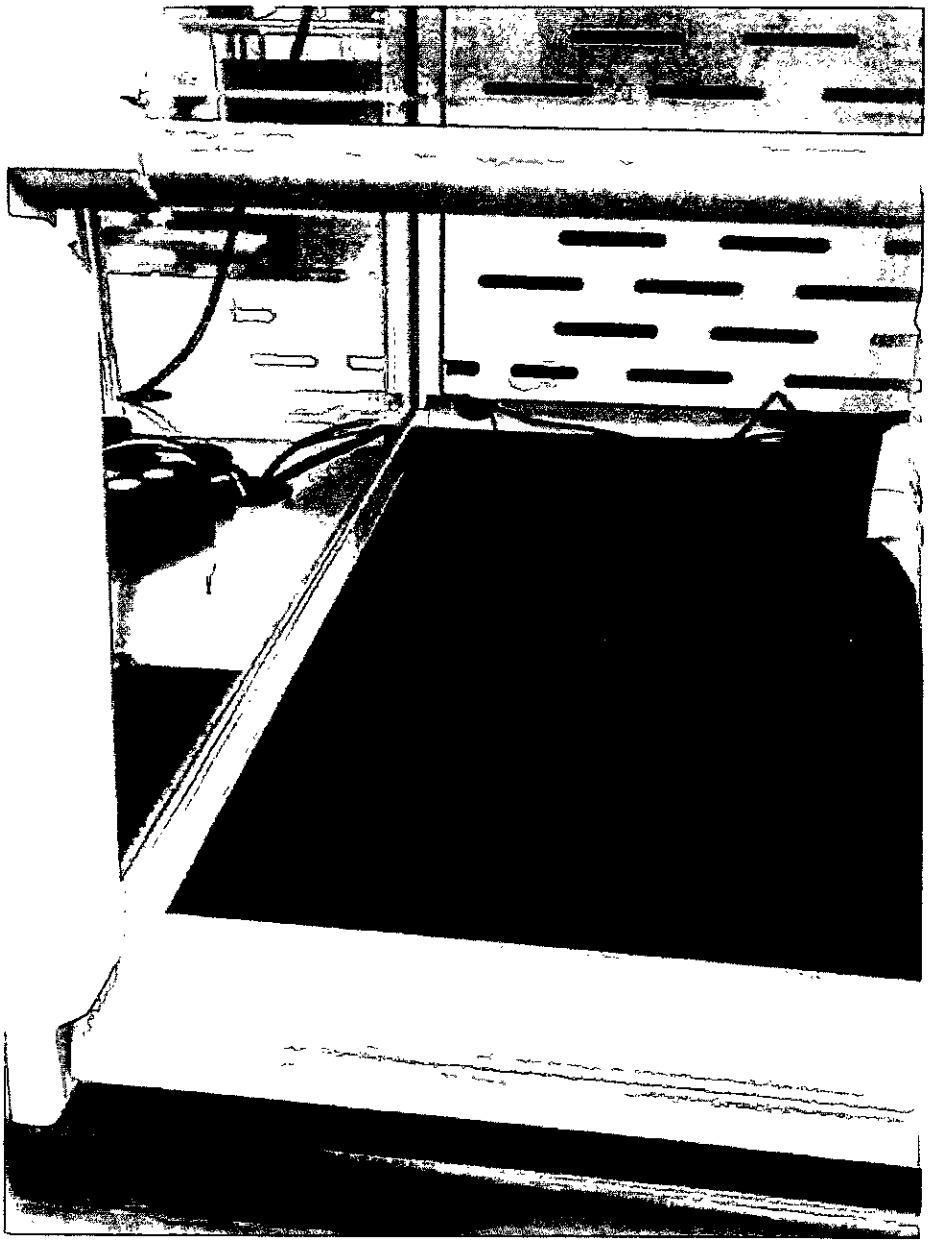
The observations of objectionable conditions and practices listed on the front of this form are reported:

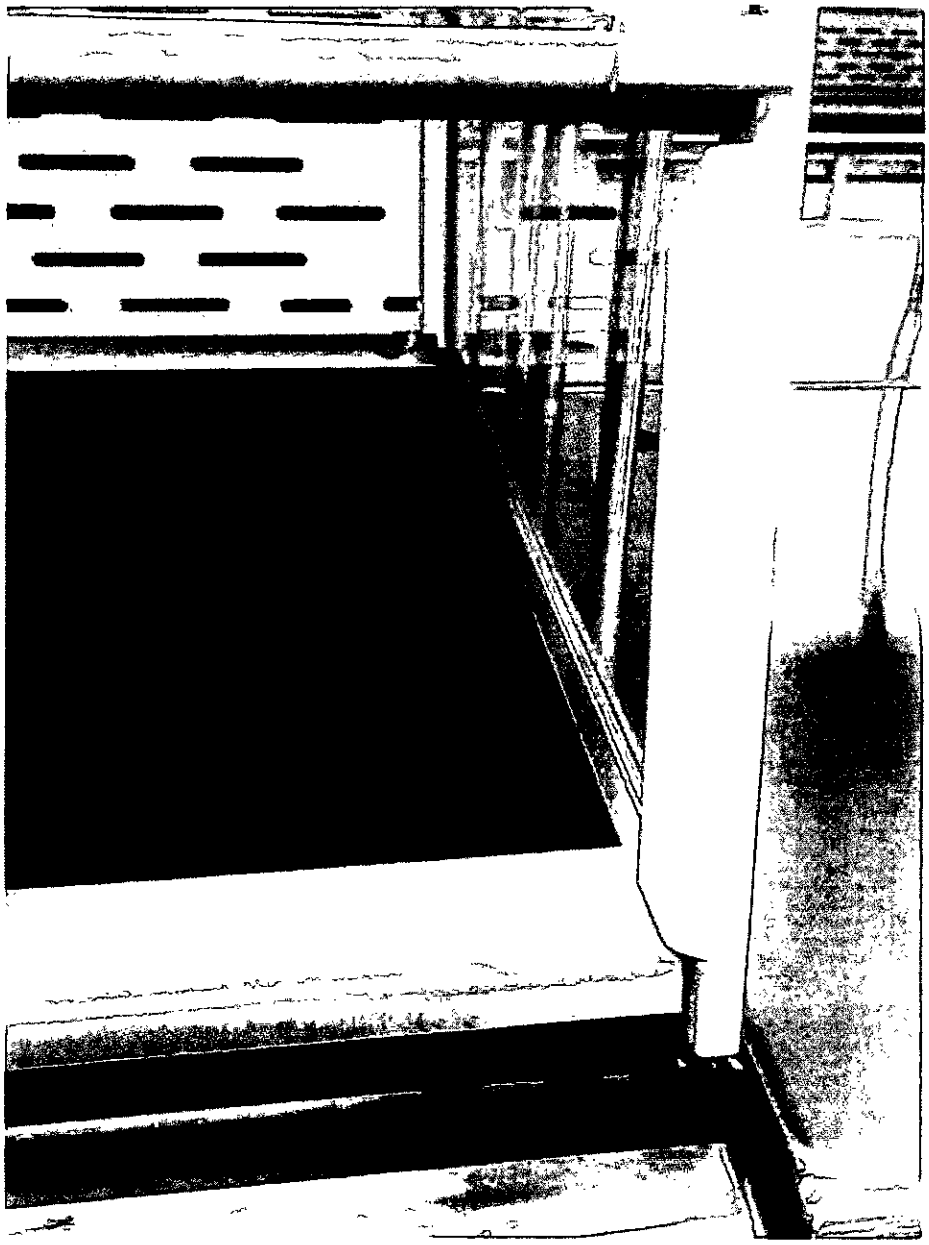
1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

Exhibit B





FDA U.S. FOOD & DRUG ADMINISTRATION
OFFICE OF REGULATORY AFFAIRS
OFFICE OF PHARMACEUTICAL QUALITY OPERATIONS

U.S. Food and Drug Administration
Division of Pharmaceutical Quality Operations I
10 Waterview Blvd, 3rd FL
Parsippany, NJ 07054
Telephone: (973) 331-4900
Fax: (973) 331-4969
www.fda.gov

Via Email
Return Receipt Requested

March 31, 2023

Sundeep Thakrar, RPh
Pharmacist-in-Charge
CareFirst Specialty Pharmacy, LLC
400 Fellowship Road, Suite 100
Mount Laurel, NJ 08054
[redacted]

Dear Mr. Thakrar:

We are enclosing a copy of the Establishment Inspection Report (EIR) for the inspection conducted at your facility, CareFirst Specialty Pharmacy, LLC, located at 400 Fellowship Road, Suite 100, Mount Laurel, NY 08054, from November 15, 2022, to November 30, 2022, by the U.S. Food and Drug Administration (FDA). In addition, we are enclosing the letter sent to the New Jersey State Board of Pharmacy for follow up.

When the Agency considers an inspection to be "closed" under 21 C.F.R. 20.64(d)(3), it will release a copy of the EIR to the inspected establishment.

The Agency continually works to make its regulatory process and activities more transparent for regulated industry. Releasing this EIR to you is part of this effort. The copy being provided to you comprises the narrative portion of the report; it may reflect redactions made by the Agency in accordance with the Freedom of Information Act (FOIA) and 21 C.F.R. Part 20. This, however, does not preclude you from requesting and possibly obtaining any additional information under FOIA.

If there is any question about the released information, please contact Yvette Johnson, Compliance Officer at Yvette.Johnson@fda.hhs.gov.

Sincerely,

Lisa M. Harlan -S Digitally signed by Lisa M. Harlan -S
Date: 2023.03.31 15:12:52 -04'00'

Lisa Harlan
Program Division Director
U.S. Food and Drug Administration
OPQO Division I

Enclosure: EIR, SRL

Cc: New Jersey State Board of Pharmacy (cover letter only)
Anthony Rubinaccio
Executive Director
PO Box 45013
Newark, NJ 07101
[redacted]

CareFirst Specialty Pharmacy Officers/Directors/Stockholders/Shareholders:

Fagron Holdings USA LLC - 100%

[redacted]

Managers of CareFirst Specialty Pharmacy:

Sundeep Thakrar

[redacted]

Hal Weaver

[redacted]

Andrew Pulido

[redacted]

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

CAREFIRST SPECIALTY PHARMACY LLC
0400695078

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on October 15, 2014.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

BHAVESH THAKRAR
400 FELLOWSHIP RD
SUITE 100
MOUNT LAUREL, NJ 08054

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 31st day of December, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6160295964

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler CareFirst Specialty Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable) PH04130

Physical Address 400 Fellowship Rd, Ste 100

City Mount Laurel State NJ Zip 08054

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 844-822-7379 Website www.cfspharmacy.pharmacy

Licensing Company Email info@cfspharmacy.com

Section 2: Personal Information

First Sundeep Middle _____ Last Thakrar

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Rutgers College of Pharmacy		08/94 - 06/97	
Address	**City**	**State**	**Zip**
160 Frelinghuysen Rd	Piscataway	NJ	08854
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
State of University of New York at Buffalo		08/92 to 06/94	
Address	**City**	**State**	**Zip**
190 Founders Prom	Getzville	NY	14068
Diploma/Degree obtained, if any			
Pre Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Sweet Home High School		09/90 to 06/92	
Address	**City**	**State**	**Zip**
1901 Sweet Home Rd	Amherst	NY	14228
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/20- Present	[redacted]	[redacted]		
From - To (MM/YY – MM/YY)	Address			
06/06 to 02/20	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
CareFirst Specialty Pharmacy			01/16 - Present
Business Address	**City**	**State**	**Zip**
400 Fellowship Rd, Ste 100	Mount Laurel	NJ	08054
Phone	**Title**		**Number of Employed Hours**
844-822-7379	Pharmacist in Charge		23,400
Description of Duties			
Pharmacist in Charge			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✓	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

See attached explanation of discipline.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2-24-2025

Date

I, Sundeep Thakrar, **certify that as the designated representative for**

CareFirst Specialty Pharmacy LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ST I am at least 21 years of age;
3. ST I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ST I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ST I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ST I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ST I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Sundeep Thakrar

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2-24-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Sundeep Thakrar

Print Name (First, Last)

[redacted] 2-24-2025

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Burlington

I, Sundeep Thakrar, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted] 2-24-2025

Original Signature **Date**

Subscribed and Sworn to before me this 24th day of February 2025

Jessi Mullenax

Notary Public Signature

JESSICA N MULLENAX
Notary Public, State of New Jersey
My Commission Expires Dec 5, 2029

(Seal)

RE: CareFirst Specialty Pharmacy – Personal History Application

Attached is the Personal History Application. It is completed to the best of our ability as the questions are not relevant to our ownership structure. Fagron Holding USA LLC has 100% ownership of CareFirst Specialty Pharmacy LLC. There are no shareholders/stockholders. Please let us know if you have any questions or need any further information.

Sincerely,

Sundeep Thakrar
Pharmacist in Charge
[redacted]

Philip D. Murphy
Governor

TAHESHA L. WAY
Lt. Governor

State of New Jersey
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
PO BOX 45013
NEWARK, NJ 07101

Matthew J. Platkin
Attorney General

CARI FAIS
Director

February 18, 2025

CareFirst Specialty Pharmacy
400 Fellowship Rd, Ste 100
Mount Laurel, NJ 08054

To Whom It May Concern:

The New Jersey Board of Pharmacy has been requested by CAREFIRST SPECIALTY PHARMACY, LLC to forward a letter of good standing regarding the Pharmacy's registration to practice in the State of New Jersey.

A review of the Board's files indicates that CAREFIRST SPECIALTY PHARMACY, LLC was issued a New Jersey registration 28RS00740200 on or about 05/05/2015 and is currently Active and in good standing with an expiration date of 06/30/2025. A review of the Board's files further indicates that public disciplinary action has been taken against this Pharmacy. A certified, true copy of the reportable action(s) filed with the New Jersey Board of Pharmacy is attached.

Very truly yours,

Anthony Rubinaccio, RPh
Executive Director

PRM-2019-09035

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6460

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

September 13, 2019

Sundeep Thakrar, RPIC
Carefirst Specialty Pharmacy, LLC
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077

Re: Inspection #8-6514-18-286
Date of Inspection: 3/26/19

Dear Sundeep Thakrar:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation of further disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

PAY A PENALTY IN THE AMOUNT OF $2,000.00 and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a re-inspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the re-inspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the

Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification **MUST** be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/rh
(8/19)

CERTIFICATION

I, Sundeep Thakrar, hereby acknowledge that I have read and reviewed the Board's letter dated September 13, 2019 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[ ] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $2,000.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action**, as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[✓] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

OCT 1 1 2019

[redacted]
(Signature)

Dated: 10/8/2019

Sundeep Thakrar
(Print Name)

Ref: Sundeep Thakrar, RPIC
Carefirst Specialty Pharmacy
(28RS00740200)
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Inspection #8-6514-18-286
AR/rh
(8/19)

10/11/19 Paid $1,000.00

CareFirst Rx Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

September 26, 2019

Anthony Rubinaccio
Division of Consumer Affairs
New Jersey State Board of Pharmacy
124 Halsey Street
Newark, NJ 07102

OCT 07 2019

Re: Inspection #8-6514-18-286
Date of Inspection 3/26/2019

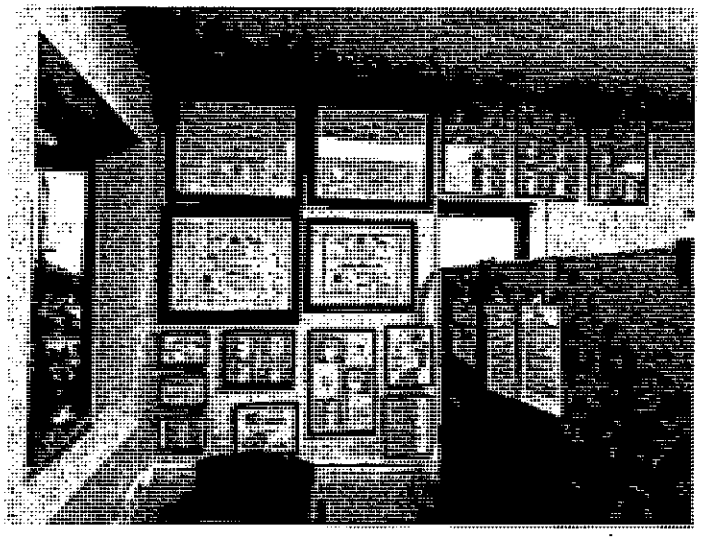
Dear Mr. Rubinaccio,

I am submitting a written statement and explanation to the board in response to your letter dated 9/13/2019 regarding the inspection findings. We would like to submit, for the Board's consideration, detailed explanations (and supporting documentation) that CareFirst Specialty Pharmacy demonstrated compliance with **N.J.A.C.13:39-6.15 (d) (e)** and **N.J.A.C.13:39-6.15(d), N.J.A.C.13:39-11A.14 (a).**

*Please note, I am not contesting CITE **N.J.A.C.13:39-6.7(b)** or CITE **N.J.A.C.13:39-5.8(a)1.** I have provided details regarding corrective actions implemented for these citations.*

In reference to CITE N.J.A.C.13:39-6.7(b):

I do not contest this finding. The Pharmacy Technician Registrations have since been relocated so that they are now in public view next to our Pharmacist licenses. I have attached a photo indicating the new location below:

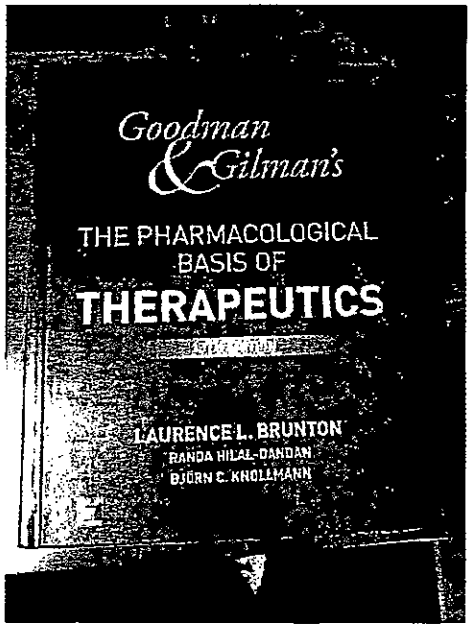


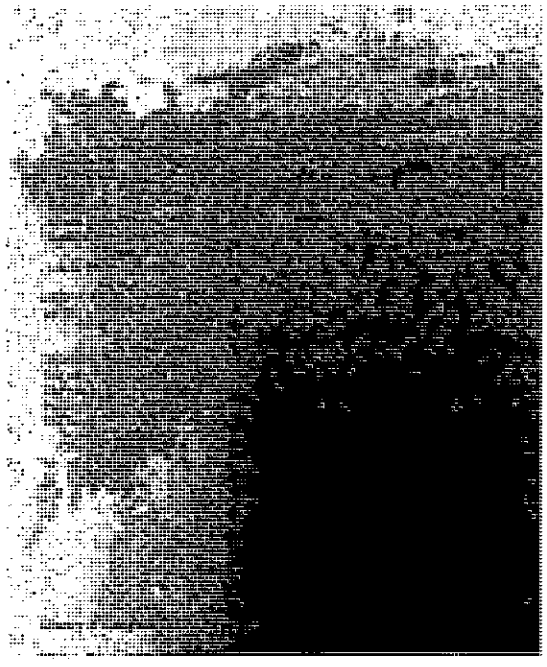
CareFirstRx Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

In reference to CITE N.J.A.C.13:39-5.18(a)1:

I do not contest this finding. Our reference library has been updated to include current versions of *General Practice of Pharmacy*, and *The Pharmacological Basis of Therapeutics McGraw-Hill Education / Medical; 13 edition (December 5, 2017).* I have attached a photo for your review below:





In reference to CITE N.J.A.C.13:39-6.15(d)(e):

I find that we were not in violation of this statute. As documented in the citation details, it is correct that we staffed 4 pharmacists and 9 supportive personnel (pharmacy technicians) on the date of the inspection. However, of the 9 technicians, one was a registered technician in training. It is our understanding that under regulation 13:39-6.15(d), a pharmacy technician in training shall be excluded from the 2:1 ratio provided that the training period does not exceed 210 days and the pharmacy technician is registered. At the time of the inspection, the technician did meet these criteria. I have attached a list of Pharmacy Technicians on staff on the date of the inspection along with their technician registration information and date of hire:

OCT 17 2019

CareFirstRx Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

Employee List
3/26/2019

Employee Name (Full)	Status	Hire Date	Position	NJ License Number	Expiration Date	Designation	PTCB/NHA Licensure	Expiration Date2
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacy Technician (IN TRAINING)	28RW01734400	8/31/2020			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacy Technician (IN TRAINING)	28RW01835000	8/31/2020	CPhT	10076958	4/30/2019
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacy Technician	28RW03219500	8/31/2020	CPhT	30078736	8/1/2020
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacy Technician	28RW01142400	8/31/2020	CPhT	30087739	11/30/2020
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacy Technician	28RW02903800	8/31/2020	CPhT	560107010226576	10/31/2019
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacy Technician	28RW02554900	8/31/2020			
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacy Technician	28RW02710200	8/31/2020	ExCPT	NSR6178	12/10/2020
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]
[redacted]	FT	[redacted]	Pharmacist	28RU02571800	4/30/2019	RPh	n/a	n/a
[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]	[redacted]

[redacted] 4 RPh

Technicians

[redacted] Technician in Training (<210 days) or Non Tech Employee

Ratio 4 RPhs 8 Technicians = 1:2

In reference to CITE N.J.A.C. 13:39-6.15(d) and N.J.A.C. 13.39 - 11A.14(a)

Our pharmacists provide immediate personal supervision of technicians that are conducting Non-Sterile Compounding. I have referenced our procedures below to demonstrate that we meet this requirement. Our process for allowing non-sterile compounding technicians to compound is as follows:

1. We conduct training and routinely evaluate Pharmacy Technician competency of non-sterile compounding by:
    a. Having the Pharmacy Technician observe compounding of a given dosage form with a PIC assigned Compounding Trainer.
    b. Having the Pharmacy Technician independently perform compounding of a given dosage form with direct, personal supervision of a Pharmacist. Documentation of training and competency assessment is recorded in our Training Compliance System called Pestle.
    c. Only if performed correctly and having demonstrated proficiency, the technician is permitted to perform applicable compounding activities. Note: Every preparation must meet certain quality checks that require documentation on the batch record that is reviewed by a Pharmacist. Additionally, the Technician in Training will have a random preparation(s) sent to an outside laboratory for testing during the training period.

CareFirstRx Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

d. This training is performed initially, before the technician is permitted to compound a given dosage form, and at least every 12 months thereafter in which the Technician's competency is evaluated. All such training and competency evaluations are documented in our Training Compliance System called Pestle. Only a fully trained Compounding Pharmacist can conduct annual competencies. An example of documentation is attached.

2. ONLY AFTER training and competencies have been successfully completed by the technician, he or she is permitted to perform nonsterile compounding under Pharmacist supervision. Our Pharmacist supervision includes:
   a. Per 13:39-11A.14, "...the checking of each ingredient used and lot number, the quantity of each ingredient whether weighed, measured, or counted, and the finished label."
   b. The supervision and checking of each of these items occurs during the appropriate step of the compounding process and is documented in EVERY batch record.
   c. The pharmacist checks that proper equipment and setup is followed and the technician wears proper garbing.
   d. The pharmacist will randomly observe the compounding technicians' technique in performing non-sterile compounding and conducts quality checks in the lab throughout the day.
   e. Upon completion, the pharmacist will check the final preparation, review the final batch record, review and confirm that all of the quality checks were conducted and documented prior to dispensing.
   f. The Pharmacist will double check calculations for the compounded preparation prior to dispensing to confirm accuracy.

Our process was assessed by our consultant, Denise M. Frank, BPharm, RPh, FACA, who found it to be compliant.

It was noted on the citation that cameras are used to supervise technicians. However, we use the cameras for ***training purposes only*** and not for actual RPh verification checks which are done in person. As noted in the Attachment A of the CITE, Pharmacists were rotating in the lab and conducting in-progress checks. Additionally, as noted on the CITE, Pharmacists spend approximately half of their time in the lab supervising the technicians during the compounding process.

We have included payment in the amount of $1000.00 for CITES N.J.A.C.13:39-6.7(b) and N.J.A.C.13:39-5.8(a)1. We will await your response regarding the other 2 citations and will follow up accordingly. Please contact me for any additional information or documentation.

Sincerely,

[redacted]

Sundeep Thakrar, RPh
Pharmacist in Charge

CareFirstRx
Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

10/8/2019

Division of Consumer Affairs
New Jersey State Board of Pharmacy
c/o Renee Hodges
124 Halsey Street
Newark, NJ 07102

Re: Inspection #8-6514-18-286
Date of Inspection 3/26/2019

Dear Renee,

I have enclosed a signed copy of the Certification per our conversation. Please let me know if anything else is needed.

Thank you,

[redacted]

Sunny Thakrar, RPh
Pharmacist In Charge

CareFirst Rx Specialty Pharmacy

2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
Tel: 844-822-7379
Fax: 844-922-7379

October 21, 2019

Anthony Rubinaccio
Division of Consumer Affairs
New Jersey State Board of Pharmacy
124 Halsey Street
Newark, NJ 07102

Re: Inspection #8-6514-18-286
Date of Inspection 3/26/2019

Dear Mr. Rubinaccio,

I recently submitted a written statement dated 9/26/2019 in response to the Board's findings regarding our above referenced inspection. I would like to submit for your consideration, this addendum to our initial response in reference to **CITE N.J.A.C. 13:39-6.15(d) and N.J.A.C. 13.39-11A.14(a):**

As noted previously, every batch made is physically supervised and verified by a pharmacist during key identified steps in the compounding process. This supervision and verification is documented along with any applicable notes by a pharmacist during the compounding process for every batch. Batch logs/records were provided on the date of the inspection for the inspector's review. I have included a sample batch record to show the documentation of the pharmacist direct supervision conducting in-process quality checks that are performed for each compounded preparation.

It is important to note that many other measures are taken in addition to the direct pharmacist supervision of our compounding technicians to ensure accuracy of our non-sterile compounded medications at CareFirst Specialty Pharmacy:

- All scales are fully integrated with the laboratory compounding software to document all actions performed on the scale.
- All scales have tolerances set to ensure accuracy of all measurements.
- All scales all locked until a calibration is first performed and recorded in the laboratory software.
- All ingredients used to compound including actives, in-actives, and flavors are barcoded, verified and signed and approved by a pharmacist prior to placement into inventory for use in compounding.

I appreciate your consideration in this matter and if there are any additional questions regarding our submitted materials, please do not hesitate to contact me.

Sincerely,

[redacted]

Sunny Thakrar, Pharmacist In Charge
Cellular: 609-706-9247
Email: sthakrar@cfspharmacy.com

OCT 29 2019

enc/st

[redacted]

(COMPOUNDED DRUG PRODUCT)
Tall Man:

NIOSH Hazard ☐

Flavor:
Quantity made: 123 CAP
Batch yield: 120.000
Qty remaining: 0.000
Schedule: L
PCCA ID: 10727
Route of admin:
Active ☑
Formula ID: 77817
Log ID: 43060

Date made: 10/18/2019
Lot number: 10182019@7
Beyond use date: 4/15/2020 8:30 AM
180 days after compounding date
Pharmacist: SUNDEEP THAKRAR
Technician: ELIZABETH HAMMERLE
Misc. Note:
NDC1:

Pricing calculations from the log
Estimated price $61.45 as of 9/11/2017
Ingredient cost $0.00
Device cost $0.00
Time cost $0.00 Time to make: 0
Profit $61.45

Picture

Description: WHITE #4 CAP
Packaging:
Equipment:

GABAPENTIN 30MG
CAPSULE #4
BY:120
10182019@7
SUNDEEP THAKRAR
ELIZABETH HAMMERLE
STORE AT ROOM TEMPERATURE
CareFirst Specialty Pharmacy
10/18/2019
4/15/2020

Manual pharmacist check of batch label after completion

Barcode system check during verification

Labeling: STORE AT ROOM TEMPERATURE
Stability information:
Storage information:

	Chemical	Lot #	NIOSH Hazard	Guidance	Quantity used	QS / balance	Active	Cost	Update
1	GABAPENTIN USP POWDER GABAPENTIN USP	19A09-U15-048734	☐		3.69 GM CAS: 60142-96-3	☐ 3.696 g Stock: 1,440,429		$0.48	9/28/2019 NDC: 00395-8058-43
	Hazard code: F:0 PH:0 PR:0	Mfg:	Volume:	Potency:	Exp. date: 11/30/2021	QS amount:	Whlsr: HUMCO	ChemInvID: 4113	
	Purity:	Tare: Sample Name: 0.000 g N	Percent off: 0.163% (your weight)	Sample Name: 3.696 g N	Pharmacist manual calculation for 30MG every batch			AWP: $479.70	
					Bar code checked: ☑ Each CAP contains 0.03 GM or 3%				
					NDC:				
2	CAPSULE #4-WHITE-OPAQUE LOCKING (GELATIN)		☐		123 CAP CAS:	☐ Stock: 18,787,1453		$1.30	9/9/2019 NDC: 62991-4108-05
	Lot #: 1904120107	Mfg: LETCO			Exp. date: 10/20/2023		Whlsr: LETCO	ChemInvID: 3711	
	Hazard code:	Volume:	Potency:		QS amount:			AWP: $0.00	
	Purity:				Bar code checked: ☑ Each CAP contains 1 CAP or 100%				
					NDC:				
3	MICROCRYSTALLINE CELLULOSE NF (PH-102)		☐		8.733 GM CAS:	☐ 8.733 g Stock: 8,683,3432		$0.18	5/29/2019 NDC: 51552-0548-06
	Lot #: 19A18-UD4-048657	Mfg: FAGRON			Exp. date: 10/13/2023		Whlsr: FAGRON	ChemInvID: 3487	
	Hazard code:	Volume:	Potency:		QS amount:			AWP: $0.00	
	Purity:	Tare: Sample Name: 0.000 g N	Percent off: 0.057% (your weight)	Sample Name: 8.733 g N					
					Bar code checked: ☑ Each CAP contains 0.071 GM or 7.1%				
					NDC:				
4	RPH VERIFICATION		☐		0 ML CAS:	☐ Stock: 626,421.9342		$0.00	12/26/2018 NDC:
	Lot #: SUNNY	Mfg:			Exp. date: 1/1/2099		Whlsr:	ChemInvID: 2817	
	Hazard code:	Volume:	Potency:		QS amount:			AWP: $0.00	
	Purity: Pharmacist verification of technician's work by electronic scanning of badge to verify ingredients/weights, equipment and process				Bar code checked: ☑ Each CAP contains 0 ML or 0%				
					NDC:				

Total ingredient cost $1.97

Instructions / Notes

New Log: Originally made as; 123 GABAPENTIN 30MG CAPSULE #4 Formula ID: 77817
Calculated lot number: 10182019@7 Beyond use date: 4/15/2020
FORMULA INSTRUCTIONS:
Gabapentin 30mg Capsule #4

Date entered: 10/18/2019 8:30:24 AM Last modified: 10/22/2019 4:50:27 PM By: MLUCAS
Checked by: _____ Date: 10/22/19

OCT 23 2019

[redacted]

(COMPOUNDED DRUG PRODUCT)
Tall Man:

NIOSH Hazard ☐

Flavor:
Quantity made: 123 CAP | Batch yield: 120.000 | Qty remaining: 0.000 | Schedule: L | PCCA ID: 10727 | Route of admin: | Active ☑ | Formula ID: 77617 | Log ID: 43060

MV/ST 8/22/18
Target Wt: 6.2115
Batch 1 6.212
Batch 2 6.070

Manual pharmacist check of technician's work for special calculations that are verified and documented during compounding

SunnyT

Note: Pack Stat for ____Gabapentin 30mg is 95mg, using avg of 10#4 capsule
Pack Stat for Microcrystalline Cellulose PH 102 is 104mg using average of 10 #4 capsule weight
Empty Capsule is 38mg using average of 10 #4 capsule

Base on calculations- **30/95mgx100= Gabapentin occupies 31.6% of the capsule**
104 x 68.4%= 71mg of microcrystalline

TOTAL WEIGHT PER CAPSULE= 101MG

Equipment:

1. Electronic Balance-OHAUS Explorer®
2. Promixer torpac and shell OR Mazerustar Jars and Caps (not required to use if active per inactive ratio is greater than 80%)
3. Promixer Encapsulator
4. Metal Spoon(s) - as required
5. Plastic Spatula(s) - as required
6. Appropriate size Glass mortar and pestle
7. Electric Tamper and tamper plastic cover
8. Appropriate Size Packer Bottle

Verified by RPh: [redacted] **Manual pharmacist check of equipment and set up documented during compounding**

Instructions:

1. Clean and inspect hood using isopropyl alcohol prior to compounding. Clean all equipment used with isopropyl alcohol.
2. Apply appropriate gowning for each compound (Note: if hazardous material use additional gowning procedures)
3. Weigh and measure all ingredients in weigh boats.
4. Using the principles for geometric dilution. Perform mixing process.
5. Mix actives and inactives together in a mortar and pestle and/or mixer.
6. Capsule formulations should have powders where the particle size is the same throughout. Once powders are thoroughly mixed, inspect for any large particle.
7. Triturate in a mortar and pestle to reduce the particle size.
8. Determine if additional mixing is required based on calculation of Active per Inactive ratio
   a. Ratio is calculated by adding the weight of active ingredients and the weight of

Date entered: 10/18/2018 8:30:24 AM Last modified: 10/22/2018 3:50:27 PM by: MEUCAS
Checked by: [redacted] Date: 10.22.18

OCT 2 3

[redacted]

(COMPOUNDED DRUG PRODUCT)
Tall Man:

NIOSH Hazard ☐

Flavor:
Quantity made: 123 CAP | Batch yield: 120.000 | Qty remaining: 0.000 | Schedule: L | PCCA ID: 10727 | Route of admin: | Active ☑ Formula ID: 77617 Log ID: 43080

inactive ingredients, this will give you total weight of ingredients.
b. Then divide the sum of the weight of the active ingredients by the total weight of ingredients.
c. Multiply the number in previous step to give you the percentage. If the answer is below 80 then additional mixing is required.

DOCUMENT IF MAZ IS REQUIRED: (Y) N

9. If no additional mixing is required, mix powder for a total of 5 minutes. If additional mixing required, mix using mortar and pestle for total of 2 minutes then proceed by using Promixer OR Mazerustar:

Promixer Instructions:
1. Add powder into Promixer shell and close securely
2. Run Promixer for 20 min.
Note: See Tech Verification below

Mazerustar Instructions:
1. Add active and inactive powders into Mazerustar jar and add to Maz mixer
2. Add water into separate jar that is equal in weight to powder then add to Maz mixer
3. Run Maz mixer at 3 Revolutions/6 Rotations for 120 seconds
4. If clumping is present, run again at 3 Revolutions/6 Rotations for 60 seconds
Note: See Tech Verification below

Note: Powder should be homogenous and static free
Note: If splitting for multiple batches is required, follow splitting procedure provided by RPh.

10. Using Promixer-Encapsulator, encapsulate in appropriate size capsule using instructions found in ProFiller 1000 Manual v1.3.1.
11. Randomly weigh 5 individual capsules per each 100 capsules made. If less than 100 capsules are made randomly weigh 5 individual capsules. Average of 5 capsules weighed must weigh +/- 10% of target weight.
12. Each capsule should weigh **_101_** mg, plus weight of empty capsule.

#1 weight 99 with in 10%
#2 weight 104 with in 10%
#3 weight 106 with in 10%
#4 weight 102 with in 10%
#5 weight 97 with in 10%

#1 weight 97 with in 10%
#2 weight 93 with in 10%
#3 weight 101 with in 10%
#4 weight 98 with in 10%
#5 weight 105 with in 10%

Pharmacist verification of any quality processes documented by the compounding technician (i.e capsule weights)

Date entered: 10/18/2019 8:30:24 AM Last modified: 10/22/2019 3:50:27 PM by: MLU
Checked by: Date: 10/22/19

OCT 23 2019

[redacted]

(COMPOUNDED DRUG PRODUCT)
Tall Man:

NIOSH Hazard ☐

Flavor:
Quantity made: 123 CAP
Batch yield: 120.000
Qty remaining: 0.000
Schedule: L
PCCA ID: 10727
Route of admin:
Active ☑
Formula ID: 77817
Log ID: 43080

13. Dispense in appropriate size packer bottle and label.
14. Promptly, spray any powder containing equipment being taken out of hood with bleach.
15. Clean hood upon completion of compounding
16. Complete verification procedures

Tech Verification:

1. Circle which mixer was used: Mazerustar / Promixer / Not Applicable due to concentration of actives
2. Batch label matches lot number on log worksheet: _____

RPh Verification:

1. Verified to be white / oblong capsule: _____
2. Batch label matches lot number on log worksheet: _____

Manual pharmacist check documented as final step prior to filling

Warning! Safety when compounding:
Precautions should be taken when compounding hormone and other steroids, as they can be absorbed through skin, mucous membranes and lungs. Wear appropriate lab apparel, eye protection and respirator. Use an appropriate filter system to reduce the amount of airborne chemical particles in your lab. Monitor to ensure there is no direct exposure to the compounder. Pregnant women and compounders with hormone related cancer should not compound hormone therapy.

Note: Appearance: Fully filled capsules
Note: Protect from light.
Note: Store at room temperature

Note: Beyond Use Dates of preparations are conservative estimates by the formulator using reference books, peer reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic stability observations and current USP guidelines. Compounders may have stability tests performed by a reputable lab.

Note: Beyond used per USP 795 non aqueous preparation is 180 days.

Date entered: 10/18/2019 8:30:24 AM Last modified: 10/22/2019 3:50:27 PM by: MLUCAS
Checked by: _____ Date: 10/22/19

Manual pharmacist check for all logs signed by pharmacist

Oct 22 2019

 INITIAL TRAINING

Report:	- Non-Sterile Compounding Competencies - Non-Sterile Compounding-Suspension Competency
Entity:	Foram Patel
Generated:	October 2, 2019 15:05 by Teresa Battaglia
Started:	September 13, 2018 13:59 by Sunny Thakrar
Locked:	September 13, 2018 13:59 by Sunny Thakrar
Due By:	September 12, 2019 23:59
Status:	Compliant
Last Update:	---

Field Name	Value
Demonstrated Proper Use of Mortar and Pestle	Yes
Demonstrated Proper Use of Mazerustar Kurabo Planetary Mixer	Yes
Demonstrated Understanding and Performed QS Procedure	Yes
Demonstrated Packaging Procedure(i.e. Use of Bottle Adapter)	Yes
Demonstrated Use of Overhead Mixer(if applicable)	Yes
Employee Suspension Competency Review	Pass

Report:	- Non-Sterile Compounding Competencies - Non-Sterile Compounding-Prescription Packaging for Verification
Entity:	Foram Patel
Generated:	October 2, 2019 15:05 by Teresa Battaglia
Started:	September 13, 2018 13:57 by Sunny Thakrar
Locked:	September 13, 2018 13:57 by Sunny Thakrar
Due By:	September 12, 2019 23:59
Status:	Compliant
Last Update:	—

Field Name	Value
Demonstrated Understanding of Proper Gowning/Handling Techniques	Yes
Demonstrated Proper Prescription Filling Procedures	Yes
Demonstrated Prioritization of Prescription (i.e. Tote Colors)	Yes
Conducted Secondary Quality Checks during Filling	Yes
Demonstrated Packaging Procedure Reviews for Refrigerated/Cool Packages	Yes
Maintained Area Supplies and Filling of Prescriptions	Yes
Demonstrated Proper Cleaning and Maintenance Procedures in Dispensing Area	Yes
Employee Prescription Packaging for Verification Competency Review	Pass

Report:	- Non-Sterile Compounding Competencies - Non-Sterile Compounding-General Lab Knowledge, Lab Safety and Maintenance Competency
Entity:	Foram Patel
Generated:	October 2, 2019 15:05 by Teresa Battaglia
Started:	September 13, 2018 13:54 by Sunny Thakrar
Locked:	September 13, 2018 13:54 by Sunny Thakrar
Due By:	September 12, 2019 23:59
Status:	Compliant
Last Update:	---

Field Name	Value
Demonstrated Ability to use Pharmacy Software	Yes
Demonstrated Understanding of General Shipping Requirements for Dispensed Drugs	Yes
Demonstrated Understanding of USP 795	Yes
Demonstrated Understanding of Proper Gowning/Handling Techniques	Yes
Demonstrated Proper Cleaning and Maintenance Procedures	Yes
Demonstrated Proper Handling of Hazardous Drugs	Yes
Employee Lab Safety and Maintenance Competency Review	Pass

Report:	- Non-Sterile Compounding Competencies - Non-Sterile Compounding-Cream Competency
Entity:	Foram Patel
Generated:	October 2, 2019 15:06 by Teresa Battaglia
Started:	September 13, 2018 13:52 by Sunny Thakrar
Locked:	September 13, 2018 13:52 by Sunny Thakrar
Due By:	September 12, 2019 23:59
Status:	Compliant
Last Update:	---

Field Name	Value
Demonstrated Proper Use and Understanding of Geometric Dilution	Yes
Demonstrated Proper Use of Unguator Electronic Mortar and Pestle	Yes
Demonstrated Proper Use and Maintenance of Exact Ointment Mill 50 and 50EC+	Yes
Demonstrated Understanding of Dispensing Containers and Priming Procedure	Yes
Demonstrated Proper Use of STS-7 Tube Sealer	Yes
Employee Cream Competency Review	Pass

Report:	- Non-Sterile Compounding Competencies - Non-Sterile Compounding-Capsule Competency
Entity:	Foram Patel
Generated:	October 2, 2019 15:06 by Teresa Battaglia
Started:	September 13, 2018 13:52 by Sunny Thakrar
Locked:	September 13, 2018 13:52 by Sunny Thakrar
Due By:	September 12, 2019 23:59
Status:	Compliant
Last Update:	---

Field Name	Value
Demonstrated Proper Use of Mortar and Pestle	Yes
Demonstrated Proper Use and Understanding of Geometric Dilution	Yes
Demonstrated Proper Use of Mazerustar Kurabo Planetary Mixer	Yes
Demonstrated Proper Use of Promixer	Yes
Demonstrated Proper Use of Profiller Capsule Machine and Electric Tamper	Yes
Demonstrated and Performed Capsule Weight Calculations including Split Calculations	Yes
Employee Capsule Competency Review	Pass

OCT 07 2019

Report:	- Non-Sterile Compounding Competencies - Non-Sterile Compounding-General Lab Equipment Competency
Entity:	Foram Patel
Generated:	October 2, 2019 15:06 by Teresa Battaglia
Started:	September 13, 2018 13:51 by Sunny Thakrar
Locked:	September 13, 2018 13:51 by Sunny Thakrar
Due By:	September 12, 2019 23:59
Status:	Compliant
Last Update:	---

Field Name	Value
Demonstrated Knowledge of Minimum Allowable Weight on Ohaus Explorer Balance (MAWQ)	Yes
Demonstrated Proper Use of Ohaus Explorer Balance	Yes
Demonstrated Leveling and Calibration Procedure of Ohaus Explorer Balance	Yes
Mazerustar: Demonstrated Proper Cleaning Techniques of Mazerustar Mixer	Yes
Mazerustar: Demonstrated Proper Knowledge of Setting Time and Run Speed	Yes
Mazerustar: Demonstrated Proper Transfer of Ingredients In and Out of Jar	Yes
Mazerustar: Demonstrated Proper Technique in Attachment of Jars to Jar Compartments	Yes
Mazerustar: Demonstrated Proper Technique in Setting Ingredient Jar and Water Jar to Equal Weights	Yes
Overhead Mixer: Demonstrated Proper Cleaning Techniques of Overhead Mixer and Blades	N/A
Overhead Mixer: Proper Technique Using Safety Clamp to Secure Container/Beaker	N/A
Overhead Mixer: Proper Technique to Choose and Assemble Stirring Rod	N/A
Overhead Mixer: Demonstrated Proper Transfer of Ingredients In and Out of Container	N/A
Overhead Mixer: Demonstrated Proper Knowledge of Setting Time and Run Speed	N/A
Unguator/EMP: Demonstrated Proper Knowledge of Setting Time and Run Speed	Yes
Unguator/EMP: Demonstrated Proper Technique in Attachment of Jar to Unguator	Yes
Unguator/EMP: Demonstrated Proper Transfer of Ingredients In and Out of Container	Yes
Unguator/EMP: Demonstrated Proper Cleaning Techniques of EMP Jar and Blade	Yes
ProMixer: Demonstrated Proper Cleaning Techniques of ProMixer	Yes

Field Name	Value
ProMixer: Demonstrated Proper Technique in Attachment of Shell to Mixing Motor	Yes
ProMixer: Demonstrated Proper Knowledge of Setting Time and Run Speed	Yes
ProMixer: Demonstrated Proper Transfer of Ingredients In and Out of Shell	Yes
Tube Sealer STS-7: Demonstrated Proper Techniques of Tube Sealer and Tube	Yes
Tube Sealer STS-7: Demonstrated Inspection of Tube for Cracks/Excess Cream Before and After Sealing/Pinching	Yes
Tube Sealer STS-7: Demonstrated Proper Knowledge for Setting Heating/Cooling Cycle Timing Knob	Yes
Ointment Mill: Demonstrated How to Adjust Roller Setting Knobs	Yes
Ointment Mill: Demonstrated Proper Throughput Adjustment	Yes
Ointment Mill: Demonstrated Proper Assembly of Ointment Mill	Yes
Ointment Mill: Demonstrated Proper Cleaning Techniques of Ointment Mill(Before and After Use)	Yes
Demonstrated Knowledge of Locations of Lab Equipment and Packing Materials	Yes
Demonstrated Efficient Use of Lab Equipment	Yes
Employee General Lab Equipment Competency Review	Pass

ANNUAL COMPETENCY ASSESSMENT

Report:	- Non-Sterile Compounding Competency Assessment- Annual - Non-Sterile Compounding Competency Assessment- Annual
Entity:	Foram Patel
Generated:	October 2, 2019 15:02 by Teresa Battaglia
Started:	August 12, 2019 12:37 by Sunny Thakrar
Locked:	August 12, 2019 12:37 by Sunny Thakrar
Due By:	August 12, 2019 23:59
Status:	Compliant
Last Update:	---

Field Name	Value
Employee Name	Foram Patel
Date of Assessment	08/12/2019
Pharmacist/Manager conducting assessment	Sunny Thakrar
Performs pharmaceutical calculations required to accurately compound various non-sterile dosage forms	Yes
Accurately and effectively utilizes various pieces of equipment available in our compounding practice	Yes
Demonstrates ability to compound SOLUTIONS AND SUSPENSIONS using appropriate techniques	Yes
Demonstrates ability to compound CREAMS, OINTMENTS and GELS using appropriate techniques	Yes
Demonstrates ability to compound LOTIONS using appropriate techniques	Yes
Demonstrates ability to compound SOLID DOSAGE FORMS (INCLUDING SUPPOSITORIES & TROCHES) using appropriate techniques	Yes
Demonstrates ability to compound CAPSULES using appropriate techniques	Yes
Demonstrates ability to compound TABLETS using appropriate techniques	NA
Demonstrates ability to compound LOLLIPOPS using appropriate techniques	NA
Demonstrates ability to compound OTHER NOVEL DOSAGE FORMS using appropriate techniques	Yes
Demonstrates how to perform relevent calculations (Example: Capsule Weights, Split Batches)	Yes

Field Name	Value
Identifies the most appropriate calculation method to use	Yes
Understands the Equipment Cleaning Procedure and Documentation before and after Compounding	Yes
Knows proper storage and delivery requirements for shipping medication (i.e. Where to place refrigerated compound, cold packs for shipping, etc)	Yes
Dispenses Compounded Medication accurately and efficiently by choosing and properly using available molds and dispensing devices	Yes
Identifies and performs the required calculations and Quality Checks required for the Formulation Record	Yes
Demonstrates understanding of USP 795 and assigning appropriate BUD	Yes
Demonstrates the ability to use Pharmacy Software	Yes
Identifies proper handling technique for NON-HAZARDOUS DRUGS and HAZARDOUS DRUGS	Yes
Knows proper GOWNING procedures for NON-HAZARDOUS DRUGS and HAZARDOUS DRUGS	Yes
Knows proper RECEIPT procedures for NON-HAZARDOUS DRUGS and HAZARDOUS DRUGS	Yes
Understands proper STORAGE requirements for NON-HAZARDOUS DRUGS and HAZARDOUS DRUGS	Yes
Demonstrates proper COMPOUNDING TECHNIQUE with HAZARDOUS DRUGS	Yes
Notes	
Did employee successfully demonstrate competency in all areas observed?	Yes
Pharmacist/Manager Signature	Sunny Thakrar

PHM-2019-09035

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

PHILIP D. MURPHY
Governor

SHEILA Y. OLIVER
Lt. Governor

GURBIR S. GREWAL
Attorney General

PAUL R. RODRÍGUEZ
Acting Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

November 21, 2019

Sunny Thakrar, RPIC
CareFirst Specialty Pharmacy
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077

Re: Inspection #8-6514-18-286
Date of Inspection: 3/26/19

Dear Mr. Thakrar:

The New Jersey State Board of Pharmacy, at the November 13, 2019 meeting, reviewed correspondence submitted requesting mitigation relating to the above-referenced inspection.

The Board moved to deny mitigation of N.J.A.C.13:39-6.15(d) and N.J.A.C.13:39-11A.14(a). The Board also moved to remove N.J.A.C.13:39-6.15(d)(e).

We are in receipt of your check in the amount of $1,000.00. Please complete the attached **Certification** form and submit the balance of **$500.00** for fines incurred to the Board within fifteen (15) days receipt of this letter.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rabinaccio, RPh
Executive Director

AR/rh
(7/19)

CERTIFICATION

I, SUNDEEP 'SUNNY' THAKRAR, hereby acknowledge that I have read and reviewed the Board's letter dated November 21, 2019 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check:

[✓] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $500.00** (to be paid upon signing of this Certification).

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[redacted]
(Signature)

Dated: 12/2/2019

SUNDEEP THAKRAR
(Print Name)

Ref: Sundeep Thakrar, RPIC
CareFirst Specialty Pharmacy
2200 Garry Road, Suite 1
Cinnaminson, NJ 08077
(28RS00740200)
Inspection #8-6514-18-286

DEC 06 2019

AR/rh
(7/19)

ATTACHMENT A

3. **Carefirst Specialty Pharmacy, LLC, Permit #28RS00740200** – 2200 Garry Road, Suite 1, Cinnaminson, NJ 08077
Pharmacist-In-Charge: Sundeep Thakrar
Bureau File #8-6514-18-286, **Period:** 3/26/19
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18 and a Memorandum dated March 12, 2018 from Anthony Rubinaccio, Executive Director, Board of Pharmacy, to Cyndy M. Gohl, Chief, Enforcement Bureau, requesting an inspection of the subject pharmacy in connection with an application for **Remodeling.** A routine inspection of the subject pharmacy was also conducted.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-6.7(b)	Pharmacy technician registrations were not conspicuously displayed in the pharmacy in view of the public. They were displayed in the back of the office in a manner that obstructs the view. Sixteen (16) technician registrations were displayed in this manner.	$800.00
N.J.A.C.13:39-5.8(a)1	The pharmacy failed to maintain a current pharmacy reference library. The reference for the General Practice of Pharmacy, The Pharmacological Basis of Therapeutics, was published more than ten (10) years ago. The pharmacy had the 11th edition, which was published in 2006.	$200.00
N.J.A.C.13:39-6.15(d) N.J.A.C.13:39-11A.14(a)	Pharmacists failed to provide immediate personal supervision to pharmacy technicians engaged in non-sterile compounding in the compounding laboratory. Pharmacists utilize cameras to supervise technicians. Pharmacists were rotating in the laboratory when the technicians required an in-progress check from the pharmacist. Mr.Thakrar verbalized that the pharmacists spend half their time in the lab and the other half performing verification outside of the lab.	$500.00
	It should be noted that a Verified Pharmacy Program inspection was conducted at the pharmacy by the National Association of Boards of Pharmacy on September 14, 2018.	
TOTAL: $1,500.00		

NABP ACCREDITED
DIGITAL PHARMACY

CareFirst Specialty Pharmacy LLC

located at

400 Fellowship Road, Suite 100, Mount Laurel, NJ 08054

This business has met all of the digital pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the digital pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/digital-pharmacy/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

10/27/2022 - 10/26/2025
Period of Accreditation

#6

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State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

CAREFIRST SPECIALTY PHARMACY, LLC
SUNDEEP THAKRAR
400 Fellowship Road, Suite 100
Mount Laurel NJ 08054

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

05/15/2024 TO 06/30/2025
VALID

[redacted]
Signature of Licensee/Registrant/Certificate Holder

28RS00740200
LICENSE/REGISTRATION/CERTIFICATION #

Cari Fais
ACTING DIRECTOR

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State Of New Jersey

NEW JERSEY OFFICE OF THE ATTORNEY GENERAL

DIVISION OF CONSUMER AFFAIRS

CONTROLLED DANGEROUS SUBSTANCES

CDS REGISTRATION NUMBER

D10590200

CAREFIRST SPECIALTY PHARMACY, LLC
CAREFIRST SPECIALTY PHARMACY, LLC
400 Fellowship Road, Suite 100
Mount Laurel NJ 08054

IS REGISTERED AS: **CDS Pharmacy** FOR SCHEDULES: **2345**

10/02/2024 TO 10/31/2025	FC5292242	28RS00740200
VALID	DEA NO.	LICENSE/REGISTRATION/CERTIFICATION #

[redacted]

Cari Bais
ACTING DIRECTOR



Cari Fa
Direct
Read E

License Information

Accurate as of April 03, 2025 9:54 AM

Return to Search Results

Name: CAREFIRST SPECIALTY PHARMACY, LLC

Address: Mount Laurel,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00740200

License Status: Active

Status Change Reason: License Issuance

Issue Date: 5/5/2015

Expiration Date: 6/30/2025

SPL: New Jersey

Board Action: YES*

Please visit DCA's website to see the final disposition documents.

* A "YES" in the "Board Action" field indicates that the licensee has a public record of some form of action on file with the Board/Committee. Board actions may come in the form o and Desist Order, Interim Order, Reprimand, a finalized Uniform Penalty Letter, agreed upon Settlement Letter or Final Order. In some instances, "Yes" will represent that a public such as an Administrative Complaint or a Provisional Order of Discipline may have been filed with the Board/Committee. Such documents represent the filing of allegations by the not represent a finding of misconduct until the matter is adjudicated by the Board. Contact the Board/Committee directly to obtain a copy of such documents.

To obtain copies of such documents not readily available on the "Actions (Disciplinary and Other)" page of the Board's website, or if no documents are displayed below, please c NJBOPVerifications@dca.lps.state.nj.us.

Documents

28RS00740200 - CAREFIRST SPECIALTY PHARMACY LLC - 09132019 - RE	Pages:	25
28RS00740200 - CAREFIRST SPECIALTY PHARMACY LLC - 09132019 - Re	Pages:	25

Division
Division Home
Consumer Protection
Licensing Boards
File a Complaint
Adoptions & Rule Proposals
Internship Opportunities

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More information about RSS feeds.

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DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	08-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	07-08-2024

CAREFIRST SPECIALTY PHARMACY LLC
CAREFIRST SPECIALTY PHARMACY, LLC
400 FELLOWSHIP RD STE 100
MOUNT LAUREL, NJ 080543437

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

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UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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CAREFIRST SPECIALTY PHARMACY, LLC
400 FELLOWSHIP RD STE 100
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Form DEA-223 (9/2016)

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1182848		**Inspection Information**
Legal Business Name:	CareFirst Specialty Pharmacy LLC	**Conference Call Date:**	1/23/2025
Doing Business As (DBA):	CareFirst Specialty Pharmacy LLC	**Start Time: 24-hour format (13:00)**	13:00
Address:	400 Fellowship Rd Ste 100	**End Time: 24-hour format (13:00)**	14:50
City:	Mount Laurel	**Onsite Inspection Date(s):**	1/27/2025
State:	New Jersey	**Start Time(s): 24-hour format (13:00)**	10:10
Zip Code:	08054	**End Time(s): 24-hour format (13:00)**	16:50
Telephone number:	856/267-0528	**Inspector Name(s):**	Ronnie Higgins, RPh
Toll free number:	844/822-7379	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	856/267-0529	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.cfspharmacy.pharmacy	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.

Additional information on NABP's Inspection website.

NABP Disclaimer: NABP can only verify the authenticity of an Inspection Report if it is transmitted directly from NABP to an intended recipient. NABP cannot verify the authenticity of an Inspection Report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			X
Monday	9:00	18:00	
Tuesday	9:00	18:00	
Wednesday	9:00	18:00	
Thursday	9:00	18:00	
Friday	9:00	18:00	
Saturday			X

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Sundeep (Sunny) Thakrar	[redacted]	144157
Nonsterile Designated person(s)	Sundeep (Sunny) Thakrar	[redacted]	144157
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	Sundeep (Sunny) Thakrar	[redacted]	144157

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	[redacted]	PIC	Y
2		Pharmacy Manager	Y
3		Administrative and Compliance Manager	Y
4		Pharmacist	Y
5		Pharmacist	Y
6		Pharmacist	Y
7		Pharmacist	Y
8		Pharmacist	Y
9		Pharmacist	Y
10		Pharmacist	Y

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present. In addition to the 10 people above there were 32 technicians (not all technicians were performing technician duties), 2 shipping clerks, 1 IT person and 3 technicians in training.

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Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
New Jersey State Board of Pharmacy	CAREFIRST SPECIALTY PHARMACY LLC	Pharmacy	28RS00740200 & 06/30/2025
New Jersey State Board of Pharmacy	CAREFIRST SPECIALTY PHARMACY LLC	Controlled Substance - Pharmacy	D10590200 & 10/31/2025
Drug Enforcement Administration	CAREFIRST SPECIALTY PHARMACY LLC	Controlled Substance - Pharmacy	FC5292242 & 08/31/2027

Inspector Notes: List states in which Non-Resident licenses are held: The pharmacy is licensed in the 48 States that require a license plus DC (Doc01_GP_15.00). "Pharmacy stated they are applying for inspection to meet licensing requirements for multiple states, including Massachusetts new Nonresident pharmacy licensing requirements."

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_GP_15.00	List of State Licenses
Doc02_NS_20.0	COAs
Doc03_HD_1.01	List of Hazardous Drugs
Doc04_HD_1.02	List of Antineoplastics that Require Manipulation

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	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	X
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)	X	Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	X
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)	X	CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement; and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement; and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals	X	CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous	X	Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations	X	Types of CSPs:	
Liquid oral preparations	X	Allergenic extracts	
Otic preparations	X	Allergenic extracts in addition to prescription patient sets	
Rectal preparations	X	Immediate Use	
Vaginal preparations	X	Proprietary bag and vial systems	
Topical preparations:	X	Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations;	X	Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	18500	Total Pharmacists:	7 full time and 7 part time
Nonsterile Compounding Room size:	2590	Number of Compounding Pharmacists:	8
Nonsterile Compounding powder hoods number:	14	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	1650	Total Technicians:	36 full time and 5 part time
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	8	Number of Compounding Technicians:	15
Sterile Compounding Ante Room size:	N/A	Of technicians, how many are nationally certified?	10
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are techs-in-training?	6
Sterile Compounding Number LAFW hoods/areas:	N/A	Total Other Unlicensed Personnel:	4
Sterile Compounding Number BSC hoods:	N/A	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	15 technicians: 7 pharmacists
Sterile Compounding Number CAI/CACI hoods:	N/A	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	N/A		
Sterile HD Compounding Number of CACI hoods:	N/A		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	375	Total Orders Distributed/day:	0
% Veterinary Prescriptions	20%	% Veterinary Orders	0
% Controlled Substance Prescriptions	7%	% Controlled Substance Orders	0
% Nonsterile Compounded Prescriptions	95%	% Nonsterile Compounded Orders	0
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0
% Hazardous Drugs (HD) Prescriptions	15%	% Hazardous Drugs (HD) Orders	0

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):

Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	45	0	December 2024
Alaska (AK)	8	0	December 2024
Arizona (AZ)	214	0	December 2024
Arkansas (AR)	19	0	December 2024
California (CA)	760	0	December 2024
Colorado (CO)	160	0	December 2024
Connecticut (CT)	173	0	December 2024
Delaware (DE)	26	0	December 2024
District of Columbia (DC)	26	0	December 2024
Florida (FL)	476	0	December 2024
Georgia (GA)	219	0	December 2024
Hawaii (HI)	11	0	December 2024
Idaho (ID)	26	0	December 2024
Illinois (IL)	363	0	December 2024
Indiana (IN)	77	0	December 2024
Iowa (IA)	58	0	December 2024
Kansas (KS)	62	0	December 2024
Kentucky (KY)	66	0	December 2024
Louisiana (LA)	55	0	December 2024
Maine (ME)	33	0	December 2024
Maryland (MD)	269	0	December 2024
Massachusetts (MA)	194	0	December 2024
Michigan (MI)	136	0	December 2024
Minnesota (MN)	164	0	December 2024
Mississippi (MS)	16	0	December 2024
Missouri (MO)	93	0	December 2024
Montana (MT)	26	0	December 2024

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	17	0	December 2024
Nevada (NV)	50	0	December 2024
New Hampshire (NH)	58	0	December 2024
New Jersey (NJ)	613	0	December 2024
New Mexico (NM)	80	0	December 2024
New York (NY)	621	0	December 2024
North Carolina (NC)	408	0	December 2024
North Dakota (ND)	18	0	December 2024
Ohio (OH)	460	0	December 2024
Oklahoma (OK)	56	0	December 2024
Oregon (OR)	106	0	December 2024
Pennsylvania (PA)	352	0	December 2024
Rhode Island (RI)	26	0	December 2024
South Carolina (SC)	112	0	December 2024
South Dakota (SD)	17	0	December 2024
Tennessee (TN)	82	0	December 2024
Texas (TX)	401	0	December 2024
Utah (UT)	49	0	December 2024
Vermont (VT)	22	0	December 2024
Virginia (VA)	309	0	December 2024
Washington (WA)	180	0	December 2024
West Virginia (WV)	39	0	December 2024
Wisconsin (WI)	74	0	December 2024
Wyoming (WY)	4	0	December 2024
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	Approximately 70
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	Yes	www.csppharmacy.com
4.01	Does the pharmacy hold .pharmacy verification?	Yes	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	Website has a link where the patient can order refills and ask the pharmacy to contact them.
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	No photos taken
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		Michael Vuong- Pharmacy Manager, Jessica Mullenax-Administrative and Compliance Manager, Charles Glatz-Pharmacist and Lisa Batastini

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	Types of Practice Additional Questions If any part of a question is no, enter "No" and explain the observation.		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Less than 1% in NJ and all other states.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prier to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	Per PIC Thakrar
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	Per PIC Thakrar
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	General Operations and Licensure If any part of a question is no, enter "No" and explain the observation.		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	All pharmacy and employee licenses are posted on the wall in the lobby in a locked cabinet as you enter the pharmacy. Doc01_GP_15.00
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	Last inspection by the NJ Board of Pharmacy was on 05/16/2022. Inspections are conducted on a random basis.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	P&P on temperature monitoring was not complete, no exterior signage noting a pharmacy, and three technicians had failed to notify the Board of a change of address were noted on the inspection. However there has been no final determination from the Board.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	Per PIC Thakrar
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	Per PIC Thakrar
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	Per PIC Thakrar
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	On June 26, 2019 NJ Board approved CareFirst Pharmacy Technician Program. On September 10, 2024 NJ Board is allowing the pharmacy to lower the temperature to a low of 65 degrees F.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	Per PIC Thakrar
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	Per PIC Thakrar
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	Yes	Dates of inspection were from 11/15/22-11/30/22 and a 483 was issued on 11/30/22 for non-microbial contamination in the production area. The pharmacy issued a response to the 483 on 12/04/22. This is the only inspection by the FDA and a letter was issued by the FDA closing this inspection on 12/16/22.

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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	NABP Digital Pharmacy-Valid from 10/27/22-10/26/25, NABP Healthcare Merchant. ACHC PCAB-Valid from 09/08/22-07/07/25 and LegitScript
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	Per PIC Thakrar
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	Per PIC Thakrar
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	All records are maintained for a minimum of 5 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Maintained electronically.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Maintained electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Maintained electronically.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	Currently all records are maintained onsite.
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is addressed in the P&Ps. This is also Ms Mullenax's responsibility to ensure that the pharmacy is operating under the most stringent law or regulation.

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		Observation	Notes
	Personnel If any part of a question is no, enter "No" and explain the observation.		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	The pharmacy utilizes LicenseTrak to electronically monitor employee and state pharmacy licenses. This is conducted monthly. The pharmacy also utilizes a manual verification of state licenses quarterly and employees licenses annually.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	The pharmacy utilizes LicenseTrak to electronically monitor employee and state pharmacy licenses. This is conducted monthly. The pharmacy also utilizes a manual verification of state licenses quarterly and employees licenses annually.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	No	Per PIC Thakrar
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	N/A	When all technicians are certified there is no ratio. Normally 2:1 in the State of NJ.
	Facility and Security If any part of a question is no, enter "No" and explain the observation.		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The pharmacy uses Vector Security for monitoring. The pharmacy is divided into three different zones for security purposes. The pharmacy has glass breakage, door contacts, motion detectors and access control. The pharmacy also has an in-house camera system for security.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	Yes	Locked in a safe. (Only one C-II)
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	The PIC or Pharmacy Manager would remain onsite until the building could be secured.
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	

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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	No	Per PIC Thakrar. No destruction onsite.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	This pharmacy utilizes Med-Flex for non-controls and Rx Exchange for controlled drugs.
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	BioServe picks up the hazardous waste when called.
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	The patient must ring a bell and be allowed to enter the pharmacy. If another patient is present the patient can be moved to a private counseling room.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	The temperatures in the three areas where drugs are stored was 69, 72 and 72 degrees F at the time of inspection. The temperatures are maintained indefinitely electronically at the present time.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Aegis and TempGenius monitors the temperature, humidity, and pressure 24/7/365. An email and text is sent to PIC Thakrar. The temperature is also being manually recorded twice a day.
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	The alerts are set for a for a low of 2.4 and a high of 7.7 degrees C. Records are maintained electronically indefinitely at the present time.

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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	The pharmacy has four refrigerators. The temperatures at the time of inspection were 41, 41, 42, and 42 degrees F. Records are maintained electronically indefinitely at the present time.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No frozen items at the present time.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	The pharmacy has four refrigerators and a back-up diesel generator that will power the entire pharmacy for 3-7 days.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Pharmacy has a service contract with a HVAC.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	4 Kirby Lester
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	

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e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	Product Receipt and Inventory If any part of a question is no, enter "No" and explain the observation.		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	Source must purchase directly from the manufacturer or a wholesaler who purchased the drug directly from the manufacturer.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Anda, Patterson, Independent Pharmacy Distributor, Smart, ParMed and PBA Health. See Nonsterile for list of API suppliers
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	Yes	All commercial product must be received with transaction statement or transaction history.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Yes	Transaction history must be provided with each product. Must be from manufacturer to wholesaler number one then to wholesaler number two.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	Ms. Mullenax maintains a 3 ring binder with all required licenses.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	Yes	Ms. Mullenax maintains a 3 ring binder with documentation of reporting.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	The product would be quarantined and the manufacturer would be contacted.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	None to date per PIC Thakrar

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		Observation	Notes
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	3T is printed with each product received and attached to the invoice.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	Any suspect or illegitimate product would be immediately quarantined and the manufacturer contacted.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA 222 forms?*	Yes	222s are locked up in the safe. Only PIC Thakrar can sign the 222s.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	No	CSOS was not active at the time of this inspection.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	Yes	Only purchased a C-II one time.
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	Reviewed by this Inspector.
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	Per PIC Thakrar
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory of commercial products in Prime Rx and of APIs in PK.

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		Observation	Notes
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	No diversions. If non-controlled the State Board and the local authorities and if a controlled substance the DEA would also be notified.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	Yes	
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	Yes	Verified annually as there has been no dispensing of Schedule IIs.
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	Last inventories were on 01/04/2024 and 01/03/2025
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	Reviewed by this Inspector.
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	Per PIC Thakrar
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	Per PIC Thakrar
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Out-of-dates are checked for on a monthly basis.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	

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		Observation	Notes
60.02	How often is active-stock examined for drugs past the expiration date?		With each dispensing.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	Per PIC Thakrar
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	Per PIC Thakrar
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	No	No return to stock. The prescription would be sent for destruction.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	A customer service representative enters the data and the data is confirmed by the pharmacist when the pharmacist speaks to the patient. Data is updated with patient contacts.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Animals are documented at two places in the Prime Rx system.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Contact the prescriber and if fraudulent contact local authorities.

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		Observation	Notes
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Patient and prescribers addresses are compared and the pharmacist talks to the patient before the prescription is compounded and dispensed. Patients and prescribers are asked when the last visit was if any questions.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both controlled and non-controlled substances.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	By the pharmacy after talking to the patient.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	At both PV1 and PV2.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	Correct dose for weight of patient.
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Weight of patient.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	Numerous online resources.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Reported electronically daily.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Only pharmacist can override a DUR and the override is documented in the Prime Rx system.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	GSDD (Gold Standard Drug Database)
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	Documented in the Prime Rx system.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	No	Veterinary DUR is a manual process and documented in the Prime Rx system. The pharmacy has numerous online references if needed.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	At PV2 by the pharmacist and documented in the Prime Rx system.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Per state law
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Rx Prime for the dispensing function and PK for the compounding function.

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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	Per PIC Thakrar
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	Per PIC Thakrar
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	Per PIC Thakrar
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Observation	Notes
	Patient Counseling and Communication If any part of a question is no, enter "No" and explain the observation.		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Pharmacist or technician
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Pharmacist or technician
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	Yes	Pharmacist or technician
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Prescriptions are delivered by UPS and FedEx. The patient is contacted before the prescription is shipped and counseling can be provided then. Prescriptions also are shipped with a printed monograph.
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	The patient is contacted before the prescription is shipped and counseling can be provided then. Prescriptions also are shipped with a printed monograph.

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		Observation	Notes
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	When PPIs are required they are printed by the Prime Rx system.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	When MedGuides are required they are printed by the Prime Rx system.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	No dispensing of REMS drugs.
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	For patients picking up their prescriptions the offer to counsel is captured electronically. For mailed and shipped prescriptions the offer is documented in the Prime Rx system.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	Patient has the ability to talk to the answering service after normal business hours who can contact the oncall pharmacist if needed.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	Pharmacy does not take-back drugs.
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	Quality Assurance/Quality Improvement Program If any part of a question is no, enter "No" and explain the observation.		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	RPh Vuong
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronically
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	Quarterly
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronically
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	

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		Observation	Notes
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	RPh Vuong with each event and is analyzed quarterly.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	No formulary
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	Quarterly
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	

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		Observation	Notes
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Pharmapod
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes	Per PIC Thakrar	11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		Under SOP Number 3	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		Under SOP Number 7.95 and 11.01	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		Under SOP 9.09 and 9.13	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		Under SOP 11.04 and 6.10	6.2, 11

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Nonsterile Compounding Inspection for USP <795>

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		Under SOP 3.80	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		Under SOP 4	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		Under SOP 7.05 and 11.08	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		Under SOP 9.04	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		Under SOP 6.02	9, 11

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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel; adherence to procedures; and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		Under SOP 9	11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		Under SOP 9	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		Under SOP 6.06	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		Under SOP 13.11 and 3.11	11, 13.2

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Nonsterile Compounding Inspection for USP <795>

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e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		Under SOP 9.08	12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes		1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
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Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes		1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	Yes	Reviewed by this Inspector.	2, 14

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	Yes		2, 14
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	Yes		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	Yes		2, 14

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	Yes		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1

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		Observation	Inspector Notes	USP Reference(s)
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes	The temperature is continuously monitored electronically.	4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes	All probes are replaced annually. Last replacement was on April 9, 2024.	4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes	Alerts are set for below 68.1 and above 76.9 degrees F.	4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		The temperature was 72 in the compounding area and 69 degrees F in the hazardous compounding area at time of inspection.	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	Yes	Purified water is utilized.	4.3 USP <1231>

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		Water, Clorox Healthcare Peroxide, Clorox Healthcare Bleach and IPA 70%	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes	Reviewed by this Inspector.	5 Table 1
15:1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components.**	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes	Monthly	5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components FDA defines manufacturer... as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	BSC	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	Yes	Reviewed by this Inspector.	6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	Yes		6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes	Last verification for scales and Kirby Lesters were May 13, 2024.	6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes	Most hoods were last certified in April 2024 and 4 were certified in September 2024.	6.1

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		Observation	Inspector Notes	USP Reference(s)
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	Yes	API Solutions, Darmerica, Letco, Medisca, PCCA, Spectrum, Willow Birch, Pharma Source Direct. Doc01_NS_20.0.	6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	Yes		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Yes	PCCA COA lists the name of the FDA registered Drug Establishment - repackager (manufacturer).	6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		Sterile water for irrigation	6.2.1

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23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2; 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797 , 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2

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24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling), are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	N/A		6.2.4

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	Yes		6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes	Reviewed by this Inspector.	7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no; go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes	This Inspector reviewed 5 MFRs and 5 CR.	7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes	Reviewed by this Inspector.	7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14

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		Observation	Inspector Notes	USP Reference(s)
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

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		Observation	Inspector Notes	USP Reference(s)
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation. Inspector should describe their observations in the Inspector Notes.***	Yes	Pharmacist are physically located in both compounding areas to perform in-process checks.	2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	Yes	Use by and the date.	9

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		Observation	Inspector Notes	USP Reference(s)
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	Yes		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A .***	Yes		9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	Yes		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	Yes		10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	Yes	Use by and the date.	10.1

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		Observation	Inspector Notes	USP Reference(s)
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms:** The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	Yes		10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	Yes		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	Yes	Progesterone Cream in VersaPro 1-40%, Estradiol 0.025-0.25%, Estriol 0.025-0.25% and Testosterone 1-10% in VersaPro, Estriol 0.01-10% in VersaPro, Estradiol 0.01-10% in VersaPro, and Estradiol 0.01-0.2%, Estriol 0.04-0.8%, Progesterone 1-20%, Testosterone 0.025-0.5% and DHEA 0.2-4% in VersaPro. BUDs are 180 days.	10.5

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		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	Yes		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes	Reviewed by this Inspector.	1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Inspector Notes	USP Reference(s)
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes	Reviewed by this Inspector.	12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	Yes		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, Inspector should answer the question as No.***	No	None since 2021.	12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documents the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	Yes		12.1

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		Observation	Inspector Notes	USP Reference(s)
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes	Observed by this Inspector.	
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1

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		Observation	Inspector Notes	USP Reference(s)
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	N/A	No accommodations	3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Yes		3.3

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		Observation	Inspector Notes	USP Reference(s)
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.		Naltrexone 4.5mg capsules	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2

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		Observation	Inspector Notes	USP Reference(s)
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation**: Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes	Naltrexone 4.5mg capsules, doxycycline capsules, fexofenadine capsules, HRT Dream and naltrexone 3.0 capsules	8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes		8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14

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		Observation	Inspector Notes	USP Reference(s)
59.8	CNSP that do not meet requirements, are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name, list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	DR	PIC	Tech	Tech	Tech	Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
1.3	The training record for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
1.4	The training record for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
1.5	The training record for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
1.6	The training record for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
1.7	The training record for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
1.8	The training record for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes	Yes	Yes	Yes	
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes	Yes	Yes	Yes	
1.12	The training record for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
2.0	The annual competency assessment was evaluated and documented on the following topics:						

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	Employee Title	DR	PIC	Tech	Tech	Tech	Notes
2.1	Compounding personnel are re-trained on facility SOPs.	Yes	Yes	Yes	Yes	Yes	
2.2	Compounding personnel are re-trained on USP <795> standards.	Yes	Yes	Yes	Yes	Yes	
2.3	The annual competency assessment for hand hygiene is complete.	Yes	Yes	Yes	Yes	Yes	
2.4	The annual competency assessment for garbing is complete.	Yes	Yes	Yes	Yes	Yes	
2.5	The annual competency assessment for cleaning and sanitizing is complete.	Yes	Yes	Yes	Yes	Yes	
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	Yes	Yes	Yes	Yes	Yes	
2.7	The annual competency assessment for measuring and mixing is complete.	Yes	Yes	Yes	Yes	Yes	
2.8	The annual competency assessment for proper use of equipment is complete.	Yes	Yes	Yes	Yes	Yes	
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes	Yes	Yes	Yes	
2.10	The annual competency assessment for interpreting a COA is complete.	Yes	Yes	Yes	Yes	Yes	
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	Yes	Yes	Yes	Yes	Yes	
2.12	The annual competency assessment for spill management is complete.	Yes	Yes	Yes	Yes	Yes	
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A.* *Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	N/A	Yes	Yes	Yes	Yes	

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.

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Glossary & References	USP <795>
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high-efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel; bearing responsibility for those actions; and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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Glossary & References	USP <795>
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	General Information and Scope:		
1.00	Does the pharmacy handle any drugs on the National Institute for Occupational Safety and Health (NIOSH) list that **require** all the containment requirements of USP <800>?	Yes	
1.01	Does the pharmacy handle any ***hazardous drug*** active pharmaceutical ingredients (HD API)? *If yes, please list.*	Yes	Doc03_HD_1.01 - a list of hazardous drugs.
1.02	Does the pharmacy handle any antineoplastic requiring manipulations (which can produce particles, aerosols, or gasses)? *If yes, please list.*	Yes	Doc04 _HD_1.02
2.00	Does the pharmacy handle any drugs on the NIOSH list that **do not** require all containment requirements of <800>?	No	
2.01	Does the pharmacy handle any final dosage forms of HDs (either compounded or manufactured unless required by the manufacturer) that do not require further manipulation other than counting and repackaging? *If yes, please list.*	Yes	Doc03_HD_1.01 - a list of commercial hazardous drugs.
2.02	Does the pharmacy handle any dosage forms of other HDs **that are handled in full compliance** with containment requirements of <800>? *If yes, please list.*	No	
2.03	Does the pharmacy handle any dosage forms of other HDs **that are not handled** using all containment requirements of <800>? *If yes, please list.*	No	

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		Observation	Notes
	List of Hazardous Drugs		
3.00	The pharmacy maintains a list of any items it handles that are included on the current NIOSH list of antineoplastic and other HDs. ***Review and attach list.*** *Verify that pharmacy has access to a copy of current NIOSH list.*	Yes	
4.00	The pharmacy reviews this list at least every 12 months for additions, deletions, or other changes and documents the review. *Verify documentation and* ***list date*** *of last change/review.*	Yes	Last updated on 01/14/2025.
5.00	The pharmacy reviews this list whenever the pharmacy adds a new agent or dosage form to the items it handles.	Yes	
6.00	The pharmacy has a system in place for the evaluation of new drugs (purchased, stored, handled, and/or dispensed) to determine whether they are considered HD.	Yes	
6.01	Pharmacy evaluates the drugs against the current version of the NIOSH list.	Yes	
6.02	In the absence of information, the pharmacy treats any new drug as an HD.	Yes	
7.00	If the pharmacy handles any HDs not using all containment requirements of <800>, an assessment of risk was performed for each drug and dosage form individually to determine alternative containment strategies, if needed, and work practices for each. *Review documentation of assessment and SOPs related to work practices/alternative containment.*	Yes	

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		Observation	Notes
8.00	The assessment of risk evaluation performed by the pharmacy's organization includes all required information, for each drug and dosage form. *The first five (5) items below must be included in the evaluation in order to be compliant.*	Yes	
8.01	Type of HD (eg, antineoplastic, non-antineoplastic, reproductive risk only);	Yes	
8.02	Dosage form;	Yes	
8.03	Risk of exposure;	Yes	
8.04	Packaging;	Yes	
8.05	Manipulation; and	Yes	
8.06	If applicable, Table II and III drugs have alternative containment strategies and/or work practices to minimize occupational exposure.	Yes	
8.07	The assessment of risk is reviewed at least every 12 months, and the review is documented. *Enter date of last review in the notes.*	Yes	Last updated on 01/14/2025.
	Personnel Responsibilities		
9.00	The pharmacy has a designated person(s) to oversee the handling of HDs who is qualified and trained for development of standard operating procedures (SOPs); overseeing compliance with standards, laws, and rules; ensuring competency of personnel; and ensuring environmental control.	Yes	
9.01	The designated person oversees the monitoring of the facility, including testing/sampling programs, maintaining, and documentation, and acting on results.	Yes	

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		Observation	Notes
	Documentation and Standard Operating Procedures (SOPs)		
10.00	The assessment of risk and SOPs for handling HDs addresses all potential types of exposure, including all activities occurring within the operation that present an opportunity for exposure:		
10.01	**Receiving**: Contacting HD residues on packaging, work surfaces, floors	Yes	
10.02	**Dispensing**: Counting or packaging tablets and capsules	Yes	
10.03	**Compounding/other manipulations**: Crushing/splitting tablets, opening capsules, pouring liquids, weighing or mixing, constituting/reconstituting powdered/lyophilized HDs, expelling air from HD syringes, HD residue on personal protective equipment (PPE), cleaning activities of HD areas, and HD equipment maintenance.	Yes	
10.04	**Administration and other patient care activities** (if applicable).	N/A	
10.05	**Spills**: Spill generation, management, and disposal.	Yes	
10.06	**Transport**	Yes	
10.07	**Waste**: Collection and disposal of HD waste and trace contaminated waste	Yes	
11.00	SOPs are reviewed at least every 12 months by the designated person, and the review is documented.	Yes	

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		Observation	Notes
12.00	SOPs are readily available to all who may need to handle HD or respond to a spill (pharmacy employees, housekeeping, nursing personnel, delivery personnel, etc). *Describe whether P&Ps are available electronically, by paper, or both.*	Yes	Both electronic and hard copy.
13.00	SOPs address at a minimum: *If no, document "missing" in Inspector Notes for each SOP topic*		**Please note NABP did not review each SOP for alignment on USP <800>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**
13.01	Hazard communication program plan	Yes	Under SOP 12.00
13.02	Competent personnel	Yes	
13.03	Occupational safety program	Yes	
13.04	Designation of HD areas	Yes	
13.05	Receiving HDs, including handling of damaged shipping containers/breakages	Yes	
13.06	A list of HDs	Yes	
13.07	Storage of HDs	Yes	
13.08	Compounding of HDs	Yes	
13.09	Use and maintenance of proper engineering controls (eg, containment primary engineering control [C-PECs], containment secondary engineering control [C-SECs], and closed system drug transfer device [CSTDs]) to include SOPs for repairs, loss of power, moving, etc.	Yes	

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		Observation	Notes
13.10	Hand hygiene and proper use of appropriate PPE based on activity (eg, receipt, transport, compounding, administration, spill, disposal).	Yes	
13.11	Deactivation, decontamination, cleaning, disinfection SOPs include all of the following:		
13.11.01	Agents used	Yes	
13.11.02	Dilutions, if used	N/A	
13.11.03	Frequency	Yes	
13.11.04	PPE to be worn (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted--addressed in SOPs)	Yes	
13.11.05	Documentation requirements	Yes	
13.12	Receiving SOPs to include communications with suppliers about packaging and visual/other inspection of shipping containers for signs of damage and how to handle damaged containers.	Yes	
13.13	If a shipping container appears damaged and **does not need to be opened:**		Under SOP 12.15
13.13.01	It is sealed without opening and wrapped in impervious plastic;	Yes	
13.13.02	Labeled as "hazardous"; and	Yes	
13.13.03	Returned to the supplier after contacting the supplier or disposed of as hazardous waste if supplier declines return.	Yes	

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		Observation	Notes
13.14	If a damaged shipping container **must be opened:**		
13.14.01	Container is sealed in plastic or an impervious container;	Yes	
13.14.02	It is transported to the C-PEC before opening, preferably nonsterile compounding C-PEC, if available;	Yes	
13.14.03	container is placed on a plastic-backed preparation mat;	Yes	
13.14.04	It is opened and undamaged items are removed and wiped down with a disposable wipe;	Yes	
13.14.05	Damaged item is enclosed in an impervious container and labeled "hazardous";	Yes	
13.14.06	Damaged item is returned to the supplier or disposed of as hazardous waste;	Yes	
13.14.07	Deactivate, decontaminate, and clean the C-PEC in accordance with SOPs; and	Yes	
13.14.08	If a sterile compounding C-PEC must be used, it is also disinfected after cleaning prior to resuming any sterile compounding activities.	N/A	No sterile compounding is conducted at this pharmacy.
13.15	Safe work Practices SOPs	Yes	
13.16	Dispensing SOPs	Yes	
13.17	Packaging and labeling SOPs	Yes	
13.18	Transport SOPs	Yes	

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		Observation	Notes
13.19	Administering SOPs, if applicable	Yes	
13.20	***Recommendation: Environmental monitoring (eg, wipe sampling) SOPs***	No	
13.21	HD waste segregation and disposal (including reference to following local, state, and federal regulations) SOPs	Yes	
13.22	Spill prevention and direction of spill cleanup and control SOPs must address the following:		Under SOP 7.03
13.22.01	Size and scope of spill;	Yes	
13.22.02	Responsible person for handling spills;	Yes	
13.22.03	Location of spill kits and clean-up materials;	Yes	
13.22.04	Capacity of the spill kits;	Yes	
13.22.05	PPE to be worn during spills;	Yes	
13.22.06	Handling of worn PPE and any exposed clothing under PPE;	Yes	
13.22.07	Use of appropriate full-face, chemical cartridge-type respirator or powered air-purifying respirators (PAPR) if capacity of spill kit is exceeded or known or suspected airborne exposure to vapors/gases; and	Yes	
13.22.08	Medical evaluation/incident reporting/documentation/other handling of persons potentially exposed or with direct skin/eye contact to the HD.	Yes	

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		Observation	Notes
13.23	***Recommendation:*** *Does the pharmacy have a medical surveillance program? (a comprehensive control program to monitor and identify potential worker health care issues from HD exposure.)*	No	
14.00	The **hazard communication program** SOP has policies and procedures that ensure worker safety in all aspects of HD handling relevant to the pharmacy and ensure effective personnel training in proper labeling, transport, storage, and disposal of HDs, use of Safety Data Sheets (SDSs), based on the Globally Harmonized System of Classification and Labeling of Chemicals (GHS).	Yes	
15.00	The pharmacy's hazard communication program includes, at a minimum, all of the following:		
15.01	A written plan that describes how the standard will be implemented;	Yes	
15.02	How containers of HDs/hazardous chemicals will be labeled, tagged, or marked with the identity of the material and appropriate hazard warnings;	Yes	
15.03	SDSs are maintained for each hazardous chemical they use (29 CFR 1910.1200);	Yes	
15.04	How SDSs are readily accessible to personnel during each work shift and when they are in their work areas;	Yes	
15.05	Information and training provided to personnel prior to initial assignment to work with a hazardous chemical and whenever the hazard changes; and	Yes	
15.06	Personnel of reproductive capability confirm in writing that they understand the risks of handling HDs.	Yes	

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		Observation	Notes
	Personnel Training —*Check four employee files for documentation*		
16.00	All personnel handling HDs are trained based on their job function prior to independently handling HDs.	Yes	
17.00	Personnel file contains the employee's acknowledgement of the risk of handling HD (as part of the hazardous communication program).	Yes	
18.00	For non-sterile HD compounding, personnel competency is observed and assessed at least annually for proper compounding technique, with no concerns identified.	Yes	
19.00	For sterile HD compounding, personnel competency is observed and assessed at least annually for proper sterile compounding aseptic technique, with no concerns identified.	N/A	No sterile compounding is conducted at this pharmacy.
20.00	After initial HD training, personnel are trained prior to introduction of any new HD or new equipment, or prior to any significant change in process or SOP.	Yes	
21.00	All HD training and assessments are documented for each employee who transports, compounds, or administers HDs, and meets Occupational Safety and Health Administration Standard 1910.120 and any other requirements of law or regulation.	Yes	
22.00	All personnel who perform custodial HD waste removal and cleaning in HD handling areas are trained in appropriate procedures to protect themselves and the environment.	Yes	
23.00	HD training, based on employee file review, all of the following are present:		
23.01	Overview of pharmacy's HD list and their risks;	Yes	

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		Observation	Notes
23.02	Review of the SOPs related to HDs;	Yes	
23.03	Proper use of PPE;	Yes	
23.04	Proper use of equipment and devices (eg, engineering controls);	Yes	
23.05	Appropriate procedures for deactivation, decontamination, cleaning, and disinfection (if applicable);	Yes	
23.06	Response to known or suspected HD exposure;	Yes	
23.07	Spill management;	Yes	
23.08	Proper disposal of HDs and trace-contaminated materials; and	Yes	
23.09	New HD drug/new equipment or prior to any significant change in process or SOP.	Yes	
24.00	If respiratory protection is needed for any HDs handled, personnel are fit tested and trained in the proper use of the respirator.	Yes	
	Personal Protective Equipment		
25.00	For sterile and nonsterile compounding with HDs, personnel wear gowns; head, hair, and shoe covers; and two pairs of chemotherapy gloves.	Yes	
26.00	Appropriate PPE is readily accessible where HD is handled, include all of the following:		

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		Observation	Notes
26.01	Receipt (PPE appropriate to HD as set forth in SOPs, and at a minimum, chemotherapy gloves worn);	Yes	
26.02	Storage;	Yes	
26.03	Transport;	Yes	
26.04	Nonsterile Compounding (if performed by the pharmacy);	Yes	
26.05	Sterile Compounding (if performed by the pharmacy);	N/A	No sterile compounding is conducted at this pharmacy.
26.06	Administration, if applicable;	N/A	No administration.
26.07	Deactivation/decontamination, cleaning, and disinfecting (appropriate PPE resistant to the agents used, two pairs of chemotherapy gloves, impermeable disposable gowns, and eye, face, and respiratory protection if warranted/addressed in SOPs);	Yes	
26.08	Spill control;	Yes	
26.09	Waste disposal; and	Yes	
26.10	If administering injectable antineoplastics, two pairs of chemotherapy gloves and permeability resistant gowns are worn.	N/A	No administration.
27.00	Disposable PPE is not reused.	Yes	
28.00	Reusable PPE is decontaminated and cleaned after each use.	Yes	

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Hazardous Drugs - Handling in Health Care Settings

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
29.00	**Gloves**: The pharmacy is using appropriate gloves for the activities conducted (chemotherapy gloves meet ASTM standard D6978 -- or its successor -- and are resistant to cleaning agents used) and are resistant to cleaning agents used.	Yes	
29.01	**Recommendation**: Are *chemotherapy gloves worn for handling all HDs including non-antineoplastics and for reproductive risk only HDs?*	Yes	
29.02	Chemotherapy gloves are powder-free.	Yes	
29.03	Chemotherapy gloves are inspected for physical defects before use and defective gloves (eg, pin holes, tears, weak spots) are discarded.	Yes	
29.04	For sterile compounding, the outer chemotherapy gloves are sterile.	N/A	No sterile compounding is conducted at this pharmacy.
29.05	Chemotherapy gloves are changed when torn, punctured, or contaminated.	Yes	
29.06	**Recommendation**: Are *chemotherapy gloves changed every 30 minutes (unless otherwise recommended by the manufacturer)?*	Yes	
29.07	Hands are washed with soap and water after removing chemotherapy gloves.	Yes	
30.00	**Gowns**: The pharmacy is using appropriate gowns for the activities conducted (if required for type of compounding based on standards or assessment of risk).	Yes	
30.01	Gowns are disposable.	Yes	

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		Observation	Notes
30.02	Gowns resist permeability of HDs and are not laboratory coats, surgical scrubs, or isolation gowns (selected based on HDs handled).	Yes	
30.03	Gowns close in the back, are long sleeved, and have closed cuffs that are elastic or knit.	Yes	
30.04	Gowns do not have seams or closures that will allow HDs to pass through.	Yes	
30.05	Gowns are changed in accordance with the manufacturer's instructions, or if no permeation information is available, they are changed every two to three hours or immediately after a spill or splash.	Yes	
30.06	Gowns worn in HD areas are not worn to other areas.	Yes	
31.00	**Head, hair** (beard and moustache, if appropriate), **and shoe and sleeve covers.** The pharmacy is using appropriate head, hair, and shoe and sleeve covers for the type of compounding based on standards or assessment of risk to provide protection from contact with HD residue, if required.	Yes	
31.01	When HD compounding, a second pair of shoe covers are donned before entering the C-SEC and doffed when exiting the C-SEC.	Yes	First pair of shoe covers are blue and the second pair are white.
31.02	Shoe covers worn in HD areas are not worn into other areas of the facility.	Yes	
32.00	**Eye and Face Protection:** The pharmacy is using appropriate eye and face PPE protection for the activities conducted (based on assessment of risk that HDs are irritating to the eyes and mucous membranes, where there is risk of spills or splashes when working outside of a C-PEC), if required.	Yes	

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		Observation	Notes
32.01	If a risk to eyes, goggles (or a full-face respirator) are worn. *Eyeglasses or safety glasses with side shields are not substituted for goggles.*	Yes	A face shield is worn.
32.02	If a risk to face and eyes, goggles plus a face shield (or a full-face respirator) are worn.	Yes	A face shield is worn.
33.00	**Respiratory Protection:** The pharmacy is using appropriate respiratory PPE protection for the activities conducted (receiving, transport, compounding, administration, and waste disposal) based on assessment of risk based on type of HD and type of activity, if required. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	Fit-tested N95, P100-filter and full face.
33.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
33.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	Yes	
33.03	Full-face piece, chemical cartridge-type respirator;	Yes	
33.04	PAPR; and/or	No	
33.05	Other (describe in notes).	N/A	
34.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	

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		Observation	Notes
35.00	The pharmacy uses an appropriate respiratory PPE for large HD spills; deactivating, decontaminating, and cleaning underneath the work surface of the C-PEC; and when there is known or suspected airborne exposure to powders or vapors. *Indicate what type of PPE which is available to employees (and is fit-tested, when required).*	Yes	Fit-tested N95, P100-filter and full face.
35.01	Fit-tested NIOSH-certified N95 respirator;	Yes	
35.02	Elastomeric half-mask with a multi-gas cartridge and P100-filter;	Yes	
35.03	Full-facepiece, chemical cartridge-type respirator;	Yes	
35.04	PAPR; and/or	No	
35.05	Other (describe in notes).	N/A	
36.00	Surgical masks are **not** used as PPE when respiratory protection is needed.	Yes	
37.00	**Disposal of Used PPE:** Is all PPE worn during handling of HDs considered contaminated with at least trace quantities?	Yes	
37.01	Worn PPE is placed in an appropriate HD waste container.	Yes	
37.02	The HD waste container is located in reasonable proximity to HD PPE doffing activities.	Yes	
37.03	Chemotherapy gloves, and sleeve covers if worn, are carefully removed and discarded immediately into an approved HD trace waste container inside the C-PEC or contained in a sealable bag for discarding outside the C-PEC.	Yes	

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		Observation	Notes
	Facilities and Engineering Controls		
38.00	There are signs prominently displayed before the entrance to all HD handling areas designating the hazard.	Yes	
38.01	Access to these areas are restricted to authorized personnel who have been appropriately trained.	Yes	
38.02	HD areas are located away from breakrooms/refreshment areas for personnel, patients, and/or visitors.	Yes	
39.00	There are designated HD areas for any of the following:		
39.01	Receiving and unpacking of HDs	Yes	
39.02	Storage of HDs	Yes	
39.03	Nonsterile HD compounding (if performed by the pharmacy)	Yes	
39.04	Sterile HD compounding (if performed by the pharmacy)	N/A	No sterile compounding is conducted at this pharmacy.
40.00	***Recommendation**: If there is a requirement for certain designated areas to have negative pressure from surrounding areas, is there an uninterrupted power source (UPS) to the ventilation systems in order to maintain negative pressure in the case of power loss?*	Yes	Diesel generator
41.00	**Receipt**: Are HDs received and unpacked (removed from external shipping containers) in an appropriate environment? *Describe.*	Yes	In a neutral pressure room under a BSC.

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		Observation	Notes
41.01	Antineoplastics and HD APIs are unpacked in an area with air pressure relative to surrounding areas that is either neutral or negative pressure. *Indicate the type of environment. If the environment is positive pressure, it is non-compliant.*	Yes	In a neutral pressure room under a BSC.
41.01.01	Neutral	Yes	
41.01.02	Negative	No	
42.00	HDs are not unpacked in a sterile compounding area (eg, no external containers are brought into C-SEC).	N/A	No sterile compounding is conducted at this pharmacy.
43.00	**Storage**: Are HDs stored in a manner to minimize accidental exposure? *Describe.*	Yes	All HDs are stored in a negative pressure room until their final dosage form.
43.01	HDs are not stored on the floor.	Yes	
43.02	HDs are stored in a manner to minimize breakage and spillage.	Yes	
43.03	If facility is in an area prone to specific types of natural disasters, appropriate precautions are taken (eg, raised front lips on shelving in earthquake prone areas).	N/A	The shelves are 15 inches deep and liquids are stored in a bin. All HDs are stored within arms reach.
44.00	Antineoplastic HDs that require manipulation (other than counting and repackaging final dosage forms) and HD API are stored separately from non-HDs.	Yes	
44.01	These HDs are stored in an externally ventilated, negative pressure room.	Yes	

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		Observation	Notes
44.02	The HD storage room has at least 12 air changes per hour (ACPH).	Yes	
44.03	Refrigerated antineoplastic HDs are stored in a dedicated refrigerator in a negative pressure area with at least 12 ACPH (eg, storage room, buffer room, or containment segregated compounding area [C-SCA]).	Yes	
44.04	**Recommendation:** *If the refrigerator is located in a buffer room, is an exhaust located adjacent to the refrigerator's compressor and behind the refrigerator?*	Yes	
45.00	If non-antineoplastic, reproductive risk only, and final dosage forms of antineoplastics are stored with other non-HD inventory, there is a written policy/SOP addressing it.	Yes	
46.00	**Compounding:** There are appropriate engineering controls to protect the HD preparation from cross-contamination, and if sterile compounding, from microbial contamination, during all phases of the compounding process.	Yes	
47.00	All HD compounding are performed within a C-PEC located in a C-SEC room.	Yes	
47.01	The C-SEC for both sterile and nonsterile HD compounding has all of the following:		
47.01.01	Has fixed walls;	Yes	
47.01.02	Is externally vented;	Yes	

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		Observation	Notes
47.01.03	Is able to meet (12) or exceed ACPH requirements;	Yes	
47.01.04	Is physically separated (ie, a different room) from other preparation areas; and	Yes	
47.01.05	Has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to all adjacent areas.	Yes	
48.00	The C-PEC operates continuously if it supplies some or all of the negative pressure in the C-SEC or if it is used for sterile compounding.	Yes	
49.00	There is a sink readily available for handwashing on the hazardous side.	Yes	
49.01	There is an eyewash station readily available.	Yes	
49.02	Water sources and drains are a minimum of 1 meter away from the C-PEC.	Yes	
50.00	Does the pharmacy engage in **nonsterile HD compounding**? If yes, complete 50.01-54. If no, skip to 55:	Yes	
50.01	Select the location where **nonsterile HD compounding** is performed type(s):		
50.01.01	C-PECs used for sterile HD compounding are located in a different room than C-PECs used for nonsterile HD compounding	N/A	No sterile compounding is conducted at this pharmacy.

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		Observation	Notes
50.01.02	C-PECs used for sterile HD compounding are located in the same room as C-PECs used for nonsterile HD compounding.	N/A	No sterile compounding is conducted at this pharmacy.
50.02	Select the type(s) of containment primary engineering control(s) used for **nonsterile HD compounding**:		
50.02.01	Class I biological safety cabinet (BSC)	Yes	
50.02.02	Class II BSC	No	
50.02.03	Containment ventilated enclosure (CVE)	No	
50.02.04	Compounding aseptic containment isolator (CACI)	No	
50.02.05	Other, describe	No	
51.00	Indicate if the C-PEC used for **nonsterile HD compounding** (must be one of two below in order to be compliant):		
51.01	Is externally vented *(preferred)* ; **and/or**	No	
51.02	Has redundant High Efficiency Particulate Air (HEPA) filters in series	Yes	
52.00	Does the pharmacy use the same C-PEC (Class II BSC or CACI) used for sterile HD compounding and nonsterile HD compounding?	N/A	No sterile compounding is conducted at this pharmacy.
52.01	Is **nonsterile HD compounding** only "occasional"? / *If yes, please describe frequency and quantity.*	No	

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		Observation	Notes
52.02	Is the **nonsterile HD compounding** activity only occurring when sterile HD compounding is not being performed?	N/A	No sterile compounding is conducted at this pharmacy.
52.03	Is the C-PEC decontaminated, cleaned, and disinfected prior to resuming sterile compounding?	N/A	No sterile compounding is conducted at this pharmacy.
53.00	The C-SEC has at least 12 ACPH. *Verify documentation and monitoring.*	Yes	Last certified on April 15, 2024.
54.00	The ceilings, walls, floors, fixtures, shelving, counters, and cabinets are smooth, impervious, free from cracks and crevices, and non-shedding. *If non-compliant describe.*	Yes	
55.00	Does the pharmacy engage in **sterile HD compounding**? If yes, complete 55.01-61.02.03. If no, skip to 62.	No	
55.01	Select the type(s) of containment primary engineering control(s) used for **sterile HD compounding**:		
55.01.01	CACI	N/A	
55.01.02	Class II BSC, Type A1 (formerly Type A and not suitable for volatile toxic chemicals and volatile radionuclides)	N/A	
55.01.03	Class II BSC, Type A2 (formerly Type B3)	N/A	
55.01.04	Class II BSC, Type B1	N/A	
55.01.05	Class II BSC, Type B2 (total exhaust for volatile components)	N/A	

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		Observation	Notes
55.01.06	Class III BSC	N/A	
55.01.07	LAFW (not for antineoplastics)	N/A	
55.01.08	CAI (not for antineoplastics)	N/A	
56.00	The C-PEC maintains ISO Class 5 or better air quality and is under continuous operation, unless power loss or repair occurs.	N/A	
57.00	Is the C-PEC used for **sterile HD compounding** externally vented?	N/A	
58.00	If a BSC or CACI that is used for **sterile HD compounding** is also used for non-HD preparations, is the non-HD preparation placed into a protective outer wrapper during removal from the C-PEC?	N/A	
58.01	If used for both, is the non-HD preparation labeled to require PPE handling precautions?	N/A	
59.00	If the C-SEC is an unclassified containment segregated HD compounding area (C-SCA: enclosed separate room with fixed walls, but not ISO classified), beyond-use dates (BUDs) are limited in accordance with <797> as Category 1 compounded sterile preparations.	N/A	
59.01	The C-SEC (C-SCA) has at least 12 ACPH. *Verify documentation and monitoring.*	N/A	
59.02	A handwashing sink is at least one meter or more away from the C-PEC	N/A	

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		Observation	Notes
59.02.01	Describe whether the sink is inside the C-SCA or directly outside the C-SCA		
60.00	If BUDs are longer than the Category 1 BUDs specified in <797>, the PEC is located in a C-SEC, which is an ISO Class 7 buffer room adjacent to an ISO Class 7 anteroom.	N/A	
60.01	The buffer room has fixed walls.	N/A	
60.02	The buffer room is externally vented.	N/A	
60.03	The buffer room has HEPA-filtered supply air.	N/A	
60.04	The buffer room has at least 30 ACPH.	N/A	
60.05	The buffer room has a negative pressure differential of between 0.01 inches and 0.03 inches of water column relative to the anteroom.	N/A	
60.06	The anteroom has fixed walls.	N/A	
60.07	The ante room has a minimum of 30 ACPH of HEPA-filtered supply air.	N/A	
60.08	The ante room maintains positive pressure of at least 0.02 inches water column relative to any adjacent unclassified areas.	N/A	
60.09	The handwashing sink is located in the anteroom at least 1 meter or more away from the door to the buffer room to prevent contamination into the negative pressure buffer room.	N/A	

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		Observation	Notes
61.00	If the negative-pressure HD buffer room is entered through a positive-pressure non-HD buffer room, there is a line of demarcation within the buffer room for donning and doffing PPE.	N/A	
61.01	There is a design and method to contain and minimize HD contamination when **transporting** HDs, HD CSPs, and HD waste into and out of the negative pressure buffer room:	N/A	
61.02	Indicate how HD contamination is minimized:		
61.02.01	Pass-through chamber between negative pressure buffer room and adjacent space included in the facility's certification not compromising air quality in the buffer room *(verified in the facility's semi-annual certification report that pass through has not compromised air quality in the buffer room).*	N/A	
61.02.02	Use of sealed containers	N/A	
61.02.03	Other, *describe*	N/A	
	Environmental Quality and Control - Surface wipe sampling		
62.00	**Recommendation: Surface wipe sampling** is performed routinely (initially and at least every six months) to monitor HD containment processes and trends, which includes all of the following:	No	
62.01	Interior of C-PEC and equipment within the C-PEC	N/A	
62.02	Pass-through chambers	N/A	
62.03	Surfaces in staging or work areas near the C-PEC	N/A	
62.04	Areas adjacent to the C-PEC (eg,. floors directly under, staging, and dispensing areas)	N/A	
62.05	Areas immediately outside the HD buffer room or the C-SCA	N/A	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Hazardous Drugs - Handling in Health Care Settings

The information and comments obtained in the Hazardous Drugs - Handling in Health Care Settings Inspection is based on USP Chapter <800>.

Any items marked "Recommendation" are considered "best practices" and are not considered requirements for compliance with USP standards, but the information is collected as it may be a requirement under state law.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	Receiving		
63.00	**Recommendation**: HDs are packaged by the supplier in impervious plastic to segregate them from other drugs and decrease possibility of exposure during unpacking and internal transfer.	Yes	
64.00	HDs are delivered to the HD storage area immediately after unpacking.	Yes	
65.00	A spill kit is readily accessible in the receiving area.	Yes	
66.00	Containers are visually examined for signs of damage or breakage prior to opening.	Yes	
67.00	If a shipping container appears damaged and does not need to be opened, it is sealed, enclosed in an impervious container, labeled "hazardous" on the outside, and returned to the supplier after contact or disposed of as hazardous waste.	Yes	
67.01	If a damaged shipping container must be opened, it is done so according to SOPs, to include sealing the container in plastic or an impervious container, transporting it to the C- PEC for unpacking, removing, and wiping the outside of the undamaged items with disposable wipes, resealing the damaged items in an impervious container and marking it "hazardous," returning it to the supplier after contact or disposing as hazardous waste, and deactivating, decontaminating, and cleaning the C-PEC.\	Yes	
68.00	Damaged packages are considered spills and reported to the designated person. ***List last date of damaged package receipt.***	Yes	No damaged package has been received from a vendor at the time of this inspection.

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	Labeling, Packaging, Transport, and Disposal		
69.00	HDs requiring special HD handling are always clearly labeled as hazardous during transport and in accordance with any laws related to labeling of HDs.	Yes	
70.00	Labeling processes do not introduce contamination into non-HD handling areas.	Yes	
71.00	Packaging materials are chosen that protect the HD and healthcare worker against damage, leakage, contamination, and degradation during transport, but also maintains the physical integrity, stability, and sterility of the HD.	Yes	
72.00	Pneumatic tubes are not used for transporting any liquid HDs or antineoplastic HDs.	N/A	No pneumatic tubes in pharmacy.
73.00	Labeling on HDs shipped outside the pharmacy meets all of the following requirements:		No shipping of HDs that require labeling on the outside per PIC Thakrar.
73.01	Labeling specified in SDS for transport;	N/A	
73.02	Storage and disposal instructions; and	N/A	
73.03	Labeled with HD category.	N/A	

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	Dispensing, Packaging, and Compounding Processes		
74.00	Counting of antineoplastics is done by hand (eg, not placed into automated counting devices).	Yes	
75.00	Clean, dedicated (not used for non-HD purposes), or disposable equipment is used for counting, packaging, and compounding of HDs.	Yes	
75.01	**Recommendation:** Equipment is decontaminated after every use.	Yes	Clorox Healthcare Hydrogen Peroxide Cleaner Disinfectant and IPA 70%
75.02	**Recommendation:** When compounding, a plastic-backed preparation mat is placed on the C-PEC work surface and changed and discarded appropriately as HD waste. All of the following should apply in order to make this a Yes.	Yes	
75.02.01	Immediately if a spill occurs	Yes	
75.02.02	Regularly during use	Yes	
75.02.03	At the end of a shift	Yes	
76.00	APIs or other powdered HDs are handled in a C-PEC during particle-generating activities, such as crushing, opening capsules, and weighing powders.	Yes	

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
	Deactivating and Decontaminating (Cleaning and Disinfecting are performed in accordance with Chapters <795> and <797>)		
77.00	The pharmacy has chosen appropriate oxidizing agent(s) for deactivation and decontamination and proven effective by testing.	Yes	Clorox Healthcare Bleach Germicidal Cleaner and Clorox HealthcareHydrogen Peroxide Cleaner Disinfectant
78.00	Wipes or other appropriate delivery mechanisms (eg, not a spray bottle) are used for deactivation and decontamination.	Yes	
79.00	The C-PEC must be decontaminated. *All of the following must be done to be compliant:*	Yes	
79.01	Between compounding of different HDs	Yes	
79.02	At least daily when used	Yes	
79.03	Any time a spill occurs	Yes	
79.04	Before and after certification	Yes	
79.05	Any time voluntary interruption occurs	Yes	
79.06	If the ventilation tool is moved	Yes	
80.00	HD containers are wiped down prior to placing them in the C-PEC and the solution used does not alter the product label.	Yes	

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Facility Name: CareFirst Specialty Pharmacy LLC dba CareFirst Specialty Pharmacy LLC
e-Profile ID: 1182848
Inspection Date: 1/23/2025 & 1/27/2025

		Observation	Notes
81.00	Areas, other than the work surface of the C-PEC, where contamination can build up (such as areas under the work tray), are deactivated, decontaminated, and cleaned at least monthly.	Yes	
82.00	Additional PPE (eg, respirator) is used in accordance with SOPs, to protect the worker if containment airflows are compromised by opening the cabinets to get to these areas.	Yes	
	Spill Control		
83.00	Spills are contained and cleaned immediately.	Yes	
84.00	Trained/qualified personnel are always available during operation with HDs to handle spills.	Yes	
85.00	Only trained/qualified personnel engage in spill containment and cleanup.	Yes	
86.00	There are signs available to restrict access to spill areas.	Yes	
87.00	Spill kits, containing all ingredients necessary to clean HD spills, are readily available in all areas where HDs are routinely handled.	Yes	
88.00	Spill materials are disposed of as hazardous waste.	Yes	
89.00	The circumstances and management of all spills are documented. ***Review documentation for spills for the last year and list the most recent date.***	Yes	Spill on 03/07/2024 of approximately 400 mls of ethoxy diglycol.

4NNN

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	☐ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH PH03172		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Flexcare Specialty Services, LLC

Physical Address: 6671 Southwest Freeway Suite 800

City: Houston State: TX Zip: 77074

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 713-360-2100 Toll Free # (NAC 639.708, NRS 639.23286): 866-205-4239

Fax: 855-222-2514 Contact Email: [redacted]

Website: https://flexcareinfusion.com/specialty-pharmacy

Nevada Business License # (if applicable) NV20232681777

Supervising/Managing Pharmacist Name (NRS 639.220): Kathleen Ann Kimball-Doyle

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21419

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Kathleen Ann Kimball-Doyle	NV Pharmacist Registration #: 21419
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Texas

Parent Company (if any): Measure Health Innovations, LLC

Corporation/Organization Name: Flexcare Specialty Services, LLC

Mailing Address: 6671 Southwest Freeway Suite 800

City: Houston State: TX Zip: 77074

Telephone: 713-360-2100 Email: [redacted]

Contact Person Name: David Vermeulen

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President (title) for Flexcare Specialty Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

David Vermeulen

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3-18-25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, David Vermeulen hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice President (title) for Flexcare Specialty Services, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 18 day of MARCH, 2025

Notary Public

K. RUIZ
COMM. # 2381402
SAN JOAQUIN COUNTY
NOTARY PUBLIC-CALIFORNIA
MY COMMISSION EXPIRES
NOVEMBER 03, 2025

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Vermeulen

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3-18-25

Date

Board Use Only	Date Received: 4/15/25	Amount: $500 - CK 1000002096

Flexcare Specialty Services, LLC
List of all Officers and Directors

Name	Title
Aaron Smith	President
David Vermeulen	Vice President

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Certificate of Formation for FlexCare Specialty Services, LLC (file number 804683809), a Domestic Limited Liability Company (LLC), was filed in this office on August 12, 2022.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on March 18, 2025.

Jane Nelson
Secretary of State

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Flexcare Specialty Services, LLC

Pharmacy/Wholesaler License # (if applicable) PH03172

Physical Address 6671 Southwest Freeway Suite 800

City Houston State TX Zip 77074

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 713-360-2100 Website flexcareinfusion.com/specialty-pharmacy/

Licensing Company Email rx@flexcarespecialty.com

Section 2: Personal Information

First Kathleen Middle Ann Last Kimball-Doyle

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Houston State TX Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	X	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UT Austin		8/78-12/81	
Address	**City**	**State**	**Zip**
2515 Speedway	Austin	TX	78712
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
SWTSU		8-/76-5/78	
Address	**City**	**State**	**Zip**
601 University Dr.	San Marcos	TX	78666
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
New Braunfels High School		8-/72-6/76	
Address	**City**	**State**	**Zip**
2551 TX337 Loop	New Braunfels	TX	78130
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Flexcare Specialty Services			11-2022 to present
Business Address	**City**	**State**	**Zip**
6671 SW Freeway, Suite 800	Houston	TX	77074
Phone	**Title**		**Number of Employed Hours**
7133602100	PIC		5200

Description of Duties

PIC, licensing, dispensing, ordering, audits, verifying prescriptions, verifying any questions with MD.

Business Name			From - To (MM/YY – MM/YY)
Biocure Pharmacy			5-2012 to 11-2022
Business Address	**City**	**State**	**Zip**
6671 SW Freeway, Suite 800	Houston	TX	77074
Phone	**Title**		**Number of Employed Hours**
866 205 4239	PIC		20800

Description of Duties

PIC, licensing, dispensing, ordering, audits, verifying prescriptions, verifying questions with MD, care plans

Business Name			From - To (MM/YY – MM/YY)
LTC Pharmacy			5-2005 to 3-2012
Business Address	**City**	**State**	**Zip**
1718 zn. Fry Rd #125	Houston	TX	77084
Phone	**Title**		**Number of Employed Hours**
2814927220	Rph		

Description of Duties

Filling prescriptions, compounding IV's, after hours calls

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	X	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
7/22/2002	9/19/2023	TX	Houston	Harris
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
H-03-027-A		Texas Board of Pharmacy		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

see attached statement

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3-10-25

Date

I, Kathleen Kimball-Doyle, **certify that as the designated representative for**

FLEXCARE SPECIALTY SERVICES,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. X I am at least 21 years of age;
3. X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. X I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. X I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. X I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. X I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Kathleen Kimball-Doyle
Print Name (First, Last)

[redacted]
Original Signature (electronic, copies or stamps not accepted)

3-10-25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kathleen Kimball-Doyle

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3-10-25

Date

Please have this section completed in the presence of a Notary Public.

State of Texas, ss. County of Harris

I, Kathleen Kimball-Doyle being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3-10-25

Date

Subscribed and Sworn to before me this 3/10 day of 2025.

Judy Thompson

Notary Public Signature

Judy Ann Thompson
My Commission Expires
10/19/2027
Notary ID 134612186

(Seal)

TEXAS STATE BOARD OF PHARMACY

Re:	Kathleen Kimball-Doyle, R.Ph.
License No.:	26081
Date Issued:	March 3, 1982
Licensure Status:	Active
Expiration Date:	June 30, 2025
Granted by:	Examination
Prior Disciplinary Orders:	Yes

The Texas State Board of Pharmacy maintains records regarding licensure and disciplinary action against a licensee. Kathleen Kimball-Doyle, R.Ph. (Texas Pharmacist License #26081) has been subject to disciplinary action by the Texas State Board of Pharmacy (see attached).

Form Completed by:

Eamon D. Briggs
Deputy General Counsel
Texas State Board of Pharmacy

September 19, 2023
Date

1801 Congress Avenue Suite 13.100 Austin, Texas 78701-1319 512-305-8000 (voice) 512-305-6778 (fax) www.pharmacy.texas.gov

AGREED BOARD ORDER #H-03-027-A

RE: IN THE MATTER OF KATHLEEN ANN KIMBALL-DOYLE (PHARMACIST LICENSE #26081)

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy the matter of pharmacist license number 26081 issued to Kathleen Ann Kimball-Doyle, [redacted]

By letter dated October 23, 2003, the Texas State Board of Pharmacy gave preliminary notice to Kathleen Ann Kimball-Doyle of its intent to take disciplinary action with respect to pharmacist license number 26081 issued to Kathleen Ann Kimball-Doyle. This action was taken as a result of an investigation which produced evidence indicating that Kathleen Ann Kimball-Doyle may have violated:

Section 565.001(a)(1), (2), (12), and (13) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Subtitle J (Vernon 2001);

Section 281.7(a)(12), (13), and (29); Section 291.31(1), (17), and (18); Section 291.32(b)(1)(D) and (E); Section 291.32(b)(2)(B), (C), and (D); Section 291.33(c)(7)(A)(xiii); and Section 295.3(b) of the Texas Pharmacy Rules of Procedure, 22 TEX. ADMIN. CODE (2002); and

Section 431.003; Section 431.021(a), (b), and (r); and Section 431.112(a)(1) of the Texas Food Drug and Cosmetic Act, TEX. HEALTH AND SAFETY CODE ANN. (Vernon 2001), in that, allegedly:

COUNT

On or about July 22, 2002, Kathleen Ann Kimball-Doyle, while acting as an employee (staff pharmacist) of PharMerica, 1289 North Post Oak Boulevard, #130, Houston, Texas, 77055, dispensed 120 Glyburide 5mg tablets to patient J.B., a fifty-year-old mentally retarded patient, on a new telephonic prescription calling for 120 Oxybutynin 5mg tablets. The prescription container was a prepackaged unit labeled as containing 120 Glyburide 5mg tablets. The prescription label affixed to the prepackaged unit at the time of delivery indicated that 120 Oxybutynin 5mg tablets was dispensed. After taking approximately sixteen doses of the incorrect medication, patient J.B.'s blood sugar level was low. Patient J.B, who was not a diabetic, became unresponsive and was admitted into Memorial Hermann

Hospital on August 7, 2002. The medical records of patient J.B. indicate a diagnosis of hypoglycemia with elevations; the patient was discharged on August 9, 2002, with instructions to follow-up in the clinic at the group home. The prescription was assigned prescription #4480786.

An informal conference was held in the office of the Texas State Board of Pharmacy on December 10, 2003, with Kathleen Ann Kimball-Doyle, R.Ph., and William L. Mertz, Legal Counsel for Kathleen Ann Kimball-Doyle, in attendance. The informal conference was heard by a Board panel comprised of: W. Michael Brimberry, R.Ph., M.B.A., Board Member; Gay Dodson, R.Ph., Executive Director/Secretary; and Carol Fisher, R.Ph., M.P.A., Director of Enforcement; with Kerstin E. Arnold, General Counsel. Also in attendance were: Stephanie C. Chambers, Assistant General Counsel, and Joe Lewis, Chief Investigator.

At the aforementioned conference, William L. Mertz stated he was present for and on behalf of Kathleen Ann Kimball-Doyle. By their appearance at the informal conference and by their signatures on this Order, Kathleen Ann Kimball-Doyle and William L. Mertz agree that the Texas State Board of Pharmacy has jurisdiction in this matter and do hereby waive the right to notice of hearing, to a formal administrative hearing, and to judicial review of this Order.

After discussion of the matters previously outlined in this Order, and subsequent communications, Kathleen Ann Kimball-Doyle and William L. Mertz agreed to the entry of an Order disposing of the need for further disciplinary action in this matter. By their signatures on this Order, Kathleen Ann Kimball-Doyle and William L. Mertz neither admit nor deny the truth of the matters previously set out in this Order with respect to the above alleged violations.

Should this Order not be accepted by the Board, it is agreed that neither the presentation of the Order to the Board nor the Board's consideration of the Order, will be deemed to have unfairly or illegally prejudiced the Board or its individual members and, therefore, will not be grounds for precluding the Board or any individual member of the Board from further participation in proceedings related to the matters set forth in the Order.

Kathleen Ann Kimball-Doyle and William L. Mertz understand that any failure to comply with the terms of this Order is a basis for discipline under the Texas Pharmacy Act.

At the conclusion of the aforementioned conference, and subsequent communications, it was agreed among the parties that Kathleen Ann Kimball-Doyle shall comply with the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Texas State Board of Pharmacy does hereby ORDER that pharmacist license number 26081 held by Kathleen Ann Kimball-Doyle (hereinafter referred to as "Respondent") shall be, and such license is hereby reprimanded.

It is further ORDERED that Respondent shall obtain twelve (12) hours of continuing education with a portion of such hours relating to the prevention of dispensing errors, which shall be in addition to the hours of continuing education required for relicensure. Respondent shall submit proof of completion of the continuing education hours to the Texas State Board of Pharmacy, Enforcement Division, within one (1) year of the entry of this Order. All continuing education must be in compliance with the continuing education requirements set forth in Section 295.8 of the Texas Pharmacy Rules, and must be completed after the entry of this Order and before one (1) year after the entry of this Order.

It is finally ORDERED that failure to comply with any of the terms and conditions in this Order constitutes a violation and shall be grounds for further disciplinary action against the Texas pharmacist license held by Respondent.

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 5th day of May, 2004.

W Michael Brimberry RPh
MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Gay Dodson, R.Ph., Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

[redacted]
Kathleen Ann Kimball-Doyle, R.Ph.

William L. Mertz, Legal Counsel for Kathleen Ann Kimball-Doyle
Director, Legal Affairs & Counsel
PharMerica, Inc.
175 Kelsey Lane
Tampa, Florida 33619

Kerstin E. Arnold, General Counsel
Texas State Board of Pharmacy

S:\Attorneys\Pnl\Kimball_Doyle_ABO.wpd

CONFIDENTIAL/EXEMPT FROM FREEDOM OF INFORMATION ACT AND SIMILAR STATE REQUESTS

Ownership Information

NV License Number: PH03172

Ownership & Leadership of Applicant Entity

Applicant

FlexCare Specialty Services, LLC
6671 Southwest Freeway, Suite 800
Houston, TX, 77074

Ownership & Leadership of FlexCare Specialty Services, LLC

Ownership: FlexCare Specialty Services, LLC is wholly owned (100%) by Measure Health Innovations, LLC

Officers of FlexCare Specialty Services, LLC

Aaron Smith	President
David Vermeulen	Vice President

Ownership & Leadership of Measure Health Innovations, LLC

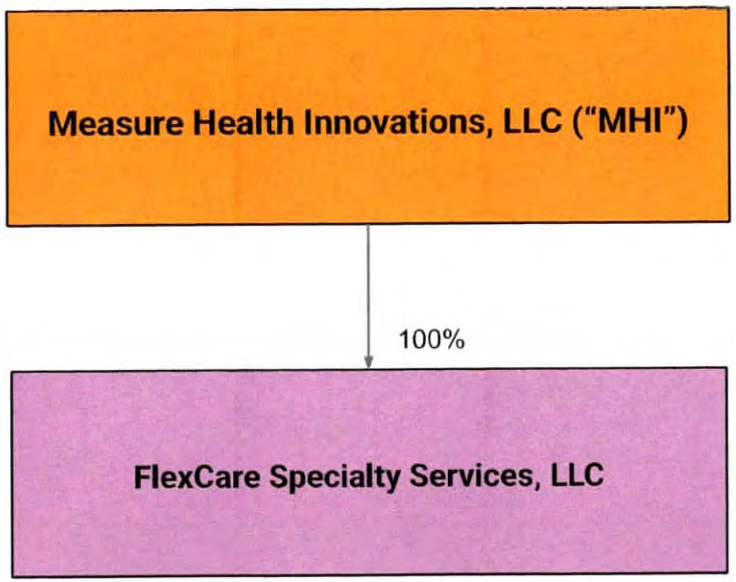
Ownership: Upon the change of ownership transaction closing on March 17, 2025, Measure Health Innovations, LLC will be acquired by OptumRX Holdings, LLC. OptumRx Holdings, LLC is ultimately owned by UnitedHealth Group Inc., a publicly traded company. Please see ownership organizational chart for the list of 100% owned subsidiaries between OptumRx Holdings, LLC and UnitedHealth Group Inc.

Ownership Information of UnitedHealth Group Inc.

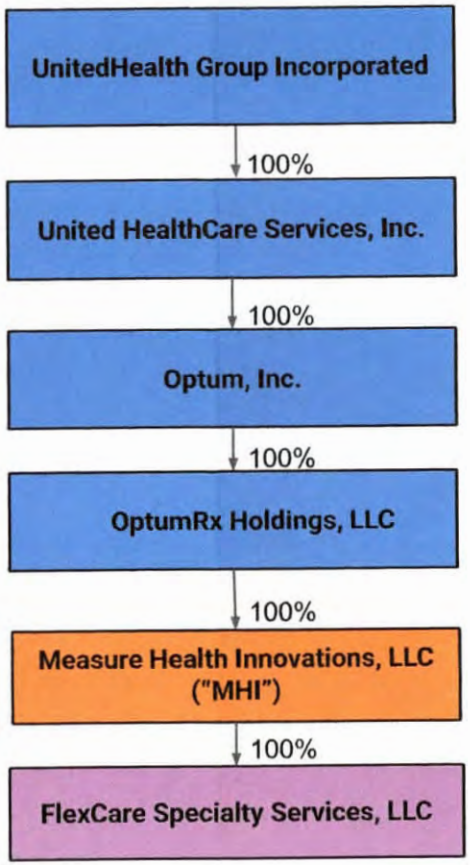
Ownership: UnitedHealth Group Inc. is a publicly traded company listed as UNH on the NYSE. UnitedHealth Group Inc. registered with the Securities and Exchange Commission on February 2, 1995, and is assigned registration number (CIK) 0000731766.

Pre-Close Ownership Organization Chart

February 1, 2025



Post-Close Ownership Organizational Chart



Texas State Board of Pharmacy
1801 Congress Avenue, Suite 13.100
Austin, TX 78701
512-305-8000

Inspection Report

Facility Information

Name: *FLEXCARE SPECIALTY SERVICES, LLC* **License Number:** *34561*

Class of License: *A*

Inspection Information

Type: *Compliance* **Purpose:** *Licensee Request*

Date: *02/19/2025* **Arrival Time:** *10:15 AM* **Departure Time:** *1:15 PM*

Action Taken: *Inspection*

General Comments:

Pharmacy holds active DEA license but does not order CS.
Pharmacy holds active out of state licenses in AL, AK, AR, CO, CT, FL, GA, ID, IL, IN, IA, KY, LA, ME, MD, MI, MS, MO, NV, NH, NJ, NM, NY, NC, OH, OK. PA, RI, TN, TX, VA, WA, WV, WI.

Licenses/Registration

Verify personnel have active licenses & address with PIC/RPh if necessary	*Satisfactory*
01. Required licenses posted	*Satisfactory*
09. Active licenses/certifications	*Satisfactory*
62. No aiding and abetting	*Satisfactory*
65. Proper registration procedures	*Satisfactory*
79. Identification badges	*Satisfactory*

Inventory Records

15. Change of PIC inventory	*Not Applicable*
17. Meets inventory requirements	*Satisfactory*
59. Proper drug destruction	*Satisfactory*
68. Change of ownership controlled substance inventory	*Not Applicable*
69. Annual controlled substance inventory	*Satisfactory*

Comment

Annual controlled substance inventory completed on: 05/01/2024 at 9am.

Notifications

31. Closed pharmacy (Is pharmacy engaged in the business described in application for licensure?) *Satisfactory*

34. Notifications *Satisfactory*

76. PIC (Does the pharmacy have a pharmacist-in-charge?) *Satisfactory*

Environment/Equipment/Security

03. Orderly/Clean *Satisfactory*

04. Balance inspection *Satisfactory*

Comment

Number of balances: zero balance on site.

05. Equipment Inspection *Satisfactory*

07. Security *Satisfactory*

08. Environment *Satisfactory*

48. Drugs (procurement, temperature, security, out-of-date, samples) *Satisfactory*

90. TSBP complaint notification *Satisfactory*

Controlled Substances

10. Prescriptions separated *Satisfactory*

24. Theft/Loss *Satisfactory*

Comment

No theft or loss has occurred.

26. Controlled substance prescription compliance *Not Applicable*

Comment

Pharmacy does not currently order, stock, or dispense any C/S.

30. Controlled substance invoices dated/initialed by pharmacist *Not Applicable*

Comment

Pharmacy does not currently order, stock, or dispense any C/S.

35. Controlled substance invoices separated *Not Applicable*

Comment

Pharmacy does not currently order, stock, or dispense any C/S.

46. Drug distribution — *Not Applicable*

53. Possession of controlled substances — *Not Applicable*

Comment

Pharmacy does not currently order, stock, or dispense any C/S.

Corresponding responsibility (Does the pharmacist exercise sound professional judgment with respect to the accuracy or authenticity of a prescription drug order?) — *Satisfactory*

Labeling/Prepackaging

32. Prescription label (Is prescription label complete?) — *Satisfactory*

45. Proper dispensing/labeling — *Satisfactory*

54. Proper prepackaging procedures — *Not Applicable*

Library

06. Required Library — *Satisfactory*

Training

60. Documentation of required training — *Satisfactory*

61. Supervision of supportive personnel — *Satisfactory*

Patient/Computer/Dispensing Records

18. Records available — *Satisfactory*

22. Data processing system compliance — *Satisfactory*

25. Prescriptions (complete, retrievable, auto-refills, accelerated refills) — *Satisfactory*

37. Legal dispensing (Are valid prescriptions being dispensed by a pharmacist?) — *Satisfactory*

56. Prescription transfers — *Satisfactory*

67. Written drug information provided — *Satisfactory*

80. Patient counseling — *Satisfactory*

82. Patient Medication Records — *Satisfactory*

84. Drug regimen review — *Satisfactory*

86. Absence of pharmacist records — *Satisfactory*

Policies & Procedures/SOPs

70. Required policies & procedures/SOPs — *Satisfactory*

92. Automated dispensing policy & procedures/SOPs	*Not Applicable*

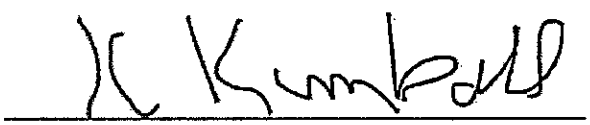
Non-Sterile Compounding

03. Orderly/Clean/Hand Hygiene	*Not Applicable*
04. Balance inspection (for non-sterile compounding)	*Not Applicable*
05. Equipment Inspection	*Not Applicable*
06. Non-sterile Library	*Not Applicable*
32. Non-sterile compound label (Is label complete?)	*Not Applicable*
38. Area/Environment for non-sterile compounding	*Not Applicable*
43. Records for non-sterile compounding	*Not Applicable*
60. Documentation of non-sterile required training	*Not Applicable*
70. Required policies & procedures/SOPs	*Not Applicable*
87. Quality Control/Assurance	*Not Applicable*

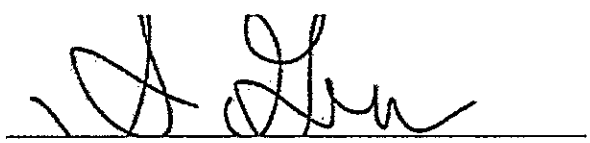
Signatures

An agent of the Texas State Board of Pharmacy has inspected your pharmacy. The results of this inspection have been noted.

- Items designated as "Refer to Legal" must be rectified immediately. In addition, the matter discovered during the inspection and deemed to be a serious violation by the inspector will be referred to the Legal Division for review and possible disciplinary action; and
- Items designated as "Warning Notice" must be corrected by the deadline noted to ensure compliance with the laws and rules governing the practice of pharmacy (Note: A "Warning Notice" is issued for a minor violation, and does not equate to disciplinary action).



KIMBALL-DOYLE, KATHLEEN ANN, PIC, 26081



Shinu George

TEXAS STATE BOARD OF PHARMACY
1801 Congress Avenue, Suite 13.100
Austin, TX 78701-1319
(512) 305-8000

License Number: 34561

(Date PDF Version Generated: 12/5/2024)

HELPFUL PHARMACY INFORMATION

- Pharmacies are required to notify TSBP within 10 days of a discontinuance of service, change of location or closure. See the TSBP website here Pharmacy - Renew & Update (texas.gov) for changes.
- Renewals open about 60 days prior to your expiration date, renewal information can be found here Renew | Pharmacy (texas.gov).
- Change of Employment or Change of PIC information can be found here Update | Employment (texas.gov).
- Change of Ownership – Call (512) 305-8021 or see Apply | Change of Ownership (texas.gov).
- For questions or assistance regarding rules, contact TSBP Rules Queue line at (512) 305-8070 see www.pharmacy.texas.gov.
- Non-Resident Pharmacy questions call (512) 305-9127 or email NonResPhcy@pharmacy.texas.gov.

An up-to-date License Verification is always available on the Board's website: http://www.pharmacy.texas.gov/

CERTIFICATE
TEXAS
BOARD OF PHARMACY

This certifies that the pharmacy named below is hereby licensed to operate as a Class **A** pharmacy.

License No. **34561** Expiration Date: **12/31/2026**

Balances: **0**

FLEXCARE SPECIALTY SERVICES, LLC
6671 SOUTHWEST FWY STE 800
HOUSTON, TX 77074

Daniel R. Carroll, Pharm.D.,
Executive Director/Secretary

MUST BE DISPLAYED IN FULL PUBLIC VIEW

TEXAS STATE BOARD OF PHARMACY

Texas Pharmacy License # 34561

FLEXCARE SPECIALTY SERVICES, LLC

License Information

License Status Active
License # 34561
Expiration Date 12/31/2026
Date License Issued 12/20/2022

Address

6671 SOUTHWEST FWY STE 800
HOUSTON, TX 77074
County HARRIS
Phone (866) 205-4239

Pharmacy Details

Prior Disciplinary Orders* No

* Information relating to disciplinary orders is current as of 30 days prior to this date. Please note that disciplinary orders entered more than 10 years ago are not available online. A written request for information regarding prior disciplinary orders may be submitted to the office of the Texas State Board of Pharmacy. Any disciplinary orders entered pursuant to Chapter 564 of the Texas Pharmacy Act are confidential and not subject to public disclosure.

Class of Pharmacy Community Pharmacy
Type of Ownership LLC
Type of Pharmacy Community Independent
# of Hospital beds

Employment Information

Pharmacist in Charge
KIMBALL-DOYLE, KATHLEEN ANN

Pharmacy Profile ¥

Accessible to disabled persons?	Yes
Participates in the Texas Medicaid program?	Yes

Translating services (Listed Below If Available)

Spanish
Vietnamese
Telecomm. for the deaf (TDD)
Other

¥ Please note: The data regarding accessibility, translating services, and insurance participation is self-reported by the license holder and no warranty regarding the information is created. Therefore, neither the State of Texas nor the licensing agency accept any legal liability or responsibility or may be held liable or responsible for the accuracy, completeness, timeliness, or usefulness of this information. Should you have any concern as to the accuracy of the data in this system, please contact the license holder or facility for clarification.

Remedial Plans and Inspection Reports

- 3276579 34561 FLEXCARESPECIALTYSERVICESLLC 2023-02 02-2028.pdf

Remedial Plans and/or Inspection Reports (if any) are shown above and subject to removal at the end of the 5th fiscal year after the Board enters the plan.

Services Provided

Nuclear	No
Out-Patient Prescriptions	No
Ship Prescription Out of State	Yes
Class D (Expanded Formulary)	No
Class D (Alternative Visit Schedule)	No
Compounding Sterile-Risk Level Low	No
Compounding Sterile-Risk Level Med	No
Compounding Sterile-Risk Level High	No
Compounding Non-Sterile	No
24 Hour Service	Yes
Closed Door	Yes
Compounding, Office Use	No
Home Delivery	Yes
Infusion	Yes
Pharmacist Administered Immunizations	No
Veterinary Prescriptions	No

In-Patient Medication Orders	No
Out-Patient Surgery	No
Rural Hospital	No
Tech Check Tech	No
503b Outsourcing Facility	No
Other Services	No

Texas Pharmacist Employment Information

Pharmacist Name	License #	Registr. Date	Expir. Date	Emp. Status	License Status
[redacted]	[redacted]	03/03/1982	06/30/2025	PIC	Active
		10/03/2002	06/30/2026	Relief	Active
		12/19/2024	08/31/2026	Staff	Active

Page 1 of 1 20 View 1 - 3 of 3

Texas Registered Technicians/Trainees Employment Information

Technician/Trainee Name	License #	Registr. Date	Expir. Date	Emp. Status	Reg. Status
[redacted]	[redacted]	11/06/2023	11/30/2025	Staff	Active
		09/08/2011	08/31/2025	Staff	Active
		06/14/2016	05/31/2026	Staff	Active
		04/12/2004	01/31/2026	Staff	Active
		06/10/2004	04/30/2026	Staff	Active

Page 1 of 1 20 View 1 - 5 of 5

Texas Remote Pharmacy Information

Remote Pharmacy Name	Registr. #	Address	City	State	Zipcode

Page 0 of 0 20 No records to view

Texas Pharmacy Owner Information

Owner Name	Owner Title	Address	City	State	Zipcode
FLEXCARE SPECIALTY SERVICES LLC	OWNER				
SMITH, AARON MICHAEL	OFFICER				

Page 1 of 1 20 View 1 - 2 of 2

The Texas State Board of Pharmacy certifies that it maintains the information for the license verification function of this website, performs daily updates to the website, and considers the website to be a secure, primary source for license verification.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	09-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-04-2023

FLEXCARE SPECIALTY SERVICES, LLC
6671 SOUTHWEST FWY STE 800
HOUSTON, TX 770742214

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	09-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-04-2023

FLEXCARE SPECIALTY SERVICES, LLC
6671 SOUTHWEST FWY STE 800
HOUSTON, TX 770742214

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4000

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH PH03690	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Mail Order	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: [redacted] ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

On-call pharmacist available 24 hours a day, 7 days a week.

Section 1: General Information

Pharmacy Name: HealthDyne Specialty Colorado, LLC

Physical Address: 7472 S. Tucson Way, Suite 100A

City: Centennial State: Colorado Zip: 80112

Mailing Address (if different from physical address): 500 Eagles Landing Drive

City: Lakeland State: Florida Zip: 33810

Telephone: 800.641.8475 Toll Free # (NAC 639.708, NRS 639.23286): 800.641.8475

Fax: 800.530.8589 Contact Email: [redacted]

Website: www.healthdyne.com

Nevada Business License # (if applicable) NV20243246210

Supervising/Managing Pharmacist Name (NRS 639.220): Michael Monroe Arnold

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): NV: 21390; CO: PHA.0015026

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Michael Monroe Arnold	NV Pharmacist Registration #: 21390
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): HealthDyne, LLC

Corporation/Organization Name: HealthDyne Specialty Colorado, LLC

Mailing Address: 500 Eagles Landing Drive

City: Lakeland State: Florida Zip: 33810

Telephone: [redacted] Email: [redacted]

Contact Person Name: Kumarie Jagnarain

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Senior Vice President & Secretary (title) for HealthDyne Specialty Colorado, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Phillip P. Bisesi

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/8/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Phillip P. Bisesi hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Senior Vice President & Secretary (title) for HealthDyne Specialty Colorado, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8th day of April, 2025

Kumarie Jagnarain

Notary Public

KUMARIE JAGNARAIN
Notary Public - State of Florida
Commission # HH 606531
My Comm. Expires Nov 1, 2028
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Phillip P. Bisesi, Senior Vice President & Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

04.08.2025

Date

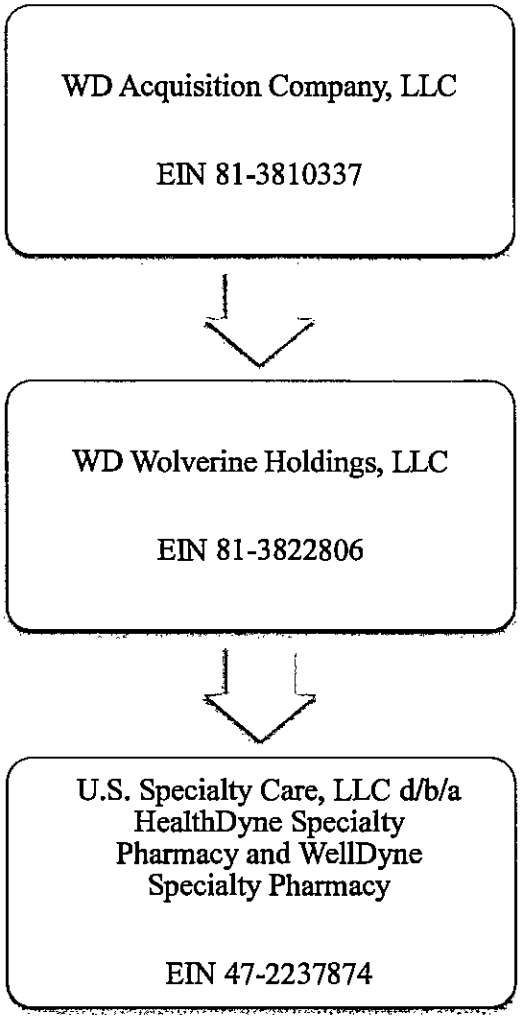
Board Use Only	Date Received: 4/4/25	Amount: [redacted]

HEALTHDYNE SPECIALTY COLORADO, LLC

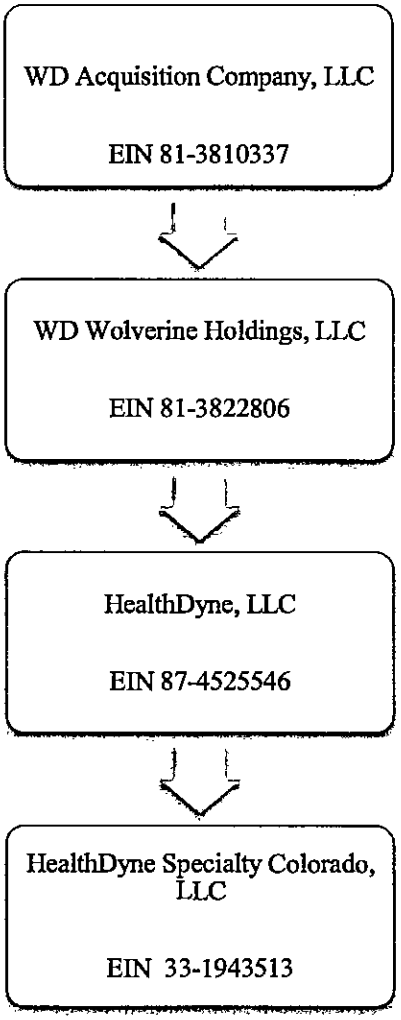
LIST OF CORPORATE OFFICERS, SOLE MEMBER

Name	Title	Address
Stephen M. Saft	Chief Executive Officer	500 Eagles Landing Drive Lakeland, FL 33810
Christopher K. Knibb	Chief Financial Officer & Treasurer	500 Eagles Landing Drive Lakeland, FL 33810
David A. Skomo	Chief Operating Officer	500 Eagles Landing Drive Lakeland, FL 33810
Phillip P. Bisesi	Senior Vice President & Secretary	500 Eagles Landing Drive Lakeland, FL 33810
HealthDyne, LLC	Sole Member	500 Eagles Landing Drive Lakeland, FL 33810

Pre-Close



Post-Close



State of Florida
Department of State

I certify from the records of this office that HEALTHDYNE SPECIALTY COLORADO, LLC is a limited liability company organized under the laws of the State of Florida, filed on November 8, 2024.

The document number of this limited liability company is L24000475042.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-eighth day of January, 2025

Secretary of State

Tracking Number: 5523460185CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HealthDyne Specialty Colorado, LLC

Pharmacy/Wholesaler License # (if applicable) PH03690

Physical Address 7472 S. Tucson Way, Suite 100A

City Centennial State CO Zip 80112-4452

Mailing Address (if different from physical address) 500 Eagles Landing Drive

City Lakeland State FL Zip 33810

Telephone 800.641.8475 Website www.healthdyne.com

Licensing Company Email administration@welldyne.com

Section 2: Personal Information

First Michael Middle Monroe Last Arnold

Alias(es, nicknames, name changes, etc.) None

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 7472 S. Tucson Way, Suite 100A

City Centennial State CO Zip 80112

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Colorado Health Sciences Center		09/94 - 05/97	
Address	**City**	**State**	**Zip**
13001 East 17th Place	Aurora	Colorado	80045
Diploma/Degree obtained, if any			
B.S. Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
West Valley College		09/90 - 05/94	
Address	**City**	**State**	**Zip**
14000 Fruitvale Avenue	Saratoga	California	95070
Diploma/Degree obtained, if any			
Pre-pharmacy Course Work			

School Name		From - To (MM/YY – MM/YY)	
Prospect High School		09/86 - 05/1990	
Address	**City**	**State**	**Zip**
18900 Prospect Road	Saratoga	California	95070
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
07/15 - Current				
From - To (MM/YY – MM/YY)				
03/11 - 07/15				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
U.S. Specialty Care, LLC dba HealthDyne Specialty Pharmacy and WellDyne Specialty Pharmacy			07/04 - Current
Business Address	**City**	**State**	**Zip**
7472 S. Tucson Way, Suite 100A	Centennial	Colorado	80112
Phone	**Title**		**Number of Employed Hours**
800.641.8475	Vice President - Specialty Operations		52,000 Hours
Description of Duties			
Pharmacist-in-Charge, Specialty Pharmacy Operations			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, Michael M. Arnold, **certify that as the designated representative for**

HealthDyne Specialty Colorado, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MA I am at least 21 years of age;
3. MA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michael M. Arnold
Print Name (First, Last)

[redacted]
Original Signature (electronic, copies or stamps not accepted)

4-7-25
Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

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Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael M. Arnold

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4-7-25

Date

Please have this section completed in the presence of a Notary Public.

State of Colorado, ss. County of Arapahoe

I, Kelsey McLean, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

April 7, 2025

Date

Subscribed and Sworn to before me this 7th day of April.

Notary Public Signature

Kelsey McLean
NOTARY PUBLIC
STATE OF COLORADO
NOTARY ID # 20254010862
MY COMMISSION EXPIRES 03-21-2029

(Seal)

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

THE COLORADO STATE BOARD OF PHARMACY
1560 Broadway, Suite 1300, Denver, CO 80202-5146
303-894-7800 FAX 303-894-7692 V/TDD 303-894-7880

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

Date of Inspection: 11/27/24 **Time In/Out:** _____/_____

PDO Name US Specialty Care **Registration No** 168-23 **Expiration Date** 10/26

Address 7472 S. Tucson Way, Ste 100-A **City** Centennial **Zip** 80112

Pharmacist Manager _____ **Llc No** _____ **Email** _____

RPH on Duty _____ **Lic No** _____ **Email** _____

Physical/Postings	Compliant?
5.01.31b&c: Clean, sanitary, adequate space	YES
5.01.31d,f&g: Hot & cold water, frig & freezer	YES
5.01.50: Pharmacy security	YES
CRS 12-280-122:RPH/tech ratio____ nametags	YES
CRS 12-280-118:Licenses and registrations posted	YES
11.08.00, 7.00.30b: Employee list, tech posting	YES
5.01.31l: Prior inspection _____# deficiencies	YES
3.00.51: Initial interpretation and final evaluation	YES
23.00.60: PDMP notice, 20.00.70; CPP notice	N/A
5.01.31h: Professional reference library	YES
Recordkeeping	
11.03.00: CS Inventory date 10/31/24 Close	N/A
11.06.00: CII, CIII-V, RX drug receipts dated	N/A
11.06.05: Receipts from registered sources	N/A
11.07.20: Casual Sale records	N/A
11.07.10: Floor stock distribution	N/A
11.04.20: Daily printouts	N/A
3.00.90b: RTS records	N/A
25.00.16: SPDO: CS inv., distribution, use records	N/A
27.00.30: HSP: CS inv., records of distribution	N/A
Dispensing	
11.04.10: Hardcopy of order filed appropriately	N/A
CII orders reviewed:_____	N/A
CIII-V orders reviewed:_____	N/A
RX orders reviewed:_____	N/A
2.01.53: Required order transfer information	N/A
2.01.10: Information to appear on each order	N/A
3.00.55: Prescription flavoring	N/A
Dispensing errors/valid prescription orders	N/A
Prescription labeling	N/A

Immunizations	Compliant?
19.01.10: Authorization, ACPE training, CPR	N/A
19.01.40: Administration records	N/A
19.01.50: Off-site administration	N/A
Non-Sterile Compounding	
21.10.10: P&P Manual annual review_____	N/A
21.10.20: Training of personnel	N/A
21.10.60: Components-expiration dating	N/A
21.10.90: Formulation records	N/A
21.11.00: Compounding records/labeling	N/A
21.10.80: Beyond use dating, studies on site	N/A
Central Prescription Processing/Remote Pharmacy Practice	
20.01.20 &26.00.20: Policy and procedure manual, written agreements _____	YES
20.00.90: Records of receipt/delivery	N/A
3.00.90e: Return to stock records	N/A
	N/A
Prepackaging/Labeling/Return Drug	N/A
3.01.20: Prepack labeling and records	N/A
3.01.22: Automated cassette labeling & records	N/A
3.03.00: Customized medication packages	N/A
3.00.80: Return for dispensing or donation	N/A
21.00.20: Casual sale of compounded products	N/A
Drug Therapy Management	
6.00.40: General authorization plan/protocols	N/A
6.00.30: Pharmacist qualifications	N/A
6.00.60: Recordkeeping	N/A
E-kits	
10.00.40: Labeling & contents of kit	N/A
10.00.71: Removal and replacement of med	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name US Specialty Care Pharmacist Manager

No deficiencies noted z

Tier 1 [✓] Tier 2 [ ]

Pursuant to CRS 12-280-108, the Colorado State Board of Pharmacy has the authority to inspect all registered outlets and investigate violations of the Board's Rules and Regulations, CRS Title 12, 280 of the Pharmacists, Pharmacy Business, and Pharmaceuticals Act; and the CRS Title 18, Article 18 of the Uniform Controlled Substance Act of 1992

I ACKNOWLEDGE THAT THE CONTENTS OF THIS INSPECTION REPORT HAVE BEEN EXPLAINED TO ME.	INSPECTOR'S SIGNATURE
11/27/24	OTHER INSPECTORS PRESENT:
PHARMACIST'S SIGNATURE DATE	

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy

US Specialty Care, LLC

HealthDyne Specialty Pharmacy, additional DBA WellDyne Specialty Pharmacy

Prescription Drug Outlet- In-State

PDO.1680000123	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy

US Specialty Care, LLC

HealthDyne Specialty Pharmacy, additional DBA WellDyne Specialty Pharmacy

Prescription Drug Outlet- In-State

PDO.1680000123	11/01/2024
Number	**Issue Date**
Active	10/31/2026
Credential Status	**Expire Date**

Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	DBA	Public Address
US Specialty Care, LLC	HealthDyne Specialty Pharmacy, additional DBA WellDyne Specialty Pharmacy	7472 S Tucson Way Ste 100A Centennial, CO 80112-4452

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
PDO.1680000123	Original	Prescription Drug Outlet- In-State	Active	09/22/2016	11/01/2024	10/31/2026

Supervision

Relationship	Supervisor/Supervisee	License	Start Date	Relationship Type
Supervised By	Michael Monroe Arnold	PHA.0015026	02/16/2017	Manager

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Generated on: 4/7/2025 1:41:12 PM

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-19-2022

US SPECIALTY CARE LLC
DBA HEALTHDYNE SPECIALTY PHARMACY, DBA WELLDYNE SPECIALTY
7472 S TUCSON WAY STE 100A
CENTENNIAL, CO 80112

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-19-2022

US SPECIALTY CARE LLC
DBA HEALTHDYNE SPECIALTY PHARMACY, DBA WELLDYNE SPECIALTY
7472 S TUCSON WAY STE 100A
CENTENNIAL, CO 80112

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

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Form DEA-223 (9/2016)

4PPP

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH PH03840	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Mail Order	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

On-Call pharmacist available 24 hours a day, 7 days a week.

Section 1: General Information

Pharmacy Name: HealthDyne Pharmacy CO, LLC

Physical Address: 7472 S. Tucson Way, Suite 100-B

City: Centennial State: CO Zip: 80112

Mailing Address (if different from physical address): 500 Eagles Landing Drive

City: Lakeland State: FL Zip: 33810

Telephone: 888.479.2000 Toll Free # (NAC 639.708, NRS 639.23286): 888.479.2000

Fax: 855.618.4615 Contact Email: [redacted]

Website: https://www.healthdyne.com/

Nevada Business License # (if applicable) NV20222414679

Supervising/Managing Pharmacist Name (NRS 639.220): Brandon Robert Green

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): NV-21332, CO-PHA.0022131

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Brandon Robert Green	NV Pharmacist Registration #: 21332
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): HealthDyne, LLC

Corporation/Organization Name: HealthDyne Pharmacy CO, LLC

Mailing Address: 500 Eagles Landing Drive

City: Lakeland State: FL Zip: 33810

Telephone: 888.479.2000 Email: [redacted]

Contact Person Name: Kumarie Jagnarain

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the SVP & Secretary (title) for HealthDyne Pharmacy CO, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Phillip P. Bisesi

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/8/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Phillip P. Bisesi hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the SVP & Secretary (title) for HealthDyne Pharmacy CO, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8th day of APRIL, 2025

Kumarie Jagnarain
Notary Public

KUMARIE JAGNARAIN
Notary Public - State of Florida
Commission # HH 606531
My Comm. Expires Nov 1, 2028
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Phillip P. Bisesi Senior Vice President & Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

04.08.2025

Date

Board Use Only	Date Received: 5/5/25	Amount: [redacted]

HealthDyne Pharmacy CO, LLC

Nevada

Non-Resident Pharmacy Application

Transfer of Ownership

HEALTHDYNE, LLC
LIST OF CORPORATE OFFICERS, SOLE MEMBER

Name	Date of Birth	Title	Address
Stephen M. Saft	[redacted]	Chief Executive Officer	500 Eagles Landing Drive Lakeland, FL 33810
Christopher K. Knibb		Chief Financial Officer & Treasurer	500 Eagles Landing Drive Lakeland, FL 33810
David A. Skomo		Chief Operating Officer	500 Eagles Landing Drive Lakeland, FL 33810
Phillip P. Bisesi		Senior Vice President & Secretary	500 Eagles Landing Drive Lakeland, FL 33810
HealthDyne, LLC		Sole Member	500 Eagles Landing Drive Lakeland, FL 33810

Pre-Close

WD Acquisition Company, LLC

EIN 81-3810337

WD Wolverine Holdings, LLC

EIN 81-3822806

WellDyneRx, LLC dba HealthDyne Pharmacy

EIN 84-1515837

Post-Close

WD Acquisition Company, LLC

EIN 81-3810337

WD Wolverine Holdings, LLC

EIN 81-3822806

HealthDyne, LLC

EIN 87-4525546

HealthDyne Pharmacy FL, LLC

EIN 33-1915543

State of Florida
Department of State

I certify from the records of this office that HEALTHDYNE PHARMACY CO, LLC is a limited liability company organized under the laws of the State of Florida, filed on November 5, 2024.

The document number of this limited liability company is L24000469597.

I further certify that said limited liability company has paid all fees due this office through December 31, 2025, that its most recent annual report was filed on January 14, 2025, and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-seventh day of January, 2025

Secretary of State

Tracking Number: 5743786227CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HealthDyne Pharmacy CO, LLC

Pharmacy/Wholesaler License # (if applicable) PH03840

Physical Address 7472 South Tucson Way, Suite 100-B

City Centennial State CO Zip 80112

Mailing Address (if different from physical address) 500 Eagles Landing Drive

City Lakeland State FL Zip 33810

Telephone 888-479-2000 Website https://healthdyne.com/

Licensing Company Email administration@welldyne.com

Section 2: Personal Information

First Brandon Middle Robert Last Green

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 7472 South Tucson Way, Suite 100-B

City Centennial State CO Zip 80112

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	N
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Butler University		08/08-05/14	
Address	**City**	**State**	**Zip**
4600 Sunset Ave.	Indianapolis	IN	46208
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Mount Vernon High School		08/04-05/08	
Address	**City**	**State**	**Zip**
700 Harriett St.	Mount Vernon	IN	47620
Diploma/Degree obtained, if any			
HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/19-Present	[redacted]			
06/18-03/19				
06/15-06/18				
08/14-06/15				
06/13-08/14				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
WellDyneRx, LLC			12/19-Present	
Business Address		**City**	**State**	**Zip**
7472 S. Tucson Way, Suite 100-B		Centennial	CO	80112
Phone	**Title**		**Number of Employed Hours**	
888.479.2000	Pharmacist-in-Charge		11,090	
Description of Duties				
Director of Pharmacy Operations				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		N/A
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted] _____ 4-8-25

Original Signature (electronic, copies or stamps not accepted) Date

I, Brandon Robert Green, **certify that as the designated representative for**

HealthDyne Pharmacy CO, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. BG I am at least 21 years of age;
3. BG I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. BG I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. BG I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. BG I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. BG I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Brandon R. Green

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4-8-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brandon R. Green

Print Name (First, Last)

[redacted] 4-8-25

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Polk

I, Brandon R. Green, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted] 4-8-25

Original Signature **Date**

Subscribed and Sworn to before me this 8th day of APRIL 2025.

Kumarie Jagnarain

Notary Public Signature

KUMARIE JAGNARAIN
Notary Public - State of Florida
Commission # HH 606531
My Comm. Expires Nov 1, 2028
Bonded through National Notary Assn.

(Seal)

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

THE COLORADO STATE BOARD OF PHARMACY
1560 Broadway, Suite 1300, Denver, CO 80202-5146
303-894-7800 FAX 303-894-7692 V/TDD 303-894-7880

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

Date of Inspection: 11/27/24 **Time In/Out:** _____/_____

PDO Name WellDyneRx **Registration No** 168-158 **Expiration Date** 10/26

Address 7472 S. Tucson Way, Ste 100-B **City** Centennial **Zip** 80112

Pharmacist Manager _____ **Lic No** _____ **Email** _____

RPH on Duty _____ **Lic No** _____ **Email** _____

Physical/Postings	Compliant?
5.01.31b&c: Clean, sanitary, adequate space	YES
5.01.31d,f&g: Hot & cold water, frig & freezer	YES
5.01.50: Pharmacy security	YES
CRS 12-280-122:RPH/tech ratio____ nametags	YES
CRS 12-280-118:Licenses and registrations posted	YES
11.08.00, 7.00.30b: Employee list, tech posting	YES
5.01.31l: Prior inspection _____# deficiencies	YES
3.00.51: Initial interpretation and final evaluation	NO
23.00.60: PDMP notice, 20.00.70; CPP notice	N/A
5.01.31h: Professional reference library	YES
Recordkeeping	
11.03.00: CS Inventory date 10/27/24 Open	YES
11.06.00: CII, CIII-V, RX drug receipts dated	YES
11.06.05: Receipts from registered sources	YES
11.07.20: Casual Sale records	N/A
11.07.10: Floor stock distribution	N/A
11.04.20: Daily printouts	NO
3.00.90b: RTS records	YES
25.00.16: SPDO: CS inv., distribution, use records	N/A
27.00.30: HSP: CS inv., records of distribution	N/A
Dispensing	
11.04.10: Hardcopy of order filed appropriately	N/A
CII orders reviewed:_____	N/A
CIII-V orders reviewed:_____	N/A
RX orders reviewed:_____	N/A
2.01.53: Required order transfer information	N/A
2.01.10: Information to appear on each order	N/A
3.00.55: Prescription flavoring	N/A
Dispensing errors/valid prescription orders	N/A
Prescription labeling	N/A

Immunizations	Compliant?
19.01.10: Authorization, ACPE training, CPR	N/A
19.01.40: Administration records	N/A
19.01.50: Off-site administration	N/A
Non-Sterile Compounding	
21.10.10: P&P Manual annual review_____	N/A
21.10.20: Training of personnel	N/A
21.10.60: Components-expiration dating	N/A
21.10.90: Formulation records	N/A
21.11.00: Compounding records/labeling	N/A
21.10.80: Beyond use dating, studies on site	N/A
Central Prescription Processing/Remote Pharmacy Practice	
20.01.20 &26.00.20: Policy and procedure manual, written agreements _____	N/A
20.00.90: Records of receipt/delivery	N/A
3.00.90e: Return to stock records	N/A
	N/A
Prepackaging/Labeling/Return Drug	NO
3.01.20: Prepack labeling and records	NO
3.01.22: Automated cassette labeling & records	NO
3.03.00: Customized medication packages	N/A
3.00.80: Return for dispensing or donation	N/A
21.00.20: Casual sale of compounded products	N/A
Drug Therapy Management	
6.00.40: General authorization plan/protocols	N/A
6.00.30: Pharmacist qualifications	N/A
6.00.60: Recordkeeping	N/A
E-kits	
10.00.40: Labeling & contents of kit	N/A
10.00.71: Removal and replacement of med	N/A

PRESCRIPTION DRUG OUTLET INSPECTION REPORT

PDO Name WellDyneRx Pharmacist Manager

1. Prepackaged amber vials shall be labeled in accordance with Rule 3.01.20. See multiple examples.

2. Prepackaging records shall include the corresponding lot number of each drug placed into cassettes. See multiple examples.

3. Please maintain at least 3 years worth of notices of initial interpretation and final evaluation.

4. Daily printouts shall include the original date each corresponding order was issued.

Tier 1 ☐ Tier 2 ☑

Pursuant to CRS 12-280-108, the Colorado State Board of Pharmacy has the authority to inspect all registered outlets and investigate violations of the Board's Rules and Regulations, CRS Title 12, 280 of the Pharmacists, Pharmacy Business, and Pharmaceuticals Act; and the CRS Title 18, Article 18 of the Uniform Controlled Substance Act of 1992

I ACKNOWLEDGE THAT THE CONTENTS OF THIS INSPECTION REPORT HAVE BEEN EXPLAINED TO ME.	INSPECTOR'S SIGNATURE
11/27/24	OTHER INSPECTORS PRESENT:
PHARMACIST'S SIGNATURE DATE	

Lookup Detail View

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	DBA	Public Address
HealthDyne Pharmacy CO, LLC		7472 S Tucson Way Ste 100-B Centennial, CO 80112-4452

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
PDO.1680000158	Original	Prescription Drug Outlet- In-State	Active	09/13/2017	11/01/2024	10/31/2026

Supervision

Relationship	Supervisor/Supervisee	License	Start Date	Relationship Type
Supervised By	Brandon R Green	PHA.0022131	10/24/2020	Manager

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

Generated on: 5/7/2025 10:46:45 AM

Lookup Detail View

3666

Licensee Information

This serves as primary source verification of the license.*

**Primary source verification: License information provided by the Colorado Division of Professions and Occupations, established by 24-34-102 C.R.S.*

Name	DBA	Public Address
WellDyneRx, LLC	HealthDyne Pharmacy	7472 S Tucson Way Ste 100-B Centennial, CO 80112-4452

Credential Information

License Number	License Method	License Type	License Status	Original Issue Date	Effective Date	Expiration Date
PDO.1680000158	Original	Prescription Drug Outlet- In-State	Active	09/13/2017	11/01/2024	10/31/2026

Supervision

Relationship	Supervisor/Supervisee	License	Start Date	Relationship Type
Supervised By	Brandon R Green	PHA.0022131	10/24/2020	Manager

Board/Program Actions

Discipline
There is no Discipline or Board Actions on file for this credential.

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3667

COLORADO
Department of Regulatory Agencies
Division of Professions and Occupations

Below are your electronic wallet cards to use as proof of your license. You can also print your license at any time by visiting www.colorado.gov/dora/DPO_Print_License and following the instructions listed.

If you would like a more durable wallet card option, you can order one for a fee by visiting www.nasbastore.org and selecting the "Colorado License Cards" link on the left hand side of the page. If you prefer, you can also contact NASBA by phone at 1-888-925-5237 or by email at nasbastore@nasba.org.

Should you have questions about your credential, or need other information please contact our Customer Service Team at 303-894-7800 or dora_dpo_licensing@state.co.us.

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
WellDyneRx, LLC
HealthDyne Pharmacy
Prescription Drug Outlet- In-State

PDO.1680000158 — **Number**
11/01/2024 — **Issue Date**
Active — **Credential Status**
10/31/2026 — **Expire Date**
Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

Colorado Department of Regulatory Agencies
Division of Professions and Occupations

State Board of Pharmacy
WellDyneRx, LLC
HealthDyne Pharmacy
Prescription Drug Outlet- In-State

PDO.1680000158 — **Number**
11/01/2024 — **Issue Date**
Active — **Credential Status**
10/31/2026 — **Expire Date**
Verify this credential at: dpo.colorado.gov

Division Director: Sam Delp | Credential Holder Signature

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-11-2023

WELLDYNERX, LLC
7472 S TUCSON WAY STE 100-B
CENTENNIAL, CO 801124452

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	04-11-2023

WELLDYNERX, LLC
7472 S TUCSON WAY STE 100-B
CENTENNIAL, CO 801124452

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

LIMITED LIABILITY COMPANY OPERATING AGREEMENT
OF
HEALTHDYNE PHARMACY CO, LLC

This LIMITED LIABILITY COMPANY OPERATING AGREEMENT (this "Agreement") of HealthDyne Pharmacy CO, LLC, a Florida limited liability company (the "Company"), is effective as of November 5, 2024, by and between the Company and WellDyneRx, LLC, a Florida limited liability company (the "Member"), as the sole member of the Company.

W I T N E S E T H:

WHEREAS, the Company was formed as a Florida limited liability company when the Articles of Organization of the Company (the "Articles of Organization") became effective upon filing with the Florida Department of State, Division of Corporations (the "DOC") pursuant to and in accordance with the Florida Revised Limited Liability Company Act, as amended (the "LLC Act"); and

WHEREAS, the Member desires that the Company operate as a Florida limited liability company upon the terms and conditions hereinafter set forth.

NOW, THEREFORE, in consideration of the mutual covenants and agreements herein contained and other good and valuable consideration, the receipt, adequacy and sufficiency of which is hereby acknowledged, the parties agree as follows:

ARTICLE I.
DEFINED TERMS; EXHIBITS, SCHEDULES, ETC.

1.1 DefinitionsAs used in this Agreement, the following terms shall have the meanings indicated below:

"Capital Contribution" means, with respect to the Member, the amount of money or property contributed to the Company by the Member from time to time.

"Membership Interest" means the Member's entire interest in the Company, which shall entitle the Member to (i) an interest in the profits, losses, distributable cash, and net proceeds of liquidation of the Company, as set forth herein; (ii) any right to vote as set forth herein or as required under the LLC Act; and (iii) any right to participate in the management of the Company as set forth herein or as required under the LLC Act. A Membership Interest is personal property and the Member shall have no interest in the specific assets or property of the Company.

"Membership Percentage" means, with respect to the Member, the Member's percentage ownership interest in the Company set forth on **Exhibit A** attached hereto, as the same may be amended from time to time to reflect the relative Capital Contribution of the Member.

"Person" means any individual, corporation, general partnership, limited partnership, limited liability company, joint venture, trust, business trust, cooperative, association or other legal entity.

1.2 ReferencesReferences to an "Exhibit" are, unless otherwise specified, to one of the exhibits attached to this Agreement, and references to an "Article" or a "Section" are, unless otherwise specified, to one of the articles or sections of this Agreement.

ARTICLE II.
ORGANIZATIONAL MATTERS

2.1 Formation of CompanyPursuant to the Articles of Organization duly filed with the DOC on November 5, 2024, the Company has been formed as a limited liability company for the purposes and upon the terms and conditions hereinafter set forth. Except as provided herein, the rights, duties and liabilities of the Member of the Company shall be as provided in the LLC Act.

2.2 NameThe name of the Company is HealthDyne Pharmacy CO, LLC, or such other name as may be selected from time to time by the Member.

2.3 PurposeThe purpose and business of the Company is to engage in any lawful business or activity permitted by the LLC Act.

2.4 TermThe term of the Company commenced on November 5, 2024 and shall continue perpetually unless earlier terminated pursuant to Section 10.1 hereof.

2.5 Principal OfficeThe location of the Company's principal office is 500 Eagles Landing Drive, Lakeland, Florida 33810 as selected by the Member. The Company may conduct business at such additional places as the Member shall deem advisable.

2.6 Registered Agent and Registered OfficeThe initial registered agent of the Company for service of process in the State of Florida and the registered office of the Company in the State of Florida shall be that person and location reflected in the Articles of Organization or such other person and location as the Member may determine from time to time. In the event the registered agent or registered office shall change, the Member shall promptly notify the DOC of such change in any manner allowed by the LLC Act.

2.7 Fiscal YearThe fiscal year of the Company shall commence on January 1 and end on December 31 of each year or such other date as the Member may select in its discretion from time to time.

ARTICLE III.
CAPITAL CONTRIBUTIONS; ETC.

3.1 Capital ContributionsThe Member shall be deemed for purposes of this Agreement to have contributed to the capital of the Company the consideration set forth opposite the Member's name on **Exhibit A** attached hereto. The Member shall not be obligated to make any additional Capital Contributions to the Company.

3.2 Withdrawal; Return of CapitalExcept as specifically provided herein, the Member shall not be entitled to any distributions from the Company or to withdraw any part of the Member's Capital Contribution prior to the Company's dissolution and liquidation or, when such withdrawal of

capital is permitted, to demand distribution of property other than money. The Member shall not be entitled to interest on its Capital Contribution.

3.3 No Appraisal RightsThe Member shall not have any appraisal rights under the LLC Act.

ARTICLE IV.
DISTRIBUTIONS AND ALLOCATIONS

4.1 DistributionsThe timing and amount of distributions shall be determined by the Member.

4.2 AllocationsThe profits and losses of the Company shall be allocated to the Member.

ARTICLE V.
ACCOUNTING AND ADMINISTRATIVE MATTERS

5.1 Books and RecordsThe Company will maintain true, complete and correct books of account of the Company, all in accordance with generally accepted accounting principles applied on a consistent basis. The books of account shall contain particulars of all monies, goods or effects belonging to or owing to or by the Company, or paid, received, sold or purchased by the Company, and all of such other transactions, matters and things relating to the business of the Company as are usually entered in books of accounts kept by Persons engaged in a business of a like kind and character or as otherwise required pursuant to the LLC Act.

ARTICLE VI.
MANAGEMENT OF COMPANY

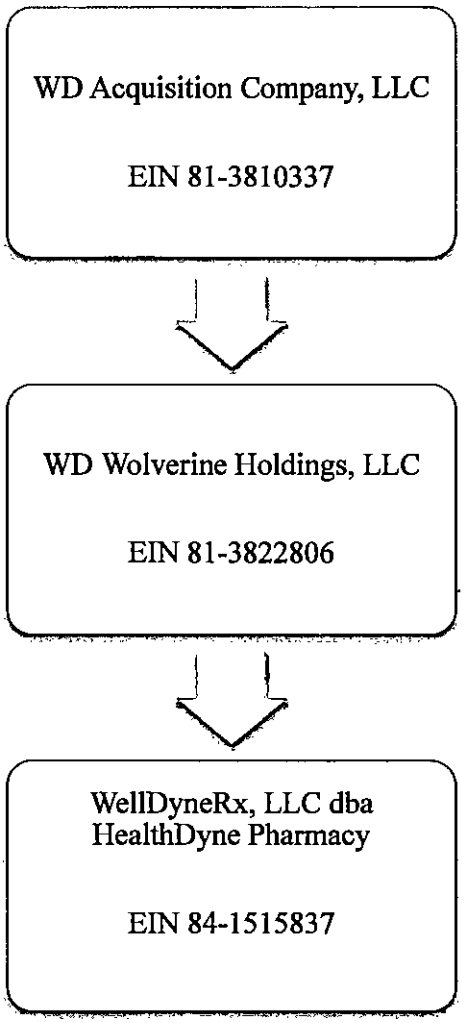
6.1 Member-ManagedExcept as specifically provided herein, the management and control of the Company shall be vested exclusively in the Member. The Member shall have the authority to appoint and remove, with or without cause, and replace, officers and assign to them such duties and provide them with such authority as it deems appropriate.

ARTICLE VII.
OFFICERS

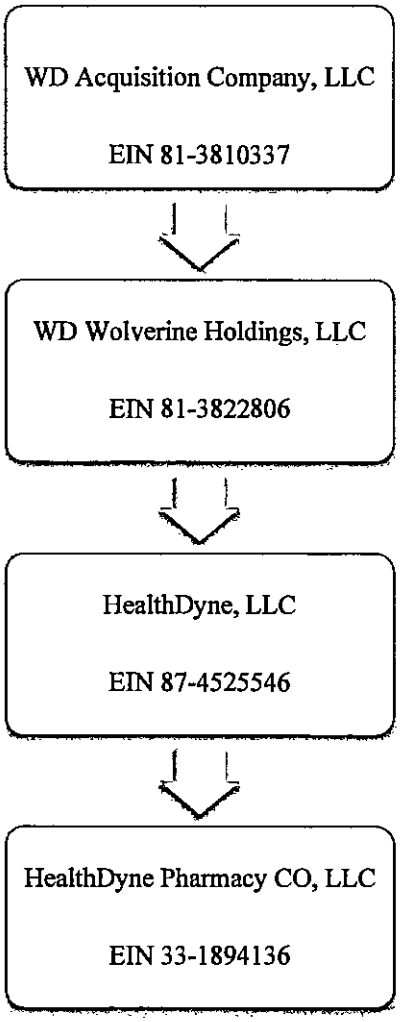
7.1 Officers: Election and Term of OfficeThe Member may (but shall not be obligated to), at any time or from time to time, designate officers of the Company (each, an "Officer"), including a Chief Executive Officer, a President or another senior officer, e.g., a Chief Operating Officer, one or more Vice Presidents, a Secretary, one or more Assistant Secretaries and a Treasurer. Vacancies may be filled or new offices may be created and filled by the Member. Each Officer shall hold office until the earlier of his or her resignation or removal, or until his or her successor shall have been duly appointed and qualified in accordance herewith. Each Officer shall perform such duties as specified in this Agreement or as may be prescribed from time to time by the Member. An individual may serve as an Officer in more than one office. The Officers of the Company are as set forth on **Exhibit B** attached hereto.

7.2 Officers: General Rights and DutiesSubject to the authority of the Member as provided in Article VI hereof, the Officers are hereby directed and authorized (which direction and authorization is revocable at any time by the Member), on behalf of and in the name of the

Pre-Close



Post-Close



Company, to implement all decisions approved by the Member and to conduct the following functions of the Company consistent with action taken by the Member:

(a) operate the day-to-day business of the Company in the ordinary course;

(b) protect and preserve the titles and interests of the Company with respect to the assets owned by or dedicated to the Company;

(c) keep all books of account and other records of the Company, in accordance with the terms of this Agreement and applicable law;

(d) carry out the responsibilities of the Company under the leasing, financing, partnership, management, operating and other contractual agreements to which it is a party;

(e) prepare and file (or cause to be prepared and filed) all necessary reports, statements, tax returns and other documents with local, state, federal, provincial, territorial, or foreign agencies or departments in connection with the business of the Company;

(f) procure and maintain insurance;

(g) employ, retain and enter into business relationships, on behalf of the Company, which are necessary or appropriate to carry out the business of the Company as shall be designated by the Member; and

(h) distribute the cash of the Company as provided in Article IV hereof and as directed by the Member.

7.3 Officers: Description of OfficesThe Officers shall have the duties and powers as set forth below:

(a) Chief Executive Officer. The Chief Executive Officer shall be the principal executive officer of the company and shall be responsible for the general care, supervision, control and direction of the business and the officers of the Company, subject only to the power and authority of the Member. The Chief Executive Officer may sign with or without the Secretary, or any other proper Officer of the Company thereunto authorized by the Member, any deeds, mortgages, bonds, contracts, or other instruments that the Member has authorized to be executed, except in cases where the signing and execution thereof shall be expressly delegated by the Member to some other Officer or agent of the Company, or shall be required by law to be otherwise signed or executed, and in general shall perform all duties incident to the office of Chief Executive Officer and such other duties as may be prescribed by the Member from time to time.

(b) President. The President shall be the principal executive officer of the company and shall be responsible for the general care, supervision, control and direction of the business of the Company, unless some other officer has been elected Chief Executive Officer of the Company. The President may sign with or without the Secretary, or any other proper Officer of the Company thereunto authorized by the Member, any deeds, mortgages, bonds, contracts, or other instruments that the Member has authorized to be

executed, except in cases where the signing and execution thereof shall be expressly delegated by the Member to some other Officer or agent of the Company, or shall be required by law to be otherwise signed or executed, and in general shall perform all duties incident to the office of President and such other duties as may be prescribed by the Member or the Chief Executive Officer from time to time.

(c) Vice Presidents. The Vice Presidents may assume and perform the duties of the President in the absence or disability of the President or whenever the office of President is vacant. The Vice Presidents shall perform other duties commonly incident to their office and shall also perform such other duties and have such other powers as the Member, the Chief Executive Officer or the President shall designate from time to time.

(d) Secretary. The Secretary shall: (i) keep and be the custodian of the books and records of the Company; (ii) see that all notices are duly given in accordance with the provisions of this Agreement or as required by the LLC Act or other applicable law; (iii) keep a register of the address of each Member, which shall be furnished to the Company by such Member; and (iv) in general perform all duties incident to the office of Secretary and such other duties as may be prescribed by the Member, the Chief Executive Officer or the President from time to time.

(e) Assistant Secretaries. The Assistant Secretaries may assume and perform the duties of the Secretary in the absence or disability of the Secretary or whenever the office of the Secretary is vacant. The Assistant Secretaries shall also perform such other duties and have such other powers as the Member, the Chief Executive Officer or the President shall designate from time to time.

(f) Treasurer. The Treasurer shall: (i) have charge and custody of and be responsible for all funds and securities of the Company; (ii) receive and give receipts of moneys due and payable to the Company from any source whatsoever, and deposit all such moneys not otherwise employed in the name of the Company in such bank, savings and loan association, trust company or other depositories as shall be selected by the Member; and (iii) in general perform all the duties incident to the office of Treasurer and such other duties as may be prescribed by the Member, the Chief Executive Officer or the President from time to time. If required by the Member, the Treasurer shall give a bond for the faithful discharge of the Treasurer's duties in such sum and with such surety or sureties as the Member shall determine.

7.4 CompensationThe Officers of the Company shall receive such compensation, if any, as may be fixed from time to time by the Member. No Officer shall be prevented from receiving such compensation by reason of the fact that such Officer is also an officer of the Member.

7.5 ResignationsAny Officer may resign at any time by giving notice to the Member. A resignation of an Officer need not be accepted in order to be effective.

7.6 RemovalAny Officer may be removed, with or without cause, by the Member.

7.7 VacanciesA vacancy in any office may be filled by the Member.

ARTICLE VIII.
LIMITATION ON LIABILITY AND INDEMNIFICATION

8.1 Limitation on LiabilityExcept as otherwise required by the LLC Act, the debts, obligations and liabilities of the Company, whether arising in contract, tort or otherwise, shall be solely the debts, obligations and liabilities of the Company, and no Indemnified Person (as defined below) shall be obligated for any such debt, obligation or liability of the Company solely by reason of being a Member or officer, director, manager, partner, principal, equity holder, employee, or affiliate of a Member or the Company. The failure of the Company to observe any formalities or requirements relating to the exercise of its powers or the management of its business or affairs under this Agreement or the LLC Act shall not be grounds for imposing personal liability on the Member or Officers for any debts, liabilities, or obligations of the Company. Except as otherwise expressly required by law, the Member, in such Member's capacity as such, shall have no liability in excess of (a) the amount of such Member's net Capital Contributions, (b) such Member's share of any assets and undistributed profits of the Company, and (c) the amount of any distributions required to be returned under Florida Statutes, §605.0406. Except as otherwise expressly required by law, no Officer, in such Officer's capacity as such, shall have liability in excess of the amount of any distributions required to be returned under Florida Statutes, §605.0406.

8.2 Indemnification and ContributionNeither the Member nor any officer, director, manager, partner, principal, equity holder, employee or affiliate of the Member or the Company (each, an "Indemnified Person"), as the case may be, shall be liable, responsible or accountable, whether directly or indirectly, in contract or tort or otherwise, to the Company or to the Member (or to any affiliate thereof), as applicable, for any losses, claims, damages, liabilities or expenses, including but not limited to, reasonable attorneys' fees (collectively, "Damages"), asserted against, suffered or incurred by the Company or by the Member (or by any affiliate thereof) arising out of, relating to or in connection with any action taken or omitted by the Indemnified Person within the scope of the authority conferred upon such Indemnified Person by this Agreement or the LLC Act, provided that such Indemnified Person shall have acted in good faith and in the belief that such act or omission was in the best interests of the Company and, provided further, that such Indemnified Person shall not have engaged in fraud, willful misconduct or gross negligence. The Company shall, and hereby does, indemnify and hold harmless and agrees to defend each Indemnified Person from and against any Damages asserted by any Person (whether against the Company, the Member or such Indemnified Person) or otherwise incurred by such Indemnified Person by reason of any act performed by such Indemnified Person in accordance with the standards set forth in this Section 8.2 or in enforcing the provisions of the indemnities contained in this Section 8.2. Notwithstanding anything to the contrary contained in this Agreement, the Member shall have no personal liability with respect to the indemnities set forth in this Section 8.2, and any such indemnities shall be satisfied solely out of the assets of the Company.

8.3 Payment of Expenses in AdvanceExpenses incurred in defending a civil or criminal action, suit or proceeding shall be paid out of Company funds in advance of the final disposition of such

action, suit or proceeding upon receipt of an undertaking by the Indemnified Person to repay such amount unless it shall ultimately be determined that it is entitled to be indemnified by the Company.

8.4 Provisions Not ExclusiveThe exculpation of liability and indemnification provided by this Article VIII shall not be deemed exclusive of any other limitation on liability or rights to which those seeking indemnification may be entitled under any statute, agreement, Member vote or otherwise.

ARTICLE IX.
TRANSFER OF MEMBERSHIP INTERESTS

9.1 No Restriction on TransferThe Member may assign, sell, pledge, encumber, give or otherwise transfer, dispose of or alienate ("Transfer") all or any portion of its Membership Interest as allowable by the LLC Act and applicable law.

9.2 Admission of New Member.

(a) Upon a Transfer or other event resulting in more than one Member of the Company, this Agreement shall be amended to reflect such multiple Members' respective rights, interests and obligations.

(b) Any transferee, assignee, designee, pledgee or legal representative (each a "Transferee") of the Member, pursuant to a Transfer permitted under this Agreement, shall execute and deliver such other instruments and documents necessary to cause the Transferee to become a Member, and pay all reasonable expenses in connection with such Transferee's admission as a Member, including, but not limited to, the cost of preparation and filing of any amendment of this Agreement.

(c) A Transferee who is admitted as a Member pursuant to this Section 9.2 shall have, to the extent transferred, the rights and powers, and shall be subject to the restrictions and liabilities, of the Member under this Agreement, as amended, and the LLC Act.

(d) In the event the Member makes any Transfer, the Member agrees to provide (and to cause the Transferee to provide) to the Company such information regarding the consideration or transfer price of such Membership Interests, and any other information that the Company may reasonably request to permit the Company to prepare financial statements and tax returns in a timely manner.

9.3 Terms of Admission of New Member; Creation of Preferred or Special InterestsThe Member shall have the right to admit new Members in exchange for property, cash or services on such terms as the Member may determine, and in connection therewith the Member may create series or classes or groups of Members (including the existing Member) having such relative rights, powers and duties as the Member may from time to time establish, including rights, powers and duties senior to the existing Member and may amend **Exhibit A** hereto to reflect changes in Membership Percentages in exchange for any such property, cash or services or resulting from the redemption of Membership Interests.

ARTICLE X.
DISSOLUTION AND TERMINATION

10.1 Dissolution.The Company shall continue in perpetuity unless earlier dissolved upon the first to occur of the following:

(a) the execution by the Member of a written instrument of dissolution;

(b) the entry of a decree of judicial dissolution of the Company under Section 605.0705 of the LLC Act; or

(c) the sale or other disposition of all or substantially all of the Company's assets.

10.2 Liquidating DistributionIn the event of the dissolution of the Company for any reason, the assets of the Company shall be liquidated for distribution in the following rank and order:

(a) first, to the payment and discharge of all the debts and liabilities in the order of priority as provided by the LLC Act;

(b) second, to the establishment of any necessary reserves to provide for contingent liabilities, if any; and

(c) third, to the Member.

10.3 Liquidating Trustee.Upon the dissolution of the Company, the affairs of the Company shall be wound up and terminated and its assets shall be distributed exclusively by the Person as is selected at the time of dissolution by the Member (the "Liquidating Trustee"). The Liquidating Trustee shall be empowered to give and receive notices, reports and payments in connection with the dissolution, liquidation and/or winding-up of the Company and shall hold and exercise such other rights and powers as are necessary or required to permit all parties to deal with the Liquidating Trustee in connection with the dissolution, liquidation, and/or winding-up of the Company and to effectuate the termination of the Company. Upon the dissolution of the Company and/or the winding up of the Company, the Member shall file a statement of termination with the DOC in accordance with the LLC Act.

ARTICLE XI.
MISCELLANEOUS

11.1 AmendmentThis Agreement may be modified or amended at any time by the written approval of the Member.

11.2 Further AssurancesThe Member agrees to execute, acknowledge, deliver, file, record and publish such further certificates, instruments and documents, and do such other acts and things as may be required by law or to carry out the intent and purposes of this Agreement.

11.3 NoticesAny and all notices or other communications provided for herein shall be in writing and shall be considered duly given upon the earliest to occur of (a) personal delivery, (b) two (2)

days after being delivered to a nationally recognized overnight courier or service, (c) three (3) days after being mailed by registered or certified mail, return receipt requested, postage prepaid or (d) the delivering party's receipt of a written confirmation of an electronic transmission. All notices shall be addressed to the Company at its principal office and to the Member at its address contained on the books of the Company. Either party may change its address by giving notice to the other party as provided herein.

11.4 Governing LawThis Agreement shall be construed and enforced in accordance with and governed by the laws of the State of Florida, without regard to the principles of conflicts of law. In the event of a conflict between any provision of this Agreement and any non-mandatory provision of the LLC Act, the provisions of this Agreement shall control and take precedence.

11.5 Captions; PronounsAll articles and section headings or captions contained in this Agreement are inserted only as a matter of convenience and for reference and in no way define, limit, extend or describe the scope of this Agreement or the intent of any provision hereof. As used herein, all pronouns shall include the masculine, feminine, neuter, singular and plural thereof wherever the context and facts require such construction.

11.6 Successor and AssignsThis Agreement shall be binding upon the parties hereto and their respective executors, administrators, legal representatives, heirs, successors and assigns, and shall inure to the benefit of the parties hereto, and, except as otherwise herein expressly provided, their respective executors, administrators, legal representatives, successors and assigns.

11.7 SeverabilityIf any provision of this Agreement or application to any party or circumstances shall be determined by any court of competent jurisdiction to be invalid or unenforceable to any extent, the remainder of this Agreement or the application of such provision to any other party or circumstances shall not be affected thereby, and each provision shall be valid and shall be enforced to the fullest extent permitted by law.

11.8 Entire AgreementThis Agreement, including any exhibits and schedules thereto, contains the entire understanding and agreement of the parties hereto relating to the subject matter and supersedes all prior agreements relative hereto which are not contained herein.

11.9 CounterpartsThis Agreement may be executed in one or more counterparts, each of which shall be deemed an original, and all of which, when taken together, shall be deemed one agreement.

Signature page follows.

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be duly executed as of the date first above written.

THE COMPANY:

HEALTHDYNE PHARMACY CO, LLC

By: WellDyneRx, LLC, its member



By: _____
Name: Phillip P. Bisesi
Title: Senior Vice President & Secretary

THE MEMBER:

WELLDYNERX, LLC



By: _____
Name: Phillip P. Bisesi
Title: Senior Vice President & Secretary

LIMITED LIABILITY COMPANY OPERATING AGREEMENT
OF
HEALTHDYNE PHARMACY CO, LLC

Exhibit A

MEMBER	CAPITAL CONTRIBUTION	MEMBERSHIP PERCENTAGE
WellDyneRx, LLC	$10	100%

LIMITED LIABILITY COMPANY OPERATING AGREEMENT
OF
HEALTHDYNE PHARMACY CO, LLC

Exhibit B

NAME	OFFICE
Stephen M. Saft	Chief Executive Officer
Christopher K. Knibb	Chief Financial Officer & Treasurer
David A. Skomo	Chief Operating Officer
Phillip P. Bisesi	Senior Vice President & Secretary

4QQQ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH PH03457	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☒ Other: Mail Order	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: [redacted] ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

On-call pharmacist available 24 hours a day, 7 days a week.

Section 1: General Information

Pharmacy Name: HealthDyne Specialty Florida, LLC

Physical Address: 500 Eagles Landing Drive, Suite A

City: Lakeland State: Florida Zip: 33810

Mailing Address (if different from physical address): 500 Eagles Landing Drive

City: Lakeland State: Florida Zip: 33810

Telephone: 800.641.8475 Toll Free # (NAC 639.708, NRS 639.23286): 800.641.8475

Fax: 800.530.8589 Contact Email: [redacted]

Website: www.healthdyne.com

Nevada Business License # (if applicable) NV20181193563

Supervising/Managing Pharmacist Name (NRS 639.220): David Farid Atallah

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): NV: 23855; FL: PS 50181

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: David Farid Atallah	NV Pharmacist Registration #: 23855
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): HealthDyne, LLC

Corporation/Organization Name: HealthDyne Specialty Florida, LLC

Mailing Address: 500 Eagles Landing Drive

City: Lakeland State: Florida Zip: 33810

Telephone: 888.479.2000 Email: [redacted]

Contact Person Name: Kumarie Jagnarain

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Senior Vice President & Secretary (title) for HealthDyne Specialty Florida, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Phillip P. Bisesi

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/8/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Phillip P. Bisesi hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Senior Vice President & Secretary (title) for HealthDyne Specialty Florida, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8th day of April, 2025

Kumarie Jagnarain

Notary Public

KUMARIE JAGNARAIN
Notary Public - State of Florida
Commission # HH 606531
My Comm. Expires Nov 1, 2028
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Phillip P. Bisesi, Senior Vice President & Secretary

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

04.08.2025

Date

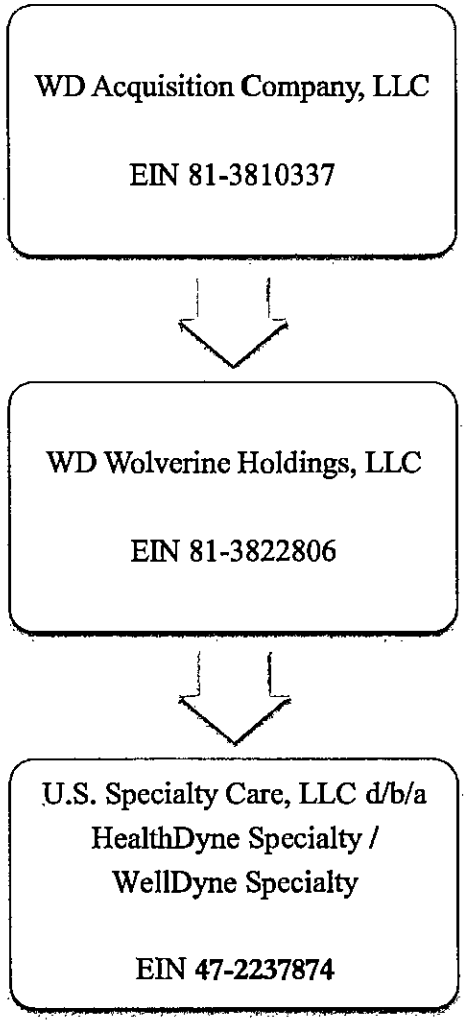
Board Use Only	Date Received: 4/14/25	Amount: [redacted]

HEALTHDYNE SPECIALTY FLORIDA, LLC

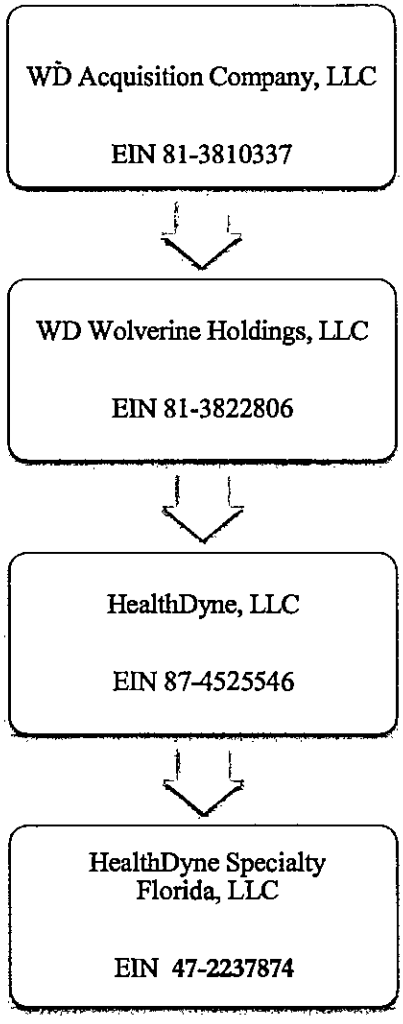
LIST OF CORPORATE OFFICERS, SOLE MEMBER

Name	Title	Address
Stephen M. Saft	Chief Executive Officer	500 Eagles Landing Drive Lakeland, FL 33810
Christopher K. Knibb	Chief Financial Officer & Treasurer	500 Eagles Landing Drive Lakeland, FL 33810
David A. Skomo	Chief Operating Officer	500 Eagles Landing Drive Lakeland, FL 33810
Phillip P. Bisesi	Senior Vice President & Secretary	500 Eagles Landing Drive Lakeland, FL 33810
HealthDyne, LLC	Sole Member	500 Eagles Landing Drive Lakeland, FL 33810

Pre-Close



Post-Close



State of Florida
Department of State

I certify from the records of this office that HEALTHDYNE SPECIALTY COLORADO, LLC is a limited liability company organized under the laws of the State of Florida, filed on November 8, 2024.

The document number of this limited liability company is L24000475042.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Twenty-eighth day of January, 2025

Secretary of State

Tracking Number: 5523460185CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler HealthDyne Specialty Florida, LLC

Pharmacy/Wholesaler License # (if applicable) PH03457

Physical Address 500 Eagles Landing Drive, Suite A

City Lakeland State FL Zip 33810

Mailing Address (if different from physical address) 500 Eagles Landing Drive

City Lakeland State FL Zip 33810

Telephone 800.641.8475 Website www.healthdyne.com

Licensing Company Email administration@welldyne.com

Section 2: Personal Information

First David Middle Farid Last Atallah

Alias(es, nicknames, name changes, etc.) None

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address 500 Eagles Landing Drive, Suite A

City Lakeland State FL Zip 33810

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Palm Beach Atlantic University		08/06 - 12/12	
Address	**City**	**State**	**Zip**
901 S Flagler Drive	West Palm Beach	FL	33401
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Florida Agricultural and Mechanical University		06/05 - 06/06	
Address	**City**	**State**	**Zip**
1500 S Martin Luther King Jr Boulevard	Tallahasse	FL	32307
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
University of Florida		06/04 - 06/05	
Address	**City**	**State**	**Zip**
428 SW 8th Street	Gainesville	FL	32601
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Lake Wales High School		05/2000 - 05/04	
Address	**City**	**State**	**Zip**
One Highlander Way	Lake Wales	FL	33853
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/18 - Present	[redacted]			
06/16 - 06/18				
01/13 - 06/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
U.S. Specialty Care, LLC DBA HealthDyne Specialty / WellDyne Specialty			04/23 - Present	
Business Address		**City**	**State**	**Zip**
500 Eagles Landing Drive, Suite A		Lakeland	FL	33810
Phone	**Title**		**Number of Employed Hours**	
888-479-2000	Pharmacist-In-Charge		4,160 Hours	
Description of Duties				
Supervising all pharmacy operations and staff. Abiding by all state laws and regulations in every state that business is conducted.				

Business Name			From - To (MM/YY – MM/YY)	
WellDyneRx, LLC			09/18 - 04/23	
Business Address		**City**	**State**	**Zip**
500 Eagles Landing Drive		Lakeland	FL	33810
Phone	**Title**		**Number of Employed Hours**	
888-479-2000	Staff Pharmacist		8,500	
Description of Duties				
Processing and checking prescriptions. Supervising pharmacy technicians. Handling incoming and outbound calls for prescription issues clarifications				

Business Name			From - To (MM/YY – MM/YY)	
Palm Beach Pharmaceuticals, Inc.				
Business Address		**City**	**State**	**Zip**
8409 N Military Trail		West Palm Beach	FL	33410
Phone	**Title**		**Number of Employed Hours**	
561-775-6430	Pharmacist-In-Charge		4,000	
Description of Duties				
Supervising all pharmacy operations and staff. Abiding by all state laws and regulations in every state that business is conducted. Following all USP Laws and regulations regarding sterile and non-sterile compounding.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A **. Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I, David Farid Atallah, **certify that as the designated representative for**

HealthDyne Specialty Florida, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MA I am at least 21 years of age;
3. MA I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MA I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MA I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MA I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MA I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Farid Atallah

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

04.08.2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Farid Atallah

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

04.08.2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Polk

I, David Farid Atallah, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

04.08.2025

Date

Subscribed and Sworn to before me this 8th day of April, 2025.

Kumarie Jagnarain

Notary Public Signature

KUMARIE JAGNARAIN
Notary Public - State of Florida
Commission # HH 606531
My Comm. Expires Nov 1, 2028
Bonded through National Notary Assn.

(Seal)

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 22273
Insp # 191432

NAME	PERMIT NUMBER	DATE OF INSPECTION
US SPECIALTY CARE LLC	28952	02/18/2025
DOING BUSINESS AS		
HEALTHDYNE SPECIALTY / WELLDYNE SPECIALT		
STREET ADDRESS	**TELEPHONE #**	**EXT**
500 EAGLES LANDING DRIVE Suite A	888-479-2000	
CITY	**COUNTY**	**STATE/ZIP**
LAKELAND	POLK	FL/33810

Additional Information

Business Operation Hours

Saturday Hours ON CALL	Sunday Hours ON CALL
M-T-W-TH-F Y	Weekly Hours 9:00 AM-6:00 PM
Monday Y	Tuesday Y
Wednesday Y	Thursday Y
Friday Y	Saturday Y
Sunday Y	

Registered Pharmacist / Intern / Tech

License # PS 53120	Licensee Name Angie Yoon
License Type Registered Pharmacists	
License # PS 50181	Licensee Name David Atallah, PDM
License Type Registered Pharmacists	
License # PS 29547	Licensee Name Haytza Berroteran
License Type Registered Pharmacists	
License # RPT 34186	Licensee Name Scott Hudson
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # FU5261285	

License Relations

Pharmacy Affiliate

PAGE, ROBERT NICHOLAS	License #
SAFT, STEPHEN	License #

RX DPT MGR/COR/POR

ATALLAH, DAVID FARID	License # 50181

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081(2), F.A.C.]	Yes

"Prescription Department Closed" sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons. [64B16-28.109, F.A.C.]	Yes
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C] [64B16-28.1035, F.A.C.]	Yes

Community Requirements General Section

Outdated medications removed from active stock. [64B16-28.110, F.A.C.] [64B16-28.1191, F.A.C.]	Yes
Prescription Department is open for a minimum of 20 hours per week. [64B16-28.1081(1), F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c), F.S.] [21CFR1306.05] *No controlled substances pertaining to Florida*	N/A
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)] [64B16-28.140(3)(d), F.A.C.]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102(5)(a), F.A.C.]	Yes
Technicians properly identified. [64B16-27.100(2), F.A.C.] [64B16-27.4001, F.A.C.] [64B16-27.410, F.A.C.] [64B16-27.420, F.A.C.]	Yes
Legend drugs properly stored within confines of pharmacy department and maintained at appropriate temperature to preserve therapeutic activity. [64B16-28.118, F.A.C.]; [64B16-28.120, F.A.C.]; [64B16-28.102, F.A.C.]	Yes
Documentation of destruction or return of controlled substances. [64B16-28.303, F.A.C.] *Pharmalink*	Yes
Generic equivalent sign is posted. [465.025(7), F.S.]	Yes

Additional Community Requirements

Prescription department is operating under clean, sanitary, and uncrowded health conditions. [64B16-28.102, F.A.C.]	Yes
Prescription department has a sink with running water easily accessible to the prescription counter. [64B16-28.102, F.A.C.]	Yes
Pharmacist is on the premises and on duty when the prescription department is open. [64B16-28.109, F.A.C.]	Yes
Pharmacy maintains a written policy and procedure manual regarding the number of registered pharmacy technician positions and the pharmacy operates within the established ratio as defined by rule. [64B16-27.410(2)(a), F.A.C.]	Yes
Pharmacists, technicians, and interns are licensed in the State of Florida. [465.015(1)(a), F.S.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication is properly labeled for dispensing to patient. [64B16-28.108, F.A.C.]	Yes
Unclaimed prescriptions are maintained in stock for no more than one year past dispensing date. [64B16-28.1191, F.A.C.]	Yes
Manufacturer containers are properly labeled. [499.003(26), F.S.]	Yes
Customized medication packages are labeled properly with beyond use date of not more than 120 days from the date of preparation but not later than the beyond use date for any of the medications in the package. [64B16-28.108(6)9., F.A.C.]	N/A
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and quarterly summarization of Quality-Related Events are available for inspection. [64B16-27.300, F.A.C.] [766.101(1)(a)(l), F.S.]	Yes
Pharmacy maintains patient profile with allergy information and medications dispensed. [64B18-27.800, F.A.C.] *Maintained in PharmAssist*	Yes
Compounding records include compounding date, lot number, expiration date, name and manufacturer of ingredients, package size, number of units, technician compounding and pharmacist verifying the final compound. [64B16-28.140(4), F.A.C.]	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005, F.S.] [61N-1.012, F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005(14), F.S.] *McKesson, Cardinal Health*	Yes
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility. [64B16-27.700(3)(g), F.A.C.]	N/A
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek follow-up care from his or her primary care physician. [465.1895(9), F.S.]	N/A
Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S.]	Yes

Requirements for Dispensing Controlled Substances

Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(e), F.S.] [21CFR1304.11] *02/01/2025 8:00 AM, 01/01/2025 8:00 AM*	N/A
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2), F.S.] [21CFR 1305.13(e)] [21CFR1305.22(g)]	N/A
Controlled substance records and prescription information in computer system are retrievable and maintained for 4 years. [465.022(12)(e), F.S.] [64B16-28.140, F.A.C.] [21CFR1306.22] [21CFR1304.04]	N/A
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b), F.S.] [465.022(11)(b), F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4)(3)(a), F.S.]	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent.	Yes

INV359 - Community Requirements

Insp # 191432

US SPECIALTY CARE LLC

File # 22273

Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs.	Yes

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Pharmacy engages in Centralized Prescription Filling [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	Yes
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	Yes
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	Yes
If a controlled substance, the word "central fill" appears on the face of the original prescription.	Yes
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	Yes

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197(3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is locatad and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

HIV Infection Prevention Drugs

Pharmacists are screening, ordering or dispensing HIV postexposure prophylaxis drugs under a written Collaborative Practice Agreement. [465.1861, F.S.]	
An access-to-care plan has been submitted to the board office and is in place to assist patients in gaining access to appropriate care settings when they present to a pharmacist for HIV screening and indicate that they lack regular access to primary care. [465.1861, F.S.]	

Remarks:

Routine inspection completed with David Atallah. Operating requirements met.

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

HODGES, PETER

Date:2/18/2025

Representative:

David Atallah

Date:2/18/2025

Your license number is PH 28952.

Please use it in all correspondence with your board/council. Each licensee is solely responsible for notifying the Department in writing of the licensee's current mailing address and practice location address. If you have not received your renewal notice 90 days prior to the expiration date shown on this license, please visit www.FLHealthSource.gov and click "Renew A License" to renew online.

The Medical Quality Assurance Online Services Portal gives you the ability to manage your license to perform address updates, name changes and much more.

Florida HEALTH

3704

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
FEBRUARY 4, 2025	PH 28952	151964

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

QUALIFICATION(S):
Community Pharmacy

EXPIRATION DATE: FEBRUARY 28, 2027

U.S. SPECIALTY CARE, LLC
HealthDyne Specialty / WellDyne Specialty
500 EAGLES LANDING DRIVE
SUITE A
LAKELAND, FL - 33810

Ron DeSantis
GOVERNOR

Joseph A. Ladapo, MD, PhD
STATE SURGEON GENERAL

Scan QR Code for
License Authentication

DISPLAY IF REQUIRED BY LAW

STATE OF FLORIDA
DEPARTMENT OF HEALTH
DIVISION OF MEDICAL QUALITY ASSURANCE

DATE	LICENSE NO.	CONTROL NO.
FEBRUARY 4, 2025	PH 28952	151964

THE PHARMACY
NAMED BELOW HAS MET ALL REQUIREMENTS OF
THE LAWS AND RULES OF THE STATE OF FLORIDA.

U.S. SPECIALTY CARE, Expiration Date: FEBRUARY 28, 2027
LLC
HealthDyne Specialty /

REGISTRANT SIGNATURE

Department of Health

U.S. SPECIALTY CARE, LLC

HealthDyne Specialty / WellDyne Specialty

License Number: PH28952

Data As Of 4/7/2025

Profession	Pharmacy
License	PH28952
License Status	CLEAR/
Qualifications	Central Fill Community Pharmacy
License Expiration Date	2/28/2027
License Original Issue Date	03/09/2015
Address of Record	500 EAGLES LANDING DRIVE Suite A LAKELAND, FL 33810
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date

Name	Relationship	Profession	License	Effective Date
SAFT, STEPHEN	PHARMACY AFFILIATE	PHARMACY AFFILIATE		09/22/2017

Click on the License Number to view License Details for that Practitioner

The information on this page is a secure, primary source for license verification provided by the Florida Department of Health, Division of Medical Quality Assurance. This website is maintained by Division staff and is updated immediately upon a change to our licensing and enforcement database.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-03-2024

US SPECIALTY CARE LLC
DBA HEALTHDYNE SPECIALTY / WELLDYNE SPECIALTY
500 EAGLES LANDING DR STE A
LAKELAND, FL 33810

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	05-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	05-03-2024

US SPECIALTY CARE LLC
DBA HEALTHDYNE SPECIALTY / WELLDYNE SPECIALTY
500 EAGLES LANDING DR STE A
LAKELAND, FL 33810

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4RRR

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: LeMed Specialty Pharmacy Arizona, LLC

Physical Address: 2450 E.Guadalupe Road; Suite 110

City: Gilbert State: AZ Zip: 85234-5116

Mailing Address (if different from physical address): 2417 3rd Avenue: STE 406

City: Bronx State: NY Zip: 10451-6330

Telephone: 800.347.1137 Toll Free # (NAC 639.708, NRS 639.23286): 800.347.1137

Fax: 718.231.2727 Contact Email: compliance@lemedrx.com

Website: www.LEMEDRX.COM

Nevada Business License # (if applicable) NV20253283850

Supervising/Managing Pharmacist Name (NRS 639.220): Melissa Ann Duchscherer (24468)

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Melissa Duchscherer	NV Pharmacist Registration #: 24468
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NEW YORK

Parent Company (if any): LMSP MIDDLE HOLDINGS LLC

Corporation/Organization Name: LEMED SPECIALTY PHARMACY ARIZONA LLC

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: COMPLIANCE@LEMEDRX.COM

Contact Person Name: BENEDICT HO

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO & PRESIDENT (title) for LEMED SPECIALTY PHARMACY ARIZONA LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

SHALEEN PATEL

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/19/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, SHALEEN PATEL hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO & PRESIDNET (title) for LEMED SPECIALTY PHARMACY ARIZONA (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19 day of March, 2025

Notary Public

BENEDICT HO
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01HO6438513
Qualified in Queens County
Commission Expires August 15, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

SHALEEN PATEL

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/19/2025

Date

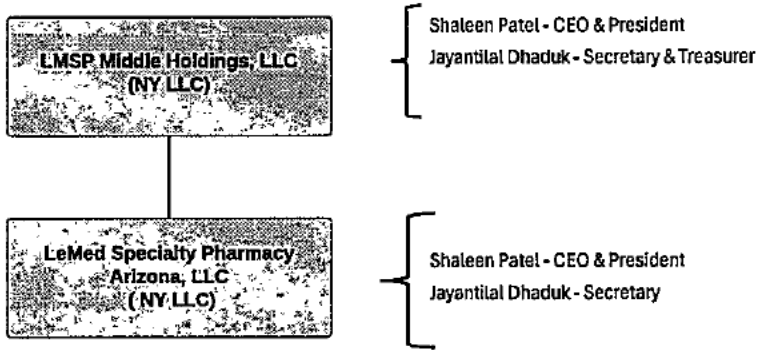
Board Use Only	Date Received: 3/20/25	Amount: $500.00

Attachment - A

Applicant: LeMed Specialty Pharmacy Arizona, LLC

The direct ownership: Of ***LeMed Specialty Pharmacy Arizona, LLC*** is held 100% by **LMSP Middle Holdings, LLC**

Entity Name	FEIN	Corporate Address
LeMed Specialty Pharmacy Arizona, LLC	99-1541550	2417 3rd Ave; STE 406, Bronx, NY 10451
LMSP Middle Holdings, LLC	85-1178669	2417 3rd Ave; STE 406, Bronx, NY 10451



Officers for LeMed Specialty Pharmacy Arizona, LLC & LMSP Middle Holdings, LLC:

Officer Name	Title	DOB	Business Address
Shaleen Patel	CEO/President	[redacted]	
Jayantilal Dhaduk	Secretary		

This filing and any documents enclosed herewith constitute privileged and confidential trade secrets and/or commercial and financial information, disclosure of which would cause substantial harm to the competitive position of the Applicant. It is therefore exempt from disclosure under applicable state and federal records laws, including but not limited to 45 CFR §5.31(d).

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	LEMED SPECIALTY PHARMACY ARIZONA, LLC
DOS ID Number:	7260994
Entity Type:	DOMESTIC LIMITED LIABILITY COMPANY
Entity Status:	EXISTING
Date of Initial Filing with DOS:	02/22/2024
Statement Status:	CURRENT
Statement Due Date:	02/28/2026

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on February 06, 2025 at 01:15 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100007428485 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: LeMed Specialty Pharmacy Arizona, LLC

Pharmacy/Wholesaler License # (if applicable): Arizona - Y009814

Physical Address: 2450 E. Guadalupe Road; Suite 110

City: Gilbert State: AZ Zip: 85234-5116

Mailing Address (if different from physical address): 2417 3rd Avenue; Suite 406

City: Bronx State: NY Zip: 10451-6330

Telephone: 866.846.6337 Website: www.LEMEDRX.COM

Licensing Company Email: COMPLIANCE@LEMEDRX.COM

Section 2: Personal Information

First: Melissa Middle: Ann Last: Duchscherer

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520; NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
South Dakota State University		9/98-05/04	
Address	**City**	**State**	**Zip**
1451 Stadium Rd	Brookings	SD	57006
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Brookings High School		9/94- 5/98	
Address	**City**	**State**	**Zip**
530 Elm Ave	Brookings	SD	57007
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
06/13-current				
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**
From - To (MM/YY – MM/YY)	**Address**	**City**	**State**	**Zip**

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
LeMed Specialty Pharmacy Arizona			07/24-current
Business Address	**City**	**State**	**Zip**
2450 E Guadalupe Rd Ste 110	Gilbert	AZ	85234
Phone	**Title**		**Number of Employed Hours**
866-846-6337	Supervising Pharmacist		1160
Description of Duties			
direct supervision throughout filling process, final verification of dispensed medications, ensured compliance with federal & state laws (multiple states), maintained prescription file system & invoices from suppliers, inventory mgmt			

Business Name			From - To (MM/YY – MM/YY)
New Pharmacy Ventures			04/20-07/24
Business Address	**City**	**State**	**Zip**
2450 E Guadalupe Rd Ste 110	Gilbert	AZ	85234
Phone	**Title**		**Number of Employed Hours**
833-206-2945	Supervising Pharmacist		8800
Description of Duties			
direct supervision of techs throughout filling process, final verification of dispensed medications, ensured compliance with federal & state laws (multiple states), maintained prescription file system & invoices from suppliers, inventory mgmt			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
11/2018	1/30/2019			

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
19-030	Kansas Board of Pharmacy

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

This case arose out of my employment with Foothills Pharmacy, which ended On November 22, 2018. At that time, I submitted the employment change and notified Kansas of my role as incoming PIC (Form LA-50) with my new employer, [redacted] The Kansas Board of Pharmacy received these notifications. However, Foothills Pharmacy and I did not complete the form (BA-50) stating I was departing as PIC. I was incorrect that notification of my role as incoming PIC to my new employer via Form LA-50 sufficed as notification that I was departing my role as PIC at Foothills Pharmacy. Upon notification by the Kansas Board of Pharmacy I promptly remitted the $200 payment for the fine.

I regret this oversight and am committed to following all state and federal licensing rules and regulations. As always, should you have any questions, please do not hesitate to contact me at Melissa.Ann9@me.com.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5-2-24

Date

March 26, 2024

RE: Letter of Explanation for Kansas Summary Order, Case No. 19-030

Dear Sir or Madam:

The purpose of this letter explains the facts surrounding the Summary Order signed on January 30, 2019 for the above-referenced case number.

This case arose out of my employment with [redacted] which ended On November 22, 2018. At that time, I submitted the employment change and notified Kansas of my role as incoming PIC (Form LA-50) with my new employer, [redacted] The Kansas Board of Pharmacy received these notifications. However, Foothills Pharmacy and I did not complete the form (BA-50) stating I was departing as PIC. I was incorrect that notification of my role as incoming PIC to my new employer via Form LA-50 sufficed as notification that I was departing my role as PIC at Foothills Pharmacy. Upon notification by the Kansas Board of Pharmacy I promptly remitted the $200 payment for the fine.

I regret this oversight and am committed to following all state and federal licensing rules and regulations. As always, should you have any questions, please do not hesitate to contact me at Melissa.Ann9@me.com.

Kind Regards,

[redacted]

Melissa Duchscherer, PharmD

BEFORE THE KANSAS BOARD OF PHARMACY

JAN 30 2019

BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 19-030
Melissa Duchscherer	)	
	)	
Registration No. 1-106903	)	

SUMMARY ORDER

NOW on this 30 day of January, 2019 comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Secretary, the matter of Melissa Duchscherer (1-106903) ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 1-106903 which entitles Respondent to practice as a pharmacist in the State of Kansas ("Respondent's Registration").

2. On November 22, 2018, Respondent resigned as Pharmacist-in-Charge ("PIC") from Foothills Professional Pharmacy, LTD, effective immediately.

3. On January 17, 2019, the Board received a Change in PIC Form BA-50, notifying of the resignation of Respondent as PIC, effective November 22, 2018.

4. Respondent had not signed the BA-50 received by the Board.

5. To date, the Board has not received any notification from Respondent regarding her resignation as PIC from Foothills Professional Pharmacy, LTD.

CONCLUSIONS OF LAW

6. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

7. Pursuant to K.A.R. 68-2-5, each pharmacist shall notify the board in writing within five days of ceasing to serve as the pharmacist-in-charge at a pharmacy or registrant required to have a pharmacist-in-charge. The notice shall include the pharmacist's name, the name and address of the pharmacy or registrant, and the date the pharmacist ceased to serve as the pharmacist-in-charge.

8. Respondent had five days to notify the Board of her resignation as PIC effective November 22, 2018, or until November 27, 2018.

9. Respondent failed to notify the Board of her resignation as PIC.

10. Respondent violated K.A.R. 68-2-5 when she failed to notify the Board of her resignation as PIC within five days.

ORDER

Based upon the foregoing findings of fact and conclusions of law, Respondent is ordered to pay a fine to the Board. A violation of K.A.R. 68-2-5 warrants a base fine of $5.00 per day that Respondent is in violation of the regulation, not to exceed $200.00. Because Respondent has not notified the Board of her resignation as PIC to date, the total fine is $200.00. Respondent has 30 days from the date of this order to pay the full $200.00.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/30/19
Date

Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 30 day of January, 2019 deposit in the United States Mail, postage prepaid, a copy of the foregoing Summary Order, properly addressed to the following:

Melissa Duchscherer
[redacted]

and the original hand delivered to:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Ste. 1414
Topeka, KS 66612

Kansas Board of Pharmacy Staff

Kansas Board of Pharmacy

License Portal

Facility/Provider Information

Search Again

Board of Pharmacy Home | License Verification | Exam Scores | Submit a Complaint

The Kansas Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board. Note Pharmacy Technicians issued after January 1, 2019 will now have a 24- prefix for their registration number until they provide proof of passage of the PTCB or ExCPT certification examination.

General

License #:	1-106903	Status:	Active
Name or Business:	Melissa Ann Duchscherer	Issue Date:	9/10/2018
Business Owner:			
Classification:	Pharmacist	On Probation:	No
License Type:	N/A	Discipline on File:	Yes Submit Complaint
		Immunization Certification:	No
		Preceptor Eligibility:	No
		Naloxone Protocol:	No

Licenses

L/P/R #	Description	Effective	Issued	Expires	Status
1-106903	Pharmacist License (Pharmacist)	7/1/2024	9/10/2018	6/30/2026	Active
1-106903	Pharmacist License (Pharmacist)	7/1/2022	9/10/2018	6/30/2024	Expired
1-106903	Pharmacist License (Pharmacist)	7/1/2020	9/10/2018	6/30/2022	Expired
1-106903	Pharmacist License (Pharmacist)	9/10/2018	9/10/2018	6/30/2020	Expired

Notes

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www.esoftwaresolutions.com

I, Melissa Duchscherer, **certify that as the designated representative for** Lenard Specialty Pharmacy Arizona, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MD I am at least 21 years of age;
3. MD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Melissa Duchscherer
Print Name (First, Last)

[redacted]
Original Signature (electronic, copies or stamps not accepted)

1/23/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Melissa Duchscherer

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

1/23/25

Date

Please have this section completed in the presence of a Notary Public.

State of NEW YORK, ss. County of BRONX

I, Melissa Duchscherer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

1/23/25

Date

Subscribed and Sworn to before me this 23 day of JANUARY, 2025.

Notary Public Signature

BENEDICT HO
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01HO6438513
Qualified in Queens County
Commission Expires August 15, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site LEMED SPECIALTY PHARMACY ARIZONA, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) AZ / Y008372

Physical Address 2450 E. GUADALUPE ROAD ; SUITE 110

City GILBERT State AZ Zip 85234

Mailing Address (if different from physical address) 2417 3RD AVENUE; STE 406

City BRONX State NY Zip 10451

Telephone 602.742.2969 Website www.LEMEDRX.COM

Licensing Company Email COMPLIANCE@LEMEDRX.COM

Section 2: Personal Information

First Shaleen Middle _____ Last PATEL

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Union College		09/93 - 06/97	
Address	City	State	Zip
807 Union Street	Schenectady	NY	12308
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Friends Academy		09/87 - 06/93	
Address	City	State	Zip
270 Duck Pond Road	Locust Valley	NY	11560
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
1/19 - present				
From - To (MM/YY – MM/YY)				
1/15 - 12/18				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
LeMed Specialty Pharmacy Arizona, LLC			02/24 - current	
Business Address		**City**	**State**	**Zip**
2450 E. Guadalupe Road; Suite 110		Gilbert	AZ	85234
Phone	**Title**			
347.913.4656	CEO & President			
Description of Duties				
Executive Leadership				

Business Name			From - To (MM/YY – MM/YY)	
LeMed Pharmacy Buffalo, LLC			09/21 - current	
Business Address		**City**	**State**	**Zip**
1091 Main St: Suite 110		Buffalo	NY	14209
Phone	**Title**			
347.913.4656	CEO & President			
Description of Duties				
Executive Leadership				

Business Name			From - To (MM/YY – MM/YY)	
LeMed Pharmacy III, LLC			05/19 - current	
Business Address		**City**	**State**	**Zip**
2417 3rd Avenue; Suite 406		Bronx	NY	10451
Phone	**Title**			
347.913.4656	CEO & President			
Description of Duties				
Executive Leadership				

Business Name			From - To (MM/YY – MM/YY)	
LMSP Middle Holdings LLC			05/20 - current	
Business Address		**City**	**State**	**Zip**
2417 3rd Avenue; Suite 406		Bronx	NY	10451
Phone	**Title**			
347.913.4656	CEO & President			
Description of Duties				
Executive Leadership				

Business Name			From - To (MM/YY – MM/YY)	
LMSP Top Holdings LLC			05/20 - current	
Business Address		**City**	**State**	**Zip**
2417 3rd Avenue; Suite 406		Bronx	NY	10451
Phone	**Title**			
347.913.4656	Manager / CEO & President			
Description of Duties				
Executive Leadership				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Shaleen Patel, CEO, President

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

03/12/2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEW YORK, ss. County of BRONX

I, Shaleen Patel, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/19/2025

Date

Subscribed and Sworn to before me this 19 day of March, 2025.

Notary Public Signature

BENEDICT HO
NOTARY PUBLIC, STATE OF NEW YORK
Registration No. 01HO6438513
Qualified in Queens County
Commission Expires August 15, 2026

(Seal)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y009814	10/31/2025	LeMed Specialty Pharmacy Arizona, LLC

Address : 2450 E Guadalupe Road Suite 110

Zip :	City :	State :
85234	Gilbert	AZ

Phone :	Fax :	Email :
(347) 913-4656	(718) 231-2727	compliance@lemedrx.com

Inspection Date :	PIC :	DEA # :
05/22/2024	Melissa Ann Duchscherer	No DEA Registration

Inspection Reviewed With :	Reviewers License# :	Inspection type :
Melissa Ann Duchscherer	S014346	Opening

Inspection Conducted By : Max Jacobson

ACTIVITIES

1	Nonsterile Compounding	☐ YES	☑ NO
2	Nonsterile Hazardous Compounding	☐ YES	☑ NO
3	Sterile Compounding	☐ YES	☑ NO
4	Sterile Hazardous Compounding	☐ YES	☑ NO

Hospital Facility Data

# Licensed Beds	DHS License #

PHARMACY DEPARTMENT

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Size/Personnel 1984 sq ft = Max 31 employees	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675
2	Shelves	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Design-efficient, safe pharmacy practice	☑ S ☐ C/P ☐ U ☐ N/A	R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)
4	Counter 120 sq ft.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
5	Aisles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
6	Consultation area Not required for a closed door pharmacy.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(D)
7	Enclosed (barrier) Not required for a closed door pharmacy.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675
8	Entry doors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
9	Lighting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

10	Temperature controlled/Ventilation HVAC throughout.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Working counter barrier Not required for a closed door pharmacy.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(H)
12	Receiving/checking area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(F)
14	Walls	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

20	Nonsterile compounding area No compounding will occur.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410(E)

SECURITY

1	Controlled substances No controlled substance are dispensed. Not a DEA Registrant.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Pharmacist access No employee is able to access the pharmacy with out a RPh on duty.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Additional pharmacy drug storage areas	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage Not required for a closed door pharmacy.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference Available online.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

2	Therapeutics reference	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Available online.					
3	Drug compatibility reference	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Available online.					
4	Drug product equivalency reference	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Available online.					
5	Sterile products reference	☐ S	☐ C/P	☐ U	☑ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)
6	Policy and procedure manual-pharmacy operations	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)
7	Policy and procedure manual-technicians	☐ S	☑ C/P	☐ U	☐ N/A	R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)
	PIC is to provide the tech training manual prior to operation.					
8	Policy and procedure manual-automation	☐ S	☑ C/P	☐ U	☐ N/A	R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04
	PIC is to provide the automation SOP if it is utilized.					
9	Policy and procedure manual-compounding	☐ S	☐ C/P	☐ U	☑ N/A	R4-23-410; R4-23-670
	No compounding will occur.					

10	Arizona statutes/rules Available online.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Current antidote/drug interaction information Available online.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
12	Poison Control # displayed Poison Control magnet provided.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

PHARMACY EQUIPMENT/FORMS

1	Refrigerator Temperature manually logged twice daily.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
2	Freezer	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3	Computer-security/data storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408
4	Computer-patient profiles	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(3)
5	Computer-single drug usage report	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-408(B)(4)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

6	Computer-pharmacist log book/hard copy print out	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-408(C)(4)
	Hard copy RPh log.					
7	Prescription label	☐ S	☑ C/P	☐ U	☐ N/A	ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C)
	PIC is to provide a complete patient test label. One was provided during inspection that did not have the pharmacy phone number.					
8	Federal transfer labels	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
9	Warning labels	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2)
10	Written patient information	☐ S	☑ C/P	☐ U	☐ N/A	R4-23-402(C)(4); R4-23-402(I)
	PIC is to provide an example of the patient written information. One was provided during inspection that did not have the pharmacy phone number.					
11	Consultation log	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-402(G)
12	Federal medication guides	☑ S	☐ C/P	☐ U	☐ N/A	21 CFR part 208
13	Hospital IV label	☐ S	☐ C/P	☐ U	☑ N/A	R4-23-658
14	Generic Rx blanks	☑ S	☐ C/P	☐ U	☐ N/A	R4-23-402(A); R4-23-407(D)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

15 Immunization administration recordkeeping ☐ S ☐ C/P ☐ U ☑ N/A
R4-23-411(F)
No immunizations will be administered.

16 Schedule V register ☐ S ☐ C/P ☐ U ☑ N/A
R4-23-612(A)(2)
Dispensed by Rx only.

17 Methamphetamine precursor sales log ☐ S ☐ C/P ☐ U ☑ N/A
ARS 32-1977
Dispensed by Rx only.

18 Red C stamp ☐ S ☐ C/P ☐ U ☑ N/A
R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
3 file system.

19 CSPMP reporting ☐ S ☐ C/P ☐ U ☑ N/A
R4-23-502
Not a DEA registrant.

20 Graduates ☑ S ☐ C/P ☐ U ☐ N/A
R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

21 Mortar & Pestle ☐ S ☐ C/P ☐ U ☑ N/A
R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
No compounding will occur.

22 Steel spatulas ☑ S ☐ C/P ☐ U ☐ N/A
R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

23	Rubber (nonmetallic) spatula	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance No compounding will occur.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
25	Weights for Rx balance No compounding will occur.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile No compounding will occur.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device No automation at this time. The PIC will provide SOP prior to usage.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-615
30	Mechanical counting device The PIC will provide SOP prior to usage.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-616
31	Emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02

32	Automated emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size No compounding will occur.	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(1); R4-23-656(5)
3	Isolated from other pharmacy functions	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(2)
4	Restricts entry/access	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

9	Environment ISO 7	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(6)
10	Hood ISO 5	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

Hours: M-F 10-6

Closed Door, Limited Service Pharmacy (Mail Order)
1984 sq ft = max 31 employees.

Compliance Pending:
Patient Label
Patient Written Information
Technician SOP
Automation SOP (if utilized)

At the time this report was completed all
compliance pending issues have been submitted and resolved.

Handouts Provided: 2020-2023 Statute/Rule Changes summary,
ARS 32-1926 reminder, DEA Form 106 Reporting reminder,
Continuing Education Audit information, AZBOP Scam Alert,
FDA advisory on insulin pen packaging and dispensing,
DEA reminder on manual signature for prescribers,
Single Ingredient Ephedrine Products, CSPMP Reporting Requirement,
AZBOP Newsletter, Small Business BOR.

METFORMIN HCL 625MG TABS

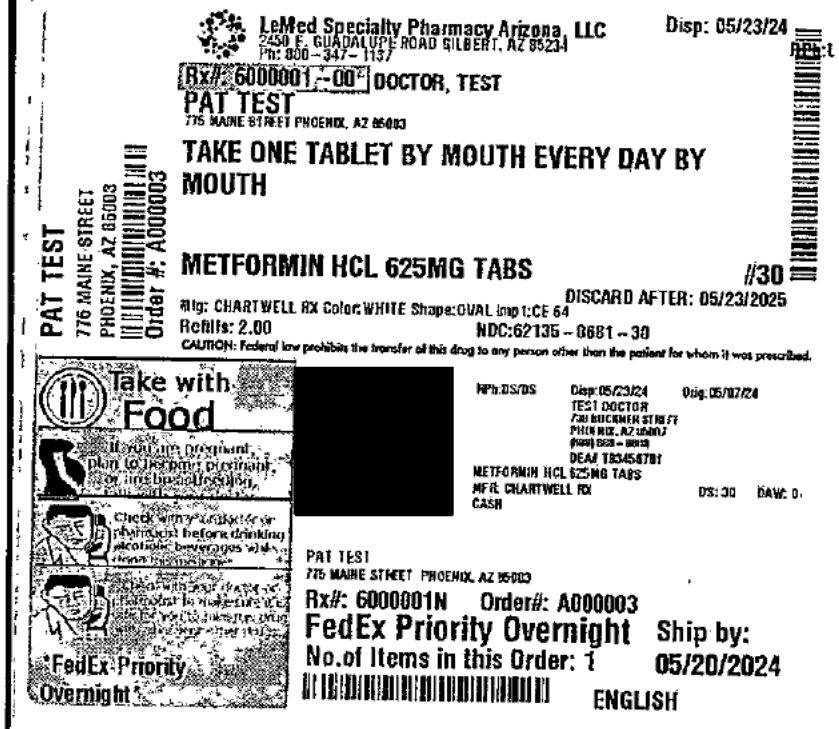
GENERIC NAME: General Monograph
Brand Name:
IDENTIFICATION:
IMPORTANT NOTE: This generalized information is a limited summary of diagnosis, treatment, and/or medication information. It is not meant to be comprehensive and should be used as a tool to help the user understand and/or assess potential diagnostic and treatment options. It does NOT include all information about conditions, treatments, medications, side effects, or risks that may apply to a specific patient. It is not intended to be medical advice or a substitute for the medical advice, diagnosis, or treatment of a health car provider based on the health care provider's examination and assessment of a patient's specific and unique circumstances. Patients must speak with a health care provider for complete information about their health, medical questions, and treatment options, including any risks or benefits regarding use of medications. This information does not endorse any treatments or medications as safe, effective, or approved for treating a specific patient. UpToDate, Inc. and its affiliates disclaim any warranty or liability relating to this information the use thereof. The use of this information is governed by the Terms of Use, available at https://www.wolterskluwer.com/en/know/clinical-effectiveness-terms.
What is this drug used for?: - It is used to treat or prevent health problems as decided by your doctor. Ta with the doctor.
How is this drug best taken?: Use this drug as ordered by your doctor. Read all information given to you. Follow all instructions closely.

- Talk with your doctor or pharmacist if you have questions about how to use this drug.
What do I do if I miss a dose?

- Take a missed dose as soon as you think about it.
- If it is close to the time for your next dose, skip the missed dose and go back to your normal time.
- Do not take 2 doses at the same time or extra doses.
What are some other side effects of this drug?: All drugs may cause side effects. However, many peopl have no side effects or only have minor side effects. Call your doctor or get medical help if any of these side effects or any other side effects bother you or do not go away:
These are not all of the side effects that may occur. If you have questions about side effects, call your docto Call your doctor for medical advice about side effects.
You may report side effects to the FDA at 1-800-332-1088. You may also report side effects at https://www.fda.gov/medwatch.
What are some things I need to know or do while I take this drug?: - Tell all of your health care provide that you take this drug. This includes your doctors, nurses, pharmacists, and dentists.
- Tell your doctor if you are pregnant or plan on getting pregnant. You will need to talk about the benefits an risks of using this drug while you are pregnant.
- Tell your doctor if you are breast-feeding. You will need to talk about any risks to your baby.
DRUG INTERACTIONS:
If OVERDOSE is suspected: If you think there has been an overdose, call your poison control center or ge medical care right away. Be ready to tell or show what was taken, how much, and when it happened.
Consumer Information Use and Disclaimer: - If your symptoms or health problems do not get better or if they become worse, call your doctor.
- Do not share your drugs with others and do not take anyone else's drugs.
- Some drugs may have another patient information leaflet. Check with your pharmacist. If you have any questions about this drug, please talk with your doctor, nurse, pharmacist, or other health care provider.
- If you think there has been an overdose, call your poison control center or get medical care right away. Be ready to tell or show what was taken, how much, and when it happened.
How do I store and/or throw out this drug?: - Store this drug as it says on the label or as you have been

METFORMIN HCL 625MG TABS

told by your doctor or pharmacist.
- Keep all drugs in a safe place. Keep all drugs out of the reach of children and pets.
- Throw away unused or expired drugs. Do not flush down a toilet or pour down a drain unless you are told to do so. Check with your pharmacist if you have questions about the best way to throw out drugs. There may be drug take-back programs in your area.



LeMed Specialty Pharmacy Arizona, LLC
2450 E. GUADALUPE ROAD GILBERT, AZ 85234
Ph: 800-347-1137

Disp: 05/23/24

Rx#: 6000001 -00 DOCTOR, TEST
PAT TEST
775 MAINE STREET PHOENIX, AZ 85003

TAKE ONE TABLET BY MOUTH EVERY DAY BY MOUTH

METFORMIN HCL 625MG TABS #30

DISCARD AFTER: 05/23/2025

Mfg: CHARTWELL RX Color:WHITE Shape:OVAL Imp1:CE 64
Refills: 2.00 NDC:62135-0681-30

CAUTION: Federal law prohibits the transfer of this drug to any person other than the patient for whom it was prescribed.

PAT TEST
775 MAINE STREET
PHOENIX, AZ 85003
Order #: A000003

Take with Food

If you are pregnant, plan to become pregnant, or are breastfeeding,

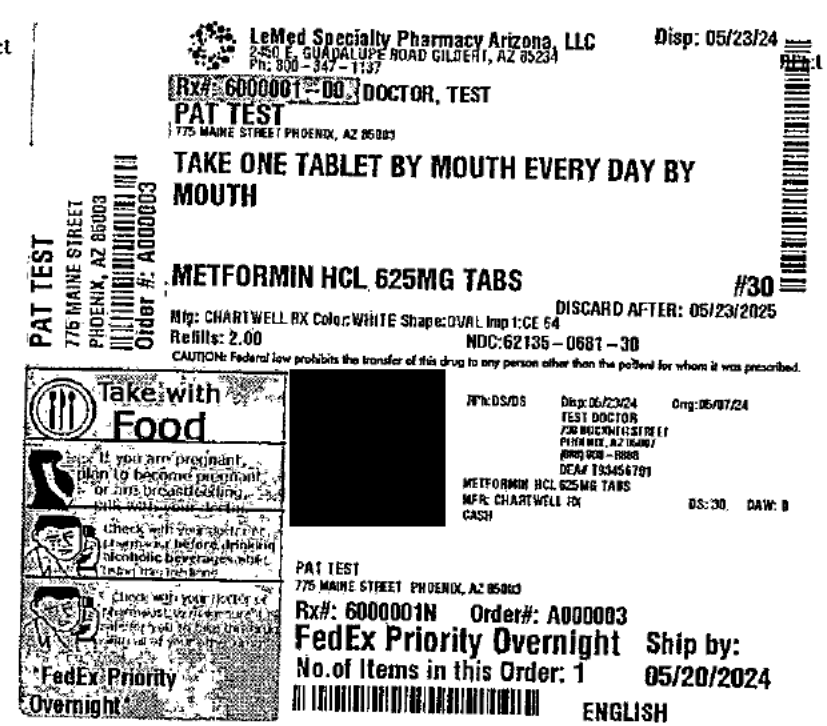
Check with your doctor or pharmacist before drinking alcoholic beverages while

FedEx Priority Overnight

[redacted]

RPh:DS/DS Disp:05/23/24 Orig:05/07/24
TEST DOCTOR
730 BUCKNER STREET
PHOENIX, AZ 85003
(800) 808-8888
DEA# T93456781
METFORMIN HCL 625MG TABS
MFR: CHARTWELL RX DS:30 DAW: 0
CASH

PAT TEST
775 MAINE STREET PHOENIX, AZ 85003
Rx#: 6000001N Order#: A000003
FedEx Priority Overnight Ship by:
No.of Items in this Order: 1 05/20/2024
ENGLISH



LeMed Specialty Pharmacy Arizona, LLC
2450 E. GUADALUPE ROAD GILBERT, AZ 85234
Ph: 800-347-1137

Disp: 05/23/24

Rx#: 6000001 -00 DOCTOR, TEST
PAT TEST
775 MAINE STREET PHOENIX, AZ 85003

TAKE ONE TABLET BY MOUTH EVERY DAY BY MOUTH

METFORMIN HCL 625MG TABS #30

DISCARD AFTER: 05/23/2025

Mfg: CHARTWELL RX Color:WHITE Shape:OVAL Imp1:CE 64
Refills: 2.00 NDC:62135-0681-30

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Order #: A000003

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PAT TEST
775 MAINE STREET PHOENIX, AZ 85003
Rx#: 6000001N Order#: A000003
FedEx Priority Overnight Ship by:
No.of Items in this Order: 1 05/20/2024
ENGLISH

Pharmacy Technicians Training Guideline

1. Purpose

The purpose of this guideline is to establish standardized training procedures for our Pharmacy Technicians to ensure they possess the necessary skills, knowledge, and competencies to perform their duties safely and effectively.

2. Scope

The operating guideline applies to all pharmacy technician and pharmacy technician trainees employed by LeMed Specialty Pharmacy.

3. Policy Statement

LeMed Specialty Pharmacy is committed to providing comprehensive training for pharmacy technician's to ensure high standards of practice and compliance with regulatory requirements. All pharmacy technician's must complete the required training program before performing their duties independently.

4. Training Objectives

- Ensure pharmacy technicians understand and comply with all relevant laws, regulations, and standards.
- Equip pharmacy technicians with the skills necessary for accurate prescription processing, medication dispensing, and patient interaction.
- Promote patient safety through thorough training in pharmacy operations and protocols.
- Foster continuous professional development and competency.

5. Training Components

The training program for pharmacy technicians consists of the following components:

5.1. Orientation

- Introduction to LeMed Specialty Pharmacy, its mission, vision, and values.
- Overview of pharmacy layout, workflow, and staff roles.
- Review of employee handbook, including policies on attendance, dress code, and confidentiality.

5.2. Regulatory Compliance and Ethics

- Training on federal and state pharmacy laws and regulations.
- HIPAA (Health Insurance Portability and Accountability Act) training.
- Review of LeMed Specialty Pharmacy's code of ethics and professional conduct.
- Accreditation training

5.3. Prescription Processing

- Instruction on receiving and interpreting prescriptions.
- Data entry procedures in the pharmacy management system.
- Verification of patient information and insurance processing.
- Overview of common drug interactions and contraindications.

5.4. Medication Dispensing

- Techniques for accurate counting and measuring.
- Labeling and packaging of medications.
- Understanding of medication storage requirements and inventory management.

5.5. Patient Interaction

- Effective communication skills for interacting with patients and healthcare providers.
- Procedures to effectively offer pharmacist medication counseling and education.
- Handling patient inquiries and resolving issues.

5.6. Safety and Quality Assurance

- Medication error prevention strategies.
- Reporting and documenting up medication errors and adverse reactions to the pharmacist
- Procedures for maintaining a clean and safe work environment.
- Regular quality checks and audits.

5.7. Continuing Education

- Encouragement of ongoing education through workshops, seminars, and online courses.
- Maintenance of certification through accredited programs (e.g., PTCB).
- Participation in regular staff meetings and training updates.

6. Training Timeline

- **Orientation:** First week or two of employment.
- **Regulatory Compliance and Ethics:** Completed within the first week.
- **Prescription Processing:** Ongoing, with initial competency achieved within three months.
- **Medication Dispensing:** Ongoing, with initial competency achieved within three months.
- **Patient Interaction:** Initial training within the first month, ongoing development.
- **Safety and Quality Assurance:** Integrated throughout the training period, with specific modules completed within three months.
- **Continuing Education:** Encouraged throughout employment, with mandatory updates as required by certification bodies.

7. Training Evaluation and Competency Assessment

- Regular assessments through verbal discussions, practical demonstrations, and peer reviews.
- Monthly progress reviews with the supervising pharmacist.
- Final competency evaluation at the end of the training period.
- Ongoing performance evaluations and feedback sessions.

8. Documentation and Record-Keeping

- Maintain detailed training records for each pharmacy technician.
- Document completion of all training modules, assessments, and evaluations.
- Ensure records are kept confidential and secure, in compliance with regulatory requirements.

9. Review and Updates

- These guidelines will be reviewed and updated as necessary to ensure compliance with new regulations and best practices.
- Feedback from pharmacy technicians and supervisors will be considered in policy updates.

10. Approval and Implementation

This guideline is approved by LeMed Specialty Pharmacy's management and will be implemented by the pharmacy manager. All pharmacy technicians are required to adhere to this training guideline.

11. Attestation

By signing below, I acknowledge that I have received, read, and understood the Pharmacy Technician Training Guidelines. I agree to adhere to these policies and procedures and understand that failure to comply may result in disciplinary action, up to and including termination. I acknowledge receipt of the respective State Boad of Pharmacy Law manual.

☐ Arizona Administrative Code Book

☐ New York Pharmacy Handbook

Pharmacy Technician:

Name: _____

Signature: _____

Date: _____

Trainer/Pharmacy Manager:

Name: _____

Signature: _____

Date: _____

Policy Number: 2	Policy Name: Human Resources	Approval Authority: The Quality Management Committee (QMC)
Effective Date: 9/6/16	Previous Review Dates: 9/6/16, 7/26/17, 8/30/18, 7/26/19, 7/22/20,7/22/21, 5/23/22, 5/25/22, 5/26/22, 5/31/22, 6/24/22, 07/15/23	Last Revision Date: 6/21/16, 7/26/17, 8/30/18, 7/16/19, 7/22/20, 1/4/21,7/22/21, 5/23/22, 5/25/22, 5/26/22, 5/31/22, 6/20/22, 6/24/22, 07/15/23
Approval Date: 07/15/23	Notation:	

I. **Scope:** Human resources will apply these principles to all staff hired on a full time, part-time, and contractual basis.

II. **Purpose:** This policy guides the Human Resource staff to apply some basic guidelines in the hiring, orientation and ongoing training of staff and contracted employees. Staff will be assessed periodically in performance appraisals measured against established.

III. **Policy:** LeMed Specialty Pharmacy's Human Resource department will ensure that all staff hired meet qualifications described in job descriptions. Job Descriptions will include job duties and responsibilities, as well as minimum required qualifications, experience, education, license/certifications, and training. Background checks and primary source verifications will be conducted in accordance with job descriptions requirements prior to an employee's hire date. Following a contractual engagement, hired staff will be oriented and receive on-going training.

IV. **Definitions**

A. **Certification:** A professional credential, granted by a national organization, signifying that an individual has met the qualifications established by that organization. To qualify under these standards, the certification program must:
   1. Establish standards through a recognized, validated program;
   2. Be research-based; and
   3. Be based (at least partially) on passing an examination.

B. **Clinical Staff:** Employees or contracted consultants of the health care organization who are clinically qualified to perform clinical triage and provide health information services.

C. **Contractor:** A business entity that performs delegated functions on behalf of the Organization. For the purposes of these standards, the term "contractor" includes;

D. **Only those contractors that perform functions related to the key processes of the Organization.** It is not URAC's intent to include contractors that provide services unrelated to key processes. For example, a contractor that provides catering services would not fall within the definition of "contractor" in these standards. Conversely, a company that provides specialty physician reviewers to a UM organization would clearly fall within the definition of "contractor."

E. **Non-Clinical Staff:** Employees or contracted consultants of a healthcare organization who do not perform clinical assessments or provide callers with clinical advice. They may be responsible for obtaining demographic information, providing benefit information, and redirecting callers.

F. **Primary Source Verification** ("PSV"): Verification of a practitioner's credentials based upon evidence obtained from the issuing source of the credential. Also known as "Primary Source."

G. **Staff:** The Organization's employees, including full-time employees, part-time employees, consultants, and temporary staff.

V. Procedures

A. Job Descriptions/Qualifications

1. Human resources will develop job descriptions for all full-time, part-time consultants and temporary employees. Consulting or temporary contributors will have their duties and qualifications outlined either in a job description or in the contract's service of work (SOW).
2. The Supervising Pharmacist will participate in the hire of clinical staff either through the interview process or the development of the clinical staff's job description(s). This participation oversees the process of hiring qualified clinical staff.
3. All current and active job descriptions will be maintained in the employees' personnel file.
4. All job descriptions will include at a minimum:
   a. Current scope of roles and responsibilities
   b. Required education, training and/or professional experience.
   c. Current and unrestricted licenses/certifications (if applicable); and
   d. Expected professional competencies.
5. Potential hires and staff considered for job role changes will submit and update resumes, CVs, bios, and/or job applications to reflect that their qualifications meet the requirements in job descriptions. These documents will be maintained in personnel files.
6. All prospective employees will complete a signed withholding statement and I-9 Form.

B. Verification of Qualifications

1. To ensure qualified staff is hired based on job descriptions, the reviewer requests an updated resume from the candidate and review the resume against the job description. If the reviewer decided to proceed, they will send the job application to the candidate and set up an interview. After the interview is completed, the reviewer contacts the references on the job application.
2. Once an individual has been deemed appropriate for hire, but prior to contracting with the individual, LeMed Specialty Pharmacy's human resources department completes the following checks that includes:
   a. Background checks (Pharmacy only)
   b. Criminal background checks will be performed using a third-party verification service, HireRight, including identification check, criminal record, sex offender
   c. Drug testing/screening by LabCorp for potential hires that will handle pharmaceuticals (not limited to illicit drugs)
3. License/certification verification
   a. Primary source verification (PSV) of licensure, certification and/or registration is performed upon hire prior to the start date and thereafter no less than every three (3) years.
   b. Verification of current licensure or certification, including expiration date, date of verification, and whether there are any sanctions, must be from the body issuing the license or certificate, through one of the following methods:
      i. Electronic (e.g. internet)
      ii. Written verification verified from the issuing source (e.g., document from the issuing entity to LeMed Specialty Pharmacy on source's letterhead or Board or Certification's form); or
      iii. Telephone (documented with the name and signature of the staff person making the call, date of call, and name of the person at the issuing identity to whom the staff person spoke).

4. It is the responsibility of each staff member to notify immediately his/her supervisor of any adverse changes related to licensure and/or certification or if the employee fails to renew the license/certification status. The supervisor will send notice of the issue via email to the Compliance Officer for review to review and determine next steps.
5. Failure to report a change in licensure and/or certification status shall result in disciplinary action up to and including suspension. The supervisor will send notice of the issue via email to the Compliance Officer for review to review and determine next steps with the CEO.
6. Failure to maintain a current and unrestricted license and/or certification shall result in immediate suspension or reassignment to a position not requiring the affected licensure and/or certification until such licensure and/or certification can be verified through primary source. The supervisor will send notice of the issue to the Compliance Officer for review to review and determine next steps with the CEO.

C. Training

1. **New Hire Orientation**
   a. Corporate Orientation

      Corporate-wide orientation is provided by the Compliance Officer prior to staff assuming assigned roles and responsibilities. It is designed to acquaint newly hired employees with various aspects of working within LeMed Specialty Pharmacy including its mission statement, values, organizational structure, privacy and security of information protections, ethics in health care, code of ethical business conduct, compliance, fire and safety procedures, incident and accident reporting procedures, and general policies and procedures necessary for the safe and effective performance of their responsibilities.

   b. Department Level Orientation

      Once corporate training is complete, all staff will complete department level training to learn their specific roles and duties prior to assuming their responsibilities. Staff will receive the most current policies and procedures, guidelines, and workflows for their duties.

   c. Compliance

      Compliance training includes:

      i. Privacy and security of information protections [Confidentiality including HIPAA & HITECH, security rules including administrative, technical, and physical safeguards, privacy rule, and breach notification rule]
      ii. Ethics in health care.
      iii. Health Care Ethics, Business Ethics Standards Policy training which reviews and covers the Code of Conduct. The Code of ethical business conduct addresses:
         1) Conflict of interest;
         2) False claims;
         3) Fraud and abuse; and
         4) Illegal activities.
         5) A requirement to report practitioners that are impaired, incompetent, or unethical;
         6) Prohibition of discrimination based on color, race, national origin, religion, age, sex, genetic information, pregnancy, disability;
         7) Prohibition of harassment, sexual or otherwise;
         8) Professional use of digital media; and

9) Compliance with the LeMed Specialty Pharmacy's legal requirements and code of conduct acknowledgement statement
    a) All staff and members of oversight committees must sign a statement to acknowledge that they:
    b) Have access to a copy of the Code of Conduct;
    c) Have received training on the Code of Conduct;
    d) Understand the consequences for failing to comply with LeMed Specialty Pharmacy's compliance program(s) as set for the in the Code of Conduct, LeMed Specialty Pharmacy's policies and procedures, as well as laws and regulations applicable to LeMed Specialty Pharmacy's business; and
    e) Have access to methods of reporting legal and regulatory breaches and/or violations. As well as nonconformance to the Code of Conduct.

d. Safety Training

   Each staff member must complete safety training which includes OSHA Requirements. Initial review of policies includes additional required safety training.

e. URAC/ACHC Training

   Each staff member must be trained in the most current version of URAC & ACHC standards applicable to his/her job responsibilities. This occurs upon hire and then ongoing thereafter as changes to the standards or the organization's procedures occur.

f. Employee Handbook/Personnel Policies
    i. Are reviewed annually.
    ii. Are in accordance with applicable laws and regulations.
    iii. Show evidence of non-discriminatory practices
    iv. Include activities and information on:
        1. Wages
        2. Benefits
        3. Complaints and grievances
        4. Recruitment/hiring/retention
        5. Disciplinary action/termination of employment
        6. Professional boundaries
        7. Conflict of interest
        8. Performance expectations and evaluations

2. **Ongoing Training to Maintain Competency in Assigned Roles and Responsibilities**
    a. On-going training is provided as needed and annually when there are changes to policies, laws and regulations, shifts in business functions or strategy or changes in accreditation standards.
    b. Staff must have access to the most current policies and procedures applicable to their duties on an ongoing basis. Staff can find this resource on LeMed's Team SharePoint site.
    c. Ongoing training and annual competency assessment will be completed on staff who set up, train, clean, test, repair and/or educate on the use of medication, equipment, and/or supplies.

3. **Documentation of Training**
   a. The Compliance Officer will track and/or log the training of staff at the time of orientation (on training checklists, attestations, and/or through printed certifications) and for ongoing training. Documentation of training will include, but not be limited to, the topics outlined in section 1 a-e of this policy. Employees are assigned training via email for them to enroll or take classes enrolled for them through Insperity (PEO)'s training portal or through a compliance program (ie: Cardinal Learning Bridge). All documentation will be filed within the individual employee file.

D. Performance Appraisal

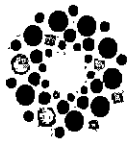
1. Annually to the quarter (Q1), each member of the staff will undergo a formal documented performance appraisal.
2. Performance appraisals are based on established expectations in their job description, documentation completed by the staff member, and/or any goals established prior to appraisal.
3. A template is used and is included in Attachment A.

E. Personnel File

1. Each personnel file will include the following:
   a. Evidence of the hire date
   b. Job description
   c. Background check (if applicable)
   d. Licensure/certification verification (PSV: The original and the most current PSV will be maintained in the file.)
   e. Corporate Orientation (on training checklists, attestations, and/or through printed certifications)
   f. Code of ethical business conduct training including: (COI) Conflict of interest, false claims fraud and abuse, illegal activities
   g. Acknowledgement Statement for training in the Code of Conduct
   h. Training in privacy and security of information protections (on training checklists, attestations, and/or through printed certifications)
   i. Training in ethics in healthcare (on training checklists, attestations, and/or through printed certifications)
   j. Evidence of training in policies, process, and procedures applicable to one's job duties and responsibilities
   k. Evidence of training in URAC standards applicable to one's job duties and responsibilities
   l. Ongoing training to maintain professional competence.
   m. Staff performance reviews
2. Personnel Records
   a. Personnel files and records are stored in a confidential location.
   b. Only certain individuals with appropriate authority have access to the files.
   c. Employees have access to their individual personnel file following the appropriate procedures.
   d. Retention of personnel files is 6 years.

F. **Direct Care Personnel**

1. LeMed Specialty Pharmacy does not employ direct care personnel, but if we do, they will have access to Hepatitis B vaccination according to CDC and OSHA standards.
   a. Declination statements will be signed within ten (10) business days of employment if vaccination is declined.
2. Exemptions for the vaccination include:
   a. Hepatitis B vaccination series previously received.
   b. Antibody testing shows immunity.
   c. Individual medical reasons
3. All direct care personnel have initial Tuberculosis (TB) testing and are reassessed annually.
   a. Test can be skin or blood.
   b. Risk will be evaluated annually



LeMed
SPECIALTY PHARMACY

Training Agenda Weekly Calendar

WEEK OF MM/DD/YY

	MORNING	AFTERNOON
M	**MM/DD** • Introductions • Tour • Corporate Training (PowerPoint/Video) • Corporate Document Review	• Review Handouts • Review Emails • Begin Accreditation SP 4.0 Training
T	**MM/DD** • Questions? • Finish Accreditation SP 4.0 Training • Start EnterpriseRx Training	• Finish EnterpriseRx Training • Review Policies & Procedures in Microsoft OneDrive
W	**MM/DD** • Questions? • Filling Coordinator Workflow Review • Filling Room Duty Overview	• Shadow/Train with xxx
T	**MM/DD** • Shadow XXX: Intake Coordinator 9-10 AM • Shadow XXX: Billing Coordinator 10-11 AM • Shadow XXX: Delivery Coordinator 11-12PM • Break • Questions	• Shadow xx: Prior Authorization Coordinator 1-2 PM • Shadow PCC's (rotate: xx, xx) 2-4 PM • Chat with Pharmacists (xx) 4-5:30 PM
F	**MM/DD** • Questions? • Soft Start	

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 03/26/2024
Receipt Number: 2024172871
Receipt Amount $: 480.00

Pharmacy - Limited Service

PERMIT NO	EXPIRES
Y009814	10/31/2025

Issued to : LeMed Specialty Pharmacy Arizona, LLC
LMSP Middle Holdings, LLC
2417 THIRD AVENUE SUITE 406 BRONX, NY 10451

LeMed Specialty Pharmacy Arizona, LLC
2450 E GUADALUPE ROAD SUITE 110
GILBERT, AZ 85234

Kam Gandhi
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : LeMed Specialty Pharmacy Arizona, LLC
LICENSE NUMBER : Y009814
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

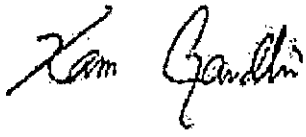
Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260,
Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

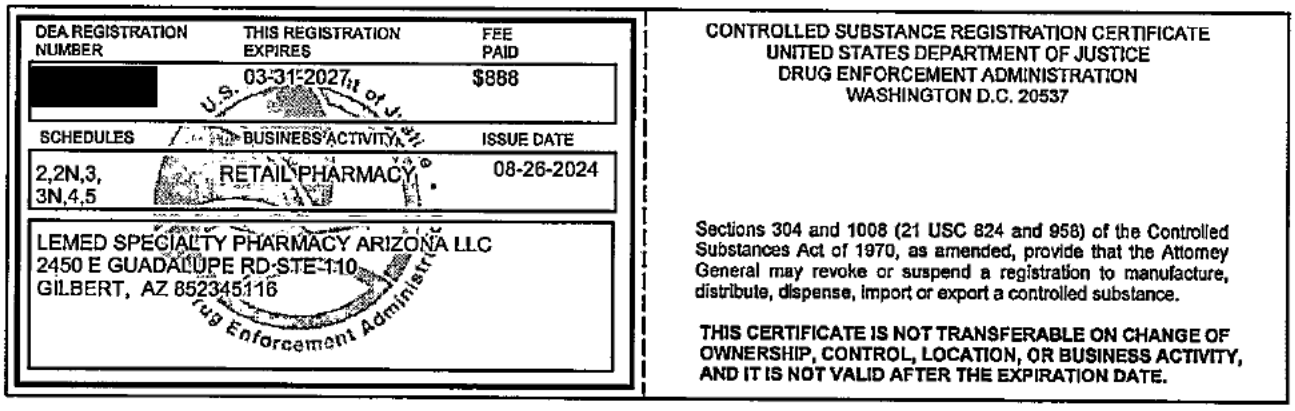
Name :	LeMed Specialty Pharmacy Arizona, LLC
Address :	2450 E Guadalupe Road Suite 110 Gilbert AZ 85234
Registration No :	Y009814
Permit Type :	Pharmacy
Sub Type :	Limited Service
Date Issued :	05/22/2024
Expiration Date :	10/31/2025
Status :	OPEN
Discipline :	No



Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 03/25/2025



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$888

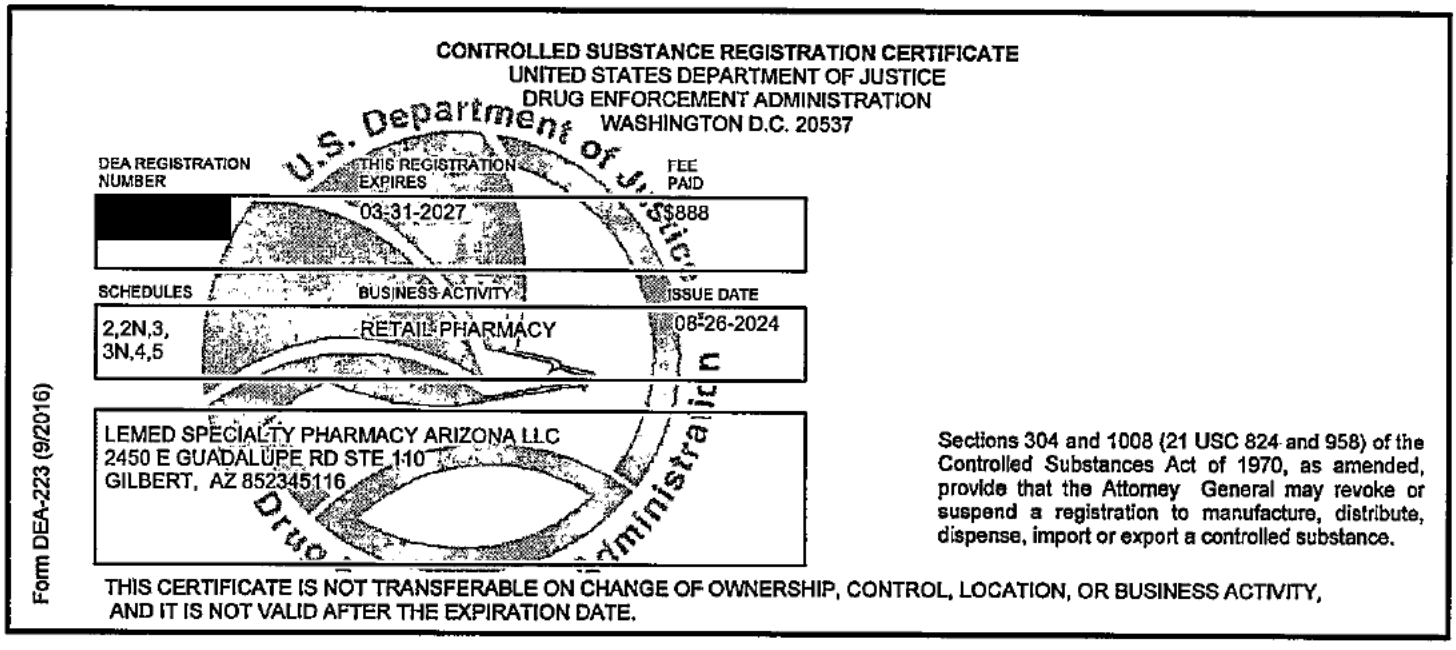
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-26-2024

LEMED SPECIALTY PHARMACY ARIZONA LLC
2450 E GUADALUPE RD STE 110
GILBERT, AZ 852345116

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	08-26-2024

LEMED SPECIALTY PHARMACY ARIZONA LLC
2450 E GUADALUPE RD STE 110
GILBERT, AZ 852345116

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Form DEA-223 (9/2016)

4SSS

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: FM1773945 ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☒ Other: Fertility Specialty

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Metro Drugs Pharmacy Department

Physical Address: 79 Hudson Street Suite 302

City: Hoboken State: NJ Zip: 07030

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 201-253-1100 Toll Free # (NAC 639.708, NRS 639.23286): 888-258-0106

Fax: 201-253-1101 Contact Email: [redacted]

Website: www.metrodrugs.pharmacy

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Mark Scovotti

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 22371

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Mark Scovotti	NV Pharmacist Registration #: 22371
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New Jersey

Parent Company (if any): N/A

Corporation/Organization Name: Metro Drugs Hoboken LLC

Mailing Address: 79 Hudson Street, Suite 302

City: Hoboken State: NJ Zip: 07030

Telephone: 201-253-1100 Email: [redacted]

Contact Person Name: Mark Scovotti

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Metro Drugs Pharmacy Department (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Joseph Tawil

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

5-1-25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Joseph Tawil hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Metro Drugs Pharmacy Department (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 01 day of May, 2025

Notary Public

WILMER J PAZMINO
Notary Public - State of New York
NO. 01PA6384619
Qualified in Queens County
My Commission Expires Dec 17, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Tawil

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

5-1-25

Date

Board Use Only	Date Received: 5/5/25	Amount: [redacted]

Owner/Officer information on:

Metro Drugs Hoboken LLC
79 Hudson Street Suite 302
Hoboken, NJ 07030
201-253-1100
NCPDP 3196498

Joseph A. Tawil President/CEO
Ownership Percentage= 100%



STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

METRO DRUGS HOBOKEN LLC
0600335505

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on November 14, 2008.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

JOSEPH TAWIL
METRO DRUGS HOBOKEN
79 HUDSON STREET STE. 302
HOBOKEN, NJ 07030

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 22nd day of April, 2025

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6163866991

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Metro Drugs Pharmacy Department

Pharmacy/Wholesaler License # (if applicable): pending

Physical Address: 79 Hudson Street Suite 3902

City: Hoboken State: NJ Zip: 07030

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 201-253-1100 Website: www.metrodrugs.pharmacy

Licensing Company Email: marks@metrodrugs.com

Section 2: Personal Information

First: Margk Middle: Last: Scovotti

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
ASt. Johns University		09/1976 to 05/1981	
Address	**City**	**State**	**Zip**
81-98 170th St,	Jamaica	NY	11432
Diploma/Degree obtained, if any			
BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Sdalesian High School		09/1973 to 06/1976	
Address	**City**	**State**	**Zip**
148 E Main Street	New Rochelle	NY	10801
Diploma/Degree obtained, if any			
General Studies			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2023 to 04/2025	[redacted]			
07/2022 to 06/2023				
05/2011 to 07/2022				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Metro Drugs Hoboken LLC			From - To (MM/YY – MM/YY): 01/2022 to present	
Business Address: 79 Hudson Street Suite 302	City: Hoboken		State: NJ	Zip: 07030
Phone: 201-253-1100	Title: Supervising Pharmacist		Number of Employed Hours: 1600	
Description of Duties: Supervising Pharmacist				

Business Name: Medical Centre Specialty Pharmacy			From - To (MM/YY – MM/YY): 01/2020 to 12/2022	
Business Address: 100 S Bedford Rd Suite 390	City: Mount Kisco		State: NY	Zip: 10549
Phone: 800-361-1260	Title: COO		Number of Employed Hours: 1440	
Description of Duties: Oversaw all pharmacy operations				

Business Name: Metro Drugs Hoboken LLC			From - To (MM/YY – MM/YY): 06/2004 to 12/2019	
Business Address: 79 Hudson Street Suite 302	City: Hoboken		State: NJ	Zip: 07030
Phone: 201-253-1100	Title: Suypervising Pharmacist		Number of Employed Hours: 6960	
Description of Duties: Supervising Pharmacist				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Business Name:			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:		Number of Employed Hours:	
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/1/2025

Date

I, Mark Scovotti, **certify that as the designated representative for**

Metro Drugs Hoboken LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ms I am at least 21 years of age;
3. ms I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ms I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ms I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ms I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ms I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Mark Scovotti

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/1/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Scovotti

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/1/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of New York

I, MARK SCOVOTTI, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

5/1/2025

Date

Subscribed and Sworn to before me this 1 day of May, 2025

Notary Public Signature

WILMER J PAZMINO
Notary Public - State of New York
NO. 01PA6384619
Qualified in Queens County
My Commission Expires Dec 17, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information:

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Metro Drugs Pharmacy Department

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): pending

Physical Address: 79 Hudson Street Suite 302

City: Hoboken State: NJ Zip: 07030

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 201-253-1100 Website: www.metrodrugs.pharmacy

Licensing Company Email: marks@metrodrugs.com

Section 2: Personal Information

First: Joseph Middle: Last: Tawil

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Brooklyn College		09/1973 to 05/1975	
Address	**City**	**State**	**Zip**
2900 Bedford Ave	Brooklyn	NY	11210
Diploma/Degree obtained, if any			
N/A			

School Name		From - To (MM/YY – MM/YY)	
Yeshivah of Flatbush		09/1969 to 06/1973	
Address	**City**	**State**	**Zip**
1609 Avenue J	Brooklyn	NY	11230
Diploma/Degree obtained, if any			
General Studies			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/1985 to Present	[redacted]	Brooklyn	NY	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Metro Compounding Corp				From - To (MM/YY – MM/YY): 12/1013 to present
Business Address: 243 East 60th St 2nd Floor		City: New York	State: NY	Zip: 10022
Phone: 212-794-7200	Title: President			
Description of Duties: Oversee all aspects of business				

Business Name: Metro Drugs Hoboken LLC				From - To (MM/YY – MM/YY): 11/2008 to present
Business Address: 79 Hudson Street Suite 302		City: Hoboken	State: NJ	Zip: 07030
Phone: 201-253-1100	Title: President			
Description of Duties: Oversee all aspects of business				

Business Name: Metro Drugs 3rd Ave Corp				From - To (MM/YY – MM/YY): 07/1996 to present
Business Address: 243 East 60th St 1st Floor		City: New York	State: NY	Zip: 10022
Phone: 212-794-7200	Title: President			
Description of Duties: Oversee all aspects of business				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name:				From - To (MM/YY – MM/YY):
Business Address:		City:	State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5-1-25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joseph Tawil

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5-1-25

Date

Please have this section completed in the presence of a Notary Public.

State of New York, ss. County of New York

I, Joseph Tawil, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

5-1-25

Date

Subscribed and Sworn to before me this 1 day of May, 2025.

Notary Public Signature

WILMER J PAZMINO
Notary Public - State of New York
NO. 01PA6384619
Qualified in Queens County
My Commission Expires Dec 17, 2026

(Seal)

New Jersey Office of the Attorney General
Division of Consumer Affairs
BOARD OF PHARMACY (973) 504-6450 • ENFORCEMENT BUREAU (973) 504-6300

Date: 12-14-2022
File number: 0[illegible]-1794

Board of Pharmacy Inspection Report

Metro Discs Pharmacy Dept
Pharmacy trade name

Corporation name (if not the same)

Owner (as identified on the occasion of this inspection)

79 Hudson St.
Street address

Hoboken NJ 07030
City State ZIP code

(Paste pharmacy label here)

I. Required pharmacy permits and licenses

A. Board of Pharmacy Permit [N.J.A.C. 13:39-4.3]

Metro Discs Pharmacy Dept — 28BC00697300 — 6-30-2024
Name of permit holder — Certificate number — Expiration date

B. New Jersey Controlled Dangerous Substance (C.D.S.) Certificate [N.J.A.C. 13:45H-1.2(c)]

0595700 — 10-31-2024
Certificate number — Expiration date

C. Drug Enforcement Administration (D.E.A.) Certificate [C.F.R. 1301.12]

FM1773945 — 1-31-2025
Certificate number — Expiration date

II. Personnel [Presence and display of required credentials, placards and/or name-tag adornments.] [N.J.A.C. 13:39-3.1(b), 13:39-5.3(b), 13:39-6.3 and 13:39-5.3(c)]

A. Pharmacist-in-charge's name (please print): Mark Scavotti
(Does the pharmacist-in-charge's name appear at the establishment's entranceway? ☑ Yes ☐ No)

28QT03542600 — 4-30-2025 — 40
Permit number — Expiration date — Hours worked per week

1. Is the registered pharmacist-in-charge's current renewal on display? ☑ Yes ☐ No

B. Personnel present for duty [N.J.S.A. 45:14-69d, 45:14-70c and 45:14-71] [N.J.A.C. 13:39-3.1(b) and 13:39-6.3]
[Identify all of the personnel who do any type of work behind the pharmacy's (or pharmacy department's) prescription filling area. For any person who holds a professional license, certificate, permit or registration, be sure to record his or her license, certificate, permit or registration number.]

1. Are all current renewals for the employed full-time pharmacists and technicians posted on display? ☑ Yes ☐ No

Name	Position (Registered pharmacist, technician, support staff, extern, etc.)	License, certificate, permit or registration number	Name tag	Hours worked per week
			☐ Yes ☐ No	
	James		☐ Yes ☐ No	
See 1D			☐ Yes ☐ No	
			☐ Yes ☐ No	
			☐ Yes ☐ No	

III. Mandatory equipment [N.J.A.C. 13:39-5.8(a)8 and 13:39-5.6]

1. Is there a sink with hot and cold running water? ☑ Yes ☐ No
2. Is there a satisfactory counting tray or device? ☑ Yes ☐ No

IV. Miscellaneous requirements

1. [16 C.F.R. 1700.14/15] Is a representative inventory of safety closures present? ☑ Yes ☐ No
2. Are prescriptions being dispensed in containers with an appropriate safety closure? ☐ Yes ☐ No
3. [N.J.A.C. 13:39-5.8(c)] Is the dispensing area in a clean, orderly and sanitary condition? ☑ Yes ☐ No
4. [N.J.S.A. 45:14-48a(10)] [N.J.A.C. 13:39-5.8(a)1] Is the pharmacy library satisfactory? ☐ Yes ☑ No
5. [N.J.A.C. 13:45H-5.7] Has the required biennial C.D.S. inventory been conducted? ☐ Yes ☑ No
6. [N.J.A.C. 13:45H-5.5] Has the C.D.S. inventory been properly documented? ☐ Yes ☑ No

RPh locked to sign on to Board of Counsel

(1 of 4)

Print the name of the registered pharmacist who was present for the survey

Signature of the registered pharmacist who was present for the survey

Signature of the Enforcement Bureau representative

Form EB-02 (10/12)

BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

METRO DRUGS PHARMACY DEPT.
MARK S SCOVOTTI
79 Hudson St.
Hoboken NJ 07030

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

04/23/2024 TO 06/30/2025
VALID

Signature of Licensee/Registrant/Certificate Holder

28RS00697300
LICENSE/REGISTRATION/CERTIFICATION #

Cari Fais
ACTING DIRECTOR

New Jersey Office of the Attorney General
Division of Consumer Affairs
THIS IS TO CERTIFY THAT THE
Board of Pharmacy
HAS LICENSED
METRO DRUGS PHARMACY DEPT.
Pharmacy
04/23/2024 TO 06/30/2025
VALID
28RS00697300
License/Registration/Certificate #
SIGNATURE
Cari Fais
ACTING DIRECTOR

PLEASE DETACH HERE

IF YOUR LICENSE/REGISTRATION/ CERTIFICATE ID CARD IS LOST PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PLEASE DETACH HERE

METRO DRUGS PHARMACY DEPT.

YOUR LICENSE/REGISTRATION/CERTIFICATE NUMBER IS **28RS 00697300** . EXPIRATION DATE **2025**
PLEASE USE IT IN ALL CORRESPONDENCE TO THE DIVISION OF CONSUMER AFFAIRS. USE THIS SECTION TO REPORT ADDRESS CHANGES. YOU ARE REQUIRED TO REPORT ANY ADDRESS CHANGES IMMEDIATELY TO THE ADDRESS NOTED BELOW.

Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PRINT YOUR NEW **ADDRESS OF RECORD** BELOW.
YOUR ADDRESS OF RECORD IS THE ADDRESS THAT WILL PRINT ON YOUR LICENSE/REGISTRATION/CERTIFICATE AND IT MAY BE MADE AVAILABLE TO THE PUBLIC.

HOME ☐
BUSINESS ☐

TELEPHONE
INCLUDE AREA CODE

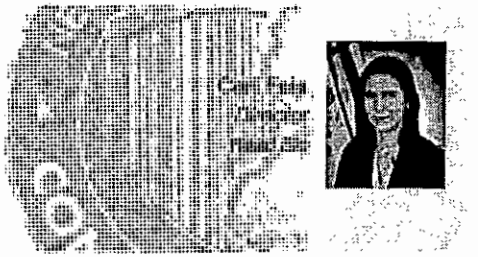
PRINT YOUR NEW **MAILING ADDRESS** BELOW.
YOUR MAILING ADDRESS IS THE ADDRESS THAT WILL BE USED BY THE DIVISION OF CONSUMER AFFAIRS TO SEND YOU ALL CORRESPONDENCE.

HOME ☐
BUSINESS ☐

TELEPHONE
INCLUDE AREA CODE

If the law governing your profession requires the current license/registration/certificate to be displayed, it should be within reasonable proximity of your original license/registration/certificate at your principal office or place of business.

NEW JERSEY DIVISION OF
CONSUMER AFFAIRS



License Information

Accurate as of April 23, 2025 11:01 AM

Return to Search Results

Name: METRO DRUGS PHARMACY DEPT.

Address: Hoboken,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00697300

License Status: Active

Status Change Reason: License Issuance

Issue Date: 10/20/2009

Expiration Date: 6/30/2025

Board Action: No

Prerequisites

Supervisor Information

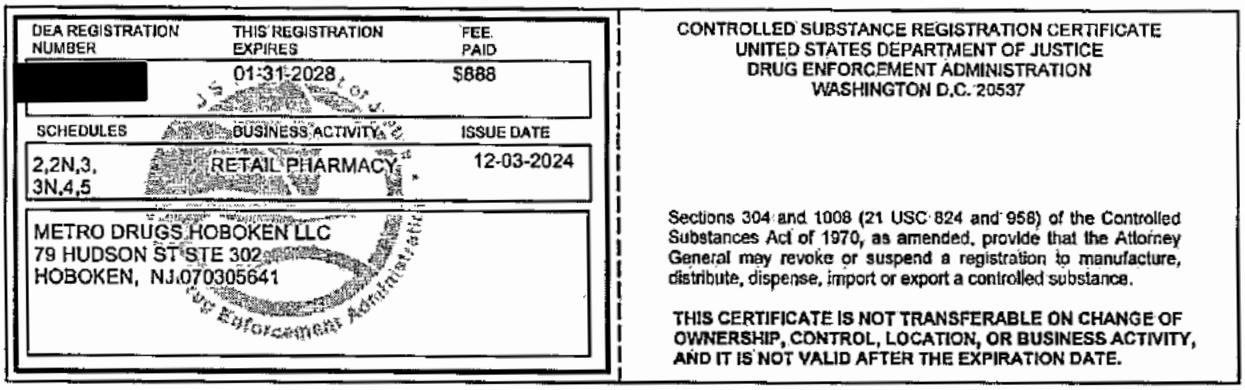
Prereq Type: Prerequisite
Licensee: METRO DRUGS PHARMACY DEPT. **License No:** D09592100 **License Type:** CDS Pharmacy **License Status:** Active
Relationship: **Association Date:** **Expiration Date:** **Date Established:** 11/19/2009

Supervisor Information

Prereq Type: Prerequisite User
Licensee: Scovotti, Mark S **License No:** 28RI03542600 **License Type:** Pharmacist **License Status:** Active
Relationship: **Association Date:** 3/22/2022 **Expiration Date:** **Date Established:**

Documents

No Public Documents



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	01-31-2028	$888

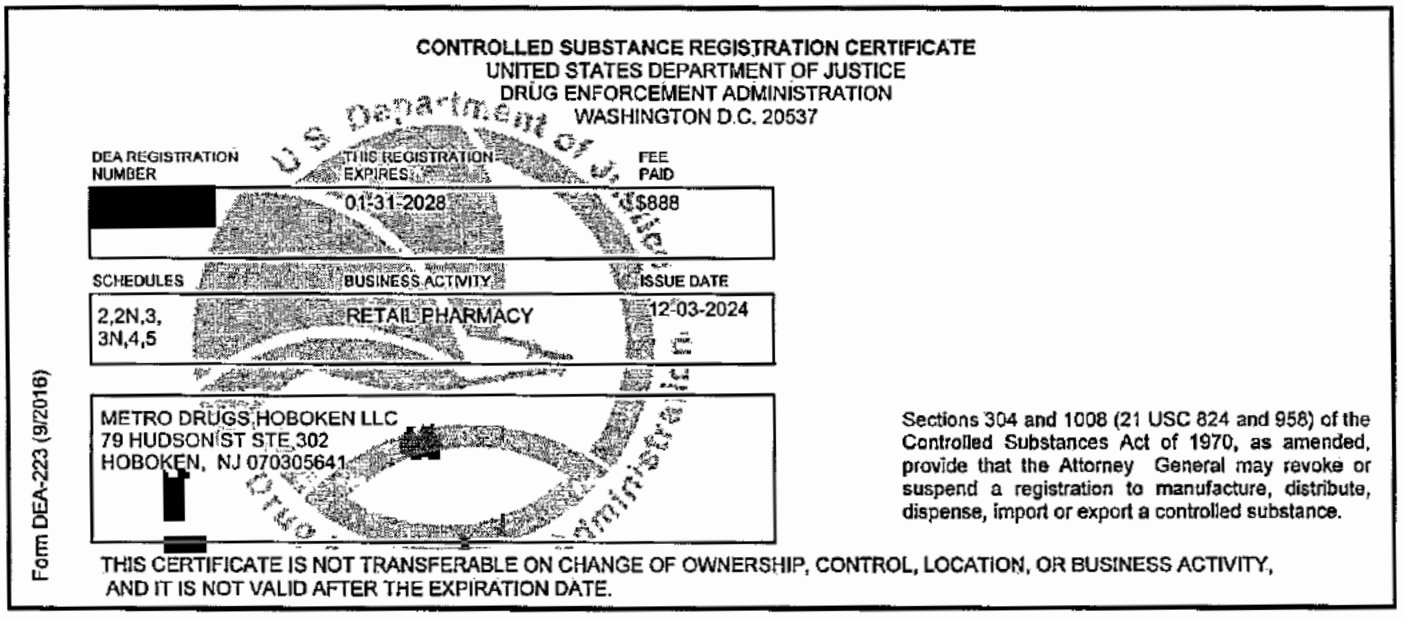
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-03-2024

METRO DRUGS HOBOKEN LLC
79 HUDSON ST STE 302
HOBOKEN, NJ 070305641

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	01-31-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	12-03-2024

METRO DRUGS HOBOKEN LLC
79 HUDSON ST STE 302
HOBOKEN, NJ 070305641
[redacted]

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4TTT

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			■ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Four Seasons Pharmacy Inc dba Phoenix Pharmacy

Physical Address: 7872 WALKER STREET SUITE 106

City: LA PALMA State: CA Zip: 90623

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 714-690-0349 Toll Free # (NAC 639.708, NRS 639.23286): 866-202-9102

Fax: 714-509-1278 Contact Email: [redacted]

Website: phoenixpharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): JEREMY HANA

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24067

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: JEREMY HANA	NV Pharmacist Registration #: 24067
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: CALIFORNIA

Parent Company (if any): _____

Corporation/Organization Name: Four Seasons Pharmacy Inc

Mailing Address: 7872 WALKER STREET SUITE 106

City: LA PALMA State: CA Zip: 90623

Telephone: 714-690-0349 Email: [redacted]

Contact Person Name: NATHAN LAM

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO/OWNER (title) for Phoenix Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

NATHAN LAM

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

Feb 25, 2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Nathan Lam hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the OWNER/CEO (title) for Phoenix Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 28th day of February, 2025

Notary Public

PRIYANKA JAIN
COMM. #2431908
Notary Public - California
Los Angeles County
My Comm. Expires Dec. 20, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

NATHAN LAM - CEO/OWNER

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

Feb 25, 2025

Date

Board Use Only	Date Received: 4/28/25	Amount: $ [redacted]

BA20242218284

STATE OF CALIFORNIA
Office of the Secretary of State
STATEMENT OF INFORMATION
CORPORATION

California Secretary of State
1500 11th Street
Sacramento, California 95814
(916) 657-5448

For Office Use Only

-FILED-

File No.: BA20242218284
Date Filed: 12/18/2024

Entity Details

Corporation Name	FOUR SEASONS PHARMACY INC.
Entity No.	4215707
Formed In	CALIFORNIA

Street Address of Principal Office of Corporation

Principal Address	7872 WALKER STREET 106 LA PALMA, CA 90623

Mailing Address of Corporation

Mailing Address	7872 WALKER STREET 106 LA PALMA, CA 90623
Attention	

Street Address of California Office of Corporation

Street Address of California Office	7872 WALKER STREET 106 LA PALMA, CA 90623

Officers

Officer Name	Officer Address	Position(s)
NATHAN LAM	7872 WALKER STREET 106 LA PALMA, CA 90623	Chief Executive Officer, Chief Financial Officer, Secretary

Additional Officers

Officer Name	Officer Address	Position	Stated Position
None Entered			

Directors

Director Name	Director Address
NATHAN LAM	7872 WALKER STREET 106 LA PALMA, CA 90623

The number of vacancies on Board of Directors is: 0

Agent for Service of Process

Agent Name	NATHAN LAM
Agent Address	7872 WALKER STREET 106 LA PALMA, CA 90623

Type of Business

Type of Business	PHARMACY SERVICE

Email Notifications

Opt-in Email Notifications	Yes, I opt-in to receive entity notifications via email.

Labor Judgment

B3275-7144 12/18/2024 11:54 AM Received by California Secretary of State

No Officer or Director of this Corporation has an outstanding final judgment issued by the Division of Labor Standards Enforcement or a court of law, for which no appeal therefrom is pending, for the violation of any wage order or provision of the Labor Code.

Electronic Signature

☒ By signing, I affirm that the information herein is true and correct and that I am authorized by California law to sign.

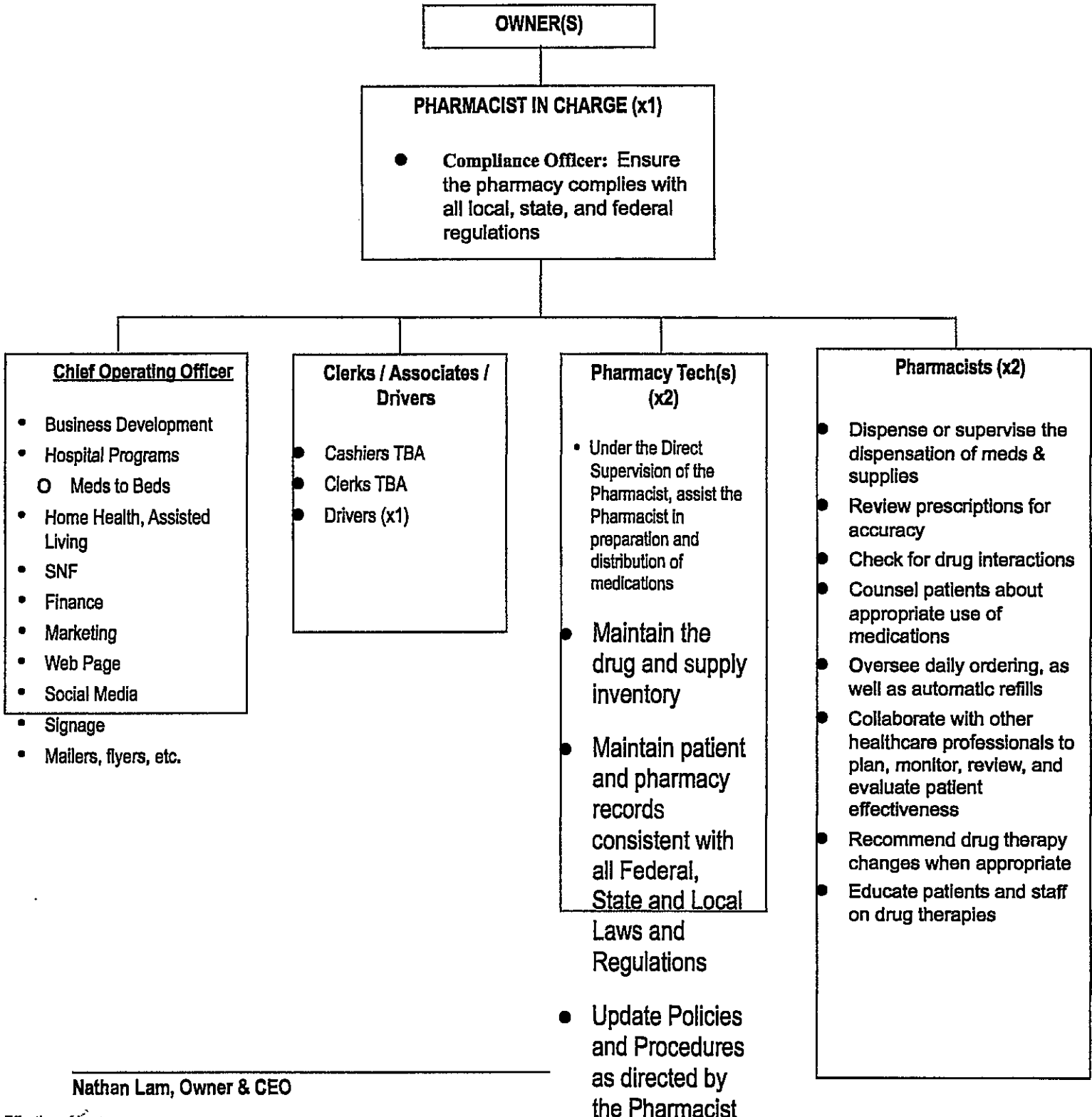
KALI CHAUDHURI
Signature

12/18/2024
Date

B3275-7145 12/18/2024 11:54 AM Received by California Secretary of State

FOUR SEASONS PHARMACY, Inc

ORGANIZATIONAL CHART



Nathan Lam, Owner & CEO

Effective:
Revised:

Secretary of State
Certificate of Status

I, SHIRLEY N. WEBER, PH.D., California Secretary of State, hereby certify:

Entity Name:	FOUR SEASONS PHARMACY INC.
Entity No.:	4215707
Registration Date:	12/03/2018
Entity Type:	Stock Corporation - CA - General
Formed In:	CALIFORNIA
Status:	Active

The above referenced entity is active on the Secretary of State's records and is authorized to exercise all its powers, rights and privileges in California.

This certificate relates to the status of the entity on the Secretary of State's records as of the date of this certificate and does not reflect documents that are pending review or other events that may impact status.

No information is available from this office regarding the financial condition, status of licenses, if any, business activities or practices of the entity.

IN WITNESS WHEREOF, I execute this certificate and affix the Great Seal of the State of California this day of February 15, 2025.

SHIRLEY N. WEBER, PH.D.
Secretary of State

Certificate No.: 296499043

To verify the issuance of this Certificate, use the Certificate No. above with the Secretary of State Certification Verification Search available at **biz**fileOnline.sos.ca.gov.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Four Seasons Pharmacy Inc dba Phoenix Pharmacy

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 7872 WALKER STREET SUITE 106

City: LA PALMA State: CA Zip: 90623

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 714-690-0349 Website: phoenixpharmacy.com

Licensing Company Email: nlam@phoenixpharmacy.com

Section 2: Personal Information

First: JEREMY Middle: Last: HANA

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: nlam@phoenixpharmacy.com

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

School Name			From - To (MM/YY – MM/YY)	
SOUTH HILLS HIGH SCHOOL			09/96-06/00	
Address	City		State	Zip
645 BARRANCA ST	WEST COVINA		CA	91791
Diploma/Degree obtained, if any				
GENERAL EDUCATION HIGH SCHOOL DIPLOMA				

School Name			From - To (MM/YY – MM/YY)	
CALIFORNIA STATE UNIVERSITY, FULLERTON			08/07-06/10	
Address	City		State	Zip
800 N STATE COLLEGE BLVD	FULLERTON		CA	92831
Diploma/Degree obtained, if any				
BACHELOR'S DEGREE - BIOLOGICAL SCIENCES- MOLECULAR BIOLOGY				

School Name			From - To (MM/YY – MM/YY)	
KECK GRADUATE INSTITUTE SCHOOL OF PHARMACY			08/16-06/20	
Address	City		State	Zip
535 WATSON DR	CLAREMONT		CA	91711
Diploma/Degree obtained, if any				
DOCTORATE OF PHARMACY				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/11-CURRENT				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Business Name			From - To (MM/YY – MM/YY)	
PHOENIX PHARMACY			02/24-CURRENT	
Business Address		City	State	Zip
7872 WALKER ST		LA PALMA	CA	90623
Phone	Title		Number of Employed Hours	
714-690-0349	PHARMACIST IN CHARGE		2,080	

Description of Duties:
MANAGE THE DAILY OPERATIONS OF A IN INDEPEDENT PHARMACY AND KEEPING THE PHARMACY
WITH RULES AND REGULATIONS SET BY THE CA BOARD OF PHARMACY.

Business Name			From - To (MM/YY – MM/YY)	
CARDINAL HEALTH INC			08/23-3/24	
Business Address		City	State	Zip
7000 Cardinal Place		DUBLIN	OH	43017
Phone	Title		Number of Employed Hours	
(614) 757-5000	HOSPITAL PHARMACIST II		1,120	

Description of Duties:
VERIFYING HOSPITAL ORDERS AND RELEASING MEDICATIONS TO NURSES AND PATIENTS
WORK FROM HOME POSITION.

Business Name			From - To (MM/YY – MM/YY)	
Providence - Cedars Sinai Tarzana Medical Center			03/23-06/23	
Business Address		City	State	Zip
18321 Clark St		TARZANA	CA	91356
Phone	Title		Number of Employed Hours	
(818) 881-0800	DISCHARGE PHARMACIST		480	

Description of Duties:
COUNSELED PATIENTS AT BEDSIDE WITH DISCHARGED MEDICATIONS.

Business Name			From - To (MM/YY – MM/YY)	
MERCY PHARMACY			11/22 08/23	
Business Address		City	State	Zip
1152 Via Verde		SAN DIMAS	CA	91773
Phone	Title		Number of Employed Hours	
(909) 599-3444	STAFF PHARMACIST PER DIEM		640	

Description of Duties:

Business Name			From - To (MM/YY – MM/YY)	
CVS CAREMARK			03/21 09/22	
Business Address		City	State	Zip
750 W John Carpenter Fwy #1200		IRVING	TX	75039
Phone	Title		Number of Employed Hours	
(469) 524-4700	FLOATER PHARMACIST		2,880	

Description of Duties:
OPENED AND CLOSED VARIOUS CVS PHARMACIES ACROSS THE LOS ANGELES DISTRIC
VERIFIED PRESCRIPTIONS, GAVE VACCINES AND COUNSELED PATIENTS ON MEDICATIO

Continue on next page if additional space is needed.

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I, JEREMY HANA, **certify that as the designated representative for**

PHOENIX PHARMACY,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. _____ I am at least 21 years of age;
3. _____ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. _____ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. _____ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. _____ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. _____ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JEREMY HANA

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/28/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

JEREMY HANA

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/28/25

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Jeremy Hana, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

2/28/25

Date

Subscribed and Sworn to before me this 28th day of February 2025

Notary Public Signature

PRIYANKA JAIN
COMM. #2431908
Notary Public - California
Los Angeles County
My Comm. Expires Dec. 20, 2026

NRO1 NRO1

[Seal]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Four Seasons Pharmacy Inc dba Phoenix Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 7872 WALKER STREET SUITE 106

City: LA PALMA State: CA Zip: 90623

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 714-690-0349 Website: phoenixpharmacy.com

Licensing Company Email: nlam@phoenixpharmacy.com

Section 2: Personal Information

First: NATHAN Middle: Last: LAM

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Pasadena City College		2024-Current	
Address	**City**	**State**	**Zip**
1570 E Colorado Blvd.	Pasadena	CA	91106
Diploma/Degree obtained, if any			
B.S. Mechanical Engineering - Transfer			

School Name		From - To (MM/YY – MM/YY)	
Loyola Marymount University		2019-2022	
Address	**City**	**State**	**Zip**
1 Loyola Marymount University Dr.	Los Angeles	CA	90045
Diploma/Degree obtained, if any			
Bachelor's of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Pasadena City College		2017-2019	
Address	**City**	**State**	**Zip**
1570 E Colorado Blvd.	Pasadena	CA	91106
Diploma/Degree obtained, if any			
Bachelor's of Business Administration - Transfer			

School Name		From - To (MM/YY – MM/YY)	
Arcadia High School		2013-2017	
Address	**City**	**State**	**Zip**
180 Campus Drive	Arcadia	CA	91006
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
10/16-Current				
From - To (MM/YY – MM/YY)				
10/13 - 10/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Phoenix Pharmacy			06/01/2022 to present
Business Address	**City**	**State**	**Zip**
7872 Walker Street Suite 106	La Palma	CA	90623
Phone	**Title**		
714-690-0349	Owner		
Description of Duties			
See attachment 1			

Business Name			From - To (MM/YY – MM/YY)
Auxilium Health Network Inc			05/30/2020-05/30/2022
Business Address	**City**	**State**	**Zip**
159 E. Huntington Dr. # 9	Arcadia	CA	91006
Phone	**Title**		
323-319-5227	Assistant Administrator		
Description of Duties			
See attachment 2			

Business Name			From - To (MM/YY – MM/YY)
Samaritan Medical Tower Pharmacy			09/06/2017-04/30/2020
Business Address	**City**	**State**	**Zip**
1127 Wilshire Blvd. # 201	Los Angeles	CA	90017
Phone	**Title**		
213-482-0644	Pharmacy Clerk		
Description of Duties			
See attachment 3			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

attachment 1

As a pharmacy owner, I am responsible for a wide range of duties to ensure the smooth operation of the business while maintaining compliance with healthcare regulations. Some of the key responsibilities include:

1. Business Management

- **Financial oversight**: Managing the pharmacy's budget, including expenses, revenue, and profits.
- **Inventory management**: Ensuring that medications and supplies are well-stocked and regularly ordered to meet patient demand.
- **Employee management**: Hiring, training, and managing staff, including pharmacists, pharmacy technicians, and other personnel.
- **Customer service**: Ensuring high-quality service and patient satisfaction.
- **Marketing and growth**: Promoting the pharmacy's services, including community outreach, promotions, or partnerships with local health professionals.

2. Regulatory Compliance

- **Adherence to laws**: Complying with state, federal, and local regulations regarding the dispensing of medications, health and safety, and business operations.
- **Record keeping**: Keeping accurate records of prescriptions, inventory, and sales for auditing and compliance purposes.
- **Licensing**: Maintaining proper licenses for operating a pharmacy and the certification of all pharmacists and staff as required by law.

3. Quality Control and Safety

- **Risk management**: Identifying and mitigating any risks associated with pharmacy operations, whether related to safety, security, or customer health.

5. Technology Management

- **Pharmacy software**: Overseeing the pharmacy management system, including prescription processing, patient records, and inventory management.
- **Data protection**: Ensuring the privacy and security of patient information in compliance with HIPAA or other applicable laws.

6. Community Involvement

- **Public health promotion**: Engaging in initiatives like immunizations, health screenings, and wellness programs for the local community.
- **Patient education**: Offering seminars, workshops, or materials that educate patients on health and wellness topics.
-

- Being a pharmacy owner means balancing the clinical aspects of healthcare with the financial and managerial duties of running a business, ensuring you can deliver high-quality care while maintaining a sustainable and compliant operation.

Attachment 2

As a healthcare assistant administrator, my responsibilities was broad and encompass both operational and strategic tasks. I was essentially responsible for support overseeing the day-to-day management of a healthcare organizations, ensuring that everything runs smoothly, efficiently, and in compliance with relevant regulations with my administrator. Here are some of my key responsibilities as a healthcare assistant administrator.

1. Support Operational Management

- **Ssupport Staff Management**: Oversee the recruitment, hiring, training, and performance management of medical, administrative, and support staff.
- **Facility Management**: Ensure that the healthcare facility is properly maintained and that equipment is functioning.

2. Support Financial Oversight

- **Budgeting**: Develop and manage budgets for the facility, ensuring resources are allocated appropriately and that the organization remains financially viable.
- **Cost Control**: Monitor expenditures and find ways to reduce unnecessary costs while maintaining quality care.

3. Support Regulatory Compliance

- **Legal and Ethical Compliance**: Ensure that the healthcare organization complies with federal, state, and local regulations, including healthcare laws (HIPAA, patient safety laws, etc.).

4. Support Quality Assurance and Improvement.

- **Patient Satisfaction**: Measure patient satisfaction and address any complaints or concerns to improve service.

5. Support Strategic Planning and Development

- **Long-term Planning**: Participate in or lead efforts to set long-term goals and strategies for the healthcare organization, including expansion, service improvements, or new offerings.
- **Innovation and Technology**: Stay updated with healthcare trends and technological advancements to improve patient care and operational efficiency.
- **Data Analysis**: Use data analytics to assess the performance of the organization and make informed decisions.

6. Support Human Resources Management

Employee Relations: Handle employee concerns, create a positive work environment, and foster professional development opportunities for staff.

- **Compliance with Employment Laws**: Ensure adherence to employment laws, including fair labor practices and employee rights.

7. Support Technology and Systems Management

- **Data Security**: Ensure that patient information is securely stored and handled, in compliance with privacy laws like HIPAA.

8. Support Crisis Management

- **Business Continuity**: Develop and implement business continuity plans to ensure that the facility can operate even during adverse situations.

9.Support Budgeting and Resource Allocation

- **Resource Management**: Ensure that the healthcare facility has the necessary equipment, supplies, and human resources to function effectively.
- **Financial Performance**: Manage the financial health of the organization, aiming to reduce costs while maintaining a high level of care.

10. Support Leadership

- **Leadership Development**: Provide leadership to staff, motivating teams, setting goals, and ensuring that the organization's mission and vision are upheld.
- **Decision-making**: Make crucial decisions regarding operational processes, personnel, and resource allocation.

See attachment 3

The Pharmacy Clerk is responsible for performing various administrative and clerical duties in a pharmacy setting. This includes assisting customers, managing inventory, processing transactions, and ensuring that the pharmacy operates efficiently and in compliance with all relevant regulations. The pharmacy clerk plays a key role in maintaining a clean, organized, and customer-friendly environment.

Key Responsibilities:

1. **Customer Service**
   - Greet customers and assist with general inquiries.
   - Answer the phone and address patient concerns or direct them to the pharmacist or pharmacy technician as needed.
   - Assist customers with locating over-the-counter products and medications.
   - Provide information on pharmacy hours, services, and policies.
2. **Clerical and Administrative Tasks**
   - Process prescription orders, including verifying customer information and entering data into the pharmacy system.
   - Maintain accurate records of prescription orders and patient information.
   - File and organize prescriptions and other documentation in an orderly manner.
   - Handle cash, credit, and insurance payments and process transactions accurately.
   - Ensure that customer receipts and prescription records are printed and provided to patients.
3. **Inventory Management**
   - Assist with receiving and stocking medication deliveries.
   - Monitor stock levels and report shortages or expired medications to the pharmacist.
   - Organize shelves and ensure medications are stored in accordance with safety and regulatory standards.
   - Assist in preparing inventory orders and managing stockroom cleanliness.
4. **Prescription Support**
   - Prepare and label prescription medication under the guidance of the pharmacist or pharmacy technician.
   - Ensure that the correct medication is dispensed, and all labels are accurate and comply with regulatory requirements.
   - Verify and maintain records for refills and patient prescriptions.
5. **Regulatory Compliance**
   - Ensure all activities comply with state and federal laws, including confidentiality regulations (HIPAA).
   - Maintain a clean and organized pharmacy area, following safety and health protocols.
6. **Customer Education and Assistance**
   - Educate customers on the proper storage of medications and over-the-counter products.
   - Provide guidance on proper usage of non-prescription items when appropriate.
   - Direct patients to the pharmacist for in-depth consultations or medication counseling.

7. **General Support**
    - Assist the pharmacist and pharmacy technician with tasks as needed, including preparation of medication orders.
    - Handle clerical duties such as faxing, emailing, and other paperwork.
    - Perform other related duties as assigned to ensure the smooth operation of the pharmacy.

Qualifications:

- High school diploma or equivalent required.
- Previous experience in a customer service role, preferably in a pharmacy or healthcare setting, is a plus.
- Basic knowledge of pharmacy operations, medications, and medical terminology is an advantage.
- Strong attention to detail and the ability to follow instructions accurately.
- Ability to multitask and work efficiently in a fast-paced environment.
- Excellent communication and interpersonal skills.
- Ability to work as part of a team and provide excellent customer service.

Skills and Abilities:

- **Communication:** Strong verbal and written communication skills to interact with customers and team members.
- **Organizational Skills:** Ability to manage multiple tasks and keep the pharmacy organized.
- **Attention to Detail:** Ensuring that all prescription orders, labels, and inventory are accurate.
- **Customer Service:** Providing friendly, helpful, and efficient service to customers and patients.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY -- MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

NATHAN LAM

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

02/28/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Los Angeles

I, Nathan Lam, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

02/28/2025

Date

Subscribed and Sworn to before me this 28th day of February, 2025

Phaia

Notary Public Signature

PRIYANKA JAIN
COMM. #2431908
Notary Public · California
Los Angeles County
My Comm. Expires Dec. 20, 2026

NRO1 NRO1

(Seal)

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 1/22/2025 Inspector: Valerie Sakamura

Firm: PHOENIX PHARMACY Phone: (714) 690-0349

Address: 7872 WALKER ST STE 106 City: LA PALMA Zip: 90623

Ownership: CORPORATION

Permit #: PHY59620 Permit Exp: 4/1/2025 DEA#: FF8244573 DEA Exp: 3/31/2027

Date of Self Assessment Form: 2/26/2024 Other Permit #: N/A Date of DEA Inventory: ___

Hours M-F: 830-17 Hours Saturday CLOSED Hours Sunday: CLOSED

PIC JEREMY HANA RPH84156 Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:	Staff Name:	License #:
		CRYSTAL AGUILAR	TCH171997
		NATHAN LAM	OWNER
		SANDRA GOMEZ	CLERK

Inspector Remarks:

Independent pharmacy recent change of ownership in October. Previous owner nurse Chris changed ownership to her son, Nathan Lam. Last inspected 4/30/24 under PHY58891. New license is PHY 59620. Pharmacy closed for lunch during inspection-stayed on premises with PIC.

PREMISES:
Pharmacy on first floor of medical building, free parking under building and around building. No drive thru. Hot water takes a long time to get hot-I had to run it for a while and it only became warm. This was previously noted during the last inspection. Later during the inspection after the water was used for a while, it got hot quicker.

STAFFING/WORKLOAD: Normal staffing: 1 RPH; 1 TCH: 1 CLK. About 30-80 prescriptions per PIC. Refill labels kept in book.

Wholesalers: In between getting new accounts, Used to have Bergen but now switching to Mckesson, Uses Quest Pharm, Buyline, API, Hygen, Keysource
Reverse distributor: Reverse Distributors /Pharmalogisitics
Computer: Prime Rx

SERVICES:
Delivery: personal (done by employee Sandra)-goes to LA, Palmdale
Meds to beds: mostly indigent.
Immunizations, oral contraception, Narcan,
LTC: Bubble packs for SNF, and Arms open wide, Colarc.

RECORDKEEPING:
Offsite waiver available

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

ORDER OF CORRECTION

Date: 1/22/2025 Permit #: PHY59620

Time of Day: 11:27 AM

Name as shown on permit: **PHOENIX PHARMACY**

Address: 7872 WALKER ST STE 106 City: LA PALMA

Please be advised it appears there is a failure to comply with the following laws governing the practice of pharmacy, and/or the rules and regulations of the Board of Pharmacy:

1. **CCR 1715(b)(1)**	Self-Assessment of a Pharmacy by the Pharmacist-in-Charge. In addition to the self-assessment required in subdivision (a) of this section, the pharmacist-in-charge shall complete a self-assessment within 30 days whenever: A new pharmacy permit has been issued, or A new license was issued but there is no new self-assessment. Please complete one and send to me within 7 days.

I have reviewed, discussed, understand and received a copy of this form.

Inspector (sign) _____ Signed _____

Inspector (print) VALERIE SARAMILLA Print Name Jeremy Hong

Date 1/22/25 Title PIC

Pursuant to Business and Professions Code §4083, a licensee of the California State Board of Pharmacy, may submit a written request within 30 days of service of the order of correction, for an office conference with the board's executive officer to contest the order of correction.

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

OFFICIAL RECEIPT

January 22, 2025

Receipt Number: 221094
Firm: PHOENIX PHARMACY
Address: 7872 WALKER ST STE 106, LA PALMA CA 90623
Permit #: PHY59620
Phone: (714) 690-0349

The following was obtained this date under provisions of the California Pharmacy Law (Chapter 9, Division 2, Business and Professions Code) or the Rules and Regulations adopted thereunder:

Qty	Units	Description
2	Page(s)	MatchRx invoice
2	Page(s)	PBA Health invoice
1	Page(s)	Independent Pharmaceutical invoice
3	Page(s)	Quest Pharmaceuticals
2	Page(s)	PBA Health invoice
1	Page(s)	Independent Pharmaceutical invoice
2	Page(s)	Bonita Pharmaceutical invoice
3	Page(s)	Quest Pharmaceutical invoice
1	Page(s)	Independent pharmaceutical invoice
3	Page(s)	API invoice
2	Page(s)	QUEST Pharmaceuticals invoice
2	Page(s)	Keysource invoice

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
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www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

OFFICIAL RECEIPT

January 22, 2025

Receipt Number: 221094

Firm: PHOENIX PHARMACY

Address: 7872 WALKER ST STE 106, LA PALMA CA 90623

Permit #: PHY59620

Phone: (714) 690-0349

The following was obtained this date under provisions of the California Pharmacy Law (Chapter 9, Division 2, Business and Professions Code) or the Rules and Regulations adopted thereunder:

Voluntarily Released for Investigation

Receipt acknowledged by: _____ PIC
Title

Inspector: _____

CA dca SEARCH

BOARD OF PHARMACY

ISSUANCE DATE
OCTOBER 9, 2024
EXPIRATION DATE
OCTOBER 1, 2025
CURRENT DATE / TIME
APRIL 24, 2025
8:9:8 AM

LICENSING DETAILS FOR: PHY 59620

NAME: PHOENIX PHARMACY
LICENSE TYPE: PHARMACY (COMMUNITY)
LICENSE STATUS: CLEAR

ADDRESS
7872 WALKER ST 106
LA PALMA CA 90623
ORANGE COUNTY

LICENSE RELATIONSHIPS

NAME: HANA, JEREMY
LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST
LICENSE NUMBER: 84166 PRIMARY STATUS: CLEAR

ADDRESS NOT DISCLOSED

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 59620

NAME: PHOENIX PHARMACY

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

7872 WALKER ST 106
LA PALMA CA 90623
ORANGE COUNTY

ISSUANCE DATE

OCTOBER 9, 2024

EXPIRATION DATE

OCTOBER 1, 2025

CURRENT DATE / TIME

APRIL 28, 2025
11:31:59 AM

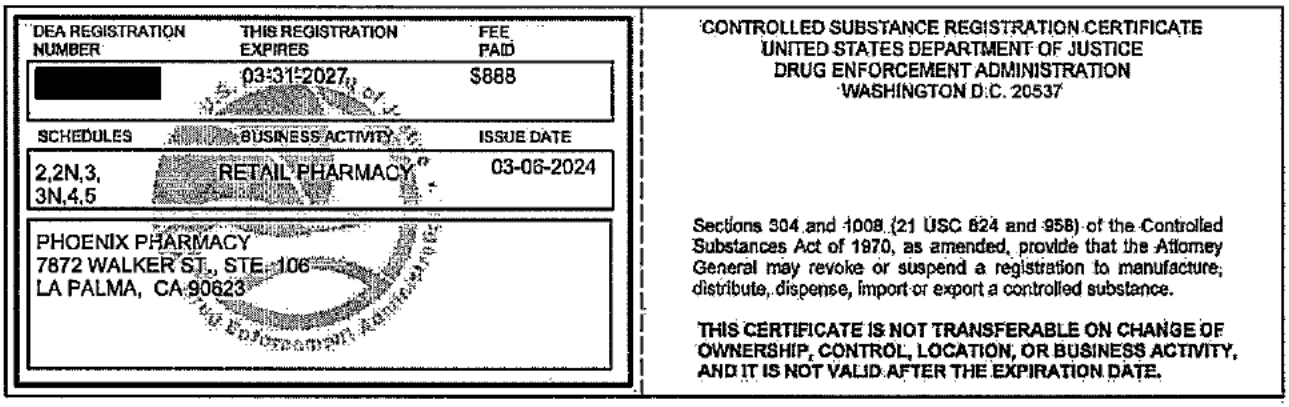
LICENSE RELATIONSHIPS

NAME: HANA, JEREMY

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 84156 **PRIMARY STATUS:** CLEAR



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-06-2024

PHOENIX PHARMACY
7872 WALKER ST., STE. 106
LA PALMA, CA 90623

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-06-2024

PHOENIX PHARMACY
7872 WALKER ST., STE. 106
LA PALMA, CA 90623

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NEVADA: Remaining Check List

*Please note, the information you provided us is the information that we have put forth on your application. EPC will not be responsible for any incorrect data.

APPLICATION (Non-Resident):

- $500.00 check made payable to:
  - Nevada State Board of Pharmacy

APPLICATION:

- Page 5: Nathan Lam – sign and date
- Page 6: Nathan Lam – sign, date and notarize
- Page 7: Jeremy Hana – initial, sign and date
- Page 9: Nathan Lam – sign and date

DESIGNATED REPRESENTATIVE APPLICATION

- Page 2: Answer Sections 5 and 6
- Page 3: Answer Section 7
- Page 8: Jeremy Hana – initial, sign and date
- Page 9: Jeremy Hana – sign, date and notarize

PERSONAL HISTORY APPLICATION:

- Page 2: Answer Sections 5 and 6
- Page 3: Answer Section 7
- Page 7: Nathan lam – sign, date, and notarize.

NEEDS TO BE ADDED:

- Certificate of Good standing

SIGN AND DATE where REQUIRED throughout the applications.

Mail completed application to: Nevada Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521

Your application is now complete.

Professionally,

Empire Pharmacy Consultants
(855) 374-1029 Office
(855) 357-2307 Direct Fax

Prepared by ML

4UUU

Precision Fulfillment Pharmacy

Retracted; continued to a future Board Meeting

4VVV

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (8/25/2023)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	■ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH NA		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	■ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: ProCompounding LLC

Physical Address: 527 N State of Franklin Rd

City: Johnson City State: TN Zip: 37604

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 423-975-0597 Toll Free # (NAC 639.708, NRS 639.23286): 855-975-0597

Fax: 423-975-6304 Contact Email: [redacted]

Website: www.procompounding.com

Nevada Business License # (if applicable) NA

Supervising/Managing Pharmacist Name (NRS 639.220): Jessica Patrone (24521)

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Jessica Patrone	NV Pharmacist Registration #: 24521
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: NA

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: NA

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☐ No

Section 7: Partnership

Partnership Name: ProCompounding LLC

Mailing Address: 527 N State of Franklin Rd

City: Johnson City State: TN Zip: 37604

Telephone: 423-975-0597 Email: [redacted]

Contact Person Name: Jessica Patrone

Please check type of partnership (NAC 639.214) ☐ General ☑ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☑ No

Section 8: Sole Owner

Owner's Name: NA

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for ProCompounding LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), *member(s), or partner(s)*.
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Jessica Patrone

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/24/24

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jessica Patrone hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for ProCompounding LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 26 day of April, 2024

Notary Public exp 8/1/2027

MERISSIA MOORE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF WASHINGTON

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Patrone

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/26/24

Date

Board Use Only	Date Received: _____	Amount: 500.00 CC

Tre Hargett
Secretary of State

Division of Business Services
Department of State
State of Tennessee
312 Rosa L. Parks AVE, 6th FL
Nashville, TN 37243-1102

LURISSIA MOORE
LURISSIA MOORE
527 N STATE OF FRANKLIN RD,
JOHNSON CITY, TN 37604-8210

May 8, 2024

Request Type: Certificate of Existence/Authorization
Request #: 0582491

Issuance Date: 05/08/2024
Copies Requested: 1

Document Receipt

Receipt # : 008987811 — Filing Fee: $20.00

Payment-Credit Card - State Payment Center - CC #: 3873744942 — $20.00

Regarding: **ProCompounding, LLC**

Filing Type: Limited Liability Company - Domestic
Formation/Qualification Date: 11/16/2021
Status: Active
Duration Term: Perpetual
Business County: WASHINGTON COUNTY

Control # : 1256384
Date Formed: 11/16/2021
Formation Locale: TENNESSEE
Inactive Date:

CERTIFICATE OF EXISTENCE

I, Tre Hargett, Secretary of State of the State of Tennessee, do hereby certify that effective as of the issuance date noted above

ProCompounding, LLC

* is a Limited Liability Company duly formed under the law of this State with a date of incorporation and duration as given above;

* has paid all fees, interest, taxes and penalties owed to this State (as reflected in the records of the Secretary of State and the Department of Revenue) which affect the existence/authorization of the business;

* has filed the most recent annual report required with this office;

* has appointed a registered agent and registered office in this State;

* has not filed Articles of Dissolution or Articles of Termination. A decree of judicial dissolution has not been filed.

Tre Hargett
Secretary of State

Processed By: Cert Web User

Verification #: 067434332

13634741

56517

State of Tennessee
Department of Health

BOARD OF PHARMACY
PHARMACY
PROCOMPOUNDING LLC
527 N STATE OF FRANKLIN RD
STE 2
JOHNSON CITY TN 37604

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000004894
EXPIRATION DATE: 11/30/2025

CONTROLLED SUBSTANCE REGISTRATION

Jennifer L. Putnam, Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion: A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Procompounding LLC

Address: 527 N State of Franklin Rd

City: Johnson City State: TN Zip: 37604

I hereby authorize the Tennessee Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant Jessica Pattare

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
4894	licensed	7/6/2011	11/30/2025

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☑ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
Sheila W Rivera	Admin. Director	TN	4/30/2024	

THE GREAT SEAL OF THE STATE OF TENNESSEE XVI AGRICULTURE COMMERCE 1796

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Procompounding, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 527 N. State of Franklin Rd

City Johnson City State TN Zip 37604

Mailing Address (if different from physical address) Same

City _____ State _____ Zip _____

Telephone 423-975-0557 Website procompounding.com

Licensing Company Email Jessica.patrone@procompounding.com

Section 2: Personal Information

First Jessica Middle Laraine Last Patrone

Alias(es, nicknames, name changes, etc.) Jessica Laraine James, Jessica Laraine Croft

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern University		8/97 - 5/01	
Address	City	State	Zip
3301 S. University Dr	Davie	Fl	33328
Diploma/Degree obtained, if any			
Pharm. D.			

School Name		From - To (MM/YY – MM/YY)	
Edison Community College - now FISW state college		8/95 - 5/97	
Address	City	State	Zip
8099 College Pkwy	Fort Myers	Fl	33919
Diploma/Degree obtained, if any			
Assoc. Arts			

School Name		From - To (MM/YY – MM/YY)	
Cape Coral High School		8/91 - 5/95	
Address	City	State	Zip
2300 Santa Barbara Blvd	Cape Coral	Fl	33991
Diploma/Degree obtained, if any			
HS diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
7/2014 - present	[redacted]			
2012 - 7/2014				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Procompounding, LLC		01/2022 - present	
Business Address	**City**	**State**	**Zip**
527 N State of Franklin Rd	Johnson City	TN	37604
Phone	**Title**		
423-975-0597	president / pharmacist		
Description of Duties			
Running business, dispensing retail & compounded medications			

Business Name		From - To (MM/YY – MM/YY)	
Clinical Management Concepts DBA Procompounding		7/2016 - 01/2022	
Business Address	**City**	**State**	**Zip**
527 N State of Franklin Rd	Johnson City	TN	37604
Phone	**Title**		
423-975-0597	pharmacist		
Description of Duties			
Dispensing retail & compounded medications			

Business Name		From - To (MM/YY – MM/YY)	
Anderson Compounding Pharmacy		2014 - 7/2016	
Business Address	**City**	**State**	**Zip**
310 Bluff City Hwy	Bristol	TN	37620
Phone	**Title**		
423-764-4136	Pharmacist		
Description of Duties			
Dispensing retail & compounded medications			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

5/8/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Patrone

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/26/24

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Washington

I, Jessica Patrone, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

4/26/24

Date

Subscribed and Sworn to before me this 26 day of April, 2024

Lurissia Moore Exp 8/1/2027

Notary Public Signature

LURISSIA MOORE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF WASHINGTON

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Procompounding Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 527 N State of Franklin Rd

City Johnson City State TN Zip 37604

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website www.procompounding.com

Licensing Company Email jessica.patton@procompounding.com

Section 2: Personal Information

First LAURA Middle BETH Last JENKS

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Addres [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: LEBANON HIGH SCHOOL		From - To (MM/YY – MM/YY): August June 1995 - 1999	
Address: 105 Charles C Long Dr	City: Lebanon	State: VA	Zip: 24266
Diploma/Degree obtained, if any: High School Diploma			
School Name: Virginia Tech		From - To (MM/YY – MM/YY): 01/00 - 05/2004	
Address: 925 Prices Fork Rd	City: Blacksburg	State: VA	Zip: 24061
Diploma/Degree obtained, if any: Bachelor of Science (Animal & Dairy Science)			
School Name: Appalachian College of Pharmacy		From - To (MM/YY – MM/YY):	
Address: 1060 Dragon Rd	City: Oakwood	State: VA	Zip: 24631
Diploma/Degree obtained, if any: Doctor of Pharmacy			
School Name:		From - To (MM/YY – MM/YY):	
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			
School Name:		From - To (MM/YY – MM/YY):	
Address:	City:	State:	Zip:
Diploma/Degree obtained, if any:			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/2009 - pres	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Dammit Brands LLC			02/2023 - present
Business Address	**City**	**State**	**Zip**
23268 N Fork River Rd	Abingdon	VA	24210
Phone	**Title**		
423-956-4463	owner / founder		
Description of Duties			
All management aspects			

Business Name			From - To (MM/YY – MM/YY)
Anderson Compounding Pharmacy			08/2008 - 12/2022
Business Address	**City**	**State**	**Zip**
310 Bluff City Hwy	Bristol	TN	37620
Phone	**Title**		
423-764-4156	pharmacist		
Description of Duties			
compounding pharmacist, lab manager			

Business Name			From - To (MM/YY – MM/YY)
ProCompounding Pharmacy			04/23 - present
Business Address	**City**	**State**	**Zip**
527 N State of Franklin Rd	Johnson City	TN	37604
Phone	**Title**		
423-975-0597	compounding pharmacist / PIC / co-owner		
Description of Duties			
staff management / compounding lab director / PIC			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic copies or stamps not accepted)

4/29/2024

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

LAURA JENKS

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/29/2024

Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Washington

I, Laura Beth Jenks, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

4/29/2024

Date

Subscribed and Sworn to before me this 29 day of April, 2024.

Notary Public Signature exp 8/1/2027

LURISSIA MOORE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF WASHINGTON
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler ProCompounding LLC

Pharmacy/Wholesaler License # (if applicable) Tennessee 4894

Physical Address 527 North State of Franklin Rd

City Johnson City State TN Zip 37604

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 427-975-0597 Website www.procompounding.com

Licensing Company Email jessica.patrone@procompounding.com

Section 2: Personal Information

First Jessica Middle Laraine Last Patrone

Alias(es, nicknames, name changes, etc.) Jessica Laraine Croft; Jessica Laraine James

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ■ F ☐ X

Mailing Address 309 Jim Ford Rd

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Nova Southeastern University		8/97 - 5/01	
Address: 3300 S. University Dr	City: Davie	State: Fl	Zip: 33328
Diploma/Degree obtained, if any: Pharm. D.			

School Name		From - To (MM/YY – MM/YY)	
Edison Community College now Fl SW State College		08/95 - 05/97	
Address: 8099 College Pkwy	City: Fort Myers	State: Fl	Zip: 33919
Diploma/Degree obtained, if any: Assoc. Arts			

School Name		From - To (MM/YY – MM/YY)	
Cape Coral High School		~~08/95 - 05/97~~ 08/91 - 5/95 Error	
Address: 2300 Santa Barbara Blvd	City: Cape Coral	State: Fl	Zip: 33991
Diploma/Degree obtained, if any: HS Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/2014 - Pres	[redacted]			
2012 - 7/2014				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Procompounding Pharmacy			07/16 – 4/24 (present)	
Business Address		City	State	Zip
527 N. State of Franklin Rd		Johnson City	TN	37604
Phone	Title		Number of Employed Hours	
423-975-0597	Pharmacist		16,000	
Description of Duties				
Dispensing retail medications, Dispensing compounded medications				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic copies or stamps not accepted)

Date 4/26/24

I, Jessica Patrone, **certify that as the designated representative for**

Procompounding Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JP I am at least 21 years of age;
3. JP I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JP I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JP I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JP I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JP I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Jessica Patrone

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/26/24

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jessica Patrone
Print Name (First, Last)

[redacted]
Original Signature (electronic, copies or stamps not accepted)

4/26/24
Date

Please have this section completed in the presence of a Notary Public.

State of Tennessee, ss. County of Washington

I, Jessica Patrone, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]
Original Signature

4/26/24
Date

Subscribed and Sworn to before me this 26 day of April, 2024.

Notary Public Signature

LURISSIA MOORE
STATE OF TENNESSEE NOTARY PUBLIC
COUNTY OF WASHINGTON
(seal)

1:7
211/525

PROCOMPOUNDING, LLC
527 N STATE OF FRANKLIN RD STE 2
JOHNSON CITY, TN 37604-8210

10003584 .2/002867-1/1-0

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-03-2022

PROCOMPOUNDING, LLC
527 N STATE OF FRANKLIN RD STE 2
JOHNSON CITY, TN 37604-8210

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	03-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N, 3,3N,4,5	RETAIL PHARMACY	02-03-2022

PROCOMPOUNDING, LLC
527 N STATE OF FRANKLIN RD STE 2
JOHNSON CITY, TN 37604-8210

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

13634741

56517

State of Tennessee
Department of Health

BOARD OF PHARMACY
PHARMACY
PROCOMPOUNDING LLC
527 N STATE OF FRANKLIN RD
STE 2
JOHNSON CITY TN 37604

This is to certify that all requirements of the State of Tennessee have been met.

ID NUMBER: 0000004894
EXPIRATION DATE: 11/30/2025

CONTROLLED SUBSTANCE REGISTRATION

Jennifer L. Rutnam Esq
ASSISTANT COMMISSIONER, HEALTH LICENSURE & REGULATION

COMMISSIONER, DEPARTMENT OF HEALTH

ACHC FOR PROVIDERS. BY PROVIDERS.

May 4, 2022

ProCompounding LLC
527 North State of Franklin Rd, Suite 2
Johnson City, TN 37604
Attention: Tandy Branham

Dear ProCompounding LLC:

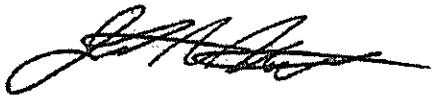
On behalf of Accreditation Commission for Health Care (ACHC), it is my pleasure to inform you that ProCompounding LLC has been ***approved for accreditation*** for the PCAB Program for patient-specific prescriptions of non-sterile compounds. PCAB is a service of ACHC.

In granting accreditation, ACHC finds that your company has demonstrated that it operates at a level of quality, integrity, and effectiveness consistent with ACHC Accreditation Standards. Your accreditation is effective May 3, 2022 through May 2, 2025. Of course, maintaining accreditation is contingent upon continued compliance with the standards during this period.

If you have any questions, please feel free to contact your organization's Account Advisor, Jasmine Johnson.

Again, ACHC extends its congratulations to ProCompounding LLC for being awarded accreditation. It is an achievement of which your organization can be proud of and one that marks your commitment to quality in the provision of care.

Sincerely,



Jon Pritchett, Pharm.D., RPh., BCSCP
Program Director

3873

CERTIFICATE *of* ACCREDITATION

ACCREDITATION COMMISSION FOR HEALTH CARE CERTIFIES THAT:

ProCompounding Pharmacy

JOHNSON CITY, TENNESSEE

HAS DEMONSTRATED A COMMITMENT TO PROVIDING QUALITY CARE AND SERVICES TO CONSUMERS THROUGH COMPLIANCE WITH ACHC'S NATIONALLY-RECOGNIZED STANDARDS FOR ACCREDITATION AND IS THEREFORE GRANTED ACCREDITATION FOR THE FOLLOWING:

PHARMACY

PCAB ACCREDITATION

For patient specific prescription compounding of

Non-Sterile Compounding, Ref. USP <795>

Accreditation #59903

FROM *May 3, 2022* THROUGH *May 2, 2025*

PRESIDENT & CHIEF EXECUTIVE OFFICER

CHAIRMAN OF THE BOARD OF COMMISSIONERS

ACCREDITATION COMMISSION FOR HEALTH CARE

PCAB PHARMACY COMPOUNDING ACCREDITATION BOARD

DEPARTMENT OF HEALTH
TENNESSEE BOARD OF PHARMACY
COMMUNITY INSPECTION
COMPLIANCE INSPECTION

PHARMACY		
STREET		
CITY	ZIP	
DATE OPENED	TELEPHONE NO. ( )	
LICENSE NO.	EXPIRY DATE	
DEA NO.	EXPIRY DATE	
PHARMACIST IN CHARGE/Duty	LIC NO.	EXPIRY DATE

Inspected by	Date

This Inspection Satisfactory Yes ☐ No ☐

☐ Opening ☐ Relocation
☐ New Ownership ☐ Follow-up
☐ Counseling Compliance
☐ Periodic ☐ Remodeling

Compliance Yes	Compliance No	PERSONNEL
		1. Appropriate identification/Name Tags
		2. D. Ph./Tech ration
		3. Personnel/apparel clean
		4. Tech registry & Affidavit

Compliance Yes	Compliance No	PHYSICAL REQUIREMENTS
		5. Certificates Displayed
		6. RX Dept. – Sufficient Space/Counseling
		7. Fully enclosed when applicable
		8. Key Lockable/Key Control

Compliance Yes	Compliance No	DRUGS AND EQUIPMENT
		9. Dispensing area clean, orderly, well lighted
		10. Sink, hot and cold water
		11. Refrigeration
		12. References, periodicals
		13. Vials and closures (child-proof)
		14. Shelves and drug stock clean
		15. Drugs in-date
		16. Labels correct on repackaging
		17. Legend drugs stored in RX Dept.
		18. Syringes/insulin, restricted products non-accessible

Compliance Yes	Compliance No	
		19. RXs numerically filed
		☐ All C's together ☐ C-11's separate ☐ Multiple file method
		20. Patients identifiable
		21. Prescribers identifiable
		22. New verbal RXs initialed by appropriate personnel
		23. Date of original dispensing
		24. Initials of dispensing D.Ph.
		25. Quantity dispensed indicated
		26. Appropriate Emergency C-11 RXs
		27. Computer labels applied appropriately to RXs
		28. Pharmacist Signature Log
		29. Daily Print Out

Compliance Yes	Compliance No	DRUG PRODUCT SUBSTITUTION
		30. Authorization documented on Rx
		31. Manufacturer indicated on Rx or System
		32. Approved products used.

Compliance Yes	Compliance No	PATIENT COUNSELING
		33. Patient profiles
		34. Drug Utilization Review
		35. Patient Counseling

Compliance Yes	Compliance No	CONTROLLED SUBSTANCE RECORDS
		36. Readily retrievable
		37. All C-11 records separate
		38. DEA Form 222 Copy 3 on hand & completed
		39. Drug Receipt date on invoices
		40. Record of drug transfers
		41. ☐ Schedule V sales record book ☐ Methamphetamine Sales Log
		42. Last DEA Inventory (date) _____
		42. Last Theft/loss report (date) _____
		43. Access to Control Substance Monitoring Database

Pharmacy Hours

ITEMS TO BE CORRECTED: **RESPONSE REQUIRED** **YES ☐** **NO ☐**

Immediately _____
Needs Improvement _____
Within 30 Days _____

Remarks or Recommendations: _____

I _____ hereby acknowledge and understand all notations made on this report; and confirm that
Pharmacist Signature
I will notify the Board of Pharmacy within 30 days, in writing, of the correction of all deficiencies. (If noted.)

PH-4031 REV 01/18 RDA SW-30

The National Association of Boards of Pharmacy (NABP) developed this inspection form for sole use by NABP and its member boards of pharmacy for inspection of facilities licensed by a member board. Disclosure of the form to or use of the form by a third party, other than a facility being inspected by NABP or a member board, is strictly prohibited without NABP's prior written permission or unless required by state law.

National Association of Boards of Pharmacy®
Universal Inspection Form

Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: ProCompounding LLC dba ProCompounding

Inspection Date: 05/22/2023

		Finding	Notes
	General Operations and Information		
1.00	Does the pharmacy **dispense** nonsterile compounded preparations pursuant to a prescription?	Yes	
1.01	Are patient profiles complete and DUR performed for each prescription? *View selected files for profile to include allergies, disease states/conditions, other medications taken not dispensed by this pharmacy.*	Yes	reviewed 3 patient files for information, allergies, disease states noted where pertinent
1.02	Do the compounded prescriptions produce a significant difference from a commercially available drug that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner?	Yes	
1.03	Are nonsterile compounded prescriptions picked up at the pharmacy?	Yes	
1.04	Are nonsterile compounded prescriptions delivered to patients in their homes or residential facilities?	Yes	
1.05	Are nonsterile compounded prescriptions mailed to patients in their homes or residential facilities?	Yes	
1.06	Are nonsterile compounded prescriptions delivered to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	Cantharidin to local providers
1.07	Are nonsterile compounded prescriptions mailed to the practitioner for administration to the patient in the office, clinic, or facility?	Yes	Cantharidin to local providers
2.00	Does the pharmacy **distribute** nonsterile compounded preparations? *Not pursuant to a prescription, not labeled by the pharmacy with a patient name.*	No	
2.01	Does the pharmacy distribute nonsterile compounded preparations to practitioners for office use?	No	
2.02	Does the pharmacy distribute nonsterile compounded preparations to hospitals, clinics, or surgery centers?	No	
2.03	Does the pharmacy have a sales force that promotes compounded preparations? *List compounds promoted.*	Yes	promote services and not specific compounds other than provide copies of preprinted prescriptions for commonly prescribed non-sterile compounded products
2.04	Does the pharmacy distribute non-patient specific compounded preparations for promotional purposes? *List compounds provided.*	No	
2.05	If yes, does the sales force hand-deliver these compounds? *List compounds provided.*	No	
2.06	If yes, are any of these controlled substances? *List compounds provided.*	No	
3.00	Does the pharmacy provide nonsterile compounded preparations to other pharmacies for dispensing?	No	
3.01	If so, does the pharmacy have central fill/shared services contracts or agreements with these pharmacies for patient specific preparations? *Provide List.*	N/A	
4.00	Does the pharmacy compound oral preparations (tablets, capsules, liquids, lozenges, etc.)? *Provide List.*	Yes	capsules, liquids. Troches, lozenge/lollipop
5.00	Does the pharmacy compound topicals (gels, creams, ointments, inserts, suppositories, patches, sprays including nasal sprays, etc.)? *Provide List.*	Yes	gels, cream, ointments, suppositories, nasal sprays, ear solutions for non-perforated ear drum

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		Finding	Notes
6.00	Does the pharmacy compound vitamin or nutritional supplements? *Provide List.*	No	
7.00	Does the pharmacy sell any compounds over-the-counter? *Provide list.*	Yes	Ivermectin with Collaborative Practice Act Agreement per TN state law
8.00	Does the pharmacy compound investigational drugs? *Provide List.*	No	
9.00	Does the pharmacy only make essential copies of a commercially available drug product on the Drug Shortage List or that is justified by a documented medical need of the individual patient as determined by the prescribing practitioner? *Indicate volume or percent compounded currently.*	Yes	zero percent compounded currently
9.01	If yes, products are verified as appearing on the Drug Shortage List in effect under 506E of the Federal Act at the time of compounding, distribution, and dispensing.	Yes	
9.02	If yes, the Drug Shortage List is monitored and when a drug product is no longer on the list, any remaining stock is quarantined and not available for distribution or dispensing. *Note: Per FDA guidance, 503B facilities may continue to distribute for 60 days following drug shortage list removal for existing orders.*	Yes	
10.00	Does the pharmacy perform compounding identified as **simple?** *Indicate percentage of simple compounding.* 1. Making a preparation that has a USP compounding monograph or that appears in a peer-reviewed journal article that contains specific quantities of all components, compounding procedure and equipment, and stability data for that formulation with appropriate beyond-use dates (BUD)s. 2. Reconstituting or manipulating commercial products that may require the addition of one or more ingredients as directed by the manufacturer. *Examples include Captopril Oral Solution, Indomethacin Topical precautions. Gel, and Potassium Bromide Oral Solution (Veterinary).*	Yes	75%
11.00	Does the pharmacy perform compounding identified as **moderate?** *Indicate percentage of moderate compounding.* 1. Making a preparation that requires special calculations or procedures (such as calibration of dosage unit mold cavities) to determine quantities of components per preparation or per individualized dosage units. 2. Making a preparation for which stability data for that specific formula is not available. *Examples include Morphine Sulfate Suppositories, diphenhydramine hydrochloride troches, and mixing two or more manufactured cream products when the stability of the mixture is not known.*	Yes	15%
12.00	Does the pharmacy perform compounding identified as **complex**? *Indicate percentage of complex compounding.* Making a preparation that requires special training, environment, facilities, equipment, and procedures to ensure appropriate therapeutic outcomes. *Examples of possible complex preparation types include transdermal dosage forms, modified-release preparations, and some inserts and suppositories for systemic effects.*	Yes	10%

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		Finding	Notes
13.00	Does the pharmacy perform compounding with **hazardous drugs**? *Indicate percentage of compounding with hazardous drugs.* NIOSH list of hazardous drugs including chemotherapy, hormones, etc.	Yes	40%
13.01	Is the pharmacy aware of the more stringent requirements of the proposed USP Chapter <800>?	Yes	
14.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
15.00	Does the pharmacy compound using any **controlled substances**? *Indicate percentage of controlled substance nonsterile compounding.*	Yes	15%
16.00	**APIs:** Does the pharmacy make any nonsterile compounded preparations using bulk powder Active Pharmaceutical Ingredients (APIs)?	Yes	
16.01	Does the pharmacy purchase APIs directly from the manufacturer/repackager? *Indicate the source of APIs.*	Yes	Medisca, Letco, Fagron, PCCA and Darmerica
16.02	Does the pharmacy verify that the manufacturer/repackager of the API is an FDA-registered facility? *If so, list how this verified.*	Yes	review annually, information kept in binder
16.03	Does the pharmacy use active ingredients that are not from an FDA-registered facility? *If so, indicate sources.*	Yes	
16.04	Does the computer track on-hand quantities of APIs used for compounding? *If not, explain.*	Yes	
17.00	Does the pharmacy perform any testing in-house (not sent to an outside lab)? *If so, what tests are performed in house?*	Yes	weight checks for capsules, troches and suppositories. pH testing for some liquids
18.00	Does the pharmacy send samples to an outside lab to perform testing? *If so, provide the name of the lab performing testing for the pharmacy and what testing is performed.*	Yes	ARRL, Quality testing for techs capsules, cream, liquid and molded product annually, also test triturates for hormones (for potency)
19.00	Does the pharmacy use scales/balances for nonsterile compounding?	Yes	
19.01	If so, what type of scale/balanced is used? *List manufacturer and model number*		AND 6-GX-2000, 5-GH-200, 1-EK-6100i, 1-FZ-1200I, Ohaus 2-EX224, 2-EX2202
19.02	If the scale/balance is electronic, does the pharmacy use the automatic calibration? *Describe process and indicate frequency*	Yes	scale is calibrated daily and may be repeated during day when needed.
19.03	Describe the pharmacist checks for the measurement of each ingredient		yes

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		Finding	Notes
20.00	**Quality Assurance/Quality Improvement:** Does the pharmacy continuous quality improvement program include nonsterile compounding measures? **Note: If the facility indicates "yes", please ask each question below to verify.**	Yes	software requires measurements fall within standards, pharmacist verify liquid quntities before compounding
20.01	Does the pharmacy continuous quality improvement program include QREs related to the preparation of compounded products?	Yes	
20.02	Does the pharmacy continuous quality improvement program include personnel testing and verification?	Yes	
20.03	Does the pharmacy continuous quality improvement program include equipment calibration, testing, etc?	Yes	
20.04	Does the pharmacy continuous quality improvement program include end product testing (such as: pH, weight, potency, particulates, consistency, etc.)?	Yes	
20.05	Does the pharmacy continuous quality improvement program include patient or prescriber reports or complaints regarding nonsterile compounded products?	Yes	
20.06	Does the facility QA program identify action limits or thresholds and the appropriate follow-up mechanisms when action limits or thresholds are exceeded including a recall system?	Yes	
20.07	Does the recall system include communication with both the patient and the physician/prescriber regarding the affected nonsterile compounded preparation?	Yes	
20.08	Are QREs involving nonsterile compounded preparations or are recalled by the pharmacy reported to the Board of Pharmacy?	Yes	
	Component Selection and Use		
	Total Non-Compliant (Includes Unknowns)	**0**	
21.00	**Active Pharmaceutical Ingredients (APIs), bulk drug substances:** All bulk drug substances (APIs) used are: 1) Compliant with the standards of an applicable USP or NF monograph, if one exists; or 2) A component of an FDA-approved human drug product; or 3) On the list of bulk drug substances for use in compounding developed by the FDA and issued through regulation (note: must comply with (1) or (2) above until the FDA list is issued)	Compliant	

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		Finding	Notes
21.01	Certificates of analysis (COAs) obtained for all bulk APIs used for compounding. *Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.* NOTE: The COA for an API should be reviewed upon receipt of the API to verify the quality of the API before using to compound.	Compliant	
21.02	USP- or NF-grade substances used, if available	Compliant	
21.03	If compendia quality components are not available, chemically pure, analytical reagent grade or American Chemical Society-certified components are used and are determined to be free from impurities.	Compliant	
21.04	APIs or other components have labeling indicating use for pharmaceutical compounding or manufacturing. Labels do not indicate "for research purposes only", "not for drug use", or are handwritten labels from other pharmacies. *Photograph and describe if found. Request copies of the invoices for products with questionable labels.*	Compliant	
21.05	If compounding for both humans and animals, APIs or other components that are labeled for veterinary use only are segregated or marked in such a way to prevent them from being used for human compounding	Compliant	
21.06	All substances and components have a complete label including a batch control or lot number, and an expiration date.	Compliant	
21.07	For APIs without an expiration date assigned by the manufacturer or supplier, the pharmacy assigns a conservative expiration date. The expiration date assigned does not exceed three (3) years for ingredients used for non-sterile compounding and does not exceed one (1) year for ingredients used for sterile compounding. *Note: purity and quality testing may be performed to extend.*	Compliant	
21.08	All APIs and components received without an expiration date are labeled with the date they were received.	Compliant	
21.09	If the pharmacy repackages APIs into smaller containers for ease of use, the expiration date assigned is conservative (typically the lesser of one year or the actual expiration from the original container). Product may be tested to extend the expiration date but may not exceed the original package expiration date.	Compliant	six months unless expires sooner
21.10	Bulk component containers are labeled with appropriate OSHA hazard communication labels and hazardous substances are segregated (including hormones).	Compliant	all hazardous chemicals are kept in USP 800 room. Final products are segregated in hazardous area per an assessment of risk.
22.00	Where water is an ingredient, purified or distilled water is used.	Compliant	
23.00	Ingredients used for dietary or nutritional supplements meet USP, Food Chemicals Codex (FCC), or NF standards, or the pharmacy has alternate means to determine if the ingredients meet food-grade quality.	Compliant	
24.00	Pharmacy confirms that there are no preparations for human use made or ingredients used that appear on the FDA list of drug products withdrawn or removed from the market for safety reasons (facility has a copy of the list or other way to determine).	Compliant	

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25.00	When manufactured products are used for compounding, all the other excipients in the product are considered relative to the use, effectiveness, and stability of the compounded preparation to be made.	Compliant	
26.00	For **animal compounding:** The compounding meets the same standards as compounding for human patients.	Compliant	
26.01	The pharmacist is knowledgeable or has references regarding the individual species' limitations in physiology and metabolic capacity that can result in toxicity when certain drugs or excipients are used.	Compliant	
26.02	It is determined and documented if the animal is used for food (meat, milk, eggs, etc.) or that the animal is a pet.	Compliant	pet animals only
26.03	The pharmacist familiar with, or has a reference regarding drug residues in the food chain and withdrawal times if compounding for food-producing animals.	N/A	
26.04	The facility has a list of drugs and components not allowed when compounding for food-producing animals.	N/A	
26.05	The pharmacist is familiar with, or has a reference regarding regulations for drug use in performance animals (e.g., race or show horses, racing dogs)	N/A	
	Beyond Use Dating (BUD)		
	Total Non-Compliant (Includes Unknowns)	**0**	
27.00	BUDs are assigned from the day of preparation.	Compliant	
28.00	BUDs are assigned based on dispensing in tight, light-resistant containers/overpacks.	Compliant	
29.00	Extended BUDs are supported by testing data. *View documentation used, preparation must exactly match formulation upon which data was obtained.*	Compliant	Fagron and PCCA studies for BUD assignment for topical hormones
29.01	Extended BUDs are assigned and the facility has performed its own stability testing. *View records, preparation must exactly match the preparation tested by the facility including concentration of all active ingredients, excipients, etc.*	N/A	Use of studies from above to assign BUD
30.00	BUDs for nonaqueous formulations are not later than the remaining time until the earliest expiration date of any API and not later than six (6) months.	Compliant	
31.00	BUDs for water-containing oral formulations are not later than 14 days when stored at controlled cold temperatures (refrigerated).	Compliant	
32.00	BUDs for water-containing topical/dermal and mucosal liquid and semisolid formulations not later than 30 days.	Compliant	
	Environment		
	Total Non-Compliant (Includes Unknowns)	**0**	
33.00	The non-sterile compounding area is a controlled environment and separate from the general pharmacy.	Compliant	

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34.00	There sufficient space available for the type and amount of compounding performed and the space is orderly to prevent mix-ups between ingredients, containers, labels, in-process materials, and finished preparations.	Compliant	
35.00	Only one preparation compounded at a time.	Compliant	
36.00	Procedures are implemented to prevent cross-contamination, especially when compounding with drugs such as hazardous drugs and known allergens like penicillin that require special precautions.	Compliant	Clean after use, save for end of day
37.00	The compounding area is well lit.	Compliant	
38.00	The pharmacy performs **hazardous** non-sterile compounding in a ventilated cabinet such as a BSC, CAI, or CACI. *Note: CAI may not be used for hazardous drugs that may volatilize.(NIOSH requirement referenced in USP<795>. Note that proposed USP Chapter <800> will change hazardous drug compounding requirements.)*	Compliant	
38.01	Ventilated cabinets (BSC, CAI, CACI) used for hazardous compounding are certified or tested periodically.	Compliant	
38.02	If the hoods or isolators are not located in a closed, controlled room environment, there is documentation from the manufacturer and site testing to verify proper functioning of equipment under dynamic conditions for the safety of personnel.	N/A	
39.00	Appropriate protective attire (gowns, gloves, masks, etc.) is available.	Compliant	
39.01	If hazardous drugs are used, appropriate protective attire is available (gowns, gloves, hair and shoe covers, eye and face protection, etc.).	Compliant	
40.00	There is a sink in the compounding area with hot and cold potable water, soap or detergent, and air-driers or single-use towels.	Compliant	
41.00	There is adequate space to wash equipment and utensils including access to water for rinsing. *(Purified water is **recommended** - not required)*	compliant	
42.00	The temperature of the compounding area is controlled by a thermostat and an air conditioning system is in place.	Compliant	
43.00	**Temperature** in the compounding area is maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	
43.01	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	
43.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
43.03	Temperature monitoring is also performed in **drug storage areas** (if separate from the compounding areas) and maintained within 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements.	Compliant	

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43.04	Temperature monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Temperature records are maintained.	Compliant	
43.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
44.00	**Humidity** in the compounding area is maintained to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally **recommended** range is 35-60%.	Compliant	
44.01	Humidity monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
44.02	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
44.03	Humidity monitoring is also performed in **drug storage areas** (if separate from the compounding areas) to provide humidity in the ranges warranted by specific drug product storage requirements. If drug products require storage in a "dry place", humidity is not to exceed 40%. Generally recommended range is 35-60%.	Compliant	
44.04	Humidity monitoring is in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max. Humidity records are maintained.	Compliant	
44.05	Excursion action plan in place including evaluating excursion effects on drug product integrity.	Compliant	
45.00	The bulk component storage area is adequately arranged and maintained in a clean and sanitary condition.	Compliant	
46.00	All components, equipment, and containers are stored off the floor, and handled and stored to prevent contamination.	Compliant	
47.00	All components and packaging containers and closures are properly rotated to use oldest first.	Compliant	
48.00	Hazardous drugs are appropriately identified and marked, received, handled and stored by appropriately trained personnel. (OSHA regulations and NIOSH Alerts)	Compliant	
49.00	Trash is disposed of in a safe, sanitary, and timely manner.	Compliant	
49.01	Hazardous waste is disposed of in a safe, sanitary, and timely manner.	Compliant	
	Training *-Verify records of all compounding personnel (up to 10).*		
	Total Non-Compliant (Includes Unknowns)	**0**	
50.00	Have all personnel of reproductive capability who handle or compound hazardous drugs or chemicals confirmed in writing that they understand the risks of handling hazardous drugs? Teratogenicity, carcinogenicity, reproductive issues.	Compliant	

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51.00	There is documentation that all personnel that perform compounding are appropriately trained including policies and procedures, documentation, hazardous drug handling, and compounding technique and not allowed to compound or supervise compounding until training is successfully completed.	Compliant	
52.00	There is documentation that the training process for the preparation of compounds includes demonstration of the compounding procedure first, followed by the trainee performing the procedure under supervision successfully before being allowed to perform compounding.	Compliant	
53.00	There is documentation that training includes the operation of any equipment that may be used when preparing compounded products. *Documentation includes operation and troubleshooting.*	Compliant	
54.00	There is documentation available showing employees performing non-sterile compounding are evaluated at least annually.	Compliant	
54.01	If performing hazardous nonsterile compounding, there is documentation available showing employees are evaluated at least annually.	Compliant	
55.00	If the pharmacy uses relief personnel from outside agencies to perform non-sterile compounding there is documentation that training is verified.	Compliant	
	Compounding Equipment		
	Total Non-Compliant (Includes Unknowns)	**0**	
56.00	Appropriate equipment and utensils are available, clean, and in good working order. *Automated, mechanical, or electronic equipment (including capsule machines, autoclaves, ovens, etc.) are periodically inspected and calibrated.*	Compliant	
57.00	Scales, balances, or other types of equipment used for measurement shall be routinely inspected, calibrated as necessary (per manufacturer instructions), and checked to ensure proper performance. *Describe procedure used.*	Compliant	scales calibrated every June, hoods certified every November, and internal calibration of thermometers and hot plates annually
58.00	Powder hoods used for nonsterile compounding are certified or tested periodically to ensure proper function.	Compliant	
58.01	Hood filters are checked regularly and replaced when necessary.	Compliant	
59.00	All equipment is cleaned promptly after each use. *Equipment and utensils washed using potable water with a soap or detergent, and rinsed.* ***Recommended*** *rinsed with purified water.*	Compliant	

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60.00	The pharmacy uses separate equipment and utensils to compound allergenic, cytotoxic, or hazardous products, or has detailed procedures for meticulous cleaning of equipment and utensils immediately after use to prevent cross-contamination or exposure.	Compliant	New Beta-Lactam SOP established to segregate these compounds and procedure for all other compounds
	Documentation		
	Total Non-Compliant (Includes Unknowns)	**0**	
61.00	The pharmacy creates a master formulation record the first time before compounding a new preparation	Compliant	
61.01	Every formulation is evaluated for incompatibilities and the potential for being ineffective or toxic.	Compliant	
61.02	The **master formulation record** includes:		
61.03	Official or assigned name, strength, and dosage form	Compliant	
61.04	All necessary calculations	Compliant	
61.05	Description of all ingredients and their quantities	Compliant	
61.06	Compatibility and stability information including references (when available)	Compliant	
61.07	Equipment used for the preparation	Compliant	
61.08	Mixing instructions (order of mixing, temperatures, duration of mixing, and other pertinent factors)	Compliant	
61.09	Container used and packaging requirements	Compliant	
61.10	Assigned BUD information	Compliant	
61.11	Labeling information including the name of and quantity or concentration of each active ingredient	compliant	
61.12	Description of the finished preparation	Compliant	
61.13	Storage requirements	Compliant	
61.14	Quality control procedures and expected results (e.g. dose measurement of capsule in the dose calibrator).	Compliant	
62.00	The pharmacy creates a compounding record for each compound prepared	Compliant	
62.01	The **compounding record** includes:		
62.02	Official or assigned name, strength and dosage of the preparation	Compliant	
62.03	Master Formulation Record reference	Compliant	
62.04	Sources, lot numbers, and expiration dates of all components	Compliant	
62.05	Total quantity or number of dosage units compounded	Compliant	
62.06	Person compounding the preparation	Compliant	
62.07	Person performing the quality control procedures	Compliant	

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Nonsterile Compounding Inspection

The information and comments obtained in the Nonsterile Compounding and Sterile Compounding Inspections are based on USP Chapters <795> and <797>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: ProCompounding LLC dba ProCompounding
Inspection Date: 05/22/2023

		Finding	Notes
62.08	Person who approved the preparation	Compliant	
62.09	Date of compounding	Compliant	
62.10	Assigned internal identification number or prescription number	Compliant	
62.11	Description of the final preparation	Compliant	
62.12	Assigned BUD	Compliant	
62.13	Duplicate label	Compliant	
62.14	Results of quality control procedures (weight range of filled capsules, pH of aqueous liquids, etc.)?	Compliant	
62.15	Documentation of any quality control issues and any adverse reactions or preparation problems reported by the patient or caregiver including investigation and recall, if appropriate	Compliant	
	Compounding Procedures		
	Total Non-Compliant (Includes Unknowns)	**0**	
63.00	The Master Formulation Record and the Compounding Record has been reviewed by the compounder to ensure it is error free.	Compliant	
64.00	Compounding personnel ascertain that ingredients for compounded preparations are of the correct identity and appropriate quality including a unit-by-unit inspection of the components.	Compliant	
65.00	The containers and closures selected meet USP standards (from container supplier).	Compliant	
66.00	Container selection determined by physical and chemical properties of the preparation.	Compliant	
67.00	Compounding personnel maintain good hand hygiene and wear clean and appropriate clothing for the compounding being performed.	Compliant	
68.00	Personnel don appropriate protective garb when performing compounding.	Compliant	
68.01	If hazardous compounding, personnel don appropriate protective garb when compounding.	Compliant	
69.00	Routine compounding procedures for batch preparation completed and verified according to written procedures. Including: *Calculations correct, weighing and measuring performed correctly, order of mixing correct, compounding techniques performed correctly*	Compliant	
70.00	Procedures for in-process checks followed. *These checks indicate that appropriate procedures and packaging are followed for each step, including addressing pharmacist verification of steps performed by non-pharmacists that includes visual inspection of product, and documentation of the compounding accuracy is performed to ensure proper measurement, reconstitution and component usage.* ***Recommended:*** *compounding accuracy checked by a person other than the compounder.*	Compliant	

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		Finding	Notes
71.00	There are no deviations from the master formulation record, unless they are approved and deemed appropriate by a pharmacist and a new master formulation record is created.	Compliant	
72.00	There is a procedure for cleaning which is followed. *After each preparation, daily tasks, monthly tasks, etc.*	Compliant	
73.00	Personnel are appropriately garbed for protection when cleaning.	Compliant	
74.00	Compounding employees are using appropriate techniques. *Inspector to observe compounding procedures, documentation, appropriate garb, cleanliness of compounding area and equipment. **Compounding MUST be observed**, if compounding is not being performed at the time of survey, mark as "Non-Compliant"*	Compliant	
74.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "**Denial of Authorization**" form. List individual who signs the Denial of Authorization*		
	Finished Preparation Release Checks and Tests		
	Total Non-Compliant (Includes Unknowns)	**0**	
75.00	The finished preparation is observed to appear as expected in the master formulation record and documented.	Compliant	
76.00	As appropriate, the final completed preparation assessed for quality control and is documented, such as weight, mixing, clarity, odor, color, consistency, pH, and strength.	Compliant	
77.00	There are established written processes that describe test or examinations conducted on the compounded preparation (degree of weight variation in capsules, for example) to ensure uniformity and integrity.	Compliant	
78.00	Preparations with extended BUDs that are not supported by testing data are sampled and tested for physical, chemical, and microbiological characteristics.	Compliant	
78.01	If any failed tests or discrepancies are observed, there is an investigation and appropriate corrective actions taken before dispensing to patient	Compliant	
78.02	If products being tested are dispensed or distributed before the test results are obtained, there is a recall procedure if the test results indicate an issue.	Compliant	
79.00	There are appropriate quality control procedures to monitor the output and to verify the performance of compounding processes and equipment that may be responsible for causing variability in the final compounded preparations. *Review validation of equipment and personnel performance documentation.*	Compliant	
80.00	Labels on immediate patient-specific containers include identifiers for the persons preparing the compound and performing the final verification, BUD, an indication that this is a compounded preparation, special requirements for storage, and appropriate packaging and labeling of hazardous materials.	Compliant	

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Facility Name: ProCompounding LLC dba ProCompounding

Inspection Date: 05/22/2023

		Finding	Notes
80.01	Labeling contains generic name and quantity or concentration of each active ingredient.	Compliant	
80.02	Labeling contains assigned BUD.	Compliant	
80.03	Labeling contains storage and handling information.	Compliant	
80.04	If hazardous, labeling contains storage and handling information.	Compliant	
80.05	Labeling contains prescription or control number, whichever is applicable.	Compliant	
81.00	Batch preparations (in anticipation of prescriptions) are of an appropriate volume and batch products in stock are all within their BUD (not outdated).	Compliant	
82.00	Labels on batch preparations include the name and quantity of all contents, date and time of preparation (or internal code/lot number indicating this information), preparer and verification pharmacist identifiers, stability (BUD), and any auxiliary labels indicated including appropriate packaging and labeling of hazardous materials.	Compliant	
83.00	Preparations are stored and secured properly prior to dispensing based upon conditions upon which BUD was assigned.	Compliant	
84.00	Preparations are examined immediately after preparation **AND** again immediately prior to dispensing for any signs of instability.	Compliant	
	Patient Counseling and Communication		
	Total Non-Compliant (Includes Unknowns)	**0**	
85.00	Do patient/caregiver training programs or materials contain information and precautions regarding the handling and disposal of products such as fentanyl, hormones and chemotherapy medications?	Compliant	
86.00	Are the required printed drug information materials (drug information sheets, Patient Package Inserts, MedGuides, etc.) provided for the compounded products?	Compliant	not required for compounded products, custom handouts are provided, for example nasal rinse or topical cream, how to use, ingredents, etc
87.00	Are patients instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Compliant	
88.00	Product recalls include documentation that both the patient AND the physician/prescriber of the potentially contaminated compounded product are notified of the potential risk.	Compliant	

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Pharmacy e-Profile ID: if available	808904		**Inspection Information**
Legal Business Name:	ProCompounding LLC	**Day 1:**	5/22/2023
Doing Business As (DBA):	ProCompounding	**Start Time: 24-hour format (13:00)**	11:00
Address:	527 N. State of Franklin Road Suite 2	**End Time: 24-hour format (13:00)**	17:30
City:	Johnson City	**Day 2:**	
State:	TN	**Start Time: 24-hour format (13:00)**	
Zip Code:	37604	**End Time: 24-hour format (13:00)**	
Telephone number:	423-975-0597	**Inspector Name:**	Rebecca Moak
Toll free number:	855-975-0597	**Inspection Performed by (NABP, State, etc):**	TN Board of Pharmacy
Fax number:	423-975-6304	**Observer Name/Affiliation (if applicable):**	
Website:	www.procompounding.com	**Observer Name/Affiliation (if applicable):**	x

Pharmacy Hours of Operation	**Check if 24/7**		
	Open		**Closed**
	Start Time: (24-hour format)	**End Time: (24-hour format)**	
Sunday			X
Monday	9:00	17:30	
Tuesday	9:00	17:30	
Wednesday	9:00	17:30	
Thursday	9:00	17:30	
Friday	9:00	17:30	
Saturday			X

Key Pharmacy Personnel	**Name**	**Contact (e-mail)**	**e-Profile ID**
Pharmacist in Charge	Tandy Branham	Tandy.Branham@ProCompounding.com	699346
Nonsterile Compounding Supervisor	Tandy Branham	Tandy.Branham@ProCompounding.com	699346
Sterile Compounding Supervisor	NA		
Hazardous Compounding Supervisor	Tandy Branham	Tandy.Branham@ProCompounding.com	699346

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Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Tandy Branham	PIC	Y
2	Jessica James	staff pharmacist	Y
3	Laura Beth Jenks	staff pharmacist	Y
4	Delery Matherne	staff pharmacist	Y
5	Nicole Hurt	CPhT compounding	Y
6	Chad DiCola	CPhT compounding	Y
7	Wendy Pierce	CPhT compounding	Y
8	Maycee Williams	CPhT packaging & fulfillment	Y
9	Melanie Malcuit	CPhT packaging & fulfillment	Y
10	Shari Rector	PTCB data processing	Y

CPhT(2)

Business Licensure Information for State of (board of pharmacy, state controlled substance,

License/Registration Agency	Business Name on License/Registration	License Type/Number	Expiration Date
TN Board of Pharmacy	ProCompounding LLC	4894	11/30/2023
DEA	ProCompounding LLC	FB1151959	3/31/2025

Georgia, Florida, Alabama, South Carolina, North Carolina, Virginia, Kentucky, Tennessee

DEA Business name to be updated to reflect new pharmacy name/change in ownership

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Attachments
(NO PHI, including prescription numbers)

Attachment Name	Description
ProCompounding Pharmacy_Johnson City	Preprinted Prescription Forms

	Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply
Traditional retail	X	Telepharmacy	
Open to the Public	X	Central Fill/Processing/Shared Services	
Closed Door		Specialty Pharmacy	
Drive-through window	X	Handles Medical Marijuana	
Mail/Deliver (in state)	X	Nuclear Pharmacy	
Mail/Deliver (out-of-state list below)	X	Manufacturer	
Veterinary Pharmacy	X	Wholesale Distributor	
Investigational Drugs, Clinical Trials/Research		Provide products for "Office Use"	X, manf products only
Institutional		Outsourcing Facility	
Long-Term Care		Nonsterile Compounding	X
HMO/PBM only		Nonsterile Hazardous Drug Compounding	X
Internet Pharmacy (New Rx)		Sterile Compounding	
Internet Pharmacy (Refill Rx)	X	Sterile Hazardous Drug Compounding	

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Facility Size in Square Feet and Number of PECs		Personnel	
Total Pharmacy size:	1300	Total Pharmacists:	4
Nonsterile Compounding Room size:	500	Number of Compounding Pharmacists	4
Nonsterile Compounding powder hoods number:	4 in use, 7 total	Total Graduate Students or Residents:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	120	Total Student Interns:	0
Nonsterile HD Compounding BSC/CACI hoods number:	1 in use, 2 total	Total Technicians:	10
Sterile Compounding Ante Room size:	0	Number of Compounding Technicians	10
Sterile Compounding Clean/Buffer Room size:	0	Of technicians, how many are certified?	8
Sterile Compounding Number LAFW hoods/areas:	0	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number BSC hoods:	0	Total Other Licensed Personnel:	0
Sterile Compounding Number CAI/CACI hoods:	0	Total Other Unlicensed Personnel:	0
Negative Pressure Sterile HD Room size:	0	Ratio #tech:#RPh present at time of inspection:	10:4
Sterile HD Compounding Number of BSC hoods:	0	Total Pharmacist Hours Per Week:	160
Sterile HD Compounding Number of CACI hoods:	0	Total Technician Hours Per Week:	420

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	100	Total Orders Distributed/day:	approximately 1 every other month
% Veterinary Prescriptions	3%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	11%	% Controlled Substance Orders	approximately 1 every other month
% Nonsterile Compounded Prescriptions	95%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	40%	% Hazardous Drugs (HD) Orders	approximately 1 every other month

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or compound pursuant to a patient-specific prescription.
compound to a prescriber or health care entity for office use or

States to which the pharmacy mails/delivers

Note: Optional at the discretion of the state; if requested

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
AK			
AL	6		month
AR			
AZ			
CA			
CO			
CT			
DC			
DE			
FL	9		month
GA	6		month
HI			
IA			
ID			
IL			
IN			
KS			
KY	99		month
LA			
MA			
MD			
ME			
MI			
MN			
MO			
MS			
MT			

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State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
NC	784		month
ND			
NE			
NH			
NJ			
NM			
NV			
NY			
OH			
OK			
OR			
PA			
RI			
SC	102		month
SD			
TN	1070		month
TX			
UT			
VA	52		month
VT			
WA			
WI			
WV			
WY			
Other:			

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General Pharmacy Inspection

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Facility Name: ProCompounding LLC dba ProCompounding

Inspection Date: 05/22/2023

		Finding	Notes
	General Pharmacy		
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	LTC Pharmacy located in suite next to pharmacy. Pharmacy Network Services has agreement to share areas of pharmacy required for sterile compounding only.
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	Yes	ProCompounding.com
4.01	Does the pharmacy hold .pharmacy verification?	No	previously held
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	Emerson Wellevate
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	Yes	refill thru portal on website Procompounding.com
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	no photos were taken
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		PIC Tandy Branham, Laura Beth Jenks, staff pharmacists
	Types of Practice Additional Questions **If any part of a question is no, enter "No" and explain the observation.**		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	Yes	Only with drugs dangerous to patient, Cantharidin compounded prescriptions are sent to the provider's office. Dispensed once or twice a month.
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	Yes	The pharmacy distributes apporximately one order every other month for Testosterone 200mg MDV to prescriber for office use. Order quantity varies from 1 to 25 vials
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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		Finding	Notes
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
	General Operations and Licensure **If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	Last inspection 12/20/2021. VPN inspection performed 11/16/2020
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	Yes	Waiver for Pharmacist to Tech ratio from 1:4 to 1:5.
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	PCAB, valid from 5/3/2022 to 5/20/2025
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	Yes	the .pharmacy accreditation was not renewed due to cost and transistion to new ownership.

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		Finding	Notes
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	No	Electronic records are maintained, printed records greater than 2 years old are archived in pharmacy office
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	No	electronic records are maintained, printed records greater than 2 years old are archived in pharmacy office
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic records are kept on RxDispense website. All records are backed up daily and stored in the cloud on their website
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic records are maintained, printed records greater than 2 years old are moved to storage in another building in office complex.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic records cannot be deleted once dispensed, plus stored on back up
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	No	no longer stored offsite
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Pharmacy follows the most stringent law in any of the 8 states it serves. SOP 1.20 vs 6.0 Pharmacy requirements, pg 5
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Current license available for inspection
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	T Branham reviews monthly
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	waiver of 5:1

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Inspection Date: 05/22/2023

		Finding	Notes
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Door, window and motion detector alarms
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	no CII's are stocked
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	PIC would be contacted in case of an emergency
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	reverse distributor handles destruction/returns
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Return Solutions, Clean Harbors
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Return Solutions
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	Private Counseling Room
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	69 degrees Farenheit
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Eco-Bee, monitors calibrated yearly
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	SOP 1.30 vs 3.0 Environmental Monitoring of Non-sterile Compounding Areas, pg 12
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Temperatures are monitored by thermometer that also records max and min temps during previous 24 hrs. Records are maintained for two years. NIST traceable thermometer, replaced annually

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		Finding	Notes
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Lab 34° F, USP 800 room 40°F, POS 38°F
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Back-up diesel generator that will run for 48 hours on a full load, three refrigerators on site
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Contract with SB White, Could move to alternate site.
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	SOP 4.50 Vs 3.0 Quality Control
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	
	Product Receipt and Inventory **If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	Yes	Only purchase from VAWD Accredited wholesalers, keep binder of VAWD accreditations and other license information
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	American Pharmaceutical distribution, ANDA, Auburn, B&B, Prescriptin supply, Masters and Amerisource Bergen. API's from Fagron, Letco, Medisca, Darmerica and PCCA
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	No	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	No	

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47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	Yes	verified online, information in binder
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	yes	verfied online
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	Quarantine product until investigation is complete, SOP 3.10 vs 3.0 Inventory Control
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	Yes	available on WD website
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	SOP SOP 3.10 vs 3.0 Inventory Control
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	do not dispense
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	Yes	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	monthly CS inventory, technicians notify pharmacist of empty containers, inventory is verified at that time. Inventory is adjusted, small amounts of shrinkage due to compounding process.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	contact local law enforcement, report loss of control substances to DEA/Board of Pharmacy
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	

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56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	23-May-23
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	monthly
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		monthly
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	Yes	Six months unless expiration date is sooner
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	
	Prescription Processing **If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Intake PT enters data. Updated with each contact. Disease/diagnosis is noted if provided by prescriber or patient
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Computer software allows notation of animal data, profile for pet and profile for owner are linked together

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65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	contact local law enforcement
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Prescriptions are from prescribers that have been vetted by the sales force. Prescriptions are for quantities commiserate for use for one patient.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	Yes	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	RPh verifies data entry before prescription is compounded
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	RPh performs DUR prior to compounding of medication and when counseling patient on medication
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	Staff conducts interview to collect information when first contacted by patient
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Any and all date provided by the patient or the provider
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	daily
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	TN Law requires review of record twice a year. Once when first filling a new prescription and at least once more within 12 months.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	Software records name of pharmacist performing override
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan

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67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	only for veterinary prescriptions
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	No	Manually-Plumb Veterinary online
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	By second pharmacist
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Per state regulations
70.00	**Confidentiality**: Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Rx Dispense
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	HIPPA shred bin
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	COVID rules have been rescinded allowing work from home
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations*	No	

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74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	No	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all new prescriptions picked up at the pharmacy (proactively, no "offer")?	Yes	Required by state law
75.01	Is an "offer" to counsel made for all new prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all refilled prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	offer may be made by cashier, pharmacy tech or pharmacist
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	Yes	changes are considered New Rxs
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Pharmacist calls patient directly, provides printed material and a toll free number
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Pharmacist calls patient directly, provides printed material and a toll free number
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	No	PPI's are provided with commercial products only
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	No	MedGuides are provided with commerical products only
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	No	No REMS
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Documented by signature capture in software
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	

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85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Pharmacists Tandy Branham, Jessica James
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	electronic
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	electronic
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	

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88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	T Branham reviews incident reports monthly, quarterly review with pharmacist staff
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	Plan of corrections
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	every other week
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	No	
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	Survey is an ongoing process, sent out with every new prescription

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		Finding	Notes
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☒ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☒ Dangerous drugs
	☐ Location Change *	☐ Internet	☒ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: FR5255028
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Realo Specialty Care Pharmacy

Physical Address: 860 Aviation Parkway, Suite 1400

City: Morrisville State: NC Zip: 27560-7399

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 910-814-1943 Toll Free # (NAC 639.708, NRS 639.23286): 844-814-1943

Fax: 844-814-1944 Contact Email: connect@realospecialtycare.com

Website: www.realospecialtycare.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Charles Frye

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24427

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Charles Frye	NV Pharmacist Registration #: 24427
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (If any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: North Carolina

Parent Company (if any): N/A

Corporation/Organization Name: Realo Specialty Care Pharmacy, Inc.

Mailing Address: 1301 Commerce Drive

City: New Bern State: NC Zip: 28562

Telephone: [redacted] Email: [redacted]

Contact Person Name: Syreeta Taylor

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Realo Specialty Care Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Robert J McLaughlin Jr.

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/11/2025

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Robert J McLaughlin Jr. hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Realo Specialty Care Pharmacy (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 11th day of March, 2025

Notary Public

MICHAELA N. WILSON NOTARY PUBLIC WAKE COUNTY, NC

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert J. McLaughlin Jr.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/11/2025

Date

Board Use Only	Date Received: 3/20/25	Amount: $500 CK 1074

REALO SPECIALTY CARE PHARMACY

Realo Specialty Care Pharmacy, Inc. Officers

Name	Title	Address	Percent Owned
Robert J. McLaughlin Jr.	President	[redacted] Trenton, NC [redacted]	50%
Tammy D. McLaughlin	Vice President	[redacted] Trenton, NC [redacted]	50%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Realo Specialty Care Pharmacy

Pharmacy/Wholesaler License # (if applicable): N/A

Physical Address: 860 Aviation Parkway, Suite 1400

City: Morrisville State: NC Zip: 27560-7399

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 910-814-1943 Website: www.realospecialtycare.com

Licensing Company Email: connect@realospecialtycare.com

Section 2: Personal Information

First: Charles Middle: Douglas Last: Frye

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
North Davidson Senior High School		08/2000-05/2004	
Address	City	State	Zip
7227 Old US Hwy 52	Lexington	NC	27295
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
The University of North Carolina at Chapel Hill		08/2004-05/2008	
Address	City	State	Zip
145 E. Cameron St	Chapel Hill	NC	27514
Diploma/Degree obtained, if any			
BS Biology			

School Name		From - To (MM/YY – MM/YY)	
UNC Eshelman School of Pharmacy		08/2009-05/2013	
Address	City	State	Zip
301 Pharmacy Ln	Chapel Hill	NC	27599
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/2014 - Present	[redacted]			
From - To (MM/YY – MM/YY)				
02/2015 - 02/2014				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Realo Specialty Care Pharmacy			06/15-Current
Business Address	**City**	**State**	**Zip**
860 Aviation Parkway, Suite 1400	Morrisville	NC	27560-7399
Phone	**Title**		**Number of Employed Hours**
844-814-1943	Director of Specialty Pharmacy, PIC		22,000 (40 hours/week)
Description of Duties			
Checking prescriptions, patient counseling, prior authorizations, administrative			

Business Name			From - To (MM/YY – MM/YY)
Brame Huie Pharmacy			06/2013-07/2014
Business Address	**City**	**State**	**Zip**
1920 W Park Dr	North Wilkesboro	NC	28569
Phone	**Title**		**Number of Employed Hours**
336-838-8988	Community Pharmacy Resident		2000 (40 hours/week)
Description of Duties			
Checking prescriptions, compounding, patient counseling			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

I, Charles Douglas Frye, **certify that as the designated representative for**

Realo Specialty Care Pharmacy,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CDF I am at least 21 years of age;
3. CDF I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CDF I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CDF I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CDF I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CDF I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Charles Frye

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/7/2025

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
05/02/2009	10/26/2009	NC	Chapel Hill	Orange
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
09CR51705		Orange County Court		
Reason/Charge				
DUI				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Charles Frye			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

On October 26, 2009 I plead guilty to DUI in Chapel Hill, North Carolina. I received the least severe penalty of DUI as there were no mitigating factors. The conviction was before I was a pharmacist. Therefore, it has never had any influence on my licensing or the status of my license. I have included the court documents from my hearing. Also, the conviction will appear on my criminal background check. If there is any additional information or documentation you require please let me know.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/7/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Charles Frye

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/11/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake

I, Charles Frye, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/11/2025

Date

Subscribed and Sworn to before me this 11th day of March.

Michaela N. Wilson

Notary Public Signature

MICHAELA N. WILSON NOTARY PUBLIC WAKE COUNTY, NC

(Seal)

STATE OF NORTH CAROLINA

File No. 09 CR 51705

ORANGE County

In The General Court Of Justice
☒ District ☐ Superior Court Division

STATE VERSUS

Name Of Defendant

Charles Douglas Frye

IMPAIRED DRIVING DETERMINATION OF SENTENCING FACTORS

G.S. 20-179

☒ **District Court:** The defendant has been convicted of impaired driving (G.S. 20-138.1). Based upon the evidence presented at the trial and sentencing hearing in District Court, the Court determines that (1) the State has proved the grossly aggravating factors and aggravating factors marked below beyond a reasonable doubt and (2) the defendant has proved the mitigating factors marked below by a preponderance of the evidence.

☐ **Superior Court:** The defendant has been convicted of impaired driving (G.S. 20-138.1). Based upon the evidence presented at the trial and sentencing hearing in Superior Court, (1) the jury has determined that the State has proved the grossly aggravating factors and aggravating factors marked below beyond a reasonable doubt, or the defendant has admitted to these grossly aggravating factors and aggravating factors, and (2) the Court determines that the defendant has proved the mitigating factors marked below by a preponderance of the evidence. If grossly aggravating factor No. 1.a., 1.b., 1.c., 1.d., 1.e., or 1.f. is marked below, the Court determines that the State has proved that grossly aggravating factor beyond a reasonable doubt. If aggravating factor No. 8 or 9 is marked below, the Court determines that the State has proved that aggravating factor beyond a reasonable doubt *(applies to offenses committed on or after August 30, 2007).*

I. GROSSLY AGGRAVATING FACTORS - G.S. 20-179(c)

(NOTE: *Either Nos. 1 and 2 or No. 3 apply in each case except aiders and abettors. If No. 1 is checked, No. 2.a. or No. 2.b. must also be checked.)*

☐ 1. The defendant
- ☐ a. has been convicted of a prior offense involving impaired driving which conviction occurred within seven (7) years before the date of this offense.
- ☐ b. has two or more convictions as described in No. 1.a. (Level One punishment is required.)
- ☐ c. has been convicted of an offense involving impaired driving which conviction occurred after the date of the offense for which the defendant is being sentenced but before or contemporaneously with the sentencing in this case.
- ☐ d. has two or more convictions as described in No. 1.c. (Level One punishment is required.)
- ☐ e. has a prior conviction in District Court for an offense involving impaired driving, the conviction was appealed to Superior Court, the appeal has been withdrawn or the case has been remanded back to District Court, and a new sentencing hearing for the case has not been held pursuant to G.S. 20-38.7. *(Applies to offenses committed on or after August 30, 2007.)*
- ☐ f. has two or more convictions as described in No.1.e. (Level One punishment is required.) *(Applies to offenses committed on or after August 30, 2007.)*
- ☐ g. drove, at the time of the current offense, while the defendant's drivers license was revoked under G.S. 20-28 and the revocation was an impaired driving revocation under G.S. 20-28.2(a).
- ☐ h. caused, by the defendant's impaired driving at the time of the current offense, serious injury to another person.
- ☐ i. drove, at the time of the current offense, while a child under the age of 16 years was in the vehicle.

☐ 2. Therefore, the following level of punishment shall be imposed:
- ☐ a. **Level One** punishment, because at least two grossly aggravating factors in No. 1 apply to this defendant. **(NOTE:** *Each prior conviction is a separate grossly aggravating factor.)*
- ☐ b. **Level Two** punishment, because only one grossly aggravating factor in No. 1 applies to this defendant.

☐ 3. There are no grossly aggravating factors.

II. AGGRAVATING AND MITIGATING FACTORS - G.S. 20-179(d) AND (e)

AGGRAVATING FACTORS - G.S. 20-179(d):

(NOTE: *Except for the factors in subdivisions 8 and 9 below, the conduct constituting the aggravating factor must occur during the same transaction or occurrence as this impaired driving offense.)*

☐ 1. The defendant's faculties were grossly impaired at the time the defendant was driving.

☑ 2. The defendant had an alcohol concentration of at least ☐ 0.16 ☑ 0.15 *(use for offenses committed on or after December 1, 2007)* within a relevant time after the driving.

☐ 3. The driving of the defendant was especially reckless.

☐ 4. The driving of the defendant was especially dangerous.

☐ 5. The negligent driving of the defendant led to an accident causing property damage of $1,000.00 or more, or property damage of any amount to a vehicle seized pursuant to G.S. 20-28.3.

☐ 6. The negligent driving of the defendant led to an accident causing personal injury.

☐ 7. The defendant was driving while the defendant's drivers license was revoked.

☐ 8. The defendant had at least two prior convictions of a motor vehicle offense not involving impaired driving, which occurred within five (5) years of this offense, and
- ☐ a. all were offenses for which at least three (3) points were assigned under G.S. 20-16.
- ☐ b. all were offenses for which the defendant's drivers license was subject to revocation.
- ☐ c. at least one was an offense for which at least three (3) points were assigned under G.S. 20-16 and at least one was an offense for which the defendant's drivers license was subject to revocation.

☐ 9. The defendant had at least one prior conviction of an offense involving impaired driving that occurred more than seven (7) years before the date of this offense.

☐ 10. The defendant has been convicted under G.S. 20-141.5 of speeding while fleeing or attempting to elude apprehension.

☐ 11. The defendant has been convicted under G.S. 20-141 of speeding by at least 30 m.p.h. over the legal limit.

A TRUE COPY
CLERK OF SUPERIOR COURT
ORANGE COUNTY
By: [signature]
Assistant, Deputy, Clerk Superior Court

Original - File
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☐ 12. The defendant passed a stopped school bus in violation of G.S. 20-217.
☐ 13. Additional factors that aggravate the seriousness of this offense:

☐ 14. There are no aggravating factors.

MITIGATING FACTORS - G.S. 20-179(e):

NOTE: *Except for the factors in subdivisions 4, 6, and 7 below, the conduct constituting the mitigating factor must occur during the same transaction or occurrence as this impaired driving offense.*

☐ 1. There was a slight impairment of the defendant's faculties resulting solely from alcohol; and, the defendant's alcohol concentration did not exceed 0.09 at any relevant time after the driving.

☐ 2. There was a slight impairment of the defendant's faculties resulting solely from alcohol; and, no chemical test was made available to the defendant.

☑ 3. The driving of the defendant was safe and lawful except for the impairment of the defendant's faculties.

☑ 4. The defendant has a safe driving record, having no convictions of any motor vehicle offense for which at least four points are assigned under G.S. 20-16 or for which the defendant's license is subject to revocation within five (5) years of the date of this offense.

☐ 5. The impairment of the defendant's faculties was caused primarily by a lawfully prescribed drug for an existing medical condition, and the amount of the medical drug taken was within the prescribed dosage.

☑ 6. After being charged in this case with impaired driving, the defendant voluntarily submitted himself/herself to a mental health facility for assessment and has voluntarily participated in any treatment recommended by such facility, if such treatment was recommended.

☐ 6a. The defendant completed a substance abuse assessment, complied with its recommendations, and simultaneously maintained 60 days of continuous abstinence from alcohol consumption, as proven by a continuous alcohol monitoring system of a type approved by the Department of Correction. *(Applies to offenses committed on or after December 1, 2007.)*

☐ 7. Additional factors that mitigate the seriousness of this offense:

☐ 8. There are no mitigating factors.

DETERMINATION - G.S. 20-179(f):

(NOTE: *Check only one.*)

☐ 1. The aggravating factors marked above substantially outweigh any mitigating factors marked above. Therefore, Level Three punishment shall be imposed.

☐ 2. There are no aggravating or mitigating factors. Therefore, Level Four punishment shall be imposed.

☐ 3. The aggravating factors marked above are substantially counterbalanced by the mitigating factors marked above. Therefore, Level Four punishment shall be imposed.

☑ 4. The mitigating factors marked above substantially outweigh any aggravating factors marked above. Therefore, Level Five punishment shall be imposed.

☐ 5. No findings of mitigating or aggravating factors were made because the defendant is an aider and abetter. Therefore, Level Five punishment shall be imposed.

Date	*Name Of Presiding Judge (Type Or Print)*	*Signature Of Presiding Judge*
12/20/07		

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STATE OF NORTH CAROLINA

File No. 09CR 51705

ORANGE County CHAPEL HILL Seat of Court

In The General Court Of Justice
☒ District ☐ Superior Court Division

(NOTE: *Except in cases involving a violation of both G.S. 20-138.1 and 138.2, this form should be used for only one DWI conviction, and no other offense should be consolidated for judgment with the DWI offense.*)

STATE VERSUS

Name Of Defendant: Charles Douglas Frye

Race	Sex	Drivers License No.	State	DOB
W	M	[redacted]	NC	[redacted]

IMPAIRED DRIVING - JUDGMENT SUSPENDING SENTENCE

☐ COMMITMENT ON SPECIAL PROBATION

G.S. 20-179

Date Of Offense	Attorney For State		Attorney For Defendant	
5-2-09	Steve Motta	☐ Def. Found Not Indigent ☒ Def. Waived Attorney	F. Bataglia	☐ Appointed ☒ Retained

Offense: ☒ Impaired Driving (G.S. 20-138.1). ☐ Impaired Driving in a commercial vehicle (G.S. 20-138.2). ☐ Operating a commercial vehicle after consuming alcohol and this was the defendant's second or subsequent conviction of this offense (G.S. 20-138.2A). ☐ Operating a school bus, school activity bus, child care vehicle after consuming alcohol and this was the defendant's second or subsequent conviction of this offense (G.S. 20-138.2B).

The defendant appeared in open court and ☒ freely, voluntarily, and understandingly pled guilty to ☐ was found guilty by the Court of ☐ was found guilty by a jury of ☐ pled no contest to the offense specified above. The Court, based upon the determinations as shown on the attached Determination of Sentencing Factors form (AOC-CR-311), has imposed the following punishment level.

☐ **Level One.** ☐ **Level Two.** ☐ **Level Three.** ☐ **Level Four.** ☒ **Level Five.**

The Court, having considered evidence, arguments of counsel and statement of defendant, ORDERS that defendant be imprisoned

for a minimum term of	for a maximum term of	In the custody of the
30 Days	30 Days	☒ N.C. Department of Correction. ☐ Sheriff of _____ County.

☐ This sentence shall run at the expiration of sentence imposed in file number _____.

The defendant shall be given credit for 0 days spent in confinement prior to the date of this Judgment as a result of this charge ☐ and as an inpatient at a facility operated or licensed by the State for the treatment of alcoholism or substance abuse after the commission of the above offense. Credit shall be applied against the ☐ minimum and maximum terms above, ☐ imprisonment for special probation below. (**NOTE:** *No credit may be given for the first 24 hours spent in confinement.*)

SUSPENSION OF SENTENCE

Subject to the conditions set out below, the execution of this sentence is suspended and the defendant is placed on
☒ unsupervised probation for 12 months.
☐ supervised probation for _____ months, the Court having received evidence and having found as a fact that supervision is necessary.

SPECIAL PROBATION - G.S. 15A-1351

☐ As a condition of special probation, the defendant shall ☐ serve an active term of _____ ☐ days ☐ months in the custody of the ☐ N.C. DOC. ☐ Sheriff of this County. ☐ *(for offenses committed prior to December 1, 1997)* submit to a combination of imprisonment and house arrest per attached AOC-CR-603, Page Two. ☐ pay jail fees.

(**NOTE:** *This term shall NOT be reduced by good time, gain time or parole, or, unless provided above, by jail or treatment time.*)

The defendant shall report in a sober condition to begin serving this term on:	Day	Date	Hour ☐ AM ☐ PM	and shall remain in custody until:	Day	Date	Hour ☐ AM ☐ PM

☐ The defendant shall again report in a sober condition to continue serving this term on the same day of the week for the next _____ consecutive weeks, and shall remain in custody during the same hours each week.

☐ The defendant shall serve the active term above as an inpatient in *(Name treatment facility)* _____ and shall follow the rules of that facility until discharged and not leave its premises except as authorized under those rules.

MONETARY CONDITIONS

The defendant shall pay to the Clerk of Superior Court the "Total Amount Due" shown below, plus the probation supervision fee, pursuant to a schedule ☐ determined by the probation officer. ☐ set out by the court as follows: _____

Costs	Fine	Restitution*	Attorney's Fee	Community Service Fee	EHA Fee/CAM Fee	Total Amount Due
$ 130.00	$ 100	$	$	$ 225.00	$	$ 455.00

*See attached "Restitution Worksheet, Notice And Order (Initial Sentencing)" AOC-CR-611, which is incorporated by reference.

☐ All payments received by the Clerk shall be distributed pro rata among the persons entitled to restitution in this priority: first among all G.S. 7A-304(d) priorities ☐ and before payment of community service and probation supervision fees.

☐ Upon payment of the "Total Amount Due," the probation officer may transfer the defendant to unsupervised probation.

REGULAR CONDITIONS OF PROBATION - G.S. 15A-1343(b)

NOTE: *Any probationary judgment may be extended pursuant to G.S. 15A-1342.*

The defendant shall: (1) Commit no criminal offense in any jurisdiction. (2) Possess no firearm, explosive device or other deadly weapon listed in G.S. 14-269. (3) Remain gainfully and suitably employed or faithfully pursue a course of study or of vocational training that will equip the defendant for suitable employment, and abide by all rules of the institution. (4) Satisfy child support and family obligations, as required by the Court.

If the defendant is on supervised probation, the defendant shall also: (5) Remain within the jurisdiction of the Court unless granted written permission to leave by the Court or the probation officer. (6) Report as directed by the Court or the probation officer to the officer at reasonable times and places and in a reasonable manner, permit the officer to visit at reasonable times, answer all reasonable inquiries by the officer and obtain prior approval from the officer for, and notify the officer of, any change in address or employment. (7) Notify the probation officer if the defendant fails to obtain or retain satisfactory employment. (8) At a time to be designated by the probation officer, visit with the probation officer a facility maintained by the Division of Prisons.

If the defendant is to serve an active sentence as a condition of special probation, the defendant shall also: (9) Obey the rules and regulations of the Department of Correction governing the conduct of inmates while imprisoned. (10) Report to a probation officer in the State of North Carolina within 72 hours of the defendant's discharge from the active term of imprisonment.

A TRUE COPY
CLERK OF SUPERIOR COURT
ORANGE COUNTY
BY _____
Assistant, Deputy, Clerk Superior Court

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(Over)

SPECIAL CONDITIONS OF PROBATION - G.S. 15A-1343(b1); 20-179

☑ 11. Obtain a substance abuse assessment and all recommended education or treatment. *(Mandatory for offenses committed on or after December 1, 1997.)* Pretrial

☑ 12. Surrender the defendant's drivers license to the Clerk of Superior Court for transmittal/notification to the Division of Motor Vehicles; and not operate a motor vehicle until the defendant's driving privilege is restored by that Division, except as may be permitted in a limited privilege.

☑ 13. Complete 24 hours of community service within 120 days from this date as directed by the Community Service Coordinator, and pay to the Clerk the community service fee prescribed by law ☐ pursuant to the schedule set out under "Monetary Conditions" above ☐ within _____ days of this date. ☐ Fee shall be paid before beginning service.

☐ 14. Not use, possess, or control any illegal drug or controlled substance unless it has been prescribed for the defendant by a licensed physician and is in the original container with the prescription number affixed on it; not knowingly associate with any previously convicted users, possessors or sellers of any such illegal drug or controlled substances; and not knowingly be present at or frequent any place where such illegal drugs or controlled substances are sold, kept or used.

☐ 15. Submit, upon the request of any law enforcement or probation officer, to any physical, chemical, blood, or breath test or to a urinalysis for the detection of alcohol or controlled substances.

☐ 16. Abstain from alcohol consumption for _____ days, as verified by a continuous alcohol monitoring system of a type approved by the Department of Correction. ☐ The defendant shall pay to the Clerk the fees associated with the system, as set by the entity providing the system, but not to exceed a total cost of $1,000. ☐ The court finds, upon good cause shown, that the defendant should not be required to pay the costs of the continuous alcohol monitoring system and _____, the local government entity responsible for the incarceration of the defendant in the local confinement facility, has agreed to pay the costs of the system to the Clerk. *(Applies to offenses committed on or after December 1, 2007.)*

☐ 17. Other:

☐ 18. Comply with the Additional Conditions of Probation which are set forth on AOC-CR-603, Page Two, attached.

[Check any that apply - G.S. 20-179(r)]

☐ The probation officer may transfer the defendant to unsupervised probation upon completion of ☐ the community service required by Special Condition No. 13 above. ☐ payment of all fines, costs and fees required above.

☐ A hearing was held in open court in the presence of the defendant at which time a fee, including expenses, was awarded the defendant's appointed counsel or assigned public defender.

SPECIAL ALCOHOL CONCENTRATION FINDING

☑ The defendant's alcohol concentration was ☐ 0.16 ☑ 0.15 *(use for offenses committed on or after December 1, 2007)* or greater.

☐ Other: _____.

ORDER OF COMMITMENT/APPEAL ENTRIES

☐ 1. It is ORDERED that the Clerk deliver two certified copies of this Commitment on Special Probation to the sheriff or other qualified officer and that the officer cause the defendant to be delivered with these copies to the custody of the agency named on the reverse to serve the sentence imposed or until the defendant shall have complied with the conditions of release pending appeal.

☐ 2. The defendant gives notice of appeal from the judgment of the District Court to the Superior Court. The current pretrial release order is modified as follows: _____.
NOTE: ***Upon notice of appeal, the District Court sentence is vacated. Withdrawal of appeal or remand to District Court requires that a new sentencing hearing be scheduled.***

☐ 3. The defendant gives notice of appeal from the judgment of the Superior Court to the appellate division. Appeal entries and any conditions of post conviction release are set forth on form AOC-CR-350.

SIGNATURE OF JUDGE

Date	*Name Of Presiding Judge (Type Or Print)*	*Signature Of Presiding Judge*
10/20/09	Hon Lunsford Long	

CERTIFICATION

I certify that this Judgment and the attachment(s) marked below are true and complete copies of the originals.

☐ 1. Determination Of Sentencing Factors (AOC-CR-311).
☐ 2. Additional Conditions of Probation (AOC-CR-603, Page Two).
☐ 3. Restitution Worksheet, Notice And Order [Initial Sentencing] (AOC-CR-611).

Date Of Certification	*Date Certified Copies Delivered To Sheriff*	*Signature And Seal*
		☐ *Deputy CSC* ☐ *Assistant CSC* ☐ *Clerk Of Superior Court*

NOTE TO CLERK: ***If the defendant's conviction is based on a violation of an offense involving impaired driving while the defendant's drivers license is revoked as a result of a prior impaired driving license revocation as defined in G.S. 20-28.2, report DWI Defendant Registration Stop to DMV using menu item #9 in STARS. Also report the defendant's conviction to DMV in the usual manner. If there is a non-defendant vehicle owner, report registration stop to DMV using menu item #10 in STARS (unless the owner has been found to be an innocent owner).***

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Realo Specialty Care Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 860 Aviation Parkway, Suite 1400

City: Morrisville State: NC Zip: 27560-7399

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 844-814-1943 Website: www.realospecialtycare.com

Licensing Company Email: connect@realospecialtycare.com

Section 2: Personal Information

First: Tammy Middle: D Last: McLaughlin

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Carteret Community College			- 08/96	- 5/98
Address: Arendell Street	City: Morehead City		State: NC	Zip: 28557
Diploma/Degree obtained, if any: Associate Degree				
School Name: East Carteret High School			From - To (MM/YY – MM/YY): 8/75 - 6/79	
Address: Hwy 70 E	City: Beaufort		State: NC	Zip: 28516
Diploma/Degree obtained, if any: High School Diploma				
School Name: N/A			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name: N/A			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name: N/A			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/06 - Present				
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY): N/A	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Carolina Home Medical, Inc.			1996-Present	
Business Address	**City**		**State**	**Zip**
1301 Commerce Drive	New Bern		NC	28562
Phone	252-636-1711	**Title**	RT	
Description of Duties	Respiratory Assistance			

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone		**Title**		
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone		**Title**		
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone		**Title**		
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone		**Title**		
Description of Duties				

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/13/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tammy D. McLaughlin

Print Name (First, Last)

[redacted] 2/13/25

Original Signature (electronic, copies or stamps not accepted) Date

---

Please have this section completed in the presence of a Notary Public.

State of North Carolina ss. County of Craven

I, Tammy McLaughlin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted] 2/13/25

Original Signature **Date**

Subscribed and Sworn to before me this 13 day of February

Syreeta Grace-Taylor

Notary Public Signature

SYREETA GRACE-TAYLOR NOTARY PUBLIC CRAVEN COUNTY, NC My Commission Expires February 8, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Realo Specialty Care Pharmacy

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): N/A

Physical Address: 860 Aviation Parkway, Suite 1400

City: Morrisville State: NC Zip: 27560-7399

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 844-814-1943 Website: www.realospecialtycare.com

Licensing Company Email: connect@realospecialtycare.com

Section 2: Personal Information

First: Robert Middle: Joseph Last: McLaughlin Jr.

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of North Carolina		8/80 – 5/83	
Address	City	State	Zip
103 South Bldg Cb 9100	Chapel Hill	NC	27599
Diploma/Degree obtained, if any: BS Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Jacksonville High School		08/74-05/78	
Address	City	State	Zip
1021 Henderson Drive	Jacksonville	NC	28540
Diploma/Degree obtained, if any: High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/06 – Present				
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip
From - To (MM/YY – MM/YY) N/A	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Realo Discount Drug Stores of Eastern North Carolina, Inc			1996-Present
Business Address	**City**	**State**	**Zip**
1301 Commerce Drive	New Bern	NC	28562
Phone	**Title**		
252-639-9006	President		
Description of Duties			
Pharmacist			

Business Name			From - To (MM/YY – MM/YY)
Carolina Home Medical, Inc.			1996-Present
Business Address	**City**	**State**	**Zip**
1301 Commerce Drive	New Bern	NC	28562
Phone	**Title**		
252-636-1711	President		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A			
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/11/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert McLaughlin Jr.

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/11/2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake

I, Robert J. McLaughlin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/11/2025

Date

Subscribed and Sworn to before me this 11th day of March.

Michaela N. Wilson

Notary Public Signature

MICHAELA N. WILSON
NOTARY
PUBLIC
WAKE COUNTY, NC

(Seal)

Inspection Details

Name	Realo Specialty Care Pharmacy	**Case #**		**Permit**	12602
Address	860 Aviation Parkway Morrisville, NC 27560	**Person Providing Info**	Charles Frye	**Inspection Date**	03/13/2023
		Person In Charge	Charles Douglas Frye	**Inspection User**	Cutbush, Christie
				Inspection District	DISTRICT3
# RPhs	4ft	**Rx Volume/Date**	80/day CII/40month		
# Techs	3FT	**Hours**	M-F 9-5		
Follow-Up CAP	No	**Office**	No		
CAP Requested	No	**Commercial Use**	No		
CAP Documentation Received	No	**Ship to Other States**	Yes		
Additional Documents	Yes	**States Shipped To**			
Non-Sterile Compounding Levels					
Sterile Compounding Levels					

Pharmacy Staffing

What is the P:T ratio at the time of inspection: 3:2

If ratio is above 1:2 at the time of inspection, how many certified technicians are on shift:

n/a

What is the approved Pharmacist: Technician ratio?

How often is there only one pharmacist on duty: Never

How many technicians are usually on shift at a time: 3

Are pharmacists asked to do any duties outside of the pharmacy :

No

Pharmacy Volume

Does pharmacy administer vaccines: No

What is the daily average of vaccines:

What staff members are administering vaccines and what type of vaccines:

How far behind is the pharmacy on filling and verifying prescriptions:

n/a

How long has this backlog persisted: n/a

Does pharmacy conduct any point of care testing such as COVID:

No

What is the daily average of testing:

What staff is responsible for administering test and what is testing procedure:

Are administered vaccines reported to the appropriate vaccine registry:

In your opinion, does the rate you are dispensing per hour or per day pose a threat to public health and safety:

No

Comments

Smith Drug
McKesson
CuraScript
HCI
PharmSaver
Applying for permits in KY, LA, AL
Return Solutions- never returned any CSs
340B Inventory
Natesto- CIII and Levorphenol CII are the only Controlled Substances in stock.

99% of medications are shipped UPS, FedEx, USPS, and using a courier.
Self-testing for cold shipping conditions was performed in April 2022. This typically is done 2x a year.
Gaines McCarthy- Marketing staff
2 fieldwork staff members for NC, SC, and Va. Joe Preston and Sandy Cartright
2 call center staff members in the office.

General Pharmacy Regulations

	Answer	Question
1)	Satisfactory	NCGS 90-85.15A (a) - tech must register with the Board within 30 days after the date of completing the training program.
2)	Satisfactory	NCGS 90-85.15A (c) - 2:1 ratio, if ratio above provide waiver documentation. Any technician above the 2:1 ratio must be certified.
3)	Satisfactory	NCGS 90-85.23- PM license, permit and current renewal shall be posted. Licenses and renewals of each RPh. are readily available for inspection.
4)	Satisfactory	NCGS 90-85.25 (b) - PM shall report within 10 days any disaster, accident, theft.
5)	Satisfactory	NCGS 90-85.26 (a) - prescriptions preserved for 3 years. (b) - Documentation of alleged medication errors.
	Comments: APMS	
6)	Satisfactory	NCGS 90-85.29 (1) - prescription label shall contain a discard date that is earlier of 1 yr. from date dispensed or manuf's exp. date, whichever is earlier. (2) - not obscure exp. date and storage statement when product dispensed in manuf's original container.
7)	Satisfactory	NCGS 90-85.32 (a) - prescriptions marked PRN not refilled more than 1 yr. after issue date.
8)	Satisfactory	NCGS 90-85.47 - Quality Assurance Program
9)	Not Applicable	NCGS 90-93 (3)(d): Sch. V log book or record of disposition.
10)	Satisfactory	NCGS 90-106.1 (a) - documentation system of photo ID. Kept on premises or central location for 3 years.
	Comments: Collect a driver's license number initially and save in computer system.	
11)	Not Applicable	NCGS 90-113.52 (b) - pseudoephedrine Products kept behind counter. (c) - record of every purchaser, amount of product in grams. (d) - records kept for two 2 years.
12)	Not Applicable	NCGS 90-113.54 - posting of sign prohibiting sale of more than 2 pkgs (3.6grams total) of pseudoeph. /day, no more than 3 pkgs (9grams total) within 30- day period.
13)	Satisfactory	NCGS 90-640 (b) - ID badge
14)	Satisfactory	21CFR 201.17- Misbranded drugs: Medications stored in pharmacy should be labeled with an expiration date and manufacturer lot number. Note: Return to stock prescription vial with the pharmacy's own label affixed will not be deemed misbranded
15)	Satisfactory	21 NCAC 46.106-134.1 (4)(b)- label lacks any requirement listed in the subsection. (px name, name/add. of pharmacy, disp. rph's name, rx #, fill date of rx, prescriber name, dir. for use, name & strength of drug.)
16)	Satisfactory	21 NCAC 46.1601 (a)(2)- posted Pharmacy hours. (4)(A-E)- reference library, hard copy or electronic. (5)- lavatory facilities w/ hot and cold running water; clean, orderly and sanitary. (b)(1)- records are readily retrievable. (b)(2)- toll free number on labels of dispensed medications. (e)- pharmacy permit is countersigned by rphmgr. as represented in the application.
17)	Satisfactory	21 NCAC 46.1802 (a) - refills limited to prescriber's orders.
18)	Satisfactory	21 NCAC 46.1803 - All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
19)	Satisfactory	21 NCAC 46.1806 - proper documentation and handling of transferred rxs
20)	Satisfactory	21 NCAC 46.1818 - label shall list generic name of drug, even if unavailable to dispense or generic is not authorized.
21)	Satisfactory	21 NCAC 46.2302 (a)(1-5) - records of dispensing shall be kept for 3 years.
22)	Satisfactory	21 NCAC 46.2303 - records of prescription filling and refilling shall be kept for 3 yrs.
23)	Satisfactory	21 NCAC 46.2304 (1) - produce sight-readable documents. (3) - RPh. responsible for completeness and accuracy of entries, provides documentation that prescription information entered is correct. (5) - pharmacy has auxiliary recordkeeping system. (7) - current version of drug interactions software is utilized
	Comments: Pioneer	
24)	Satisfactory	21 NCAC 46.2305 - To maintain the confidentiality of patients' prescription orders, there must be adequate safeguards or security of the records.
25)	Satisfactory	21 NCAC 46.2502 (a) - PM shall assure that rx meds & cs meds are safe/secure within the pharmacy. (b) - PM is present one-half the hrs. the pharmacy is open or 32 hrs. /wk., whichever is less. (d) - system of inventory recordkeeping and control to detect any shortage or discrepancies of cs meds. (e) - control of all keys to pharmacy. (j) - written disaster plan. (k) - separate from the dispensing stock all drugs more than 6 months out of date.

General Pharmacy Regulations

	Answer	Question
26)	Satisfactory	21 NCAC 46.2504 (a) - effective communication of information to the patient(s). (b) - offer to counsel for all new and transfer prescriptions. (g) - Documentation of refusals.
27)	Satisfactory	21 NCAC 46.3001 (a) - policy/procedure for all out dated, improperly labeled, adulterated damaged or unwanted drugs or drug containers are destroyed or disposed.
		Comments: Return Solutions
28)	Satisfactory	21 NCAC 46.3301 (b) - Current registration of a pharmacy tech shall be readily available for inspection.
29)	Satisfactory	21CFR 1301.75 (b) - controlled substances listed in II, III, IV, and V shall be stored in a substantially constructed cabinet, or disbursed throughout the non-controlled substances
30)	Satisfactory	21CFR 1304.04 (2)(h)(1) - inventories and records of Sch. I & II substances maintained separate from all other records (2)(h)(2)- paper prescriptions for Sch. II substances maintained in separate file.
31)	Satisfactory	21CFR 1304.11 (a) - complete/accurate inventory of all cs meds and maintained at the registered location. (c) - Biennial inventory.
32)	Satisfactory	21CFR 1305.05 (a) - power of attorney on file at registered location.
33)	Satisfactory	21CFR 1305.12 (b) - purchaser shall record 1 item on each numbered line. (c) - name/address of supplier on form. Only 1 supplier on any form. (d)- DEA Form 222 properly signed and dated.
		Comments: Exchanges between stores.
34)	Satisfactory	21CFR 1305.13 (e) - purchaser must record the number of commercial or bulk containers furnished on each item and dates on which the containers are received.
35)	Satisfactory	21CFR 1305.22 Procedure for filling electronic orders. (g) - purchaser receives shipment, purchaser must create a record of the quantity of each item received and date received. Record must be electronically linked to the original order and archived.
36)	Satisfactory	21CFR 1305.27 Preservation of electronic orders. (a) purchaser must, for each order filled, retain the original signed order and all linked records for that order for 2 years. Purchaser must also retain all copies of each unaccepted or defective order and each linked statement. (b) supplier must retain each original order filled and the linked records . (Note: 2yrs for Federal Law; 3yrs for NC Law) (c) If electronic order records are maintained on a central server, records must be readily retrievable at the registered location. (Note: 2yrs for Federal Law; 3yrs for NC Law)
37)	Satisfactory	21CFR 1306.05 (a) - all cs prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, dirs. for use, and name, address and registration number of practitioner. (d) - computer generated prescription that is printed or faxed must be manually signed
38)	Satisfactory	21CFR 1306.08 (3)(b) - pharmacy may fill electronically transmitted prescription for a cs med provided the pharmacy complies with all requirements. A Sch. II order signed by the prac- titioner.
39)	Satisfactory	21CFR 1306.14 (a) - prescription vials labeled for Sch. II display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
40)	Satisfactory	21CFR 1306.21 (a) - order for Sch. III, IV, or V that is a facsimile is signed by practitioner.
41)	Satisfactory	21CFR 1306.22 (b) - cs refills entered on a medication record or electronic record must be uniformly maintained and readily retrievable.
42)	Satisfactory	21CFR 1306.24 (a) - prescription vials labeled for Sch. III, IV, or V display pharmacy name and address, rx #, initial fill date, patient name, practitioner name, dirs. for use and any cautionary statements.
43)	Not Applicable	21CFR 1306.26 (b) - not more than 8oz. of any cs containing opium, nor more than 4oz. of any other cs; not more than 48 dosage units of any such cs containing opium, nor more than 24 dosage units of any other such cs to the same purchaser in any 48-hr. period. (c) - purchaser at least 18 yoa (d) - furnish suitable ID (e) - maintain log containing name and address of purchaser, name and qty. of cs, date of purchase, name or initials of RPh. who dispensed the substance.
44)	Satisfactory	21CFR 1311.10 Eligibility to obtain a CSOS digital certificate. (a) - person who signed the most recent DEA registration application or renewal application and a person authorized to sign a registration application. (b) - person granted power of attorney by a DEA registrant to sign orders for one or more schedules of controlled substances.
45)	Satisfactory	21CFR 1311.30 Requirements for storing and using a private key for digitally signing orders. (a) - Only the certificate holder may access or use his or her digital certificate and private key. (b) - The certificate holder must provide FIPSapproved secure storage for the private key, as discussed by FIPS 140-2, 180-2, 186-2, and accompanying change notices and annexes, as incorporated by reference in §1311.08. (c) - A certificate holder

General Pharmacy Regulations		
	Answer	**Question**
		must ensure that no one else uses the private key. While the private key is activated, the certificate holder must prevent unauthorized use of that private key.
46)	Satisfactory	21CFR 1311.35 Number of CSOS digital certificates needed. A purchaser of Schedule I and II controlled substances must obtain a separate CSOS certificate for each registered location for which the purchaser will order these controlled substances.
47)	Satisfactory	21CFR 1311.60 Recordkeeping. (a) - supplier and purchaser must maintain records of CSOS electronic orders and any linked records for 2 years. Records may be maintained electronically. Records regarding controlled substances that are maintained electronically must be readily retrievable from all other records. (Note: 2yrs for Federal Law; 3yrs for NC Law) (b) - Electronic records must be easily readable or easily rendered into a format that a person can read. Must be made available to the Administration upon request. (c) - CSOS certificate holders must maintain a copy of the subscriber agreement that the Certification Authority provides for the life of the certificate.

Jack W. Campbell, IV
Executive Director

Barbara Ellen Vick
Associate Executive Director

Mailing Address:
6015 Farrington Rd., Suite 201
Chapel Hill, NC 27517
919-246-1050 FAX: 919-246-1056
www.ncbop.org

Clinton R. Pinyan
Brooks, Pierce, McLendon,
Humphrey & Leonard, LLP
Legal Counsel

NORTH CAROLINA

BOARD OF PHARMACY

President
Dr. Chris Sain

Vice President
Mischelle Corbin

Members
Dr. Ashley Duggins
R. Joseph (Joey) McLaughlin, Jr
Wallace Nelson
Dr. Keith A. Vance

3/14/2025

RE: PHARMACY PERMIT VERIFICATION

This is to certify that the following was permitted in the state of North Carolina as a pharmacy:

Realo Specialty Care Pharmacy, Inc.
DBA: Realo Specialty Care Pharmacy

Permit Number: 12602

Issue Date: 05/18/2015

Expires: 12/31/2025

Registration Status: Active

Our files show no disciplinary action against this permit.

NORTH CAROLINA BOARD OF PHARMACY

Jack W. Campbell
Executive Director

Revised 8/2024

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy Suite 206 – Reno, NV 89521 – (775) 850-1440

Send to State Board of Pharmacy for completion. A separate letter is acceptable. Do not return with application unless it has been completed by the licensing agency.

LICENSE VERIFICATION

Name: Realo Specialty Care Pharmacy

Address: 860 Aviation Parkway, Suite 1400

City: Morrisville State: NC Zip: 27560

I hereby authorize the North Caroline Board of Pharmacy to furnish to the Nevada State Board of Pharmacy, the information requested below.

Signature of Applicant [signature]

THIS FORM MUST BE FORWARDED TO THE HOME STATE LICENSING AGENCY FOR COMPLETION. DO **NOT** WRITE BELOW THIS LINE

License Number	License Status	Date License Issued	Date License Expires
12602	active	5/18/15.	12/31/25

Has this license been encumbered in any way?	Type of Encumbrance: (if any)
☐ Yes ☑ No	☐ Revoked ☐ Surrendered ☐ Limited ☐ Suspended ☐ Restricted ☐ Probation Please attach copies of any pertinent legal documents

USE REVERSE SIDE OF THIS FORM FOR EXPLANATIONS IF NECESSARY

Has the applicant been convicted of any federal, state or local laws relating to drug samples, wholesale or retail drug distribution, or distribution of controlled substances? (If yes, please explain)	☐ Yes ☑ No
Has the applicant furnished any false or fraudulent material in any applications made in connection with drug manufacturing or distribution? (if yes, please explain)	☐ Yes ☑ No
Have any inspections of the applicant resulted in deficient ratings? (If yes, please explain)	☐ Yes ☑ No
Has applicant met all licensing requirements of your state? (If no, please explain)	☑ Yes ☐ No

Signature of State Official	Title	State	Date	State Seal
[signature]	admin	NC	8/24/25	

North Carolina Board of Pharmacy

Only the top 250 records are shown

This serves as Primary Source Verification of the credential issued by the North Carolina Board of Pharmacy

Name:	Realo Specialty Care Pharmacy	**Permit #:**	12602
Address:	860 Aviation Parkway Suite 1400	**Permit Status:**	Active
City:	Morrisville	**Issue Date:**	05/18/2015
State/Zip:	NC 27560	**Expire Date:**	12/31/2025
Manager:	Charles Douglas Frye	**Discipline:**	No

Information loaded from this database is current as of 3/25/2025 4:33:50 PM

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	04-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-18-2024

REALO SPECIALTY CARE PHARMACY, INC
DBA REALO SPECIALTY CARE PHARMACY
860 AVIATION PKWY STE 1400
MORRISVILLE, NC 27560

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	04-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	03-18-2024

REALO SPECIALTY CARE PHARMACY, INC
DBA REALO SPECIALTY CARE PHARMACY
860 AVIATION PKWY STE 1400
MORRISVILLE, NC 27560

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4XXX

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH 04655	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☐ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Seven Hills Pharmacy LLC

Physical Address: 2722 E. Kemper Rd.

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: _____ State: _____ Zip: _____

Telephone: 517-771-0367 Toll Free # (NAC 639.708, NRS 639.23286): 844-643-0169

Fax: 513-771-0369 Contact Email: compliance@truepill.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Spitzer

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21780

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Spitzer	NV Pharmacist Registration #: 21780
Name: Christopher Gibson	NV Pharmacist Registration #: 22645
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Postmeds, Inc.

Corporation/Organization Name: Seven Hills Pharmacy LLC

Mailing Address: 2722 E. Kemper Rd.

City: Sharonville State: OH Zip: 45241

Telephone: [redacted] Email: compliance@truepill.com

Contact Person Name: Artiom Solovei

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Co-Manager (title) for Seven Hills Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Paul Greenall

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

3/5/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Paul Greenall hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Co-Manager (title) for Seven Hills Pharmacy LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

CALIFORNIA
JURAT
ATTACHED

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 5 day of March, 2025, by Paul Greenall,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

M. DEMERS
COMM. # 2378608
SAN JOAQUIN COUNTY
NOTARY PUBLIC-CALIFORNIA
MY COMMISSION EXPIRES
OCTOBER 15, 2025

(Seal) Signature M. Demers

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/5/25

Date

Board Use Only	Date Received: 3/13/25	Amount: $ [redacted]

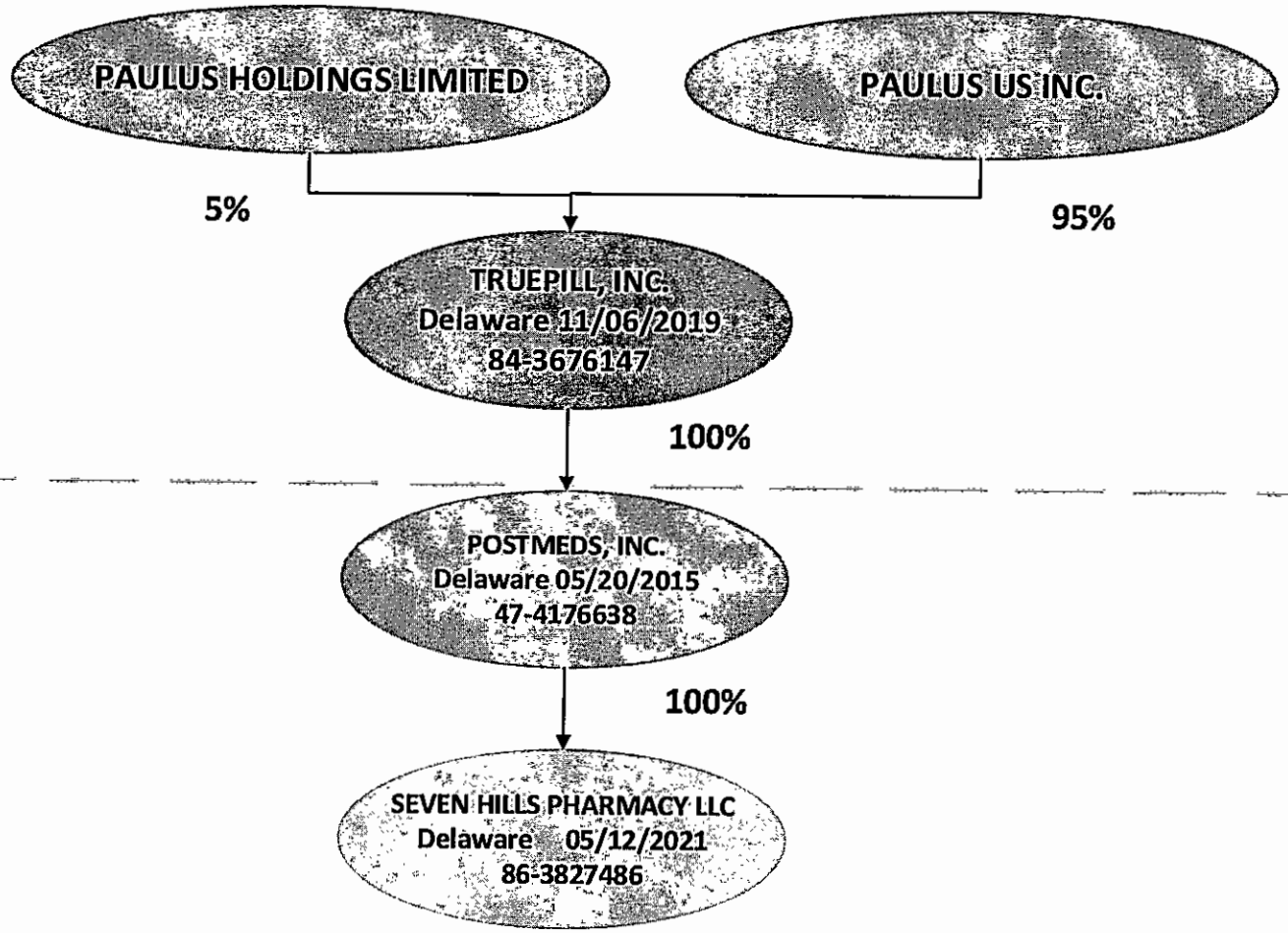
List of Officers

Paul Greenall - [redacted]

Aaron Wurst - [redacted]

03/28/2025

SEVEN HILLS PHARMACY LLC POST-RESTRUCTURE ORGANIZATIONAL CHART



This organizational chart was prepared by Truepill, Inc.'s Legal Team and may not be distributed to third parties without prior approval. For futher information, please reach out to entities@truepill.com

Seven Hills Pharmacy LLC
3121 Diablo Ave.
Hayward, CA 94545

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "SEVEN HILLS PHARMACY LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "SEVEN HILLS PHARMACY LLC" WAS FORMED ON THE TWELFTH DAY OF MAY, A.D. 2021.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN PAID TO DATE.

C. J. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

Authentication: 203003911

Date: 02-24-25

5917238 8300

SR# 20250688303

You may verify this certificate online at corp.delaware.gov/authver.shtml

POSTMEDS, INC. DBA TRUEPILL DISCIPLINARY SUMMARY

California resident license PHY 60061

California old resident license numbers: PHY 58585, PHY 56100

Illinois Board of Pharmacy

The Illinois Board issued the pharmacy (non-resident license #054.022249) a Consent Order of Discipline effective **August 8, 2024** resolving alleged violations of the Illinois Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Illinois State Board of Pharmacy.

Alaska Board of Pharmacy

The Alaska Board issued the pharmacy (non resident license #166601) a Consent Order of Discipline effective **February 15, 2024** resolving alleged violations of the Alaska Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Alaska State Board of Pharmacy.

Pennsylvania Board of Pharmacy

The Pennsylvania Board issued the pharmacy (non resident license #NP000931) a Consent Order of Discipline effective **November 7, 2023** resolving alleged violations of the Pennsylvania Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,500 administrative fine to the Pennsylvania State Board of Pharmacy.

Alabama Board of Pharmacy

The Alabama Board issued the pharmacy (non resident license #114861) a Consent Order of Discipline dated **June 6, 2023**. The Pharmacy has resolved alleged violations of the Alabama Pharmacy Practice Act through entry of a Consent Order with the Alabama State Board of Pharmacy on June 8, 2023. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,000 administrative fine to the Alabama State Board of Pharmacy.

Kansas Board of Pharmacy

The Kansas Board of Pharmacy issued the pharmacy (non resident license #22-117859) an amended Summary Order effective **February 8, 2023**. The pharmacy did not report the change of ownership in a timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy (non resident license #PHY.007761-NR) a Consent Order of Discipline dated **May 11, 2022**. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated **March 8, 2022**. The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on **March 30, 2022** that its non-resident license (#MO40002429) was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license (#MO40003167) on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a letter of admonishment CI 2019 84877 dated **January 23, 2020**, concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a modified citation and fine CI 2019 78633 dated **June 16, 2020**, with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a citation and fine order of abatement CI 2020 89223 dated **August 25, 2021**, with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

PENDING MATTERS

The following Actions are currently pending or threatened against the Company. The below Actions are currently subject to ongoing discussions, negotiations, and developments.

California Board of Pharmacy

California CI 2024 105307: On August 9, 2024, the California State Board of Pharmacy sent notice of a pending citation along with information on contesting or appealing. Truepill is in process of requesting an informal hearing to contest the citation.

South Carolina Board of Pharmacy

South Carolina 2022-49: On May 3, 2023, Postmeds agreed in principle to a proposed consent order with the South Carolina Board of Pharmacy to resolve inaccuracies in prior ownership information provided to the Board. The agreement would be categorized as a public reprimand but would not be a public document and would not be reported to the National Practitioner Data Bank. The negotiated fine was $30,000. The South Carolina Board of Pharmacy has not finalized this consent order or initiated formal disciplinary proceedings.

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

IN RE: The Application of POSTMEDS INC DBA TRUEPILL, 054-app-4237687	)) APPLICANT.)	Case No. 2023-00783

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Nicholas V. Gallo, and Applicant POSTMEDS INC ("Applicant"), by its attorney Marc N. Wagner, hereby agree to the following:

STIPULATIONS

On or about August 22, 2022, Applicant submitted to the Department a change of ownership application (the "application") for Illinois licensed pharmacy license no. 054.022350.

On or about June 16, 2020, the California State Board of Pharmacy issued Applicant a disciplinary modified citation and fine ("California Citation and Fine") under case no. 2017-78633 for Applicant filling prescriptions issued to Applicant by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. The California Citation and Fine constitutes grounds for disciplinary action against Applicant on the authority of the Illinois Pharmacy Practice Act ("Act") at 225 ILCS 85/30(a)(8) as the grounds for action in the California Citation and Fine are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/4(g).

On or about August 25, 2021, the California State Board of Pharmacy issued Applicant a disciplinary citation and fine order of abatement ("California Citation and Fine Order of Abatement") under case no. 2020-89223 for, including but not limited to, Applicant storing dangerous drugs in temperatures exceeding the recommended storage temperatures. The California Citation and Fine Order of Abatement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8)

as the grounds for action in the California Citation and Fine Order of Abatement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/3(d)(12).

On or about March 8, 2022, Applicant and the North Carolina Board of Pharmacy entered into a Consent Order of Discipline for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The North Carolina Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the North Carolina Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via the Act's Administrative Rules ("Rules") at 68 IAC 1330.780(a)(1).

On or about May 11, 2022, Applicant and the Louisiana Board of Pharmacy entered into a disciplinary Consent Agreement ("Louisiana Agreement") under case no. 21-0456 for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The Louisiana Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Louisiana Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.780(a)(1).

On or about February 15, 2024, Applicant and the Board of Pharmacy for the State of Alaska entered into a disciplinary Consent Agreement ("Alaska Agreement") under case no. 2022-000434 for, including but not limited to, Applicant failing to disclose prior disciplines from another state within the required timeframe. The Alaska Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Alaska Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.40(c).

Pursuant to 68 IAC 1130.300(a) the following factor is considered in aggravation: (a) the presence of multiple adverse actions taken by other states against Applicant.

Pursuant to 68 IAC 1130.300(b) the following factors are considered in mitigation: (a) Applicant has cooperated with the Department in its investigation; and (b) Applicant has no prior disciplinary history with the Department.

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Applicant has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, to contest any charges brought and present mitigating evidence, and to administrative review of any order resulting from a hearing. Applicant knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Secretary or the Secretary's designee or the Board. Applicant acknowledges that it has entered into this Consent Order freely and of Applicant's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Applicant acknowledges that the Department attorney may be requested to communicate with the Board or the Secretary or the Secretary's designee in furtherance of the approval of this Consent Order. Applicant acknowledges that this Consent Order will be presented to the Secretary or the Secretary's designee. If this Consent Order is not approved, Applicant waives any right to raise any prejudice resulting from the Secretary or the Secretary's designee's consideration of this Consent Order. Applicant understands that this Consent Order is not effective unless and until it is adopted by the Secretary or the Secretary's designee. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Applicant and the Department agree, in order to resolve this case, that the Applicant be permitted to enter into a Consent Order with the Department providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Nicholas V. Gallo, and Applicant, by its attorney Marc N. Wagner, agree:

A. Applicant's Illinois licensed pharmacy license no. 054.022350 shall be issued with a Reprimand.

B. Applicant shall pay a five-thousand-dollar ($5,000.00 USD) disciplinary fine within sixty (60) days of the effective date of this Consent Order.

C. All fines issued pursuant to this Consent Order are to be paid by personal check, company check, cashier's check, or personal money order. Said monetary instrument(s) shall be made payable to "Illinois Department of Financial and Professional Regulation," clearly indicate on the face of the monetary instrument the case number of 2023-00783 as well as license no. 054.022350, and be mailed to the following address:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section - Fines
P.O. Box 7086
Springfield, IL 62791-7086

D. Prior to the satisfaction of subsections B and C, above, Applicant shall not violate any state or federal law, rule, or regulation concerning controlled substances or the practice of wholesale drug distribution.

E. Applicant agrees that any violation of this Consent Order permits the Secretary or Secretary's designee to issue an Order forthwith mandating the automatic, indefinite, and immediate suspension of Applicant's license for a minimum period of twelve (12) months. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. In the event that Applicant(s) contest(s) in writing (by the filing with the Department within thirty (30) days the effective date of the suspension, a Petition complying with the Department's Rules of Practice in Administrative Hearings) the factual basis underlying said suspension, then Applicant(s) shall be afforded a hearing on the merits in accordance with the Department's Rules of Practice in Administrative Hearings, 68 Ill. Admin. Code 1110/et seq.

F. Applicant acknowledges that this Consent Order is a public disciplinary action and will be made available to the public. It will be reported to all applicable reporting databases.

G. This Consent Order is a final administrative order. This Consent Order shall become effective upon the signature of the Secretary or the Secretary's designee below unless otherwise stated herein.

Signatures on the following page

July 12, 2024
Date

Department Attorney – Nicholas V. Gallo

7/11/2024 | 1:39 PM PDT
Date

DocuSigned by:
Laura Peterson
Applicant – POSTMEDS INC
By: General Counsel, Truepill Inc. - Laura Peterson

7/11/2024 | 5:00 PM CDT
Date

DocuSigned by:
Lee Rosebush
Applicant's Attorney – Lee H. Rosebush

7/12/24
Date

Illinois State Board of Pharmacy Member

The foregoing Consent Order is approved in full.

DATED THIS 8th day of August, 2024.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY MARIO TRETO, JR.

Mario Treto, Jr. Secretary
Illinois Department of Financial and Professional Regulation

Case No. 2023-00783
Application No.: 054-app-4237687

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. doing business as (Dba) TRUEPILL)
Respondent)
Case No. 2022-000434

CONSENT AGREEMENT

IT IS HEREBY AGREED by the Department of Commerce, Community and Economic Development, Division of Corporations, Business and Professional Licensing (Division) and TRUEPILL (Respondent) as follows:

1) **Licensure.** Respondent is currently registered as an Out-of-State Pharmacy in the State of Alaska and holds License number #166601. This license was first issued on 08/27/2020 and will lapse unless renewed by 06/30/2024.

2) **Admission/Jurisdiction**. Respondent admits and agrees that the Board of Pharmacy has jurisdiction over the subject matter of their license in Alaska and over this Consent Agreement.

3) **Admission/Facts.** Respondent admits to the following facts:

a) On September 25, 2017, Staff Pharmacist working for TRUEPILL, Curtis Ancar, received a disciplinary order from the California Board of Pharmacy for failure to exercise corresponding responsibility and excessive furnishing of controlled substances.

b) On January 24, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for failure to provide documentation substantiating completion of continuing education and knowingly making or signing a document with false information.

c) On December 16, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for furnishing and dispensing dangerous drugs without a prescription and dispensing on order of nurse practitioner (or person of similar status).

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

d) On January 23, 2020, the California Board of Pharmacy issued a letter of admonishment to Respondent for shipping a prescription to the wrong address and shipping two prescriptions with the wrong return address.

e) On June 16, 2020, the California Board of Pharmacy issued a modified citation and fine CI 2019 78633 with the fine amount of $0.00 for receiving prescriptions by prescribers that were not licensed or have not entered into procedures with supervising physicians.

f) On April 08, 2022, Respondent submitted an Out-of-State Pharmacy Registration Ownership Change Application from license no. 166601 to license no. 193858 (now withdrawn) to the Division. Professional Fitness Question #1 was marked "Yes" indicating disciplinary actions had been issued against their license as listed above in sections a) through e).

g) Subsequent background investigation revealed Respondent failed to disclose the abovementioned 2017, 2019, and 2020 licensing actions from the California Board of Pharmacy on previous State of Alaska applications for TRUEPILL (formerly DBA Postmeds, Inc.) for licenses 137655 and 166601 dated June 08, 2018, August 06, 2020, and August 27, 2020.

h) Respondent admits that as a result of the above facts, grounds exist for possible suspension, revocation, or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.261(a)(1), AS 08.80.261(a)(6), AS 08.80.261(a)(9), AS 08.80.261(a)(11)(12)(14), 12 AAC 52.920(a)(13), and 52.920(a)(14)(c).

4) **Formal Hearing Process.** It is the intent of the parties to this Consent Agreement to provide for the compromise and settlement of all issues addressed in Paragraph 3 (above) that could be raised by an Accusation to revoke, suspend, or impose disciplinary sanctions against Respondent's license through a formal hearing process.

5) **Waiver of Rights.** Respondent understands they have the right to consult with an attorney of their own choosing and has a right to an administrative hearing on the facts in this case. Respondent understands and agrees that by signing this Consent Agreement, Respondent is waiving their rights to counsel and to a hearing. Further, Respondent understands and agrees that they are relieving the Division of any burden it has of proving the facts admitted above. Respondent further understands and agrees that by signing this Consent Agreement they are voluntarily and knowingly giving up their right to present oral and documentary evidence, to present rebuttal evidence, to cross-examine witnesses against Respondent, and to appeal the Board's decision to Superior Court.

6) **Effect of Non-Acceptance of Consent Agreement.** Respondent and the Division agree that this Consent Agreement is subject to the approval of the Board. They agree that, if the Board rejects this Consent Agreement, it will be void, and an Accusation may be filed. If this Consent Agreement is rejected by the Board, it will not constitute a waiver of Respondent's right to a hearing on the matters alleged in an Accusation and the admissions contained herein will have no effect. Respondent agrees that, if the Board rejects this Consent Agreement, the Board may decide the matter after a hearing, and its consideration of this Consent Agreement shall not alone be grounds for claiming that the Board is biased against Respondent, that it cannot fairly decide the case, or that it has received ex parte communication.

7) **Consent Agreement, Decision, and Order.** Respondent agrees that the Board has the authority to enter into this Consent Agreement and to issue the following Decision and Order.

PROPOSED DECISION AND ORDER

IT IS HEREBY ORDERED that any license issued to Respondent by the Board shall be subject to the following terms and conditions:

A. Violation of Agreement

If Respondent fails to comply with any term or condition of this Consent Agreement, the Division may enforce this agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of this agreement. In addition, any suspended portion of the civil fine will be immediately due.

If Respondent's license is suspended under this paragraph, as provided above, they will be entitled to a hearing, on an expedited basis, regarding the issue of the suspension. If Respondent's license is suspended, they will continue to be responsible for all license requirements pursuant to AS 08.80.

Respondent shall maintain an active license for the entire duration of this Consent Agreement. If the Respondent lets their license lapse, and after receiving adequate notice from the Board fails to correct the problem, the failure to maintain active licensure will be considered a violation of this Consent Agreement.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

B. Respondent Address

It is the responsibility of the Respondent to keep the Board's agent advised, in writing, at all times of their current mailing address, physical address, telephone number, current employment and any change in employment.

Failure to provide notice of any changes within 10 calendar days will constitute grounds for suspension of his or her license in accordance with paragraph 'B' above.

C. Compliance with Laws

Respondent shall obey all federal, state and local laws governing their license.

D. Authorization

Within 10 calendar days of a request by the Board agent, Respondent will sign all authorizations necessary for the release of information required by this Consent Agreement.

E. Good Faith

All parties agree to act in good faith in carrying out the stated intentions of this Consent Agreement.

F. Address of the Board

All required reports or other communication concerning compliance with this Consent Agreement shall be addressed to:

Attn: Holly Handley, Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8124 Fax (907) 269-8195

G. Civil Fine

Respondent shall pay a fine of five thousand dollars ($5,000.00). This civil fine is due within 180 days of the adoption of this agreement and is payable to the "State of Alaska" in cash, certified check, or money order or via credit card.

All payments required by this Consent Agreement shall be addressed to:

Erika Prieksat, Chief Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

//

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State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

IT IS HEREBY FURTHER ORDERED that this Decision and Order shall take effect immediately upon its adoption by the Board of Pharmacy and is a public record of the Board of Pharmacy and the State of Alaska. The State may provide a copy of it to any person or entity, professional licensing board, federal, state, or local government, or other entity making a relevant inquiry.

The action taken by the Board of Pharmacy in this Consent Agreement will be reported to the National Association of Boards of Pharmacy (NABP) and the National Practitioner Data Bank (NPDB) other entities as required by law.

DATED this 5 day of October 2023, at Anchorage, Alaska.

JULIE SANDE, COMMISSIONER

DocuSigned by:
By: Erika Prieksat
34F98CE5F1DF48C...

Erika Prieksat, Chief Investigator for
Sylvan Robb, Director
Division of Corporations, Business and
Professional Licensing

I, TRUEPILL, have read the Consent Agreement, understand it, and agree to be bound by its terms and conditions.

Joseph Alexander Cipriani

DATED: 20th November 2023

SUBSCRIBED AND SWORN TO before me this 20th day of November, 2023, at Newport News, Virginia.

(city) (state)

SEAL

Winston Ndow

REGISTRATION NUMBER
6040550
COMMISSION EXPIRES
February 28, 2027

Virginia

Notary Public in and for (state).

Winston Ndow

Notary Printed Name

Notarized online using audio-video communication

My commission expires: 02/28/2027

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. dba TRUEPILL)
)
Respondent)
Case No. 2022-000434

ORDER

The Board of Pharmacy for the State of Alaska, having examined the Consent Agreement and Proposed Decision and Order, Case No. 2022-000434, Respondent, license number #166601, adopts the Consent Agreement and Decision and Order in this matter.

This Consent Agreement takes effect immediately upon signature of this Order in accordance with the approval of the Board of Pharmacy.

The Division may enforce the Consent Agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of the Consent Agreement.

DATED this 15th day of February, 2024, at Anchorage, Alaska.

Board of Pharmacy

By: Ashley Schaber
Chairperson

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

NOTICE

Formal disciplinary action has been filed against you. You may lose your license, certificate, registration or permit to practice your profession or occupation. You may be subject to civil penalties of up to $10,000 for each violation, and the imposition of costs of investigation.

If you wish to defend against the charges in the attached order to show cause or to present evidence to mitigate any penalty that may be imposed, the procedures for doing so are explained in the Order to Show Cause.

You have the right to retain an attorney. Although you may represent yourself without an attorney, you are advised to seek the help of an attorney. You also have the right to have an interpreter provided should you request one.

All proceedings are conducted under the Administrative Agency Law and the General Rules of Administrative Practice and Procedures.

You are directed to respond to the charges by filing a written answer within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. IF YOU DO NOT FILE AN ANSWER, DISCIPLINARY ACTION MAY BE TAKEN AGAINST YOU WITHOUT A HEARING. Any answer submitted in this matter must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

You must also send or email a separate copy of your answer and any other pleadings or documents related to this case to the prosecuting attorney named in the Order to Show Cause.

Prothonotary Filed On:
May 10 2023 02:10 PM
Department of State

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

ORDER TO SHOW CAUSE

AND NOW, this 10th day of May 2023, **PostMeds Inc** ("Respondent") is hereby ORDERED TO SHOW CAUSE why the Pennsylvania State Board of Pharmacy ("Pennsylvania Board"), upon consideration of the Factual Allegations and the applicable law, should not suspend, revoke or otherwise restrict Respondent's registration, impose a civil penalty, or impose the costs of investigation. This action is brought pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and 63 Pa.C.S. Chapter 31 ("Chapter 31"); and will be conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704, Chapter 31, and the General Rules of Administrative Practice and Procedure ("GRAPP"), 1 Pa. Code §§ 31.1-35.251.

IT IS FURTHER ORDERED that Respondent file an Answer to this Order to Show Cause in writing within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, in accordance with Rule 35.37 of GRAPP, 1 Pa. Code § 35.37, *as amended.*

FACTUAL ALLEGATIONS

1. Respondent holds the following registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania: registration no. NP000931.

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2. Respondent's registration was originally issued on July 3, 2017, and it is currently set to expire on August 31, 2023.

3. Absent further action by the Pennsylvania Board, the Respondent's registration may be renewed or reactivated upon the filing of the appropriate documentation and payment of the necessary fees.

4. At all times pertinent to the Factual Allegations, Respondent held a registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania.

5. Respondent's last known address on file with the Board is: 3131 Diablo Ave, Hayward, CA 94545.

COUNT ONE

6. Paragraphs 1 through 5 are incorporated by reference.

7. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of North Carolina.

8. On or about March 8, 2022, the State of North Carlina Board of Pharmacy ("North Carolina Board"), by way of Consent Order of Discipline, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of North Carolina because Respondent failed to report a restructuring of ownership to the North Carolina Board.

9. In the March 8, 2022 Consent Order of Discipline, the North Carolina Board voided Respondent's permit from the time it was issued until the time the restructuring began and approved Respondent's change of ownership application as a successor permit.

10. A true and correct copy of the North Carolina Board's March 8, 2022 Consent Order of Discipline is attached as **EXHIBIT A** and is incorporated by reference.

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11. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Louisiana.

12. On or about May 11, 2022, the State of Louisiana Board of Pharmacy ("Louisiana Board"), by way of Consent Agreement at Louisiana Board Case Number 21-0456, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Louisiana because Respondent failed to report a restructuring of ownership to the Louisiana Board.

13. In the May 11, 2022 Consent Agreement, the Louisiana Board imposed a ten thousand dollar ($10,000.00) fine, two hundred fifty dollars ($250.00) in administrative costs, and three hundred twenty-four dollars and forty-eight cents ($324.48) in investigative costs.

14. A true and correct copy of the Louisiana Board's May 11, 2022 Consent Agreement, Louisiana Board Case Number 21-0456, is attached as **EXHIBIT B** and is incorporated by reference.

15. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Kansas.

16. On or about January 20, 2023, the State of Kansas Board of Pharmacy ("Kansas Board"), by way of Amended Summary Order at Kansas Board Case Number 22-183, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Kansas because Respondent failed to report a restructuring of ownership to the Kansas Board and failed to report disciplinary actions from North Carolina, Alabama, and California which also pertained to a failure to report a restructuring of ownership to each respective Board.

17. In the January 20, 2023 Amended Summary Order, the Kansas Board imposed a three thousand five hundred dollar ($3,500.00) fine.

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18. A true and correct copy of the Kansas Board's January 20, 2023 Amended Summary Order, Kansas Board Case Number 22-183, is attached as **EXHIBIT C** and is incorporated by reference.

19. Based upon the foregoing Factual Allegations, the Pennsylvania Board is authorized to suspend or revoke, or otherwise restrict Respondent's nonresident pharmacy registration under section 4.1(e) of the Act, 63 P.S. §§ 390-4.1(e); or impose a civil penalty under section 63 Pa.C.S. § 3108(b)(4), and/or impose the costs of investigation under 63 Pa.C.S. § 3108(b)(5), because Respondent violated the Act at section 4.1(g), 63 P.S. § 390-4.1(g), in that Respondent had a permit to conduct a pharmacy suspended or revoked or the nonresident pharmacy was otherwise disciplined by the proper licensing authority of another state.

PENALTIES

If the Pennsylvania Board finds that the Factual Allegations are true and correct, and determines that it has the authority to suspend or revoke the Respondent's registration, the Pennsylvania Board may, in its discretion, impose one or more of the following penalties:

- The revocation, suspension or other restriction of any licenses, certifications, registrations, permits or other authorizations to practice a profession held by Respondent in the Commonwealth of Pennsylvania, or the imposition of any other disciplinary or corrective action that the Act authorizes the Board to impose.
- The imposition of a civil penalty of up to ten thousand dollars ($10,000.00) for each and every violation of the Act. Where criminal proceedings are a basis for a violation of the Act, each count for which the Respondent was convicted may be considered a separate violation of the Act.

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PROCEDURES

All proceedings are conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704; Chapter 31; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§ 31.1-35.251. **RESPONDENT IS HEREBY ORDERED TO FILE A WRITTEN ANSWER TO THIS ORDER TO SHOW CAUSE WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE.** The Answer shall specifically admit or deny each of the Factual Allegations made herein, and shall set forth the facts and state concisely the matter of law upon which Respondent relies. If Respondent fails to file an Answer within the time allowed herein, the Factual Allegations may be deemed admitted, and the Pennsylvania Board will issue an Order which may impose penalties as set forth above.

If Respondent desires a formal administrative hearing, at which Respondent may defend against the allegations in the Order to Show Cause or to present evidence in mitigation of any penalty which may be imposed upon Respondent or any of Respondent's licenses, certifications, registrations, permits or other authorizations to practice a profession, a written request for hearing must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. **IF RESPONDENT FAILS TO FILE A WRITTEN REQUEST FOR HEARING WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE, RESPONDENT WILL BE DEEMED TO HAVE WAIVED HIS OR HER RIGHT TO A HEARING AND FINAL JUDGMENT MAY BE ENTERED WITHOUT A HEARING.**

If a hearing is scheduled, Respondent will be notified of the specific time and place of the hearing. The hearing will be held before the Board or its duly designated Presiding Officer, in

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accordance with Section 35.185 of GRAPP, 1 Pa. Code § 35.185. Respondent may appear, with or without counsel, offer testimony or other evidence on his or her behalf, and confront and cross-examine the Commonwealth's witnesses.

Answers, requests for hearings, preliminary motions, protests, petitions to intervene, or any other pleading must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

Also, you must send or e-mail a separate copy of any documents submitted in this matter to the prosecuting attorney named below at:

By Mail:
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521

By E-mail:
gmasser@pa.gov

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May 10 2023

Notices and petitions to intervene must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, unless in extraordinary circumstances for good cause shown, a later filing is authorized by the agency.

BY ORDER:
DEPARTMENT OF STATE

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DATE: 05.10.2023

DOS Prothonotary
May 10 2023

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

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Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

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PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

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2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

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transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

DOS Prothonotary
May 10 2023

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Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

DOS Prothonotary:
May 10 2023

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STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

DOS Prothonotary:
May 10 2023

EXHIBIT B

DOS Prothonotary.
May 10 2023

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

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La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

DOS Prothonotary:
May 10 2023

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

DOS Prothonotary:
May 10 2023

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, 2022, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

DOS Prothonotary:
May 10 2023

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

DOS Prothonotary:
May 10 2023

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

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7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

DOS Prothonotary:
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that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

DOS Prothonotary:
May 10 2023

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registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

DOS Prothonotary:
May 10 2023

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS. 66612

IT IS SO ORDERED.

1/20/2023
Date

Kansas Board of Pharmacy

DDS Prothonotary:
May 10 2023

3999

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave.
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

/s/ Brenda L. Head
Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

4000

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

CERTIFICATE OF SERVICE

I, Glenn P. Masser, hereby certify that I have this 11th day of May 2023 caused a true and correct copy of the foregoing Notice and Order to Show Cause to be served upon all parties of record in this proceeding in accordance with the requirements of Rule 33.31 of the General Rules of Administrative Practice and Procedure, 1 Pa. Code § 33.31 (relating to service by the agency).

CERTIFIED MAIL, ELECTRONIC RETURN RECEIPT REQUESTED AND FIRST-CLASS MAIL, POSTAGE PREPAID:

PostMeds Inc
3121 Diablo Ave
Hayward, CA 94545
9171.9690.0935.0253.8568.95

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P. O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DOS Prothonotary
May 10 2023

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IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
POSTMEDS INC. dba TRUEPILL and/or TRUEPILL f/k/a POSTMEDS INC.	)	**BOARD OF PHARMACY**
	)	
	)	
Non-Resident Pharmacy Permit Number: 114861	)	**CASE NO: 22-L-0114**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** has violated the provisions of law set out in the Statement.

2. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama

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Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** further waives any objection to the attorney for the Board preparing, drafting, or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees, or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.'s** permit, including, but not limited to revocation.

6. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions, and contents of the same. **PostMeds Inc. dba Truepill and/or**

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Truepill f/k/a PostMeds Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 6th of June, 2023.

PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.

BY: Donny Simkin
Donny Simkin

ITS: General Counsel, Truepill, Inc.

James Hoover
Counsel for **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.**

DONE this the 8th of JUNE, 2023.

ALABAMA STATE BOARD OF PHARMACY

By: Robert M. Colburn, Jr., R. Ph., President

Jennifer Muro Neumann,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
[redacted]
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date: _____

_____
Notary Public

_____

My commission expires: _____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a)On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b)On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c)On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021	TOTAL AMOUNT OF FINE(S): $5,000.00
PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021	

COPY

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination	Citation without a fine
Bus. & Prof. Code § 4174	Dispensing on order of nurse practitioner or person of similar status.	Citation without a fine

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	TOTAL AMOUNT OF FINE(S): $0.00
PAYMENT OF FINE(S) DUE BY: July 16, 2020	

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Seven Hills Pharmacy LLC

Pharmacy/Wholesaler License # (if applicable): PH04655

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website:

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Christopher Middle: William Last: Spitzer

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Massachusetts, Dartmouth		09/16 - 05/18	
Address	**City**	**State**	**Zip**
285 Old Westport Rd	North Dartmouth	MA	02747
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Massachusetts College of Pharmacy and Health Sciences		09/04 - 05/10	
Address	**City**	**State**	**Zip**
179 Longwood Ave	Boston	MA	02115
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
Gateway Regional High School		09/00 - 06/04	
Address	**City**	**State**	**Zip**
12 Littleville Rd	Huntington	MA	01050
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/18 - present	[redacted]			
10/17 - 03/18				
09/13 - 09/17				
09/10 - 08/13				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Seven Hills Pharamacy			09/21 - present	
Business Address		**City**	**State**	**Zip**
2722 E. Kemper Rd		Sharonville	OH	45241
Phone	**Title**		**Number of Employed Hours**	
(513) 771-0367	Pharmacist in Charge		2,200	
Description of Duties				
Managing all pharmacy operations, hiring pharmacy/warehouse personnel, filling/shipping prescriptions, inventory management				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			1/18 - 8/21	
Business Address		**City**	**State**	**Zip**
13 Mary St		Cincinnati	OH	45216
Phone	**Title**		**Number of Employed Hours**	
(800) 746-7287	District Leader, Pharmacy Supervisor, Pharmacy Manager		7,040	
Description of Duties				
Responsible for the overall retail store operations in assigned district (28 stores), P&L manager, operating COVID clinics, inventory management				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Christopher Spitzer, **certify that as the designated representative for**

Seven Hills Pharmacy, LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CS I am at least 21 years of age;
3. CS I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Spitzer

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/7/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Spitzer

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/7/25

Date

Please have this section completed in the presence of a Notary Public.

State of OHIO, ss. County of Hamilton

I, Christopher W. Spitzer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/7/25

Date

Subscribed and Sworn to before me this 7 day of MARCH, 2025

Notary Public Signature

NOTARIAL SEAL
STATE OF OHIO

SPENCER SMITH
NOTARY PUBLIC - OHIO
MY COMMISSION EXPIRES 03-18-25
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Seven Hills Pharmacy, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04655

Physical Address: 2722 EE. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: Sharonville State: _____ Zip: _____

Telephone: 513-771-0367 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Paul Middle: James Last: Greenall

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bayes Business School, University of London			10/98 - 07/02	
Address		City	State	Zip
106 Bunhill Row		London	UK	EC1Y 8TZ
Diploma/Degree obtained, if any				
BSC Business Management				
School Name			From - To (MM/YY – MM/YY)	
Abbotsfield School			09/91-07/98	
Address		City	State	Zip
Clifton Gardens		Hillingdon	UK	UB10 0EX
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20-Date	[redacted]	Healdsburg	CA	[redacted]
09/11 - 07/20		San Francisco	CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Postmeds Inc D/B/A Truepill			07/22 - Date
Business Address	**City**	**State**	**Zip**
3121 Diablo Ave	Hayward	CA	94545
Phone	**Title**		
855-910-8606	CEO		

Description of Duties
Managing the overall resources and operations of company, making major corporate decisions, and acting as the main point of contact between the board of directors, employees, and the public.

Business Name			From - To (MM/YY – MM/YY)
Prophet Brand Strategy LLC			04/19 - 06/22
Business Address	**City**	**State**	**Zip**
150 Spear St Ste 1300	San Francisco	CA	94105
Phone	**Title**		
(415) 518-5692	Senior Partner, Chief Strategy Officer		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
McKesson Corporation			07/09-12/18
Business Address	**City**	**State**	**Zip**
1 Post Street	San Francisco	CA	94104
Phone	**Title**		
415-983-8300	Sr Vice President, Enterprise Strategy		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 3 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/01/2007	06/01/2007	MN	Metropolitan Airport	Hennepin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
225001		Metropolitan Airport		
Reason/Charge				
Petty Misdemeanor - Airport Ordinance Violation				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Self		N/A		
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Petty Misdemeanor Airport Ordinance Violation with $300 fine, expunged 9/27/2021 by State Statute. Original documentation unavailable due to fire loss.

MN Statute 609.2 - "Petty misdemeanor" a petty offense which is prohibited by ordinance or statute, which does not constitute a crime and for which a sentence of a fine of not more than $300 may be imposed.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/8/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PAUL GREENALL

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/5/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

CALIFORNIA JURAT ATTACHED

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 5 day of March, 2025, by Paul Greenall,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

M. DEMERS
COMM. # 2378608
SAN JOAQUIN COUNTY
NOTARY PUBLIC-CALIFORNIA
MY COMMISSION EXPIRES
OCTOBER 15, 2025

(Seal)

Signature M. DeMers

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Seven Hills Pharmacy LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH04655

Physical Address: 2722 E. Kemper Rd

City: Sharonville State: OH Zip: 45241

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 513-771-0367 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Aaron Middle: Michael Last: Wurst

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Harvard Business School		08/13 - 05/15	
Address	**City**	**State**	**Zip**
Harvard Business School	Boston	MA	02163
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Cornell University		09/05 - 05/07	
Address	**City**	**State**	**Zip**
Cornell University	Ithaca	NY	14850
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
United States Military Academy		06/03 - 06/05	
Address	**City**	**State**	**Zip**
606 Thayer Rd	West Point	NY	10996
Diploma/Degree obtained, if any			
no degree			

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		08/02 - 05/03	
Address	**City**	**State**	**Zip**
2801 Bancroft St	Toledo	OH	43606
Diploma/Degree obtained, if any			
no degree			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
09/16 - current				
08/15 - 08/16				
06/13 - 07/15				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Postmeds Inc D/B/A Truepill			11/23 - current	
Business Address		**City**	**State**	**Zip**
3121 Diablo Ave		Hayward	CA	94545
Phone	**Title**			
650-353-5495	President			
Description of Duties				
Oversee P&L and the development and execution of our business strategy, and commercial growth.				

Business Name			From - To (MM/YY – MM/YY)	
The Carlyle Group			01/21 - 11/23	
Business Address		**City**	**State**	**Zip**
1001 Pennsylvania Ave NW		Washington	DC	20004
Phone	**Title**			
	Principal			
Description of Duties				
Lead the Healthcare team for Carlyle' s Global Portfolio Solutions (GPS) group				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			08/11 - 01/23	
Business Address		**City**	**State**	**Zip**
1 CVS Drive		Woonsocket	RI	02895
Phone	**Title**			
	Vice President			
Description of Duties				
Managed and sat on the Retail Leadership Team				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Aaron Wurst

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

6 March 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Rhode Island, ss. County of Providence

I, Katarina Chapman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/6/2025

Date

Subscribed and Sworn to before me this 6th day of March 2025

Notary Public Signature

Katarina Chapman
Notary Public, State of Rhode Island
My Commission Expires October 17, 2028
Notary # 772653

(Seal)

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836 | http://www.pharmacy.ohio.gov

License 0232000312

Seven Hills Pharmacy Llc

2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Terminal - Pharmacy - Category 3

TDDD Inspection Updated 7/8/24

August 7, 2024

License 0232000312 - Seven Hills Pharmacy Llc

Full

State of Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215-6126
(614) 466-4143 | Fax (614) 752-4836
http://www.pharmacy.ohio.gov

Completed by Elizabeth Bond
Start 8/7/2024 10:07 AM
End 8/7/2024 1:04 PM

Organization

Name
Seven Hills Pharmacy Llc

License Type
Terminal - Pharmacy - Category 3

Category

License Number
0232000312

Business Type
II - Independent Community Retail (1 Outlet)

DEA Number

Responsible Person
Christopher Spitzer, R.Ph.

Hours of Operation
M-F:9AM-5PM; SaSu: Closed

Contact

Address
2722 E Kemper Rd
Sharonville, OH 45241-1818
Hamilton County

Primary Number
(727) 421-8504

Fax Number
(513) 771-0369

Website

Personnel

Name	Initials	Position	I.D. No.	Phone	Email
Christopher Gibson, RPH		Pharmacist	03236967	(513) 771-0369	[redacted]
Christopher Spitzer, R.Ph.		Pharmacist	03236754	(513) 771-0367	

1) *Initial Inspection Information

1) Personnel conducting inspection

Observation
Compliance Specialist Elizabeth Bond, RPh

2) Were multiple inspection guides used during this inspection?

No

3) Facility Description

Observation
Facility is a retail pharmacy servicing the patients of various online prescriber entities. Pharmacy has the ability to serve the community (walk-in patient). Pharmacy does not accept insurance. Pharmacy has limited drug stock and focuses on veterinary medicine, women's health, non-controlled weight loss and Zepbound. Pharmacy processes approximately 2,000 prescriptions per day. Pharmacy employs 12 pharmacists, 9 pharmacy technicians and 17 delivery/support personnel. Pharmacy ships prescriptions to patients in Ohio and 48 other states using USPS, UPS, and FedEx. The site doesn't currently house any controlled substances.

4) Have there been any changes in the TDDD's ownership, business name or trade name, category, or address without submitting a new application to the Board?

No

5) *Does the TDDD have a valid registration issued by the Drug Enforcement Administration?

Yes

Observation
FS1293884 EXP: 2/28/2025

6) Is the Responsible Person present during the inspection?

Yes

Observation
RP: Christopher Spitzer, RPh

7) How often is the Responsible Person at the TDDD?

Observation
40 hours per week

8) Does the TDDD distribute dangerous drugs outside of Ohio?

Yes

Observation
The pharmacy is licensed in 48 states in addition to Ohio.

9) Does the TDDD ensure all individuals are acting within their scope of practice?

Yes

12) Additional Observations

Observation
This routine inspection was conducted at the request of the licensee for out of state license renewals. No issues noted.

17.1) Disposal of controlled substances (OAC 4729:5-3-01)

1) Does the facility dispose of controlled substances?

No

Primarily utilizes reverse distributor

Observation

Pharmacy has not disposed of any controlled substances to date but would utilize Inmar (reverse distributor) for destruction.

2) REMINDER: Facility is required to dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317.

Observation

Facility is required to dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317.

The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (9/25/2023) shall be maintained for a minimum of three years and made readily retrievable.

Non-retrievable means, for the purpose of destruction, the condition or state to which a controlled substance shall be rendered following a process that permanently alters that controlled substance's physical or chemical condition or state through irreversible means and thereby renders the controlled substance unavailable and unusable for all practical purposes. The process to achieve a non-retrievable condition or state may be unique to a substance's chemical or physical properties. A controlled substance is considered "non-retrievable" when it cannot be transformed to a physical or chemical condition or state as a controlled substance or controlled substance analogue. The purpose of destruction is to render the controlled substance(s) to a non-retrievable state and thus prevent diversion of any such substance to illicit purposes.

3) Does the method of destruction render the controlled substances to a state of non-retrievable?

Yes

4) Are records of controlled substance destruction maintained for a minimum of three years?

No

Observation

For Information:
Rule 4729:5-3-01 | Disposal of controlled substances. Effective 7/1/24
(B) A terminal distributor of dangerous drugs shall dispose of controlled substance dangerous drugs in accordance with 21 C.F.R. 1317 (9/25/2023). The method of destruction must render the controlled substances to a state of non-retrievable. Records of controlled substance destruction that are required pursuant to 21 C.F.R. 1304 (9/25/2023) shall be maintained for a minimum of three years and made readily retrievable.

21 CFR 1304 is extensive. Form 41 is required for destruction.
1304.21 General requirements of continuing records
(e) Record of destruction. In addition to any other recordkeeping requirements, any registered person that destroys a controlled substance pursuant to § 1317.95(d), or causes the destruction of a controlled substance pursuant to § 1317.95(c), shall maintain a record of destruction on a DEA Form 41. The records shall be complete and accurate, and include the name and signature of the two employees who witnessed the destruction. Except, destruction of a controlled substance dispensed by a practitioner for immediate administration at the practitioner's registered location, when the substance is not fully exhausted (e.g., some of the substance remains in a vial, tube, or syringe after administration but cannot or may not be further utilized), shall be properly recorded in accordance with § 1304.22(c), and such record need not be maintained on a DEA Form 41.

17.2) *Report theft/significant loss: dangerous drug, controlled substance, drug document(OAC 4729:5-3-02)

1) *REMINDER: Theft or significant loss of dangerous drugs and drug documents

Observation
A terminal distributor of dangerous drugs shall notify the following upon discovery of the theft or significant loss of any dangerous drug or controlled substance, including drugs in transit that were either shipped from or to the licensed location: (1) The state board of pharmacy, by telephone or other method determined by the board, immediately upon discovery of the theft or significant loss; (2) If a controlled substance, the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1301.76 (9/9/2014); (3) Law enforcement authorities pursuant to section 2921.22 of the Revised Code.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, and law enforcement authorities of any theft or loss of uncompleted prescription blank(s) used for writing a prescription, written prescription order(s) not yet dispensed and original prescription order(s) that have been dispensed.

A terminal distributor of dangerous drugs shall, immediately upon discovery, notify the state board of pharmacy, in a manner determined by the board, law enforcement authorities and the drug enforcement administration (DEA) pursuant to 21 C.F.R. 1305.16 (9/9/2014) of the theft or loss of any DEA form 222.

For more information on reporting, visit: www.pharmacy.ohio.gov/theft

2) *Has the TDDD experienced any theft or significant loss of any dangerous drugs in the past twenty-four months?

No

3) Controlled Substances: Was the theft or significant loss of controlled substances reported using the federal DEA report?

Not Applicable

4) Non-Controls: Was the theft or significant loss of non-controlled dangerous drugs reported to the board?

Not Applicable

5) Has the TDDD experienced any theft or loss of uncompleted prescription blank(s), written prescription order (s) not yet dispensed, or original prescription order(s) that have been dispensed in the past twenty-four months?

No.

6) Has the TDDD reported any theft or loss of any DEA form 222 in the past twenty-four months?

No. No losses have occurred.

8) Reporting Theft or Loss Guidance Document

Observation
The guidance document "Reporting Theft or Loss of Dangerous Drugs and Drug Documents" can be found here: www.pharmacy.ohio.gov/theft

17.4) Verification of licensure prior to sale or purchase (OAC 4729:5-3-04)

1) What drug distributors does the TDDD purchase from?

Observation
Wholesalers:

- McKesson
- TopRx
- Keysource
- Anda
- Drug Manufacturers (Merck Vet Health, BI, and Zoetis)

2) Purchase: Has the TDDD completed an annual query of the board's online roster prior to purchase of dangerous drugs at wholesale?

Yes

17.6) Storage of adulterated drugs (OAC 4729:5-3-06)

1) Does the facility have expired/adulterated drugs on site?

No

Observation
Randomly audited stock and no expired medications were identified.

17.7) Controlled substances inventory requirements (OAC 4729:5-3-07)

1) Are controlled substance inventory records maintained as required by rule?

Yes: Initial inventory completed

Yes: Annual inventory is completed

Yes: Inventory records are maintained for three years and are readily retrievable

Observation

Observed inventories dated September 6, 2022, January 10, 2023, and January 24, 2024
For Information:
CFR Requirements as of 3/2/22:
-The inventory may be taken either as of opening of business or as of the close of business on the inventory date and it shall be indicated on the inventory.
-If no initial inventory- record zero balance
-DEA biennial inventory may be done on date within two years of previous biennial inventory
-If drug becomes scheduled that previously was not: every registrant required to keep records who possesses that substance shall take an inventory of all stocks of the substance on hand.
-Inventories of dispensers: In determining the number of units of each finished form of a controlled substance in a commercial container that has been opened, the dispenser shall do as follows:
(i) Schedules I or II: make an exact count or measure of contents; or
(ii) Schedule III, IV, or V, make an estimated count or measure of contents, unless the container holds more than 1,000 tablets or capsules in which case he/she must make an exact count of the contents.

Rule 4729:5-3-07 | Controlled substances inventory requirements. Effective 3/1/19
(A) Unless otherwise stated in this division of the Administrative Code, all category III terminal distributor licensees shall complete a controlled substances inventory in accordance with 21 CFR 1304.11 (9/9/2014).
(B) All controlled substance inventories performed in accordance with this rule shall be conducted on an annual basis. The annual inventory may be taken on any date which is within thirteen months of the previous inventory date.
(C) The terminal distributor's responsible person shall be responsible for completing and maintaining this inventory record at the location licensed as a terminal distributor of dangerous drugs.
(D) All inventory records shall be maintained for a period of three years from the completion date of the inventory and made readily retrievable.
(E) When a drug or compound is added to the schedule of controlled substances by state or federal law, rule or regulation, a terminal distributor shall complete an inventory pursuant to this rule of all stocks of such drug or compound no later than ten days of the drug or compound being added to the schedule.
(F) In the event a terminal distributor of dangerous drugs commences business with no controlled substances on hand, this fact shall be recorded as the initial inventory.

17.14) General security requirements (OAC 4729:5-3-14)

1) Does the TDDD provide effective controls and procedures to deter and detect the theft and diversion of dangerous drugs?

Yes

2) Observations of Overall Security System

Observation

The pharmacy is located in a single story building of solid construction and is the sole occupant of the space. Pharmacy has ten exterior entry doors. All doors have turn key locks. All doors are electronically alarmed. Two of the back doors have lock plates. Walls and floors are solid and all walls go deck to ceiling. Pharmacy space has non-opening windows. Pharmacy has one metal roll down bay-style door that is secured by the alarm system. The keys are under the control of licensed pharmacists only. Once unlocking the door, a pharmacist has to badge tap to disarm the alarm. Only pharmacist badges are programmed to disarm the alarm. Pharmacy is equipped with cameras throughout on the interior and exterior of the building. Motion sensors are located throughout. Each section of windows is equipped with a glass break. Pharmacy alarm system alerts the responsible person when the alarm is triggered or has not been set. Pharmacy barricade is adequate with no issues noted.

18.2.1) Minimum Standards (OAC 4729:5-5-02)

1) Does the TDDD ensure sufficient personnel are scheduled to work at all times?

Yes

2) Does the TDDD provide sufficient tools and equipment in updated and good repair?

Yes

3) Does the TDDD provide pharmacy personnel access to the required references?

Yes: Internet access to the board's website

Yes: Internet access Ohio laws and administrative rules (https://codes.ohio.gov)

Yes: Internet access to the code of laws of the United States of America (variously abbreviated to Code of Laws of the United States, United States Code, U.S. Code, U.S.C., or USC)

Yes: Internet access to the code of federal regulations

Yes: Access to hard copy or internet access to appropriate pharmacy reference materials

Yes: Access of telephone number of a poison control center

Observation

Micromedex and Plums

4) Does the TDDD ensure pharmacy personnel are sufficiently trained to safely and adequately perform their assigned duties?

Yes

5) Does the TDDD maintain a stock of drugs sufficient to compound and prepare the types of prescriptions offered by the pharmacy?

Yes

6) Does the TDDD maintain stock of prescription containers necessary to dispense drugs in accordance with federal and state laws?

Yes

7) *Does the TDDD ensure all areas where drugs and devices are stored and prepared are dry, welllit, well-ventilated, and maintained in a clean, sanitary, and orderly condition?

Yes

Observation

Current controlled room temperature was 69.2 degrees F and humidity was 54%.

8) *Are hours of operation of the pharmacy department posted?

Yes

9) *Are all employees of the pharmacy identified by a name tag?

Yes: Name tag includes job title

10) Does the TDDD provide adequate security for all dangerous drugs?

Yes

11) Does the TDDD provide sufficient time for pharmacists to complete professional duties and responsibilities?

Yes

18.8) *Prospective drug utilization review (OAC 4729:5-5-08)

1) Do pharmacists review the patient profile prior to dispensing a prescription?

Yes: Reviews over-utilization or under-utilization
Yes: Reviews therapeutic duplication
Yes: Reviews drug-disease state contraindications
Yes: Reviews drug-drug interactions
Yes: Reviews incorrect drug dosage
Yes: Reviews drug-allergy interactions
Yes: Reviews abuse/misuse
Yes: Reviews inappropriate duration of drug treatment
Yes: Reviews food-nutritional supplements-drug interactions

2) Do pharmacists take appropriate steps to avoid or resolve the potential problem identified during prospective drug utilization review?

Yes: Requests and reviews an OARRS report or another state's prescription drug monitoring report
Yes: Consults with the prescriber
Yes: Counsels the patient

4) Do pharmacists request and review an OARRS report covering at least one year time period prior to dispensing an outpatient prescription in specific circumstances?

Other

Observation
The site does not dispense controlled substances or reportable drugs. The site would follow applicable regulations if doing so.

5) REMINDER: Professional Judgment regarding OARRS

Observation
In the event an OARRS report is not immediately available, the pharmacist shall use professional judgment in determining whether it is appropriate and in the patient's best interest to dispense the prescription prior to reviewing a report

6) *Do any of the pharmacists use delegates to request OARRS reports?

No

7) *REMINDER: A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

Observation
Based upon information obtained during a prospective drug utilization review, a pharmacist shall use professional judgment when making a determination about the legitimacy of a prescription. A pharmacist shall not dispense a prescription of doubtful, questionable, or suspicious origin.

8) *REMINDER: OARRS reports cannot be provided directly to a patients or other health care professionals.

Observation
REMINDER: OARRS reports may be reviewed with the patient or another health care provider, however a copy may not be provided to the patient. Patients requesting a copy of their OARRS report must submit a notarized request to the Board of Pharmacy in person or by mail, and the report must be received in person at the Board office during normal business hours. Proof of identity is required to obtain an OARRS report.

18.9) Patient counseling (OAC 4729:5-5-09)

1) Do Pharmacists or pharmacists designee verbally offer to provide the service of counseling for any prescription, new or refills, dispensed?

Yes

Observation
The company has a call center located at in CA and remote services to provide verbal counseling via telephone to all patients.

3) Does the Pharmacist or Pharmacy Intern counsel the patient or caregiver when requested?

Yes

4) Are other forms of information used to supplement counseling by the Pharmacist or Intern?

Yes

Observation
Drug information sheets and/or MedGuides if applicable are sent to the patient with each dispensing.

18.14) Prescription pick-up station (OAC 4729:5-5-14)

1) PHARMACY: Does the pharmacy act as a "pick-up" station or intermediary for the purpose of having prescriptions filled?

No

2) PHARMACY: Does the pharmacy dispense dangerous drugs to a PHARMACY which offers, in any manner, its services as a "pick-up station" or intermediary for the purpose of having prescriptions filled or delivered?

No

18.17) Drugs repackaged or relabeled by a pharmacy

1) Does the pharmacy repackage dangerous drugs?

No

18.18) Dispensing customized patient medication packages by an outpatient pharmacy (OAC 4729:5-5-18)

1) Does the pharmacy dispense customized patient medication packages?

No

18.23) *Security, control and storage of dangerous drugs in an outpatient pharmacy (OAC 4729:5-5-23)

1) *Does a pharmacist provide supervision of the dangerous drugs, hypodermics, D.E.A. controlled substance order forms, and all records relating to the distribution of dangerous drugs?

Yes

2) Is the pharmacy separated from the merchandising or public areas?

Yes

Observation
In the event a patient was in-house, the patient would remain in the OTC area of the pharmacy and would be supervised by pharmacy personnel at all times. The pharmacy distribution area is separated from the OTC area by double doors.

3) Is the pharmacist on duty responsible for the security of the pharmacy and supervision of pharmacy personnel?

Yes: Pharmacist is physically present at TDDD

5) Is a pharmacist present at all times a person enters the pharmacy?

Yes

6) *Are all schedule II controlled substance dangerous drugs stored in a securely locked, substantially constructed cabinet or safe?

Not Applicable

Observation
The site does not house controlled substances. The site obtained a DEA Registration for contractual reasons and to allow for possible future growth.

7) *How is the pharmacy secured when a pharmacist cannot be present and responsible for security?

A physical barrier with suitable locks

An alarm system approved by the board

Observation
Kastle is the alarm monitoring company.
Suitable locks are approved by the board. Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to a physical barrier prior to implementation.

Except for extraordinary circumstances beyond the pharmacy's control, a pharmacy shall notify the board of any installation or modification to an alarm system prior to implementation. This notification requirement does not apply if a pharmacy also utilizes an approved physical barrier

8) Does the alarm system and testing meet the requirements of the rule?

Yes: It is monitored by a central station for control and can detect unauthorized access to the pharmacy

Yes: The alarm system is tested on a biannual basis.

Yes: Testing records are maintained for three years

Observation
Kastle is the alarm monitoring company. The alarm is tested on an annual basis.

9) Does the pharmacy contain all dangerous drugs, hypodermics, and D.E.A. controlled substance order forms and every other item or product that requires the supervision or sale by a pharmacist?

Yes

10) *Does only a licensed pharmacist have access to keys or other methods of gaining access to the pharmacy?

Yes

12) Are records relating to the distribution of dangerous drugs only maintained in the pharmacy?

Yes

14) Does only a pharmacist have access to the pharmacy or stock of dangerous drugs or assume responsibility for the security of dangerous drugs, hypodermics, and any other item or product that requires the supervision or sale by a pharmacist?

Yes

18) *Does the pharmacy provide services by means of a drive-through facility that can be secured?

No: No drive-thru facilities

19) *Do refrigerators and freezers used for the storage of dangerous drugs monitor the temperature?

Yes: Uses temperature monitoring system capable of detecting and alerting staff of a temperature excursion

Observation
Pharmacy uses SmartSense by Digi (TempAlert) to monitor the temperatures of the refrigerators. The current refrigerated temperature was 39.7 degrees F.

20) *Does the TDDD have policies and procedures to respond to any out of range individual temperature readings or excursions to ensure the integrity of stored drugs in the refrigerator(s) and freezer(s)?

Yes

21) *Does the TDDD have a policy that no food or beverage products are permitted to be stored in refrigerators or freezers used to store dangerous drugs?

Yes

18.24) *Drug inventory records and other record keeping provisions (OAC 4729:5-5-24)

9) *Are all records readily retrievable and uniformly maintained for a period of three years?

Yes

10) Are all records within the past 3 years maintained on site?

Yes

Observation
The site was licensed in March of 2022 and has all applicable records on-site since license issuance.

11) *Are all records maintained under appropriate supervision and control to restrict unauthorized access?

Yes

Observation
All records are under the supervision of a licensed pharmacist.

49) Substance Abuse and Mental Health Resources for Healthcare Professionals

1) Substance Abuse and Mental Health Resources for Healthcare Professionals

Observation
The healthcare profession is not immune to substance use disorder and mental health conditions. Such medical conditions impair a healthcare professional's competency, ability, and judgment. Substance use disorder and/or mental health conditions that are left untreated may not only cause a healthcare professional to risk their career, but may also endanger the life of a patient. These medical conditions can be effectively treated, and it is possible for healthcare professionals that are in treatment or recovery to return to practice.

The State of Ohio Board of Pharmacy encourages all healthcare professionals who may be struggling with substance use disorder or mental health condition to seek help. The following are resources that can assist healthcare professionals in getting help: (The resources listed here are for informational purposes only and do not constitute an endorsement by the State of Ohio Board of Pharmacy. They do not represent a complete list of the resources available)

Ohio Careline 1-800-720-9616, emotional support, with referral to other resources if needed.
Crisis text line, text "4hope" to 741 741 to speak with a crisis counselor.
Treatment Bridge 1-877-275-6364, for addiction and mental health services.
National Suicide prevention dial 988, or call 1-800-273-8255.
Ohio Domestic Violence Network 1-800-934-9840
Pharmacist Rehabilitation Organization (www.ohiopro.org) for pharmacists and pharmacy interns.
Ohio Physicians Health Program (www.ophp.org)

50) Inspection Affirmation

1) Inspection Affirmation

Observation
As the person in charge at the time of this inspection, I affirm that I have reviewed this inspection report with the Specialist/Agent/Inspector, and understand its content.

If this inspection report requires a written response, I understand, per OAC 4729:5-3-03, that either of the following must be submitted to the State of Ohio Board of Pharmacy within 30 days of this inspection:
(1) The action(s) the licensee or applicant has taken to correct the violation(s) and the date of implementation of the corrective action(s); or
(2) An explanation disputing the observed violations.

I understand that if I am not the responsible person documented on this site's Ohio terminal distributor of dangerous drugs license, I will ensure the responsible person is provided a complete copy of this inspection report in a timely manner.

I further acknowledge that a written response does not release the licensee listed in this inspection report from potential disciplinary action.

Responses must be either emailed (with a copy of the inspection report) to WRITTENRESPONSE@PHARMACY.OHIO.GOV or mailed to 77 South High Street, 17th Floor, Columbus, Ohio 43215.

Summary

No Issue Found

Reviewed by Christopher Spitzer, R.Ph. [redacted]
(signature)

Board of Pharmacy

LICENSE TO DISTRIBUTE DANGEROUS DRUGS

The entity named below is duly licensed, and is entitled to conduct business in the state of Ohio until March 31, 2027.

Seven Hills Pharmacy LLC

2722 E Kemper Rd

Sharonville, OH 45241-1818

License Number: 0232000312

License Type: Terminal - Pharmacy - Category 3

Sub-Category: II - Independent Community Retail (1 Outlet)

Expiration Date: March 31, 2027

Responsible Person – Print, sign, and keep license in a readily retrievable location at the address listed on this license.

Responsible Person Name (Print)	Signature of Responsible Person

Any change of responsible person must be reported within ten days of the effective date of the appointment of the new responsible person via Service Request in eLicense Ohio - elicense.ohio.gov.

Ohio Board of Pharmacy
77 South High Street, 17th Floor, Columbus, Ohio 43215
T: 614/466-4143 | F: 614/752-4836 | licensing@pharmacy.ohio.gov

eLicense Ohio
Professional Licensure

License Look Up

4/3/2025 2:26 PM

Seven Hills Pharmacy LLC

License Number	0232000312
Status	Active
Sub-Status	
Board	Board of Pharmacy
License Type	Terminal - Pharmacy - Category 3
License Issue Date	03/22/2022
License Expiration Date	03/31/2027
License Effective Date	04/01/2025
Street Address	2722 E Kemper Rd
City	Sharonville
State	OH
Zipcode	45241-1818
Country	United States
Board Action	No

Supervised By:

Supervisor Name	Supervisor License	Status	Start Date	End Date
CHRISTOPHER SPITZER	03236754	Active	Mon Jan 03 00:00:00 GMT 2022	

Current date & time: **4/3/2025 2:26 PM**

Disclaimer: The Joint Commission and NCQA consider on-line status information as fulfilling the primary source verification requirement for verification of licensure in compliance with their respective credentialing standards.

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	02-29-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-24-2025

SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	02-29-2028	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	01-24-2025

SEVEN HILLS PHARMACY LLC
2722 E. KEMPER RD
SHARONVILLE, OH 45241

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4YYY

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☒ New Pharmacy ☐ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH_____	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☐ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: pending ☒ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation CSF		Ownership Type (check applicable box)
☒ Monday 8:30-5pm	☒ Friday 8:30-5pm	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday 8:30-5pm	☒ Saturday 8:30-11:30 AM	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday 8:30-5pm	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday 8:30-5pm	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Synergy Apothecary LLC DBA Synergy Apothecary

Physical Address: 10101 W. Innovation Drive Suite 600

City: Wauwatosa State: WI Zip: 53226

Mailing Address (if different from physical address): same

City: — State: — Zip: —

Telephone: 1-833-504-2966 Toll Free # (NAC 639.708, NRS 639.23286): 1-833-504-2966

Fax: 1-800-917-2591 Contact Email: [redacted]

Website: www.Synergyapothecary.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Theresa Burgh RPh (24460)

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): _____

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Theresa Bergh	NV Pharmacist Registration #: 24460
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		X
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		X
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		X
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		X
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		X

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: NA	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Wisconsin

Parent Company (if any): N/A

Corporation/Organization Name: Synergy Apothecary LLC ~~#600~~

Mailing Address: 10101 W. Innovation Drive #600

City: Wauwatosa State: WI Zip: 53226

Telephone: 1-833-504-2966 Email: pharmacy@synergyapothecary.com

Contact Person Name: Theresa Bergh RPh

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Pharmacist in Charge (title) for Synergy Apothecary, LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Theresa Bergh
Print Name of Authorized Person

[redacted]
Original signature of Authorized Person (copies or stamps not accepted)

3/18/25
Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Theresa Bergh hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Pharmacist in Charge (title) for Synergy Apothecary LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 19 day of March, 2025

Notary Public

NOTARY PUBLIC
AZHARIA Z. MIRANDA BONILLA
STATE OF WISCONSIN

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Theresa Bergh

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/18/25

Date

Board Use Only	Date Received: 3/24/25	Amount [redacted]

SYNERGY APOTHECARY ORGANIZATION CHART

SYNERGY APOTHECARY
A WELLNESS PHARMACY

OWNER
SYNERGY APOTHECARY LLC

PIC
THERESA BERGH, RPH

CIO
MARC LEVY, RDN CIO

CO - SECURITY OFFICER
THERESA BERGH, RPH

PRIVACY OFFICER
MARC LEVY, RDN CIO

COMPLIANCE OFFICER
THERESA BERGH, RPH

HIPPA OFFICER
MARC LEVY, RDN CIO

CO-QUALITY OFFICER
THERESA BERGH, RPH

CO-QUALITY OFFICER
MARC LEVY, RDN CIO

CO-SECURITY OFFICER
MARC LEVY, RDN CIO

PHARMACIST STAFF

PHARMACY TECHNICIANS

OFFICE SUPPORT STAFF

United States of America

State of Wisconsin

DEPARTMENT OF FINANCIAL INSTITUTIONS

To All to Whom These Presents Shall Come, Greeting:

I, Kristie Pulvermacher, Administrator, Division of Corporate and Consumer Services, Department of Financial Institutions, do hereby certify that the annexed copy has been compared by me with the record on file in the Corporation Section of the Division of Corporate & Consumer Services of this department and that the same is a true copy thereof and that I am the legal custodian of said record, and that this certification is in due form.



IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed the official seal of the Department.

Kristie Pulvermacher

KRISTIE PULVERMACHER, Administrator
Division of Corporate and Consumer Services
Department of Financial Institutions

Monika Van Rossum

DATE: 11.6.2024

By: Monika Van Rossum

Sec. 183.0202
Wis. Stats.

State of Wisconsin
Department of Financial Institutions

ARTICLES OF ORGANIZATION - LIMITED LIABILITY COMPANY

Executed by the undersigned for the purpose of forming a Wisconsin Limited Liability Company under Chapter 183 of the Wisconsin Statutes:

Article 1. **Name of the limited liability company:**

Synergy Apothecary, LLC

Article 2. **The limited liability company is organized under Ch. 183 of the Wisconsin Statutes.**

Article 3. **Name and email address of the initial registered agent:**

Daniel Leben
[redacted]

Article 4. **Street address of the initial registered office:**

[redacted]
johnson creek, WI [redacted]
United States of America

Article 5. **Street address of the principal office:**

24 dockside lane #185
key largo, fl 33037
United States of America

Article 6. **Name and complete address of each organizer:**

daniel leben
24 dockside ln #185
key largo, fl 33037
United States of America

Other provisions (optional). (No other provisions declared.)

Other Information. **This document was drafted by:**

daniel leben

Organizer Signature:

daniel leben

ARTICLES OF ORGANIZATION - Limited Liability Company(Ch. 183)

Filing Fee: $130.00
Expedite Fee: $25.00
Total Fee: $155.00

ENDORSEMENT

State of Wisconsin
Department of Financial Institutions

EFFECTIVE DATE	
3/8/2024	

FILED	Entity ID Number S153136

Wisconsin Department of Financial Institutions

Strengthening Wisconsin's Financial Future

Corporations Bureau

Form 504 - Limited Liability Company Articles of Amendment

Name of Limited Liability Company

Entity Name or Entity Id:	SYNERGY APOTHECARY, LLC Entity ID: S153136
Date the Articles of Organization were filed:	03-08-2024

Entity Name Amendment

The text of the amendment to the articles of organization amends the name of limited liability company:	No
The Name of the LLC is amended to be:	

Registered Agent Name Amendment

The text of the amendment to the articles of organization amends the name of the Registered Agent:	No
The Registered Agent name is amended to:	
Name of Entity:	

Registered Agent Address Amendment

The text of the amendment to the articles of organization amends the street address of the Registered Agent.	No
The Registered Agent address is amended to:	
Street Address:	
Address 2:	
City:	
State:	
Zip Code:	
Email:	

Principal Office Address

The text of the amendment to the articles of organization amends the street address of the Pricinpal Office.	Yes
The Principal Office address is amended to:	
Address:	[redacted]
Address 2:	

City:	Menomonee Falls
State:	WI
Zip Code:	53051

Other Provisions

Drafter

This document was drafted by:	daniel leben

Signature

Title:	owner
Date:	03/08/2024
I understand that checking this box constitutes a legal signature:	Yes
Signatory's Name:	daniel leben

Delayed Effective Date (Optional)

This document will be effective on the date it is received by the department unless a delayed (future) date is included here.

(Optional) This document has a delayed effective date of:

Contact Information (Optional)

Name:	
Address:	
City:	
State:	
Zip Code:	
Phone Number:	
Email Address:	[redacted]

Endorsement

FILED

Received Date:	03/08/2024

Synergy Apothecary, LLC OWNERSHIP

Owner: Daniel Leben 100%

[redacted]

Officers: None

Pharmacist in Charge: Theresa Bergh, Rph, PIC

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Synergy Apothecary LLC DBA SynergyApothecary
Pharmacy/Wholesaler License # (if applicable) pending -
Physical Address 10101 W. Innovation Drive Suite 600
City Wauwatosa State WI Zip 53226
Mailing Address (if different from physical address) same
City — State — Zip —
Telephone 1-833-504-2966 Website www.synergyapothecary.com
Licensing Company Email pharmacy@synergyapothecary.com

Section 2: Personal Information

First Theresa Middle Jane Last Bergh
Alias(es, nicknames, name changes, etc.) maiden name - Theresa Jane Foegen
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address [redacted]
City [redacted] State [redacted] Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120) — no military service	**Yes**	**No**
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	**Yes**	**No**
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Wisconsin - Madison			
Address	**City**	**State**	**Zip**
500 Lincoln Drive	Madison	WI	53706
Diploma/Degree obtained, if any			
BS Pharmacy			
School Name		**From - To (MM/YY – MM/YY)**	
University of Wisconsin - LaCrosse		9/85 –	
Address	**City**	**State**	**Zip**
1725 State Street	LaCrosse	WI	54601
Diploma/Degree obtained, if any			
N/A transferred last 2 yrs of college			
School Name		**From - To (MM/YY – MM/YY)**	
Waukesha South High School		09/81 – 6/85	
Address	**City**	**State**	**Zip**
401 E Roberta Avenue	Waukesha	WI	53186
Diploma/Degree obtained, if any			
High School graduate with honors			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			
School Name		**From - To (MM/YY – MM/YY)**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
09/04 – present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)
Synergy Apothecary LLC DBA Synergy Apothecary			10/24 - present
Business Address	**City**	**State**	**Zip**
10101 W. Innovation Drive Suite 600	Wauwatosa	WI	53226
Phone	**Title**	**Number of Employed Hours**	
1-833-504-2966	Pharmacist in Charge	960	
Description of Duties			
Startup and oversee operations of new compounding pharmacy			

Business Name			From - To (MM/YY – MM/YY)
Walgreens			10/23 – 10/24
Business Address	**City**	**State**	**Zip**
Float position	Wales	WI	53183
Phone	**Title**	**Number of Employed Hours**	
1-262-968-6900	Staff Pharmacist	~1250	
Description of Duties			
typical retail pharmacy duties			

Business Name			From - To (MM/YY – MM/YY)
Ascension At-Home			9/21 - 9/23
Business Address	**City**	**State**	**Zip**
10050 S. 27th St. Ste 100	Oak Creek	WI	53154
Phone	**Title**	**Number of Employed Hours**	
414-296-6720	Staff Pharmacist	~2900	
Description of Duties			
Home infusion/specialty pharmacy duties			

Business Name			From - To (MM/YY – MM/YY)
Aurora Visiting Nurse			-
Business Address	**City**	**State**	**Zip**
11333 W. National Avenue	West Allis	WI	53227
Phone	**Title**	**Number of Employed Hours**	
414-327-2295	Staff pharmacist	~40,000	
Description of Duties			
Home infusion/specialty pharmacy services			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/18/25

Date

I, Theresa Bergh, **certify that as the designated representative for** Synergy Apothecary LLC DBA Synergy Apothecary,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TJ I am at least 21 years of age;
3. TJ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TJ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TJ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TJ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TJ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Theresa Bergh

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/18/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Theresa Bergh

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/18/25

Date

Please have this section completed in the presence of a Notary Public.

State of Wisconsin, ss. County of Milwaukee

I, Theresa Bergh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/19/25

Date

Subscribed and Sworn to before me this 19 day of March 2025.

Notary Public Signature

NOTARY PUBLIC
AZHARIA Z. MIRANDA BONILLA
STATE OF WISCONSIN
(Seal)

Exp 10-25-26

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Synergy Apothecary LLC DBA Synergy Apothecary

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): pending

Physical Address: 10101 W. Innovation Drive Suite 600

City: Wauwatosa State: WI Zip: 53226

Mailing Address (if different from physical address): same

City: State: WI Zip: 53226

Telephone: 1-833-504-2966 Website: www.synergyapothecary.com

Licensing Company Email: pharmacy@synergyapothecary.com

Section 2: Personal Information

First: Daniel Middle: Scott Last: Leben

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Marquette University			08/90 – 06/96	
Address	City		State	Zip
1250 W Wisconsin Ave	Milwaukee		WI	53233
Diploma/Degree obtained, if any				
Business Ad				

School Name			From - To (MM/YY – MM/YY)	
Marquette High School			08/86 – 06/90	
Address	City		State	Zip
3401	Milwaukee		WI	53208
Diploma/Degree obtained, if any				
High School Diploma				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/12 – Current	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Smart Script Pharmacy			From - To (MM/YY – MM/YY): 06/12 – Current	
Business Address: 4041 State Road 91	City: Oshkosh		State: WI	Zip: 54904
Phone: 920/378 4156	Title: Owner			
Description of Duties: Owner				

Business Name: Synergy Apothecary			From - To (MM/YY – MM/YY): 09/24 – Present	
Business Address: 10101 W Innovation Pc #100	City: Milwaukee Wauwatosa		State: WI	Zip: 53226
Phone: 920/378 4156	Title: Owner			
Description of Duties: Owner				

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

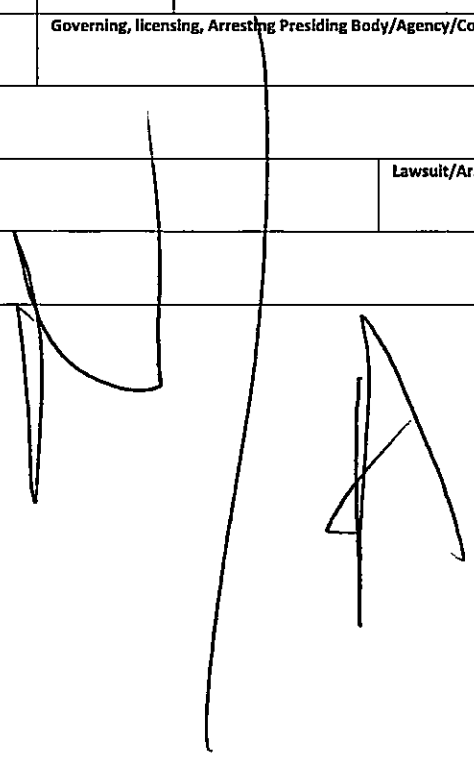
Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Daniel Leben

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Wisconsin, ss. County of Milwaukee

I, Daniel Leben, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/19/25

Date

Subscribed and Sworn to before me this 19 day of March 2025

Notary Public Signature

NOTARY PUBLIC
AZHARIA Z. MIRANDA BONILLA
STATE OF WISCONSIN

exp 10-25-26

(Seal)

NO. 10097 - 42

4098

THE STATE OF WISCONSIN

PHARMACY EXAMINING BOARD

Hereby certifies that

SYNERGY APOTHECARY LLC DBA SYNERGY APOTHECARY

THERESA J BERGH

10101 WEST INNOVATION DRIVE , SUITE 600, WAUWATOSA , WISCONSIN

was granted a license to operate as a

PHARMACY

in the State of Wisconsin in accordance with Wisconsin Law

on the 24th day of October in the year 2024.

The authority granted herein must be renewed each biennium by the granting authority.

In witness thereof, the State of Wisconsin

Pharmacy Examining Board

has caused this certificate to be issued under

the seal of the Department of Safety and Professional Services

Dan Hereth, Secretary

Tony Evers, Governor

STATE OF WISCONSIN
DEPT. OF SAFETY AND PROFESSIONAL SERVICES

This certificate was printed on the 11th day of November in the year 2024

STATE OF WISCONSIN
Department of Safety and Professional Services

Electronic Licensure Verification

This real-time Licensure Verification page is electronically certified proof of licensure, as requested, and as it appears in the files of the State Of Wisconsin - DSPS as of Tuesday, March 25, 2025 1:45:34 PM - Central Daylight Time

Printer Friendly

License Information

Name	SYNERGY APOTHECARY LLC DBA SYNERGY APOTHECARY
Credential Type	Pharmacy (in state)
Credential Number	10097-42
Location	WAUWATOSA, WI
Status	credential license is current (active)
Issue Date	10/24/2024
Expiration Date	05/31/2026
Disciplinary Order(s)	No
Licensee	SYNERGY APOTHECARY LLC DBA SYNERGY APOTHECARY

The information above is the only certification information provided by this Department. To expedite the certification process, the above format is the standard format for all professions required by this Department.

Aloysius F. Rohmeyer

Aloysius F. Rohmeyer
Record Custodian
Department of Safety and Professional Services

LicensE (/s/)

Home

Request Support



DSPS Site Guest User

Third Party Document Upload Application Status Lookup LEAP Login

Provider Login Performance Data File a Complaint

Orders and Disciplinary Actions License Lookup

Credential/License Summary for 10097 - 42 As of March 25, 2025 9:17:19 AM

Name : Synergy Apothecary LLC DBA Synergy Apothecary

Credential/License Number : 10097 - 42

Professions : Pharmacy (In-State)

Location : Wauwatosa, Wisconsin - 53226

Credential/License Type : Regular

Status : License is current (Active)

Eligible To Practice : Eligible

Credential Expiration Date : 2026-05-31

Granted Date : 2024-10-24

Multi-State : N

Orders : 0

Specialities :

Other Names : Synergy Apothecary LLC DBA Synergy Apothecary

Orders for 10097 - 42

No Orders Found

Relationships for 10097 - 42

Individual

NAME
Theresa J Bergh

LICENSE NO 11508 - 40 (/s/licenseView?id=0cE3d0000000oC3EAI)

LOCATION Waukesha, Wisconsin

TYPE Managing Person

START DATE 2024-10-24

1 - 1 Records:
of 1

1

Organization

No Organization Relationships Found

ATTENTION: The information provided through this public lookup constitutes official certification of licensure information and credential verification for professions regulated by the Wisconsin Department of Safety and Professional Services and its attached boards. If a renewal application including payment is received by the expiration date, the credential holder is eligible to practice while the credential renewal is processed. The credential holder must respond to any requests for information during the renewal process. See Wis. Stat § 227 51(2). Consistent with The Joint Commission and NCQA standards for primary source verification. Send questions or comments to dsps@wisconsin.gov (mailto:dsps@wisconsin.gov)

Contact Information

4822 Madison Yards Way Madison, WI 53705

(608) 266-2112 (tel:+6082662112) (877) 617-1565 (tel:+8776171565)

(https://www.wisconsin.gov/)

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Pharmacy Name:	Synergy Apothecary LLC DBA Synergy Apothecary
Pharmacy Address:	10101 W Innovation Dr #600, Wauwatosa, WI 53226
NABP Business e-Profile ID:	1856106
VPP Inspection Date(s):	2/11/25-2/12/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included Y/N	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	18	47.00	Policy for Product Inventory now updated to include the process of validating that a wholesaler has completed their annual report with the FDA. PIC was already obtaining a copy of the wholesaler licenses and DEA registrations and provided copies to inspector.	2/24/25	Y	Green coversheet labeled 47.0 starts with Policy 5.06 which now updated on process to establish vendors. Policy includes DSCSA steps for how to validate a vendor with the FDA. Copy of FDA searches shows our vendors to be registered with the FDA. Guidance and websites included at the end of the policy plus a copy of DSCSA info . We are currently a small dispenser with only 2 employees in start up mode so policies are in line with current DSCSA guidelines. Our policies are in compliance currently but are also updated in anticipation of full implementation in 2026. Our 4 wholesalers were verified in the database. Printscreens include Darmerica, Letco/Fagron, Medisca andTopRx to show proof of process.
Updates/New SOPs or P&Ps	18	47.04-47.07, 47.10	TopRx has given Synergy Apothecary access to the Pedigree of Orders (3T data of commercially available products) Attached is the process and screenshot after our login	2/24/25	Y	Green coversheet labeled 47.04-47.07 - We are a compounding pharmacy with very minimal commercial Rx products. TopRx is a typical supplier for smaller pharmacies such as ours. PIC was told by TopRx that at this point in time, TopRx prefers to purchase direct from manufacture but can't always promise ed in this goal. Therefore, distributors are also used. TopRx is NABP accredited and PIC has been given access to the Synchrony Pedigree Viewer to verify the supply chain intregrity. P&P updated to include 3 or 10% of products receive. We now have access our API powders from Darmerica, Letco/Fagron and Medisca. Manufacturer of powders validated via FDA website. See copies of CofA with manufacturer cross referenced to FDA website. Also see copy of Syncrony Pedigree Process.
Clarification or Further Explanation	22	65.02	Inspector answer is Yes that we have an adequate process in place already. Unsure of reason that it is on report.	2/21/25	N	n/a
Clarification or Further Explanation	25	71.00	We have process in place for testing packaging and temperature integrity and will send a log tag to a warm climate for testing with an API free sample troche tray. Log Tags are in house and were shown to inspector.	2/27/25	Y	Green cover sheet labeled 71.0 that starts with LogTagRecorder (12 pages total). Sample sent to Florida with drug free sample to assess how product arrives after shippiing conditions.

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name:	Synergy Apothecary LLC DBA Synergy Apothecary
Pharmacy Address:	10101 W Innovation Dr #600, Wauwatosa, WI 53226
NABP Business e-Profile ID:	1856106
VPP Inspection Date(s):	2/11/25-2/12/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included Y/N	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	36	3.0-3.3	Standard is to review 5 personnel records but we are in a start up mode and only have 2 employeees, so answer was no but was review was 100% of staff. Additional input from inspector provided some advice on how to improve our forms and will be used as we hire our first employees in March. We didn't have a completed employee packet to show as we haven't hired yet but are now interviewing and hiring. Training logs we did have were shown to inspector.	2/21/25	Y	Green coversheet labeled 3.0-3.3 contains Synergy Apothecary Orientation checklist +10 pages. Attached are updated training signoff sheets and a sample of our training and validation process called a Standard Work that goes step through step on a process that requires training and validation before being considered qualified and competent to do a role independently.
Clarification or Further Explanation	42	13.0	To clarify, use of purified water, distilled water or RO water is recommended, not required but our policy is to use those options for rinsing glassware or utensils. Distilled water was already in bottles in the compounding lab for the final rinse after cleaning those items. A dishwasher is planned for larger equipment and items once we are in full operation.	2/21/25	Y	Green coversheet labeled 13.0 includes Policy 4.05 that is attached - 6 pages
Clarification or Further Explanation	44	18.0	Equipment is chosen with cleaning, ease of use, purpose and maintainence in mind for 795 guidelines. As we are a new pharmacy, we've had no maintainence needs yet. Log sheets already exist for equipment we use and standard works include the cleaning and calibration of equipment. Standard works in place for all active equipment and new ones to be created as we add new equipment to more accurately and efficiently make troches . The equipment must be calibrated potency/accuracy tests with an independent lab. but we can't order controlled substances yet. Therefore, Standard work for cleaning, use and maintainence of new equipment is not finished until we get our DEA license.	2/21/25	Y	Green coversheet labeled 18.0 Equipment/Balance Mantenance/Repair Log . Samples of equipment logs attached. - 3 pages
Updates/New SOPs or P&Ps	45	18.3	Underside of BSC, per policy, is cleaned monthly and was done in February prior to visit and handwritten on montly log but log sheet was an old copy that inspector saw. Correct log sheets now in the compounding room	2/21/25	y	Green coversheet labeled 18.3 - Synergy Apothecary Non-Sterile Compounding Lab Log 2 pages, old and new formatting plus a copy of our policy 4.050 with cleaning frequencies - 6 pages

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Pharmacy Name:	Synergy Apothecary LLC DBA Synergy Apothecary
Pharmacy Address:	10101 W Innovation Dr #600, Wauwatosa, WI 53226
NABP Business e-Profile ID:	1856106
VPP Inspection Date(s):	2/11/25-2/12/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included Y/N	Title of Document (Must be indicated at top of document attachment)
Updates/New SOPs or P&Ps	46	20.0 + 20.3	C of A were all readily available based on PIC interpretation of DSCA. Based on inspector interpretation, the original manufacturer C of A is also needed. These now obtained and process is part of policy. Manufacturers are now confirmed as FDA approved.	2/21/25	Y	Green cover sheet labeled 20.0 + 20.3. All suppliers were able and willing to provide the manufacturer C of A. Letco will now routinely provide both CofA for our shipments and sent copies via email of products we already had in stock. Medisca website offers both options and both will be printed. Darmerica is able to to routinely provide both CofA to us. All C of A to be downloaded and saved to our shared drive for ready access. Manufacturer info provided in C of A to be verified in FDA. website. Policy 5.06 updated (same policy as line item labeled 47.00 above. Sample of each wholesalers "original" that was provided to us plus the manufacturers CofA for comparison purposes per policy (10 pages) are included in this response.
Updates/New SOPs or P&Ps	49	26.0, 26.2	Related to drug spills, information was under Hazardous Spill management in the event we pursued USP 800 and also under Safety policy 3.160. That information was not directly labelled as non-hazardous so policy and Standard Work were updated to reflect how to handle a drug/chemical spill	2/21/25	Y	Green coversheet labeled 26.0, 26.2 See original policy 3.160 secton 4.5, updated policy 2.05, Standard work labeled Non hazardous spill clean up (6 pages) for detailed process of cleaning a spill, and orientation checklist which includes training/education plus annual review on how to handle a drug or chemical spill.
Clarification or Further Explanation	53, 54	31.0 & 31.6 36.0-36.2	Labeling of CSP compliance all related to one issue of using "EXP" instead of BUD for verbiage to match the MFR. PIC contacted the software vendor and labelling for both patient prescription labels and compound batch labels were updated.	2/21/25	Y	Green coversheet labelled 31.0-31.6 and 36.0-36.2 - See updated old versus new labels. Both label types now updated to now reflect the verbiage of BUD-Discard after. This was done to reflect BUD verbiage but also to provide a lay language wording of what BUD implies.
Clarification or Further Explanation	58	44.0-44.2	This category should be labeled as N/A or Yes. The only non-aqueous product that has been made is a cream and that was given a 30 day BUD	2/21/25	Y	Green coversheet labeled 44.0-44.2. Logged Formula Worksheet is a copy of actual Rx Compound record provided with PHI crossed off shows the 30 day BUD.
Clarification or Further Explanation	62	50.0	Regarding prescriber notification in case of recall, policy 3.08 stated that patient is informed but process noted for MD notification. This was verbally described to inspector as this process is noted in policy 3.010 with medication errors and notification of MD is described there.	2/24/25	Y	Green coversheet labelled 50.0 contains Old and new copies of Policies 3.010 and 3.080 provided to show cross coverage and updates to show process of MD being notified of drug recall situations when immediate notification is needed due to potential caus of harm. Of note, this is a recommendation, not a requirement but it is a good way of cross referencing that incorrect potency or purity are part of a potential medication error.

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Pharmacy Name:	Synergy Apothecary LLC DBA Synergy Apothecary
Pharmacy Address:	10101 W Innovation Dr #600, Wauwatosa, WI 53226
NABP Business e-Profile ID:	1856106
VPP Inspection Date(s):	2/11/25-2/12/2025
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Point of Reference (Optional Input Field Provided)	VPP Inspection Report Page No.	VPP Inspection Report Area No.	Facility Response/Corrective Action Comments	Estimated Date of Completion for Corrective Action (If Any)	Action Taken Y/N	Proof of Documentation (Must be Included at End of Uploaded Attachment)
[Redacted]	64	64.8	[Redacted]	[Redacted]	Y	[Redacted]

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1856106		**Inspection Information**
Legal Business Name:	Synergy Apothecary LLC	**Conference Call Date:**	2/10/2025
Doing Business As (DBA):	Synergy Apothecary	**Start Time: 24-hour format (13:00)**	11:40
Address:	10101 W Innovation Dr. Ste 600	**End Time: 24-hour format (13:00)**	12:52
City:	Wauwatosa	**Onsite Inspection Date(s):**	2/11/2025 & 2/12/2025
State:	Wisconsin	**Start Time(s): 24-hour format (13:00)**	11:20 & 8:20
Zip Code:	53226	**End Time(s): 24-hour format (13:00)**	16:54 & 12:15
Telephone number:	833/504-2966	**Inspector Name(s):**	Jennifer Tiffany, RPh
Toll free number:	833/504-2966	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	800/917-2591	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.synergyapothecary.com	**Observer Name/Affiliation (if applicable):**	N/A

Personal Information

The following is a list of specific Sections and/or Questions which the facility may wish to consider Not Applicable. The facility is encouraged to read the inspection report in its entirety and carefully review Personal Information sections that it believes may be Not Applicable. Select Sections and/or Questions below which the facility may wish to consider for the inspection.

General Pharmacy- [illegible]

Non-Sterile - [illegible]

Additional Information for NABP Inspection Report

NABP Disclaimer: NABP can only verify the authenticity of an inspection report if it is received directly from NABP for an intended recipient. NABP cannot verify the authenticity of an inspection report transmitted from any other party.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open Start Time: (24-hour format)	End Time: (24-hour format)	Closed (X)
Sunday			X
Monday	8:30	17:00	
Tuesday	8:30	17:00	
Wednesday	8:30	17:00	
Thursday	8:30	17:00	
Friday	8:30	17:00	
Saturday	8:30	11:30	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Theresa Bergh	[redacted]	435685
Nonsterile Designated person(s)	Theresa Bergh		435685
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Theresa Bergh	Pharmacist in Charge (PIC)	Y
2	Marc Levy	Chief Innovation Officer (CIO)	N/A
3	Dan Leben	Owner	N/A
4			
5			
6			
7			
8			
9			
10			

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

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Business Licensure Information for State of Residence and Federal (board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
Wisconsin Pharmacy Examining Board	Synergy Apothecary LLC DBA Synergy Apothecary	Pharmacy	10097-42 & 5/31/2026

Inspector Notes: Non-Resident licenses are held in New York, Pennsylvania and Arizona. Synergy Apothecary's status with California as a Non-Resident Pharmacy is "Pending", as is their application for a DEA registration. Compounding with controlled substances, specifically ketamine, will begin once the pharmacy obtains their DEA registration. The majority of their compounding will be batch production of ketamine troches. Between the months of December 2024 and January 2025, the pharmacy dispensed just 17 prescriptions. The low volume can be attributed to being in start-up mode.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
N/A	N/A

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Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public		Nuclear Pharmacy	
Closed Door	X	Specialty Pharmacy	
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)		Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	X
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement, and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement, and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients	X	CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous	X	Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations	X	Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations	X	Proprietary bag and vial systems	
Topical preparations:	X	Blood-derived or other biological material (eg autologous serum)	
Nasal and sinus preparations:		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/ Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	5000	Total Pharmacists:	1
Nonsterile Compounding Room size:	850	Number of Compounding Pharmacists:	1
Nonsterile Compounding powder hoods number:	0	Total Student Interns:	0
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Technicians:	0
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	1	Number of Compounding Technicians:	0
Sterile Compounding Ante Room size:	N/A	Of technicians, how many are nationally certified?	0
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	N/A	Total Other Unlicensed Personnel:	1
Sterile Compounding Number BSC hoods:	N/A	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	0:1
Sterile Compounding Number CAI/CACI hoods:	N/A	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	0		
Sterile HD Compounding Number of CACI hoods:	0		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	N/A

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	<1	Total Orders Distributed/day:	0
% Veterinary Prescriptions	0%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	100%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	0%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)	0	0	December 2024 and January 2025
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)	0	0	December 2024 and January 2025
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)	0	0	December 2024 and January 2025
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)	17	0	December 2024 and January 2025
Wyoming (WY)			
Other			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	40
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	No	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	
9.00	List of additional personnel **interviewed as part of the inspection, including name and title:**		N/A

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Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Notes
	Types of Practice Additional Questions If any part of a question is no, enter "No" and explain the observation.		
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	No	Posted in front lobby. This is a closed-door pharmacy.
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	N/A	The Wisconsin Board of Pharmacy has not been out for an on-site inspection to follow-up on the self-inspection that was submitted by the pharmacy. Per PIC Bergh, after the initial inspection the Wisconsin Board of Pharmacy does not conduct routine inspections. The only cause for a visit would likely be to investigate a complaint.
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	N/A	
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	Yes	Two DEA agents visited the pharmacy on 1/16/2025, as part of the new applicant registration process. No deficiencies were noted. The pharmacy is still awaiting approval of their application to obtain a DEA registration number.
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	

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Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Notes
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	No	
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	No	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	There is a secure office area where documents can be stored in locked cabinets. Electronic patient records are stored/backed-up every 15 minutes by Pioneers to offsite servers.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	E-scripts are kept electronically as are faxed prescriptions.
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Dispensing records are maintained electronically.
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	While the PioneerRx system does allow for deletion of a prescription after it has been filled, PIC Bergh requested for PioneerRx to deactivate that feature for anyone without administrator privileges. If deleted by an administrator, PioneerRx is still able to retrieve the record for 90 days. PIC Bergh has instituted a policy that administrators must print an image of any Rx to be deleted and provide it to he for manual storage in the event the record would need to be reviewed in the future.
28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	PIC Bergh has created a spreadsheet that outlines state-specific rules. Additionally, notes can be added to the "Critical Comments" field in the PioneerRx system to alert pharmacists performing prescription verifications of unique rules.

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Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Notes
Personnel	**If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Pharmacy has a subscription with PRS Pharmacy Services ComplianceTrack/LicenseTrack software. The LicenseTrack module monitors the license and registration expiration dates of the employees. Additionally, it runs checks through the Office of Inspector General's Exclusion List and the Wisconsin Board of Pharmacy's discipline database. This check is done on a monthly basis and documented online within the LicenseTrack platform.
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	LicenseTrack sends an email to PIC Bergh on a monthly basis after license and registration verifications are complete.
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	Wisconsin's maximum technician to pharmacist ratio is 4:1. At the time of inspection, PIC Bergh was the only pharmacist on staff and no technicians had been hired.
Facility and Security	**If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Pharmacy's security system is through ADT's commercial platform know as Everon. There are 13 video cameras mounted throughout the pharmacy and at the front and back doors. PIC Bergh can access all real-time video footage through an app on her phone. Motion and glass break sensors are also installed.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	The pharmacy does not have any controlled substances in stock as they do not have a DEA registration yet. The pending registration is for Schedule III, IV and V controlled substances.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Per PIC Bergh, drug products, APIs and finished compounded nonsterile preparations would be packed up and transferred to a secure location able to provide CRT until the facility can be secured. The pharmacy will call the Wisconsin Board of Pharmacy to receive approval to move the inventory to another location. This alternate location could possibly be SmartScript Pharmacy in Oshkosh, WI, which is the sister pharmacy to Synergy Apothecary.

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e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Notes
37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	Yes	Pharmacy plans to engage in on-site destruction of expired or damaged compounded nonsterile products that do not contain any controlled substances as ingredients. They will employ a destruction log that identifies the items destroyed, the date destroyed, and the individual responsible for the destruction. Any controlled substance compounded preparations will be sent to a reverse distributor for destruction.
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	PharmaLogic
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	N/A	
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	No	This is a closed-door pharmacy.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	24 hour temperature reporting is attached to the security system. If the temperature goes out of the programmed range of 59-77 degrees Celsius, PIC Bergh will be contacted by the security company (Everon). Temperature in the drug storage room at time of inspection was 74 degrees Fahrenheit.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Retroactive temperature monitoring of CRT spaces is tied to the pharmacy's alarm system. Per PIC Bergh, 59-77 degrees Fahrenheit is the programmed min/max range. PIC Bergh will receive a phone call from Everon security alerting her of any excursion. A manual check of the CRTs in the building is completed and logged every business day. During the manual CRT check, if the temperature in the compounding room is not between 68 and 77 degrees Fahrenheit they will cease compounding operations until an in-range temperature can be achieved.

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General Pharmacy Inspection

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Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
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		Observation	Notes
39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	Per PIC Bergh, a visual inspection of the compounded medication will be completed, and no assessment of altered potency would be done because potency was verified during the compounding process.
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	N/A	The pharmacy does not have any drug products or APIs that require storage at either refrigerated or frozen temperatures. There is a functional refrigerator in the compounding lab that could be used for drug storage if need be.
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Retroactive temperature monitoring of the 1 refrigerator earmarked by drug storage is tied to the pharmacy's alarm system. Per PIC Bergh, 2-8 degrees Celsius is the programmed min/max range. PIC Bergh will receive a phone call from Everon security alerting her of any excursion. A manual check of the refrigerator temperature is completed and logged every business day. The logs will be kept for at least 2 years.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	4.6 degrees Celsius.
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	This pharmacy does not have any drugs in stock that are required to be stored in a freezer.
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	This pharmacy does not have any drugs in stock that are required to be stored in a freezer.
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	There is a natural gas backup generator on the roof of the building.
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Per PIC Bergh, if they have to move products out of the pharmacy due to extreme temperatures, they would like take them to their sister pharmacy, SmartScript Pharmacy, in Oshkosh WI.

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		Observation	Notes
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	Per PIC Bergh, a visual assessment for any damages would be completed to validate the product is safe and consistent.
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	No	
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	N/A	
	Product Receipt and Inventory If any part of a question is no, enter "No" and explain the observation.		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	No	Per PIC Bergh, there is not any official policy, but they will develop one.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	No	
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	TopRx (for commercially available drug products) PCCA, Medisca, Fagron/Letco, Darmerica (for APIs)
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	No	
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance. does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Unknown	Per PIC Bergh, the only DSCSA drug products they have purchased since the pharmacy opened came from TopRx, and TopRx has not given them access to their interoperable system. The invoices received by Synergy Pharmacy for the products they purchased do not show the Transaction History. Per PIC Bergh, TopRx told them they would not give them access to that until they have a DEA registration.

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		Observation	Notes
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	If the pharmacy receives stock they question to be suspect or illegitimate, it will be put into the quarantine box. The supplier will be contacted and the product will remain in quarantine until the supplier gives further direction to the pharmacy.
47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	TopRx is the wholesaler used to obtain commercially available prescription drugs. Per PIC Bergh, TopRx will not grant them access to their 3T/DSCSA data portal without having a valid DEA registration.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	N/A	Pharmacy does not have DEA registration, and they have no plans to stock Schedule II controlled substances.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	N/A	Pharmacy does not have DEA registration, and they have no plans to stock Schedule II controlled substances.
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	

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		Observation	Notes
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	N/A	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	
54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	A manual perpetual inventory of all controlled substance medications will be maintained.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	The Wisconsin Board of Pharmacy and local law enforcement would be contacted.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	The pharmacy does not have a DEA registration at this time, and therefore does not have any controlled substances as part of their inventory.
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	N/A	
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	N/A	Pharmacy does not have a DEA registration at this time.

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		Observation	Notes
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Pharmacy plans to check for out-of-date products on a quarterly basis. Pharmacy does not stock any OTC products.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?		Will check quarterly. If anything is to expire within the next 3 months it will be pulled from the shelf and put into quarantine.
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	N/A	All prescriptions are mailed out after they are prepared. If any prescription drug were to be returned to the pharmacy from the United States Postal Service as "undeliverable" it would be placed in quarantine for future destruction.
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	N/A	

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		Observation	Notes
Prescription Processing	**If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Until technicians are hired, patient profile data will be entered by PIC Bergh. As explained by PIC Bergh, there is Artificial Intelligence (AI) functionality that helps auto-populate some data fields. The Joyous practitioner group (see 65.02) has given them access to their EMR. With that visibility, staff at Synergy Apothecary will be able to update data on a regular basis.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	N/A	
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	The pharmacy would contact the prescriber's office to determine if the prescription is legitimate. If it is not, the local police would be alerted, as would other area pharmacies.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? Describe. Do the processes include comparing the physical addresses of the patient and prescriber?	Yes	Per PIC Bergh, the majority of their prescriptions will be for low-dose ketamine troches from prescribers affiliated with a telehealth subscription program called Joyous (www.joyous.team). The owner of Synergy Apothecary is related to one of the co-founders of Joyous. PIC Bergh explained that patients affected by such mental health conditions as PTSD, anxiety and depression can apply to have an video consultation with a Joyous provider. A participating practitioner from the same state the patient resides in will be assigned to the consult. If the practitioner determines the patient is a good candidate for very low-dose ketamine treatment, the patient must agree to Joyous' subscription requirements. Those requirements include responding to provider-initiated daily text messages used for the purpose of assessing for tolerability and side effects. PIC Bergh, Synergy Apothecary and SmartScript Pharmacy (Oshkosh, WI) are the preferred pharmacies for Joyous. Synergy Apothecary is able to login to Joyous' EMR and has visibility into provider documentation.

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		Observation	Notes
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Both
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	Pharmacy does not have a DEA registration at this time, and, therefore, are not filing any prescriptions for controlled substances.
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	A pharmacist will verify all elements of patient and prescription data entered during the pre-verification step.
67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	If a technician performed the intake portion/data entry for a prescription received for a Joyous patient, a pharmacist will complete the DUR during pre-verification. If the prescription is for a medication prescribed by a Joyous practitioner, the pharmacist can access the EMR in order to assist in the DUR. If a prescription is being filled for an individual that did not obtain a prescription through Joyous, the pharmacist will contact the patient by phone to inquire about other medications the patient takes and if the patient has any know medication allergies.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Per PIC Bergh, information from the Joyous EMR will also be used to complete a Drug Utilization Review.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	

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		Observation	Notes
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	N/A	PIC Bergh stated that until the pharmacy receives their DEA registration number, they are not given permission by the PDMP administrator (Bamboo Health) to submit reports, even "zero reports".
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	PIC Bergh has a personal account to check the PDMP in the states in which she is licensed.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	The PioneerRx prescription dispensing software will electronically log the identification of the employee who approved an override. Only pharmacists are authorized to override.
67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	First Databank
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	Yes	Per PIC Bergh, there is an "Annotations" field in each prescription record within the PioneerRx software system that is not able to be deleted once populated. Any DUR-related notes are entered into this field.
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	During entry of prescription data, a technician will select a lot number from a pull-down tab of the medication to be dispensed. Another technician will manually fill the prescription and bring it out for final verification by a pharmacist. During that final verification the pharmacist will scan the barcode on the label of the selected compound and then scans the barcode on the patient label to ensure a match. A technician will package the patient's prescription, but before sealing up the mailer, a pharmacist will check to make sure the patient name on the medication matches that on the mailing label.

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		Observation	Notes
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	Prescription labels include all required elements including federal law "Caution" statement, the word "Compound" if it is a CNSP, and the compound's lot number.
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	PioneerRx is the pharmacy's prescription processing software platform. Logins for each individual require entry of a unique password and a pin number.
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Unknown	Per PIC Bergh, their proposed packing process will be tested by the pharmacy once in a full-service, operational mode.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	

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		Observation	Notes
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication If any part of a question is no, enter "No" and explain the observation.		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	This is a closed-door pharmacy. No patients pick up their prescriptions. All prescriptions are mailed out.
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	N/A	
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	N/A	
76.01	Is an "offer" to counsel made for all <u>refilled</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer"*	N/A	
77.00	Does the pharmacist provide counseling for <u>refilled</u> prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	N/A	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Notes
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer"*	N/A	
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Printed prescription information is mailed to the patient with their compounded medication. The information includes the pharmacy's toll-free number. Per PIC Bergh, an offer to counsel is sufficient in Wisconsin.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	PPIs will automatically print off with the label for any commercially-available product that is dispensed at this pharmacy. This feature is standard in the PioneerRx software program.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	MedGuides will automatically print off with the label for any commercially available product that is dispensed at this pharmacy. This feature is standard in the PioneerRx software program.
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	N/A	Per PIC Bergh, pharmacies are not required by the state of Wisconsin to document the offer or refusal of counseling.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	No	Per PIC Bergh, this is not required by the state of Wisconsin for retail pharmacies.

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		Observation	Notes
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	
	Quality Assurance/Quality Improvement Program **If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	PIC Bergh oversees the QA program.
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	

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		Observation	Notes
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Per policy, QREs need to be brought to the PIC immediately and it must be documented within 24 hours of discovery. If the QRE involves ingestion of an incorrect medication by the patient, the doctor would need to be contacted within the next business day.
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	PIC Bergh will be completing the analysis on a quarterly basis.
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	

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		Observation	Notes
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	This pharmacy does not use a drug formulary.
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	PIC Bergh anticipates that quarterly meetings will look items such as, but not limited to, medication errors, complaints, trends in potency via spectrometer readings, and reminders about simple math calculations.
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	ISMP National Medication Error Reporting Program
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	

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		Observation	Notes
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and services at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	Per PIC Bergh they will be sending out patient surveys on an annual basis.
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	Have a dedicated "Customer Complaint Log" and a "Customer/Internal Complaint Record".

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National Association of Boards of Pharmacy®
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Nonsterile Compounding Inspection for USP <795>

Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Inspector Notes	USP Reference(s)
	Standard Operating Procedures for Compounded Nonsterile Preparations (CNSPs)		**Please note NABP did not review each SOP for alignment on USP <795>. The SOP(s) described below is/are a reflection of any self-assessment completed by the pharmacy and/or shared with the inspector during the onsite inspection.**	
1.0	Does the pharmacy have standard operating procedures (SOPs) on all aspects of the compounding operation that cover the minimum topic requirements in USP <795> standards? ***If no, document "missing" in Inspector Notes*** ***If yes, document the name, number, and version of each SOP in the Inspector Notes.***	Yes		11
1.1	**Buildings and Facilities:** The pharmacy has an SOP for the compounding facility. ***Inspector note: Per USP <795>, there is a written SOP for "the method of designation" for the area designated specifically for nonsterile compounding and processes for maintaining, cleaning, and sanitizing the compounding area and equipment.***		4.05 - Section 8.0 to end of P&P	4.1, 5, 11
1.2	**Personnel Training and Evaluation:** The pharmacy has an SOP describing the training program, the frequency of training, and the process for evaluating the competency of personnel. ***Inspector note: Per USP <795>, "Facility SOPs must describe procedures for monitoring and observing of compounding activities and personnel."***		2.010 and 2.02 - Entire policies	2, 11
1.3	**Personal Hygiene and Garbing:** The pharmacy has an SOP regarding personal hygiene, glove, and garbing requirements consistent with compounding activities. ***Inspector note: Per USP <795>, "Garbing requirements and frequency of changing garb must be determined by the facility and documented in the facility's SOPs."***		1.050 and 3.09 - Section 4	3.3, 11
1.4	**Components:** The pharmacy has an SOP describing selection, handling, storage, and inventory control of all components used in compounding. ***Inspector note: Per USP <795>, "The compounding facility must have written SOPs for the selection and inventory control of all components from receipt to use in a CNSP."***		5.06 - Section 4.02 and onward	6.2, 11

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		Observation	Inspector Notes	USP Reference(s)
1.5	**Temperature Monitoring:** The pharmacy has an SOP regarding temperature monitoring and handling of excursions. ***Inspector note: Per USP <795>, "The compounding facility must adhere to SOPs to detect and reduce the risk of temperature excursions within the storage area(s)."***		4.051, 4.050 - Section 8.5 plus log sheet	4.2, 11
1.6	**Equipment**: The pharmacy has an SOP for assessment of need for closed system processing devices (based on the types of CNSPs prepared). ***Inspector note: Per USP <795>, "Weighing, measuring, or otherwise manipulating components that could generate airborne chemical particles (e.g., active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples of closed-system processing devices include containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags. The process evaluation must be carried out in accordance with the facility's SOPs, and the assessment must be documented."***		4.01 - Section 4 and onward	6.1, 11
1.7	**Safety Data Sheet (SDS)/Spill Management:** The pharmacy has an SOP describing spill management and disposal. ***Inspector note: Per USP <795>, "The management and documentation of nonhazardous component spills and disposal must be described in the facility's SOPs."***		5.015, SW for spill - Section 4.19	6.2.5, 11
1.8	**Master Formulation Records (MFR):** The pharmacy has an SOP on the process for MFR creation and content. ***Inspector note: Per USP <795>, "Any changes or alterations to a Master Formulation Record are approved and documented in accordance with the facility's written SOP."***		5.05 - 4.1, 4.4, 4.5	7.1, 11
1.9	**Labeling:** The pharmacy has an SOP on the processes for labeling, label verification (confirming against the prescription or medication order, the MFR, and the compounding record (CR)) in order to prevent errors and CNSP mix-ups and required displayed information. ***Inspector note: Per USP <795>, "Labeling procedures must be followed as described in the facility's SOPs to prevent labeling errors and CNSP mix-ups."***		5.015, 4.012 - Section 4.4	9, 11

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		Observation	Inspector Notes	USP Reference(s)
1.10	**Quality Assurance (QA)/Quality Control (QC) Program:** The pharmacy has an SOP regarding its QA and QC program, including roles of the designated person(s), trainers, compounding personnel, adherence to procedures, and prevention and detection of errors and quality issues. ***Inspector note: Per USP <795>, "QA and QC programs must be formally established and documented in SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with this chapter, and laws and regulations of the applicable regulatory jurisdiction."***		3.01 - Entire policy	11, 12 USP <1163>
1.11	**QA/QC Program Complaint Handling and Adverse Event Reporting:** The pharmacy has an SOP for evaluation of complaints and adverse events, including investigations and corrective actions. ***Inspector note: Per USP <795>, the pharmacy, "must develop and implement SOPs for complaint handling." SOPs are to include any state or federal requirements for reporting to government agencies (example adverse event reporting). Further, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease compounding until problems have been identified and corrected."***		5.02, 5.05 - 4.2 complaints (5.02) 4.2 quarantine, recalls	1.1.3, 11, 12.1, 12.2, 12.3
1.12	**Packaging:** The pharmacy has an SOP describing packaging CNSPs. ***Inspector note: Per USP <795>, "SOPs must describe packaging of CNSPs."***		5.015 - Entire policy	11, 13.1
1.13	**Transporting:** The pharmacy has an SOP describing transporting CNSPs. ***Inspector note: Per USP <795>, there must be "written SOPs to describe the mode of transportation, any special handling instructions, and whether temperature monitoring devices are needed."*** ***If the pharmacy does not transport CNSPs, inspector should answer statement as N/A.***		5.015 - Section 4.19	11, 13.2

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		Observation	Inspector Notes	USP Reference(s)
1.14	**Recalls:** The pharmacy has an SOP describing minimum requirements for recalls. ***Inspector note: Per USP, "The facility must have procedures in place to:*** ***- Determine when recalls must be initiated, which should include procedures to immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, strength, purity, or other quality attributes)*** ***- Recall any unused dispensed CNSPs and quarantine any stock remaining in the pharmacy*** ***- Investigate if other lots are affected and recall if necessary*** ***An SOP for recall of dispensed CNSPs must contain:*** ***- Procedures to determine the severity of the problem and the urgency for implementation and completion of the recall*** ***- Procedures to determine the distribution of any affected CNSP, including the data and quantity of distribution*** ***- Procedures to identify patients who have received the CNSP*** ***- Procedures for disposal and documentation of the recalled CNSP (and)*** ***- Procedures to investigate and document the reason for recall."***		3.08 - Section 4.2-4.6	12.1
	Designated Person(s) and Personnel Training Program **Inspector must complete the <795> Records Review module to complete this section.**			
2.0	Does the pharmacy have a designated person(s) who meets the requirements in USP <795> standards? ***Inspector note: Per USP, "The compounding facility must designate one or more individuals to be responsible and accountable for the performance and operation of the facility and personnel in the preparation of CNSPs."*** ***If no, go to compliance statements.***	Yes		1.1.4
2.1	The designated person(s) (for the QA program) has the training, experience, responsibility, and authority to perform the duties required of them.	Yes		1.1.4, 12

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		Observation	Inspector Notes	USP Reference(s)
2.2	The designated person(s) reviews facility SOPs at least every 12 months to ensure that they reflect current practice and such review is documented. ***Inspector note: Per USP, "The facility's SOPs must describe the roles, duties, and training of the personnel responsible for each aspect of the QA program... The overall QA and QC program must be reviewed at least once every 12 months by the designated person(s). The results of the review must be documented, and appropriate action must be taken if needed."***	Yes	SOPs indicate annual reviews will be conducted	1.1.4, 12
2.3	The designated person(s) is responsible for overseeing a training program to ensure competency of personnel involved in compounding, handling, and preparing CNSPs.	Yes		1.1.4, 2
2.4	The designated person(s) is responsible for selecting components used by the pharmacy.	Yes		1.1.4, 6.2.1
2.5	The designated person(s) is responsible for monitoring and observing compounding activities and taking immediate corrective action if deficient practices are observed.	Yes		1.1.4
2.6	The designated person(s) is responsible for ensuring SOPs are fully implemented and following up if problems, deviations, or errors are identified.	Yes		1.1.4, 11
2.7	The designated person(s) is responsible for establishing, monitoring, and documenting procedures for the handling and storage of CNSPs and/or components of CNSPs.	Yes		1.1.4
3.0	Has the pharmacy created and implemented a training program that is in compliance with USP <795> standards? ***Inspector note: Per USP, "Training and competency of personnel must be documented."*** ***Inspector is to review a minimum of five personnel records and document their observations (see <795> Records Review module).*** ***If no, go to compliance statements.***	No	This startup pharmacy only has 2 employees that are compounding.	2, 14

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		Observation	Inspector Notes	USP Reference(s)
3.1	All personnel who compound CNSPs have been initially trained and qualified before being allowed to independently compound (eg, perform their job functions). ***Inspector note: Per USP, compounding personnel are defined as "Personnel trained to compound or oversee compounding of preparations."*** ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14
3.2	All personnel who have direct oversight, perform in-process checks, final verification of a CNSP, and/or dispense a CNSP have been initially trained and qualified (according to SOPs) being allowed to independently perform their job functions. ***If questions 1.0-1.12 in the records review tab for compounding personnel are answered "no" or "missing," this statement should be answered as no. For details, see Records Review module.***	No		2, 14
3.3	All compounding personnel, including those who have direct oversight of compounding personnel, have completed an initial training and at least every 12 months thereafter. ***Inspector note: Per USP, "Other personnel, who do not compound and only perform functions such as in-process checks, final verification, or dispensing of CNSPs must undergo training as required by the facility's SOPs."*** ***If questions 2.0-2.12 in the records review tab for compounding personnel or personnel who have direct oversight over compounding personnel are answered "no" or "missing," this statement should be answered no. For details, see the Records Review module.***	No		2, 14
4.0	Does the designated person(s) have a documented (periodic) evaluation of their direct observations for compounding activities and documentation of any deficiencies in the record? ***Inspector note: Per USP, this is a recommendation, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*** ***Inspector should complete the <795> Records Review module question 3.0.***	N/A	Nothing is currently in place, yet PIC Bergh stated there will be annual samples sent out to Analytical Research Labs for all compounding staff to assess potency of each type of preparation they are trained to prepare.	2, 14

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		Observation	Inspector Notes	USP Reference(s)
	Compounding Personal Hygiene and Garbing			
5.0	Does the pharmacy have a process to ensure all personnel entering the compounding area adhere to restrictions intended to minimize the risk of contamination in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3
5.1	Compounding personnel are required to report to the designated person(s)conditions that may contaminate the compounding preparation area. ***Inspector note: Per USP <795>, examples of conditions that have a higher risk of contaminating the CNSP include: rashes, recent tattoos, open sores, conjunctivitis, and active respiratory infection.***	Yes		
5.2	The designated person(s) is responsible for evaluating whether compounding personnel should be excluded from working in the compounding areas before their conditions have resolved.	Yes		3
5.3	Personnel removes any unnecessary items (outer garments, jewelry that could interfere with garbing, and earbuds/headphones) before entering the compounding area. ***Inspector note: Inspector should also observe compounding area to identify any items stored that do not belong (ie, dirty garments, jackets, or electronics).***	Yes		3.1
5.4	If personnel do not remove an item, the designated person has determined that the quality of the environment and CNSPs are not adversely affected by the accommodation.	N/A		3.1
6.0	Do personnel perform hand hygiene, wear required garb and gloves, and follow requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3
6.1	All personnel entering the compounding area complete hand hygiene procedures.	Yes		3.2 Box 1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Inspector Notes	USP Reference(s)
6.2	Garb is used for all compounding activities. ***Inspector note: Per USP <795>, gloves are mandatory garb for all compounding activities.***	Yes		3.2, 3.3 Box 1
6.3	Pharmacy uses SDS to determine other garb requirements for the components and compounding activity.	Yes		3.3
6.4	Additional garb (shoe covers, hair and facial hair covers, face masks, gowns) is worn as needed for protection of the personnel/CNSPs. ***If no, please list the garb worn for the type of component and compounding activity.***	Yes		3.3
6.5	The garb purchased by the pharmacy is appropriate for the type of compounding being performed.	Yes		3.3
6.6	Garb is stored in manner that minimizes risk of contamination (away from sinks to avoid splashing, etc).	Yes		3.3
6.7	Gowns that are reused do not leave the compounding area.	Yes		3.3
6.8	Visibly soiled garb or garb with tears or punctures are changed immediately (are not reused).	Yes		3.3
6.9	Soiled garb is disposed of or sent for laundering.	Yes		3.3
6.10	Shoe covers, hair and facial hair covers, face masks, and head covers are not reused once personnel have left the compounding area.	Yes		3.3
7.0	Are non-disposable garb such as goggles cleaned then sanitized with 70% isopropyl alcohol before re-use?	N/A		3.3

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		Observation	Inspector Notes	USP Reference(s)
	Buildings and Facilities			
8.0	Does the compounding area meet the facility requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.1
8.1	The pharmacy has a designated compounding space for nonsterile compounding.	Yes		4.1
8.2	The compounding area is well lit.	Yes		4.1
8.3	The compounding area is clean and sanitary.	Yes		4.1
8.4	The compounding area is orderly (eg, clutter free, no tripping hazards).	Yes		4.1
8.5	The compounding area is in a good state of repair.	Yes		4.1
8.6	The compounding area is designed for orderly placement of equipment and materials to prevent mix- ups among components, containers, labels, in-process materials, and finished CNSPs.	Yes		4.1
8.7	The compounding area is not being used for other activities at the same time that it is used for compounding.	Yes		4.1
8.8	The compounding area is designed, arranged, and used in a manner that minimizes cross contamination from non-compounding areas.	Yes		4.1
9.0	Is the compounding area free of carpet?	Yes		4.1

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		Observation	Inspector Notes	USP Reference(s)
10.0	Does the pharmacy's storage area (for CNSPs, components, equipment, and containers) meet requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.2
10.1	The pharmacy records the temperature of the compounding storage area on days when the pharmacy is open. ***Inspector note: Per USP, "Compounding personnel must monitor temperatures in the storage area(s) either manually at least once daily on days that the facility is open, or continuously with a temperature recording device to ensure the temperature remains within the appropriate range for the CNSPs and components."*** ***If pharmacy does not use a continuous recording system, describe the frequency of temperature recording in the notes.***	Yes		4.2
10.2	The pharmacy's temperature monitoring records are readily retrievable. ***Inspector note: Per USP, "The results of the temperature readings must be documented on a temperature log or stored in the continuous temperature recording device and must be retrievable."***	Yes		4.2
10.3	Temperature monitoring devices are verified for accuracy at least every 12 months or as required by the manufacturer. ***Inspector note: Per USP, "All temperature monitoring equipment must be calibrated or verified for accuracy as recommended by the manufacturer or every 12 months if not specified by the manufacturer." USP reports that these devices may be verified against a calibrated device.*** ***Monitoring devices are typically calibrated or replaced.***	Yes		4.2
10.4	Pharmacy has a process to evaluate temperature excursions. ***Inspector note: Per USP, "When it is known that a CNSP or component has been exposed to temperatures either below or above the storage temperature limits for the CNSP or component, personnel must determine whether the CNSP or component integrity or quality has been compromised and if so, the CNSP or component must be discarded."***	Yes	Per PIC Bergh, a visual assessment would be completed to validate the product is safe and consistent.	4.2
10.5	CNSPs, components, equipment, and containers are stored off the floor.	Yes		4.2

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		Observation	Inspector Notes	USP Reference(s)
10.6	CNSPs, components, equipment, and containers are stored in a manner that permits inspection and cleaning of the storage area(s).	Yes		4.2
10.7	CNSPs, components, equipment, and containers are stored in a clean environment (free of dirt, dust, and debris, and rodent/pest/insect free) to prevent contamination.	Yes		4.2
11.0	What is the current temperature of the nonsterile compounding storage area? ***Record in the Inspector Notes.***		74 degrees Celsius	4.2
12.0	Are plumbing fixtures, water sources, and cleanliness of sink in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		4.3
12.1	The pharmacy staff can easily access a sink within or nearby the nonsterile compounding area.	Yes		4.3
12.2	There is hot and cold running water available at the sink within or nearby the nonsterile compounding area.	Yes		4.3
12.3	The sink is emptied of all items unrelated to compounding and before being used to clean any equipment used in nonsterile compounding.	Yes		4.3
12.4	The sink is cleaned when visibly soiled (before being used to clean equipment used in nonsterile compounding).	Yes		4.3
12.5	The plumbing system is free of any defects that may contribute to contamination of CNSPs.	Yes		4.3
13.0	Is purified water, distilled water, or reverse osmosis water used for rinsing equipment and utensils used in nonsterile compounding? ***Inspector note: This is a USP recommendation.***	No		4.3 USP <1231>

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		Observation	Inspector Notes	USP Reference(s)
	Cleaning and Sanitizing			
14.0	What agent(s) are used for cleaning and sanitizing the nonsterile compounding area? ***Inspector note: Per USP <795>, "agents must be selected and used with consideration of compatibilities, effectiveness, and minimal potential to leave residues."*** ***List the agents in the Inspector Notes.***		70% Isopropyl Alcohol and RTU Neutral Disinfectant	5
15.0	Does the pharmacy perform cleaning and sanitizing activities on all surfaces at the minimum frequency per Table 1 and documented in a log or other record in compliance with USP <795> standards? ***Review compounding cleaning logs.*** ***If no, go to compliance statements.***	Yes		5 Table 1
15.1	All work surfaces are cleaned and sanitized at the **beginning of each shift** on days when compounding occurs.	Yes		5 Table 1
15.2	All work surfaces are cleaned and sanitized at the **end of each shift** on days when compounding occurs.	Yes		5 Table 1
15.3	All work surfaces are cleaned and sanitized **between compounding CNSPs with different components**.	Yes		5 Table 1
15.4	Floors are cleaned and sanitized daily on days when compounding occurs.	Yes		5 Table 1
15.5	Walls and ceilings are cleaned and sanitized when visibly soiled. ***Inspector note: No specific frequency is specified by USP. View compounding area walls and ceilings. If inspector observes soiled walls or ceilings, inspector should answer statement as no.***	Yes		5 Table 1
15.6	All work surfaces, floors, walls, ceilings and storage shelving are cleaned and sanitized when surface contamination (eg, splashes) or spills are known or suspected.	Yes		5 Table 1
15.7	Storage shelving is cleaned and sanitized at least every three months.	Yes		5 Table 1
16.0	Are floors in the compounding area easily cleanable, non-porous, and non-particle generating? ***Inspector note: This is a USP recommendation. Per USP, "Surfaces should be resistant to damage by cleaning and sanitizing agents."***	Yes		5

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		Observation	Inspector Notes	USP Reference(s)
	Equipment and Components FDA defines manufacturer, as used in section 510 of the Federal Food, Drug, and Cosmetic Act, includes the activities of relabelers, repackers, and salvagers. When not modified by "domestic" or "foreign," the term includes both domestic manufacturers and foreign manufacturers.			
17.0	Does the pharmacy use a closed-system processing device (eg, CVE, BSC, and single-use containment glove bags)? ***Inspector note: Per USP, examples of closed-system processing devices include: containment ventilated enclosures (CVEs), biological safety cabinets (BSCs), and single-use containment glove bags.*** ***If yes, list the type(s) in the Inspector Notes.***	Yes	BSC is being used for weighing powders	6.1
18.0	Does the pharmacy select, store, clean, and maintain equipment in compliance with USP <795> standards? ***Inspector note: Per USP <795>, "Equipment surfaces that contact components are not reactive, additive, or sorptive, and must not alter the quality of CNSPs."*** ***Review certification reports, calibration records, and cleaning logs.*** ***If no, go to compliance statements.***	No		6.1
18.1	Equipment and supplies are readily available at the pharmacy for the types of CNSPs prepared. ***Inspector note: For example, if the pharmacy compounds with API as a component, which must be weighed, a scale or balance would be expected.***	Yes		6.1
18.2	Pharmacy has evaluated and documented the nonsterile compounding pharmacy activities for weighing, measuring, and otherwise manipulating for an assessment of risk. ***Inspector note: Per USP, "components that could generate airborne chemical particles (eg, active pharmaceutical ingredients [APIs], added substances, and conventionally manufactured products) must be evaluated to determine if these activities must be performed in a closed-system processing device to reduce the potential exposure to personnel or contamination of the facility or CNSPs."*** ***If no, inspector should describe observations.***	Yes		6.1

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		Observation	Inspector Notes	USP Reference(s)
18.3	The equipment and devices used for compounding CNSPs are clean and stored in a manner and frequency that minimizes the risk of contamination. ***Inspector note: Per USP <795>, "After compounding, the equipment must be cleaned to prevent cross contamination of the next preparation." Additionally, per Table 2:*** ***- CVE/BSC are cleaned and sanitized at the beginning and end of each shift when compounding occurs, after spills, and when surface contamination (e.g., from splashes) is known or suspected;*** ***- CVE/BSC horizontal surfaces are cleaned and sanitized between compounding of different components;*** ***- Under the work surface of a BSC is cleaned and sanitized at least monthly; and*** ***- Other devices and equipment used in compounding are cleaned before initial use, in between compounding CNSPs with different components, and following manufacturer recommendations.*** ***If no, inspector should describe observations.***	No	Most equipment is cleaned right after use, but the underside tray of the BSC is not listed as being cleaned either daily, weekly or monthly.	6.1 Table 2
18.4	Equipment and devices used in compounding or testing of CNSPs are inspected prior to use (to ensure they are in good working order). ***Inspector note: For example, the pharmacy may need to tare a scale and/or balance prior to use.***	Yes		6.1
18.5	Equipment and devices are verified for accuracy as recommended by the manufacturer (at the frequency recommended by the manufacturer or at least every 12 months, whichever is more frequent). ***If the pharmacy does not compound CNSPs that require equipment or devices that must be calibrated for accuracy (such as ones needed for weighing or measuring), the inspector should answer this statement as N/A.***	Yes		6.1
18.6	If a CVE or BSC is used by the pharmacy, it is certified at least every 12 months, according to the manufacturer specifications or regulations of the applicable regulatory jurisdiction. ***If the pharmacy does not have the record or documentation of the certification and maintenance of the CVE/BSC, the inspector should answer this statement as no. If the pharmacy does not have a CVE or BSC, the inspector should answer this statement as N/A.***	Yes	Certification of the BSC was completed on 10/31/2024 by Northern Air Flow.	6.1

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		Observation	Inspector Notes	USP Reference(s)
19.0	Does the pharmacy compounding CNSPs use APIs?	Yes		6.2
20.0	Does the pharmacy select APIs that comply with the requirements in USP <795> standards? ***Verify by selecting products from the shelf from different suppliers and ask to see the COAs for those products.*** ***If no, go to compliance statements.***	No		6.2.1
20.1	APIs comply with criteria in the USP-NF monograph, if one exists. ***If the pharmacy does not compound any CSPs that have an available USP monograph, the inspector should answer this statement as N/A.***	N/A		6.2.1
20.2	All APIs used have a COA that includes the specifications (eg, compendial requirements for quality) and that the test results for the component show the API meets expected quality. ***Inspector note: Per USP, the API should be checked to ensure it is pharmaceutical grade and meets the requirements in the chemical monograph. COA will report an assay has been performed and will include water content (so any corrections/calculations can be performed).***	Yes		6.2.1
20.3	All APIs used are manufactured by an FDA-registered facility. ***Inspector note: This is a Federal Food, Drug, and Cosmetic Act, Section 503A, requirement as well. Inspector should verify the pharmacy looks up the name of the manufacturer listed on the COA to determine if they are registered as an FDA drug establishment https://dps.fda.gov/decrs.***	Unknown	Discussed with PIC Bergh - this is not currently being done by staff when COAs are received and reviewed.	6.2.1
21.0	When formulations indicate the inclusion of water, is purified water or better quality (eg, sterile water for irrigation) used in compliance with USP <795> standards?	Yes		6.2.1
22.0	What type(s) of water is used for compounding CNSP? ***List the type(s) in the Inspector Notes.***		Distilled Water	6.2.1

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		Observation	Inspector Notes	USP Reference(s)
23.0	Do the pharmacy's component receipt processes comply with the requirements in USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.2
23.1	For non-conventionally manufactured components, the COA is reviewed upon receipt. ***Inspector note: Per USP, "the COA must be reviewed to ensure that the component has met the acceptance criteria in an appropriate USP–NF monograph, if one exists." Pharmacy's review should be documented. Alternatively, the pharmacy can demonstrate how it's been reviewed (for example, there are notes to show a water content calculation back to 100% based on the specific COA). Inspector can verify the COA is retrievable.***	Yes		6.2.2
23.2	The pharmacy documents specific information according to the facility's SOP, including: receipt date, quantity received, supplier name, lot number, expiration date, and the results of any testing performed (whether performed in-house or through a third-party).	Yes		6.2.2, 14
23.3	For all components that lack a vendor expiration date, the pharmacy clearly and indelibly marks on each packaging system received the date the component must no longer be used by the pharmacy. ***Inspector note: Per USP, "Packaging systems of components (i.e., API and added substances) that lack a vendor's expiration date must not be used by the compounding facility after 3 years from the date of receipt. A shorter expiration date must be assigned according to Pharmaceutical Compounding—Sterile Preparations 797, 9.3.2 Component receipt if the same component container is also used in sterile compounding or if the ingredient is known to be susceptible to degradation."***	Yes		6.2.2
23.4	Any component found to be of unacceptable quality upon receipt or reinspection prior to use is promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before appropriate disposal.	Yes		6.2.2
23.5	Any other lots of that (rejected) component from that vendor are examined to determine whether other lots have the same defect.	Yes		6.2.2

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		Observation	Inspector Notes	USP Reference(s)
24.0	Does the pharmacy re-inspect all components before use and handle them in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		6.2.3, 6.2.4
24.1	Compounding personnel visually re-inspect each component, including packaging system (any evidence of container breakage, looseness of cap or closure) and deviation from the expected appearance or texture of the contents (that might have changed during storage).	Yes		6.2.3
24.2	Compounding personnel ascertain before use that components are the correct identity based on labeling, that they have been stored under required conditions, and there is no evidence of deterioration or other aspects of unacceptable quality before use of component.	Yes		6.2.3
24.3	Components where correct identity, strength, purity, and quality cannot be confirmed (eg, containers with damaged or incomplete labeling) are immediately rejected and if not immediately discarded, labeled as rejected and segregated from active stock.	Yes		6.2.3
24.4	Compounding personnel handle all components following facility SOPs, manufacturer's instructions/labeling, and laws/regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.4
24.5	All components are handled in a manner that minimizes the risk of contamination, mix-ups, and deterioration.	Yes		6.2.4
25.0	When components are removed from the original container and not used in compounding (eg, excess after weighing), are they discarded and not returned to the original container (to minimize risk of contamination of the original component container)? ***Inspector note: This is a USP recommendation.***	Yes		6.2.4

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		Observation	Inspector Notes	USP Reference(s)
26.0	Does the pharmacy maintain a chemical hazard, spill management, and disposal information program in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		6.2.5
26.1	Pharmacy staff have access to safety data sheets (SDS).	Yes		6.2.5
26.2	Pharmacy staff have documented, annual training for those who might have to clean up a spill.	No	Documentation of training on use of spill kits was not able to be produced.	6.2.5, 14
26.3	The pharmacy has a readily accessible spill kit in the compounding area.	Yes		6.2.5
26.4	The pharmacy has a process to manage and document any nonhazardous spills and disposal.	Yes		6.2.5
26.5	Waste of any component is disposed of in accordance with laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 6.2.5
	Master Formulation Records (MFR) and Compounding Records (CR) **Inspector should review a minimum of five (5) MFRs and five (5) CRs.**			
27.0	Is an MFR created for each unique formulation of a CNSP in compliance with USP <795> standards? ***Inspector note: Per USP, an MFR is a detailed record of procedures that describes how the CNSP is to be prepared.*** ***If no, go to compliance statements.***	Yes		7.1
27.1	An MFR is created for each unique formulation.	Yes		7.1 Box2
27.2	Any changes or alterations to the MFR are approved and documented.	Yes		7.1

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27.3	Does the designated person(s) or designee evaluate CNSP's characteristics when considering the assigned BUD for an MFR? ***Inspector note: Per USP, "When establishing a BUD for a CNSP, compounders must consider parameters that may affect quality, including but not limited to the following:*** ***- Chemical and physical stability properties of the API and any added substances in the preparation (e.g., if the API and added substances in the preparation are known to rapidly degrade over time and/or under certain storage conditions, reduce the strength of the preparation, or produce harmful impurities)*** ***- Compatibility of the container closure system with the finished preparation (e.g., leachables, interactions, adsorption, and storage conditions)*** ***- Degradation of the container closure system, which can lead to a reduction in integrity of the CNSP*** ***- Potential for microbial proliferation in the CNSP (and)*** ***- Significant deviations from essential compounding steps and procedures; changes to essential compounding steps may have an impact on the stability of the formulation."***	Yes		7.1, 10.2 Table 4
28.0	Does the pharmacy's MFRs contain all requirements in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and include as an attachment.***	Yes		7.1
28.1	MFR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.1
28.2	MFR identifies the identities and amounts of all components and, if applicable, relevant characteristics of components (eg, particle size, salt form, purity grade, solubility).	Yes		7.1
28.3	MFR includes the type of container–closure system(s).	Yes		7.1

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		Observation	Inspector Notes	USP Reference(s)
28.4	MFR has complete instructions for preparing the CNSP, including equipment, supplies, and a description of the compounding steps. ***Inspector note: Per USP, the MFR will also include, "Other information needed to describe the compounding process and ensure repeatability (e.g., adjusting pH, temperature)." MFRs will include the detailed instructions necessary for an experienced compounder. Some examples of other details to ensure repeatability include, but are not limited to: speed duration, settings on equipment, and specific order of mixing (if applicable).*** ***Inspector should review several MFRs for completeness of instructions.***	Yes		7.1
28.5	MFR has a physical description of the final CNSP.	Yes		7.1
28.6	MFR includes the assigned beyond-use date (BUD) and storage requirements.	Yes		7.1
28.7	MFR contains the reference source to support the assigned BUD.	Yes		7.1
28.8	Labeling requirements (eg, shake well) are described on the MFR.	Yes		7.1
28.9	If applicable, the MFR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of APIs.	Yes		7.1
28.10	An MFR has QC procedures (eg, pH testing, visual inspection) and expected results.	Yes		7.1
29.0	Does the pharmacy complete a Compounding Record (CR) for all CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements. Additionally, collect a copy of the MFR and the CR (no PHI or PII is to be collected).***	Yes		7.2, 14
29.1	A CR is completed for each CNSP prepared.	Yes		7.2, 14
29.2	The CR includes the name, strength or activity, and dosage form of the CNSP.	Yes		7.2, 14

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Inspector Notes	USP Reference(s)
29.3	The CR includes the date (or date and time) the CNSP was prepared.	Yes		7.2, 14
29.4	The CR includes the assigned internal identification number (eg, prescription, order, or lot number).	Yes		7.2, 14
29.5	The CR has a method to identify the individuals involved in the compounding process of the CNSP.	Yes		7.2, 14
29.6	The CR has a method to identify the individual who completed the review and verified the final CNSP.	Yes		7.2, 14
29.7	The CR includes: name, vendor or manufacturer, lot number, and expiration date of each component.	Yes		7.2, 14
29.8	The CR includes the weight or measurement of each component.	Yes		7.2, 14
29.9	The CR identifies the total quantity compounded.	Yes		7.2, 14
29.10	The CR lists the assigned BUD and storage requirements.	Yes		7.2, 14
29.11	If applicable, the CR contains the calculations to determine and verify quantities and/or concentrations of components and strength or activity of API.	Yes		7.2, 14
29.12	The CR has a physical description of the final CNSP.	Yes		7.2, 14
29.13	The CR includes the results of quality control procedures (eg, pH testing, visual inspection).	Yes		7.2, 14
29.14	The CR contains a MFR reference for the CNSP.	Yes		7.2, 14
29.15	Each CR is reviewed for completeness before the CNSP is released.	Yes		7.2, 8
29.16	The CR shows traceability of all components in the case of a recall or known quality issue.	Yes		7.2, 12.1, 14

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		Observation	Inspector Notes	USP Reference(s)
30.0	Are there procedures for in-process checks performed by a pharmacist? ***Inspector note: In-process checks are safety steps for complex, multi-step compounding processes. These checks indicate that appropriate procedures for measuring/mixing are followed for each step, including pharmacist verification of steps performed by non-pharmacists and visual inspection of preparation. Inspector should describe their observations in the Inspector Notes.***	Yes		2, 7.2, 8
	Labeling			
31.0	Are the pharmacy's labels for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		9
31.1	Information on the label is prominently and legibly displayed. ***Inspector note: Per USP, labeling includes other accompanying materials along with the CSP, which is defined as "All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container."***	Yes		9
31.2	The labeling meets any state or federal regulatory requirements.	Yes		1.1.3, 9
31.3	The label on the immediate container includes an assigned internal identification number (eg, barcode, prescription, order, or lot number).	Yes		9
31.4	The label on the immediate container includes the active ingredients and their amount(s), activity(ies), or concentration(s).	Yes		9
31.5	The label on the immediate container includes the storage conditions, if other than controlled room temperature.	Yes		9
31.6	The label on the immediate container includes the BUD. ***If no, please describe whether the pharmacy instead used the term "expiration date" or similar language or if this information was not included on the label.***	No	"Expiration Date" is the verbiage used on the immediate container label. The MFR uses "BUD".	9

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		Observation	Inspector Notes	USP Reference(s)
31.7	The label on the immediate container includes the dosage form.	Yes		9
31.8	The label on the immediate container includes the total amount or volume, if it is not obvious from the container.	Yes		9
32.0	Does the labeling on the dispensed CNSP include the route of administration? ***Inspector note: This is a USP recommendation.***	Yes		9
33.0	Does the labeling contain information identifying the CNSP as a compounded preparation? ***Inspector note: Per USP, this is a recommendation.***	Yes		9 USP <7>
34.0	Does the labeling on the dispensed CNSP display any applicable special handling instructions or warning statements? ***Inspector note: This is a USP recommendation.***	No		9
35.0	Does the labeling on the dispensed CNSP display the name of the compounding facility and contact information if the CNSP was to be sent outside of the facility or health care system? ***Inspector note: This is a USP recommendation.*** ***If the pharmacy only compounds CNSPs for patient use onsite (eg, a health care facility), inspector should answer this question as N/A***	Yes		9
	Establishing Beyond Use Dating (BUDs)			
36.0	Is each CNSP assigned and labeled with a BUD in compliance with USP <795> standards? ***Inspector note: Per USP, the BUD is defined as, "The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded." This is not the same term as "expiration date."*** ***If no, go to compliance statements.***	No		10 USP <7>
36.1	CNSP label has a BUD that specifies the date, or the hour and date, beyond which the preparation cannot be used and must be discarded.	No	Labels on CNSPs list an "Expiration Date"	10.1
36.2	CNSP labels do not list an "expiration date" or equivalent language.	No	Labels on CNSPs list an "Expiration Date"	10.1

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		Observation	Inspector Notes	USP Reference(s)
36.3	BUDs are assigned from the date (and time) of preparation.	Yes		10.1
36.4	BUDs are assigned based on dispensing in tight, light resistant containers/overpacks. ***Inspector note: Per USP, the Table 4 maximum limits for BUD are, "based on the ability of the CNSP to maintain chemical and physical stability and to suppress microbial growth. These BUDs represent the limit for CNSPs that are packaged in tight, light-resistant containers unless conditions in 10.4 CNSPs Requiring Shorter BUDs or 10.5 Extending BUDs for CNSPs apply."***	Yes		10.3
36.5	The BUD assigned to the CNSP does not exceed the shortest remaining expiration date of any of the commercially available starting components.	Yes		10.4
37.0	Does the pharmacy ensure the assigned BUD does not exceed the shortest BUD of any individual compounded components? ***Inspector note: Per USP, "For CNSPs prepared from one or more compounded components, the BUD should generally not exceed the shortest BUD of any of the individual compounded components. However, there may be acceptable instances when the BUD of the final CNSP exceeds the BUD assigned to compounded components (e.g., pH-altering solutions). If the assigned BUD of the final CNSP exceeds the BUD of the compounded components, the physical, chemical, and microbiological quality of the final CNSP must not be negatively impacted." Another example of these "acceptable instances" (similar to pH-altering components mentioned above) inspectors may see are stock solutions (and other formulas within a formula) such as methocel 1%.*** ***If no, inspector should describe the observations, including the name of the component whose BUD was shorter than the assigned BUD of the final CSP.***	Yes		10.4
38.0	Does the designated person(s) evaluate a CNSP formulation to establish the maximum BUD? ***If no, who establishes the maximum BUD for a MFR?***	Yes		7.1, 10.2, 10.3
39.0	Does the pharmacy compound CNSPs with a USP monograph?	No		10.5

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		Observation	Inspector Notes	USP Reference(s)
40.0	Does the pharmacy compound CNSPs following the USP monograph precisely? ***If no, go to compliance statements.***	N/A		10.5
40.1	Pharmacy staff have access to the USP monograph for reference.	N/A		10.5
40.2	CNSPs are prepared in accordance with the USP monographs. ***If no, inspector to collect a copy of the compounding record, label; and describe what specific steps of the monograph were not followed.***	N/A		10.5
40.3	Components used by the compounder match those listed in the monograph. ***If no, describe the source of the component in monograph and the source that the pharmacy used.***	N/A		10.5
40.4	The maximum BUD specified in the USP monograph is not exceeded. ***If no, identify the drug, monograph-stated BUD, and the BUD used by the pharmacy.***	N/A		10.5
41.0	Does the pharmacy compound CNSPs that are not available from a USP monograph?	Yes		10.4
42.0	Does the pharmacy adhere to the BUD (maximum) limits established in Table 4 for CNSPs in compliance with USP <795> standards? ***Inspector note: This question is for the CNSPs compounded that are <u>not</u> following a USP monograph or those CNSPs where extending BUD requirements were applied (where pharmacy has completed or has access to CNSP-Specific Stability Information). Per USP, the pharmacy is not required to measure water activity (A_w) for a CNSP.*** ***If no, go to compliance statements.*** ***If <u>all</u> CNSPs compounded at the pharmacy are following a USP monograph or the pharmacy is following a stability study that used a stability-indicating assay analytical method for the API, CNSP formulation, and material of composition of the container closure system, then the inspector should answer this question as N/A.***	Yes		10.4

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		Observation	Inspector Notes	USP Reference(s)
42.1	**Non-preserved, Aqueous Dosage Forms:** The non-preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 14 days with refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound non-preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.2	**Preserved, Aqueous Dosage Forms:** The preserved, aqueous dosage form CNSP is labeled with a BUD that does not exceed 35 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Aqueous dosage forms are ones that have a Aw ≥ 0.6, eg, emulsions, gels, creams, solutions, sprays, or suspensions.*** ***If pharmacy does not compound preserved aqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>
42.3	**Nonaqueous, Oral Liquid Dosage Forms:** The nonaqueous, oral liquid dosage form CNSP is labeled with a BUD that does not exceed 90 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous oral liquid dosage forms are ones that have a A_w < 0.6. Some examples of oral liquids that are nonaqueous include: oil-based oral solution or suspension.*** ***If pharmacy does not compound nonaqueous dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD, and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	N/A		10.4 Table 4 USP <659>

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		Observation	Inspector Notes	USP Reference(s)
42.4	**Nonaqueous Dosage Forms:** The nonaqueous dosage form CNSP is labeled with a BUD that does not exceed 180 days with controlled room temperature or refrigerated storage temperature. ***Inspector note: Per USP <795>, Nonaqueous (Solid) dosage forms are ones that have a A_w < 0.6. Some examples include capsules, tablets, granules, powders, nonaqueous topicals, suppositories, and troches or lozenges.*** ***If pharmacy does not compound other nonaqueous solid dosage forms, inspector should answer statement as N/A.*** ***If no, describe your observations including but not limited to: the name of the compounded preparation, the labeled BUD and the storage environment. Additionally, collect a copy of the master formulation record, the compounding record, and a copy of a label without PHI.***	Yes		10.4 Table 4 USP <659>
43.0	Does the pharmacy label any CNSPs with BUDs that extend beyond the maximum limits in Table 4 USP <795>?	No		10.5 Table 4
44.0	Does the pharmacy follow the requirements for labeling a CNSP with a BUD that exceeds Table 4 in compliance with USP <795> standards? ***If no, go to compliance statements.***	No		10.5
44.1	The labeled BUD for an aqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	No	Labels on CNSPs list an "Expiration Date"	10.5
44.2	The labeled BUD for a nonaqueous dosage form does not exceed 180 days. ***If no, collect a copy of the MFR, the CR, and a copy of a label without PHI.***	No	Labels on CNSPs list an "Expiration Date"	10.5
44.3	Pharmacy is following the results of their own stability study. ***If the pharmacy only follows cited stability studies (does not conduct their own stability studies) for extending BUDs, answer this question as N/A.*** ***If pharmacy is following a bracketed study, inspector may mark this statement as yes if concentrations of CNSPs are at or within the concentrations specified within the study.*** ***If pharmacy is following a bracketed study and is using a concentration outside the study, answer this question as a no and describe observations.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.4	The pharmacy has a copy of the cited stability study, which used a stability-indicating analytical method, for extending BUDs. ***Per USP, any stability study that meets the requirements of a stability-indicating assay method can be used (whether it is published or unpublished, such as a study provided by a chemical supplier) to extend BUDs up to 180 days for a CNSP.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A		10.5
44.5	The cited stability study (which uses a stability-indicating analytical method for extending BUDs) describes the API(s), CNSP formulation, and material composition of the container closure used. ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.*** ***If no, please describe the inspector observations.***	N/A*		10.5
44.6	If the cited stability study (which uses a stability-indicating analytical method for extending BUDs) is bracketed, the pharmacy's CNSP formulation is at or within the low and high concentration of each active ingredient within the stability study. ***If no, describe the concentrations cited in the stability study and the concentration of the CNSP compounded by the pharmacy.*** ***If pharmacy only conducts their own stability studies (does not use published or unpublished study performed by another entity) for extending BUDs, inspector should answer this question as N/A.***	N/A		10.5

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		Observation	Inspector Notes	USP Reference(s)
44.7	Aqueous CNSPs whose labeled BUDs are extended beyond Table 4, have: - been tested for antimicrobial effectiveness at least once for each formulation in the type of (with the same material composition of the) container closure system that will be used; - received study results from an FDA-registered facility (for the same CNSP formulation using the same material composition of the container closure system); or - a study published from peer-reviewed literature (for the same CNSP formulation using the same material composition of the container closure system). ***Inspector note: Pharmacy may rely on a bracketed study from the above options as long as the bracketed study information includes the low and high concentration of each active ingredient in the formulation. Per USP, this is "to establish preservative effectiveness across various strengths of the same formulation (e.g., bracketing). The concentration of all other ingredients (including preservatives) must fall within the bracketed range.***	N/A		10.5
	Quality Assurance (QA), Quality Control (QC), and Quality Management (QM) Inspector to review at least one complaint, one adverse event, and one recall (if applicable).			
45.0	Does the pharmacy have a QA/QC program to ensure that CNSPs are prepared per the requirements in USP <795> standards and any applicable regulatory requirements? ***If no, go to compliance statements.***	Yes		1.1.3, 12
45.1	The pharmacy has a formal QA/QC program with documented activities. ***Inspector note: Per USP, "A facility's QA and QC programs must be formally established and documented in the facility's SOPs that ensure that all aspects of the preparation of CNSPs are conducted in accordance with the requirements in this chapter (<795>) and the laws and regulations of the applicable regulatory jurisdiction."***	Yes		12
45.2	The QA/QC programs address adherence to procedures.	Yes		12
45.3	The QA/QC programs address prevention and detection of errors and other quality problems.	Yes		12

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		Observation	Inspector Notes	USP Reference(s)
45.4	The QA/QC programs address evaluation of complaints and adverse events. ***Review at least one complaint and one adverse event. If there are no complaints or adverse events, review the process that the pharmacy would follow in the event of a complaint or adverse event.***	Yes		12
45.5	The QA/QC programs address appropriate investigations and corrective actions.	Yes		12
46.0	Has the pharmacy received any complaints related to CNSPs within the past year?	No		12
47.0	Does the pharmacy follow complaint handling requirements in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.2
47.1	The pharmacy has a complete written or electronic record of each complaint made. ***Inspector note: Per USP, "The record must contain the name of the complainant or other unique identifier, the date the complaint was received, the nature of the complaint, and the response to the complaint. In addition, to the extent that the information is known, the following should be recorded: the name and strength of the CNSP and the assigned internal identification number (e.g., prescription, order, or lot number). The record must also include the findings of any investigation and any follow-up. Records of complaints must be easily retrievable for review and evaluation for possible trends and must be retained."***	Yes		12.2
47.2	Complaints are reviewed in accordance with SOPs by the designated person for the QA program.	Yes		12.2
47.3	Complaints are reviewed to determine whether it indicates a potential quality problem with the CNSP.	Yes		12.2
47.4	Complaints are fully investigated.	Yes		12.2
47.5	Complaint investigations consider whether the quality problem extends to other CNSPs.	Yes		12.2

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		Observation	Inspector Notes	USP Reference(s)
47.6	Corrective action, if necessary, is implemented for all potentially affected CNSPs. ***Inspector note: Per USP, the pharmacy is to, "Consider whether to initiate a recall of potentially affected CNSPs and whether to cease nonsterile compounding processes until all underlying problems have been identified and corrected."***	Yes		12, 14
47.7	A CNSP that is returned in connection with a complaint is quarantined until it is destroyed after the completion of the investigation and in accordance with the laws and regulations of the applicable regulatory jurisdiction.	Yes		1.1.3, 12.2
48.0	Has the pharmacy initiated any recalls of CNSPs within the past two years? ***Inspector note: Per USP <795> requires all records to be readily retrievable for two years, including recalls; However, the state/jurisdictional regulator may require records to be kept for a longer period of time.*** ***Review most recent recall and describe in the Inspector Notes.*** ***If the pharmacy has not had any recalls within the past two years, inspector should answer the question as No.***	No		12.1, 14
49.0	Does the pharmacy follow recall and adverse event procedures for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		12.1, 12.2, 12.3
49.1	The pharmacy has procedures to determine when recalls must be initiated.	Yes		12.1
49.2	The pharmacy documents the implementation of the recall.	Yes		12.1
49.3	Pharmacy reports recalled CNSPs to the appropriate regulatory bodies (as required by laws and regulations of the applicable regulatory jurisdiction).	Yes		1.1.3, 12.1
49.4	Investigations into an adverse event that reveals a quality problem with a CNSP that is likely to affect other patients are reported to both patients and their prescribers.	Yes		12.3
50.0	Does the pharmacy procedures include a step to immediately notify the prescriber of a failure of specifications with potential to cause harm (eg, strength, purity, or other quality attributes)? ***Inspector note: This is a USP recommendation.***	No	Recall SOP 3.08 does not list this as an included step.	12.1

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		Observation	Inspector Notes	USP Reference(s)
	CNSP Packaging			
51.0	Does the pharmacy's packaging processes and materials meet the requirements in USP <795>? ***If no, go to compliance statements.***	Yes		13.1
51.1	The packaging materials protect CNSPs from damage, leakage, contamination, and degradation.	Yes		13.1
51.2	The packaging materials used protects personnel from exposure (from the packaged CNSP).	Yes		13.1
52.0	The packaging materials selected by the pharmacy maintain the physical and chemical integrity and stability needed for CNSPs (eg, protect from light).	Yes		13.1
	Compounding Personnel Observations - *Inspector must observe personnel performing compounding and related activities. This section will require the inspector to observe the staff while performing compounding and related activities. It is acceptable for pharmacy staff to perform mock compounding activities (with two creams or other drugs) as long as all observations can be viewed.*			
53.0	**Personal Preparation Observation:** Before entering the compounding area, do personnel remove any items that are not easily cleanable or are not necessary for compounding in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		
53.1	Personnel removed all outer garments (eg, hats, scarves, bandanas, vests, coats, and jackets).	Yes		3.1
53.2	Personnel removed all items that are not easily cleanable and that might interfere with garbing.	Yes		3.1
53.3	Personnel removed all hand, wrist, and other exposed jewelry, including piercings, that could interfere with the effectiveness of garbing and hand hygiene (eg, watches, rings that may tear gloves).	Yes		3.1
53.4	Personnel removed earbuds or headphones.	Yes		3.1

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National Association of Boards of Pharmacy®
Verified Pharmacy Program Inspection Form

Nonsterile Compounding Inspection for USP <795>

Facility Name: Synergy Apothecary LLC dba Synergy Apothecary
e-Profile ID: 1856106
Inspection Date: 2/10/2025 - 2/12/2025

		Observation	Inspector Notes	USP Reference(s)
53.5	Any accommodations permitted by the designated person(s) should be documented. ***Inspector note: Per USP <795>, accommodations may be permitted as long as the quality of the CSP and environment will not be affected.***	Yes		3.1
54.0	**Hand Hygiene Observation:** Were personnel who enter the compounding area to compound observed performing the appropriate hand washing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.2, Box 1
54.1	All personnel who enter the compounding area to compound performed hand hygiene.	Yes		3.2 Box 1
54.2	Personnel wash hands with soap and water for at least 30 seconds.	Yes		3.2
54.3	Personnel dry their hands completely with disposable towels or wipers.	Yes		3.2
54.4	Personnel do not solely rely on the use of alcohol hand sanitizers.	Yes		3.2
55.0	***Garbing Observation:*** Were compounding personnel observed following the appropriate garbing procedures in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		3.3 Box 1
55.1	All personnel entering the compounding area are fully garbed (with the required garb as determined by the facility SOPs).	Yes		3.3 Box 1
55.2	All personnel who perform compounding activities don gloves. ***Inspector note: Per USP, "Gloves must be worn for all compounding activities."***	Yes		3.2, 3.3 Box 1
55.3	Gloves are inspected periodically for holes, punctures, or tears and replaced immediately if a defect is detected.	Yes		3.3 Box 1
56.0	Are gloves wiped or replaced before beginning compounding a CNSP with a different component or when other objects were touched (eg, pens, keyboards) to minimize risk of cross contamination with other CNSPs? ***Inspector note: This is a USP recommendation.***	Unknown		3.3

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		Observation	Inspector Notes	USP Reference(s)
57.0	List the name(s) of the CNSPs observed by the inspector as part of live compounding demonstration.	[redacted]	Sildenafil 60mg troche	
58.0	**Compounding Observation:** Are compounding personnel using appropriate nonsterile compounding techniques for CNSPs in compliance with USP <795> standards? ***If no, go to compliance statements.***	Yes		2 Box 3
58.1	The compounding personnel enter the nonsterile compounding area in accordance with the SOPs.	Yes		3.1, 4.1
58.2	The compounding personnel started with a clean compounding area for CNSPs.	Yes		4.1, 4.3, 5 Table 1
58.3	The compounding personnel selected the correct MFR for the CNSP to be prepared.	Yes		7, 7.1 Box 2
58.4	The compounding personnel performed hand hygiene. ***Inspector note: Per USP <795>, Box 1, personnel are to: wash hands with soap and water for at least 30 seconds, dry hands completely with disposable towels or wipers, and then don gloves.***	Yes		3.2 Box 1
58.5	The compounding personnel are appropriately garbed for the type of CNSP prepared.	Yes		3.3
58.6	The compounding personnel obtained the proper ingredients (APIs and/or components). ***Inspector note: All ingredients must be within date and match what is listed in the MFR. If the ingredient is an API, the COA must have already been reviewed and approved for use.***	Yes		6.2 (6.2.1 - 6.2.5)
58.7	The compounding personnel gathered all necessary materials, equipment, and supplies necessary and/or specified in the MFR and is in good working order prior to use for the CNSP. ***Inspector note: All items must be clean prior to use. If equipment requires calibration and/or certification, compounder must ensure the equipment or device is within proper specifications (eg, tare scales and/or balances).***	Yes		6.1 Table 2

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		Observation	Inspector Notes	USP Reference(s)
58.8	The compounding personnel have knowledge of and access to any SDS.	Yes		6.2
58.9	The compounding personnel only compound one CNSP at a time (to proactively prevent mix-ups, errors, and cross contamination).	Yes		1.1.3
58.10	The compounding personnel compound the CNSP according to the MFR. ***If no, inspector needs to describe in detail their observations in the Inspector Notes and collect a copy of the MFR and CR (no PHI or PII to be collected).***	Yes		7.1, 7.2 Box 2
58.11	The compounding personnel document any required steps listed in the MFR on the CR. ***Inspector note: This would include any weights, volume, and any in-process checks needed.***	Yes		7.2, 14 Box 3
58.12	Documentation in the CR is legible. ***If no, collect copy of record that is illegible. Redact any PHI on record.***	Yes		14
58.13	The compounding personnel verify the correct BUD in accordance with the MFR requirements in USP <795>.	Yes		10 Table 3, Table 4
58.14	The compounding personnel performed any quality control steps specified in the MFR. ***Inspector note: Examples of this include, but are not limited to: testing of pH for a suspension, weighing of capsules, and visual inspection against product description specifications.*** ***If no, describe observations in Inspector Notes.***	Yes		7.2, 8, 8.1, 12 Box 3
58.15	The compounding personnel placed the CNSP into the proper container closure system.	Yes		8.1 Box 2
58.16	The compounding personnel labeled the CNSP. ***Inspector note: Storage requirements must be included on the label if refrigerated or frozen (so patient can identify the storage temperature requirements).***	Yes		9

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		Observation	Inspector Notes	USP Reference(s)
58.17	The compounding personnel completed any documentation on the CR. ***If no, describe observations of what was missing or omitted in Inspector Notes.***	Yes		7.2, 8, 14 Box 3
58.18	The compounding personnel cleaned and sanitized the compounding area before the next CNSP (with differing ingredients) is prepared.	Yes		5
59.0	**Final CNSP check observation:** Does the visual inspection of the CNSP by the pharmacist confirm all USP <795> requirements? ***Observe a pharmacist check several CNSP prescriptions. List the name of CNSPs release inspection observed in the Inspector Notes.*** ***If no, go to compliance statements.***	Yes		8, 8.1, 9
59.1	CNSP was visually inspected to determine the physical appearance of the CNSP is as expected (eg, color, texture, physical uniformity), including any special characteristics listed in the MFR (eg, emulsions must be checked for phase separation).	Yes		8, 8.1
59.2	Visual inspection included checking for container closure integrity (eg, leakage, cracks, improper seals).	Yes		8, 8.1
59.3	CNSP label was verified against the prescription or medication order.	Yes		8, 8.1, 9
59.4	CNSP label was verified against the MFR.	Yes		8, 8.1, 9
59.5	CNSP label was verified against the CR.	Yes	MFR and CR are one-in-the-same.	8, 8.1, 9
59.6	If a CNSP will not be released or dispensed on the day the preparation was made, a visual inspection was conducted immediately before it is released or dispensed to make sure the CNSP did not develop any defects during storage.	Yes		8, 8.1
59.7	All checks and inspection that are performed are properly documented.	Yes		8.1, 14

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		Observation	Inspector Notes	USP Reference(s)
59.8	CNSP that do not meet requirements are promptly rejected, clearly labeled as rejected, and segregated from active stock to prevent use before disposal.	Yes		8.1
60.0	Inspect several different finished compounded nonsterile preparations. Are all the finished compounded preparations free from any evidence of signs of contamination? ***Inspector note: If found, request the compounded preparation to be quarantined and notify NABP immediately.*** ***Additionally, list the name(s) of the compounded preparation(s) observed; description of type of contamination suspected (eg, particulates, dirt/debris/(suspected) mold within container closure); number of preparations affected (eg, two of the five containers on the shelf); lot or batch information; BUD assigned; and collect photographs, copy of MFR, and CR.***	Yes		12
61.0	**Cleaning and Disinfection Observation:** Does the pharmacy perform cleaning and sanitizing activities in the compounding area in compliance with USP <795> standards? ***Document observations while pharmacy staff are performing live compounding activities in Inspector Notes.*** ***If no, go to compliance statements.***	Yes		5
61.1	Pharmacy staff starts with a clean and sanitized work surface prior to compounding a CNSP.	Yes		5 Table 1
61.2	Pharmacy staff perform cleaning and sanitizing between compounding CNSPs with different components. ***Inspector note: Per USP, "If cleaning and sanitizing are performed as separate steps, cleaning must be performed first."***	Yes		5 Table 1
61.3	Pharmacy staff ensure equipment and devices used in compounding activities are clean and sanitized after use (to prevent cross contamination of the next preparation).	Yes		6.1 Table 2
61.4	Pharmacy staff perform cleaning and sanitizing on work surfaces when visibly soiled, after spills, and/or when surface contamination is known or suspected.	Yes		5 Table 1

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Nonsterile <795> Employee File Records Review

Select the PIC, designated person, a staff pharmacist that checks compounded preparations, and two to three compounding pharmacy technicians. *Do not record the employee name; list only their title or position.
From the drop-down List:
*Mark as "Yes" if the document is present in the records and the competency evaluation was conducted in compliance with USP <795> requirements.
*Mark as "No" if the document is present in the records but is not in compliance with USP <795> requirements.
*Mark as "Missing" if any part of the record is missing and explain in Notes column.
*Mark as "N/A" if the training does not apply (eg, long-term employee may not have initial training available). Document further in the Notes column.

		Employee Records #1	Employee Records #2	Employee Records #3	Employee Records #4	Employee Records #5	
	Employee Title	PIC	CIO				Notes
1.0	The training program provides initial training, evaluation, and documentation on the core competencies listed below:						
1.1	Compounding personnel are trained on facility SOPs.	Yes	Yes				
1.2	Compounding personnel are trained on USP <795> standards.	Yes	Yes				
1.3	The training record for hand hygiene is complete.	Yes	Yes				
1.4	The training record for garbing is complete.	Yes	Yes				
1.5	The training record for cleaning and sanitizing is complete.	No	No				
1.6	The training record for handling and transporting components and CNSPs is complete.	No	No				There is a form entitled "Staff Training and Validation - Receiving Chemicals/Devices", but a copy of it has not filled out for PIC or CIO.
1.7	The training record for measuring and mixing is complete.	No	No				There is a form/checklist entitled "Staff Training and Validation - Weighing and Mixing" but it was not completed for PIC or CIO.
1.8	The training record for proper use of equipment is complete.	Yes	Yes				For scale use
1.9	The training record for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	Yes	Yes				Via SOP and Standard Works review during orientation training
1.10	The training record for interpreting a Certification of Analysis (COA) is complete.	Yes	Yes				
1.11	The training record for how to read/interpret a Safety Data Sheet (SDS) is complete.	Yes	Yes				

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	Employee Title	PIC	CIO				Notes
1.12	The training record for spill management is complete.	Yes	Yes				Via Non-Hazardous Spill Clean up SOP
2.0	The annual competency assessment was evaluated and documented on the following topics:						This pharmacy has only been open since November 2024. PIC Bergh plans to re-assess compounding personnel on a yearly basis.
2.1	Compounding personnel are re-trained on facility SOPs.	N/A	N/A				
2.2	Compounding personnel are re-trained on USP <795> standards.	N/A	N/A				
2.3	The annual competency assessment for hand hygiene is complete.	N/A	N/A				
2.4	The annual competency assessment for garbing is complete.	N/A	N/A				
2.5	The annual competency assessment for cleaning and sanitizing is complete.	N/A	N/A				
2.6	The annual competency assessment for handling and transporting components and CNSPs is complete.	N/A	N/A				
2.7	The annual competency assessment for measuring and mixing is complete.	N/A	N/A				
2.8	The annual competency assessment for proper use of equipment is complete.	N/A	N/A				
2.9	The annual competency assessment for documentation of compounding processes (eg, Master Formulation Records or Compounding Records) is complete.	N/A	N/A				
2.10	The annual competency assessment for interpreting a COA is complete.	N/A	N/A				
2.11	The annual competency assessment for how to read/interpret a SDS is complete.	N/A	N/A				
2.12	The annual competency assessment for spill management is complete.	N/A	N/A				
3.0	The designated person(s) has documented a (periodic) evaluation of their direct observations for compounding activities and documented any deficiencies in the record. *Inspector note: if there are not observations documented, the inspector should answer this question as N/A.* *Per USP, "the designated person(s) should monitor and observe compounding activities and must take immediate corrective action if deficient practices are observed. Facility SOPs must describe procedures for monitoring and observing compounding activities and personnel."*	N/A	N/A				

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Glossary & References	USP <795>
Active Pharmaceutical Ingredient (API)	Any substance or mixture of substances intended to be used in the compounding of a preparation, thereby becoming the active ingredient in that preparation and furnishing pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans or animals or affecting the structure and function of the body. Also referred to as a bulk drug substance. A conventionally manufactured drug product is not an API but is typically manufactured from an API(s).
Added Substance	An ingredient that is necessary to compound a preparation but is not intended or expected to cause a pharmacologic response if administered alone in the amount or concentration contained in a single dose of the compounded preparation. The term is used synonymously with inactive ingredient, excipient, and pharmaceutical ingredient.
Administration	The preparation of a nonsterile pharmacologic or other therapeutic agent for ingesting, inserting, applying, or otherwise providing a nonsterile medication in its final form to a single patient. This includes crushing a tablet(s) or opening a capsule(s) to mix with food or liquids to facilitate patient dosing.
Alcohol-based hand rub	An alcohol-containing preparation (liquid, gel, or foam) designed for application to the hands of health care personnel to inactivate microorganisms and/or temporarily suppress their growth. Such preparations may contain one or more types of alcohol, other active ingredients, excipients, and humectants.
Assigned trainer	One or more individuals assigned by the designated person(s) to be responsible and accountable for directly providing the training, observation, and/or evaluation of personnel for the preparation of CNSPs.
Beyond-use date (BUD)	The date, or hour and date, after which a CNSP must not be used, stored, or transported. The date is determined from the date or time the preparation is compounded.
Biological Safety Cabinet (BSC)	A ventilated cabinet that may be used for compounding. These cabinets are divided into three general classes (Class I, Class II, and Class III). Class II BSCs are further divided into types (Type A1, Type A2, Type B1, Type B2, and Type C1).
Bulk drug substance	See the entry for Active Pharmaceutical Ingredient.
Certificate of analysis (COA)	A report from the supplier of a component, container, or closure that accompanies the supplier's material and contains the specifications and results of all analyses and a description of the material.
Cleaning	The process of removing substances (eg, organic and inorganic material) from objects and surfaces, normally accomplished by manually or mechanically using water with detergents or enzymatic products.
Cleaning agent	An agent, usually containing a surfactant, used for the removal of substances (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Closed-system processing device	A device designed to reduce the potential exposure to personnel or contamination of the facility or CNSPs. Examples include CVEs, BSCs, or single-use containment glove bags.
Component	Any ingredient used in the compounding of a preparation, including any API, added substance, or conventionally manufactured product.
Compounded nonsterile preparation (CNSP)	A preparation not intended to be sterile that is created by combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance.

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Glossary & References	USP <795>
Compounding	The process of combining, admixing, diluting, pooling, reconstituting other than as provided in the manufacturer's labeling, or otherwise altering a drug product or bulk drug substance to create a nonsterile preparation.
Compounding area	An area that is specifically designated for nonsterile compounding.
Compounding personnel	Personnel trained to compound or oversee compounding of preparations.
Compounding record (CR)	Documents the compounding of each CNSP.
Container closure system	Packaging system components that together contain and protect the dosage form. This includes primary packaging system components and secondary packaging system components if the latter are intended to provide additional protection.
Containment glove bag	A single-use disposable glove bag that is capable of containing airborne chemical particles.
Containment ventilated enclosure (CVE)	A full or partial enclosure that uses ventilation principles to capture, contain, and remove airborne contaminants through high- efficiency particulate air (HEPA) filtration and to prevent their release into the work environment.
Conventionally manufactured product	A pharmaceutical dosage form, usually the subject of an application approved by the applicable national regulatory agency, that is manufactured under current good manufacturing practice conditions.
Designated person(s)	One or more individuals assigned to be responsible and accountable for the performance and operation of the facility and personnel as related to the preparation of CNSPs.
FDA	US Food and Drug Administration
Formulation	The specific qualitative and quantitative composition of the final CNSP.
Hazardous Drug (HD)	Any drug identified by at least one of the following criteria: carcinogenicity, teratogenicity or developmental toxicity; reproductive toxicity in humans; organ toxicity at low dose in humans or animals; genotoxicity or new drugs that mimic existing HDs in structure or toxicity. See <800>.
Label	The part of the labeling on the immediate container.
Labeling	All labels and other written, printed, or graphic matter on the immediate container or on or inside any packaging system or wrapper in which the article is enclosed, except for any outer shipping container.
Master formulation record (MFR)	A detailed record of procedures that describes how the CNSP is to be prepared.
Monograph	A quality documentary standard within USP–NF that articulates the quality expectations for a medicine including for its identity, strength, purity, and performance. It also describes the tests to validate that a medicine and its ingredients meet these criteria.
Oversight	The review, monitoring, and supervision of actions taken by personnel, bearing responsibility for those actions, and being available if and when needed for consultation, even if not physically present.
Preservative	A substance added to inhibit microbial growth.
Purified water	The minimal quality of source water for the production of Purified Water is drinking water whose attributes are prescribed by the US Environmental Protection Agency (EPA), the European Union, Japan, or the World Health Organization (WHO). This source water may be purified using unit operations that include deionization, distillation, ion exchange, reverse osmosis, filtration, or other suitable purification procedures. (See <1231>, 3.1.1 Purified Water.)

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Glossary & References	USP <795>
Quality Assurance (QA)	A system of procedures, activities, and oversight that ensures that the compounding process consistently meets quality standards.

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Glossary & References	USP <795>
Quality Control (QC)	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met for the CNSP.
Reconstitution	The process of adding a diluent to a conventionally manufactured product to prepare a solution or suspension.
Release inspection and testing	Visual inspection and testing performed to ensure that a preparation meets appropriate quality characteristics.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of microorganisms (eg, 70% isopropyl alcohol).
SDS	Safety data sheet.
SOP	Standard operating procedure.
Specification	The tests, analytical methods, and acceptance criteria to which any components, CNSP, container closure system, equipment, or other material used in the compounding of CNSPs must conform to be considered acceptable for its intended use.
Stability	The extent to which a product or preparation retains physical and chemical properties and characteristics within specified limits throughout its expiration or BUD.
Verify	To confirm that a method, process, system, or equipment will perform as expected under the conditions of actual use.
Water activity (a_w)	A measure of the fraction of total water that is unbound and freely available to participate in chemical, biochemical, or physicochemical reactions or provide an environment that can support microbial growth. Note that a_w is not water content.

Scan VPP response

part 1 of 2

General Pharmacy Portion

5.060 SOP PRODUCT INVENTORY (Version 1.0)

Synergy Apothecary

1.0 Purpose

1.1 The purpose of this procedure is to establish requirements for proper inventory of active and inactive raw pharmaceutical products, manufactured products, components and devices used in compounded preparations. No pharmaceuticals are used that are listed on the FDA's "list of drug products that have been withdrawn or removed from the market for reasons of safety or effectiveness".

1.2 All receiving and inspecting of chemicals, devices, containers, closures, and other components or supplies used for compounding operations will be completed in the area designated "Receiving" which is identified by signage.

1.3 Formal product inventories must be taken according to state and federal laws.

1.4 The purpose of this procedure is to establish requirements for product procurement, receipt and inspection.

1.5 To reduce the amount of particulate matter and airborne microbial contamination all products and new inventory are removed from the external packaging before entering the compounding area.

1.6 A complete inventory is confirmed at least annually (or as needed) per PIC.

2.0 Responsibility

2.1 All personnel at Synergy Apothecary are responsible for following this procedure.

2.2 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task of completing the quarterly inventory.

2.3 The PIC is responsible to input the inventory into the software.

2.4 The PIC will train the relief pharmacist to maintain the inventory into the software.

3.0 Definitions

3.1 SDS – Safety Data Sheet

3.2 Components – Any ingredient used in the compounding of a drug preparation, including any active ingredient or added substance that is used in its preparation.

3.3 C of A – Certificate of Analysis

3.4 NOISH – National Institute for Occupational Safety and Health

3.5 OSHA – Occupational Safety and Health Administration

3.6 PPE – Personal Protective Equipment

3.7 SW – Standard Work

3.8 http://www.fda.gov/drugs/developmentapprovalprocess/howdrugsaredevelopedandapproved/approvalapplications/investigationalnewdrugindapplicaions/ucm368736htm.

4.0 Procedure

4.1 EQUIPMENT & SUPPLIES

- 4.1.1 Certificate(s) of analysis
- 4.1.2 Quarantine area
- 4.1.3 Purchase order

4.2 FREQUENCY & SUPPLIERS

- 4.2.1 Unless specified by the manufacturer, the expiration date is three years from receipt. Upon receipt of product, pharmacy staff member signs or stickers bottle with date of delivery in MM/DD/YEAR format.
- 4.2.2 All invoices shall be maintained for at least six (6) years according to the Drug Supply Chain Security Act. A separate file is maintained for each supplier of any controlled substance invoices that are received. As we don't stock C-II, only one controlled substance invoice file is needed per supplier
- 4.2.3 Appropriate inspection or testing of the material may indicate that the substance has retained its purity and quality for use in the preparation.
- 4.2.4 No components may be utilized that have been pulled or withdrawn from the market for safety reasons. The Food and Drug Administration will provide, in the form of a "Negative List," all medication recalls. Monthly e-mails are received by Pharmacist-in-Charge and/or Quality Control Officer from MedWatch and ISMP that alert of changes to this list.
- 4.2.5 Suppliers shall be FDA registered for all prescription drugs and if applicable, comply with current GOOD Manufacturing Practices. They are to have licenses in good standing with applicable state and federal agencies. C of A and SDS shall be supplied with bulk chemicals, obtained from wholesaler or readily accessible on their website if not included with the packing list. FDA requires that wholesalers complete an annual report and steps to obtain and review these are found in appendix labeled Drug Supply Chain Security Act.
  - 4.2.5.1 Quality of chemicals received from another pharmacy shall be ensured by confirming C of A, chemical grade, appropriate handling and appropriate storage. Of note this would be very rare and would only be done in an emergency drug shortage situation.
  - 4.2.5.2 C of A is to be obtained for every new lot of an API. If C of A is not from original manufacturer, PIC or delegate will obtain the original C of A from wholesaler and compare accuracy. For example, Letco provides a statement certifying that the provided C of A is a true duplication of the original, but this should also be obtained to ensure chain of custody of the product. See attachments labeled CofAExamples. Manufacturer of product must be registered with the FDA for product to be USP 795 compliant. Use FDA website https://dps.fda.gov/decrs to confirm manufacturer is approved.
  - 4.2.5.3 Commercially available components utilized in compounded preparations shall be visually inspected to ensure they are free from defects and are otherwise suitable for their intended use.
  - 4.2.5.4 Commercially available prescription products obtained from a wholesaler shall be validated by confirming wholesaler state license, confirming active status in the FDA database as described above. Also, audit is to be done reviewing the pedigree of 3 products or 10% of items received, whichever is greater, to assess compliance. TopRx has given access to the Synchrony Pedigree viewer. This to be done annually.

4.2.5.5 In the event components are not available from the primary vendor due to back-order, a second wholesaler will be used to acquire back-ordered items

4.2.5.6 When USP or NF ingredients are not available, the pharmacist-in-charge may employ professional judgment in choosing an alternative high-quality ingredient which may include.

4.2.5.6.1 Analytical Reagent (AR)

4.2.5.6.2 Certified American Chemical Society (ACS)

4.2.5.6.3 3.4.3 Food Chemicals Codex (FCC) (when appropriate)

4.2.5.6.4 3.4.4 Dietary and nutritional supplements that are "Generally Recognized as Safe"

4.2.5.7 Shipments shall be quarantined in the receiving area and released upon satisfactory inspection as defined per the "Product Receiving" SW

4.2.5.7.1 Hazardous products will be stored in a separate receiving area (of note, not currently doing HD products)

4.2.5.7.2 Appropriate handling and storage determined by hazard code on label or SDS.

4.2.5.7.3 SDS shall be available and readily retrievable for all chemicals. Any new products SDS to be added to the binder for that area and any area it would be used.

4.2.5.7.4 Upon receipt, chemicals are checked, and the C of A should be reviewed per the process defined by the "Product Receiving" SW

4.2.5.7.4.1 Special considerations, such as unusual water content, shall be entered into compounding software when calculations are necessary.

4.2.5.7.4.2 C of A shall be retained for six (6) years from the date that the product is all used.

4.2.5.7.4.3 The acceptable assay range is defined in the C of A of each chemical. Anything found to be outside of this range will be rejected upon receipt.

4.2.5.7.5 Pharmacist-in-charge shall be notified if inspection is not satisfactory and:

4.2.5.7.5.1 Shipment shall be quarantined.

4.2.5.7.5.1.1 The manufacturer or supplier shall be contacted for advice on return of shipment.

4.2.5.7.6 Components and applicable supplies shall be entered into compounding software and include the following information:

4.2.5.7.6.1.1 Name

4.2.5.7.6.1.2 Manufacturer

4.2.5.7.6.1.3 NDC

4.2.5.7.6.1.4 Quantity

4.2.5.7.6.1.5 Purity assay if not within 3% purity

4.2.5.7.6.1.6 Lot number

4.2.5.7.6.1.6.1 The lot number is entered into the compounding software at the time of receiving each product, and the correct lot number is chosen at time of compounding.

4.2.5.7.6.1.6.2 Non-drug product and device lot numbers will be kept in the "Non-drug Product Lot Number" binder. These invoices will be written to reflect the date range that we dispensed these products to patients. These invoices are retained for one year from the date that the product is all used.

4.2.5.7.6.1.7 Expiration-Will not accept inventory if product will expire in less than 1 year unless there are drug shortages and short dated drug will be expected to be used within that time frame. Items will be highlighted with stickers noting the short dating and BUD dating will be reduced as appropriate for the dating of the ingredients.

4.2.5.7.6.1.8 Hazard codes or special handling

4.2.5.7.6.1.9 Special storage requirements

4.2.6 Non-sterile ingredients and components

4.2.6.1 It is preferable to utilize official USP or NF articles for non-sterile active ingredients, added substances or excipients.

4.2.6.2 When non-official ingredients are used, certificates of analysis from their supplier shall accompany the ingredients.

4.3 MEDICATION STORAGE

4.3.1 All medications and devices will be stored off the floor in such a manner to ensure their integrity, stability, and effectiveness, and in a manner consistent with US Pharmacopeia/National Formulary (USP/NF) standard, legal or accreditation requirements, and/or manufacturer's recommendations.

4.3.1.1 Controlled substances shall be stored according to state law.

4.3.2 Acids and Bases should not be stored next to each other.

4.3.3 Drug storage areas will be well lit, neat, organized, clear of obstructions, free of any material not for the storage, preparation, dispensing, or administration process; and located where personnel preparing drugs for dispensing and/or administration will not be interrupted or distracted.

4.3.4 Medications will be stored under the proper conditions of sanitation, temperature, light and moisture. The medication storage area will have proper ventilation, organization, segregation, safety, and security. Temperatures and ventilation in

the work areas shall ensure the integrity of the drugs and the comfort of the personnel working with them. Drugs will be stored in stock bottles until the time of dispensing.

4.3.5 Food should ***NOT*** be stored in areas designated for medication storage and/or preparation or dispensing of medications.

4.3.6 NIOSH Sample list of drugs that shall be handled as hazardous (Attachment 2) should be stored in "Hazardous Storage." Refer to SOP 6.010 "Handling Hazardous Drug Compounds" for more information regarding hazardous drugs.

4.3.7 Flammable Chemical Inventory components in excess of ten gallons shall be stored in an approved flammable cabinet.

4.3.8 Corrosive Chemical Inventory should be stored below eye level on a corrosive-resistant container labeled "Corrosive Storage".

4.3.9 Medications, unless they have more specific requirements for storage, will be stored at controlled room temperature 59° to 77° Fahrenheit {F}). This will be measured by personal comfort, with additional monitoring of ambient air temperatures as appropriate. Humidity should be maintained between 20-60% as based on personal comfort and adjusted if affecting compounding drying times. Temperature monitoring is being done continuously via ADT and management is alerted of temperatures or humidities out of the approved range.

4.3.10 Medications that must be refrigerated or frozen:

4.3.10.1 Medications requiring refrigeration will be stored in a refrigerator that maintains a temperature of 2° to 8° C (36° to 46° F). *The refrigerator will be marked for "Medication Storage Only".

4.3.10.2 Medications that require that they be frozen for storage will be stored in a freezer that maintains a temperature of at least -20° to -10° Celsius (C) (-4° to 14° F).

4.3.10.3 Medication refrigerator and freezer temperatures will be monitored and recorded daily when the pharmacy is open.

4.3.10.4 If there is a temperature variation outside the normal limits the refrigerator will be checked again one (1) hour later. If the temperature variation is not resolved, the items will be removed and placed in cooler with ice or moved to another secured refrigeration unit and a service repair person will be called.

4.3.11 Medication storage areas will be inspected monthly by a member of the pharmacy staff.

4.3.11.1 FDA inspections of wholesaler and manufacturers facilities should be available and requested yearly for review and retention at pharmacy.

4.3.11.2 All medications will be inspected, and the following will be removed:

4.3.11.2.1 Expired

4.3.11.2.2 Recalled

4.3.11.2.3 Defective, contaminated, or deteriorated

4.3.11.2.4 Broken or damaged

4.3.11.2.5 Mislabeled (according to standards, law or policy. Labels must include the entire description of the medication, including drug or chemical name, strength or concentration, expiration date, applicable warnings and lot number or

otherwise unsuitable for administration or use as determined by pharmacy staff

4.3.11.2.6 Unusable drugs or devices will not be dispensed or administered. Pharmacy staff will dispose of these drugs or devices in accordance with the law and manufacturer's recommendations.

4.3.11.2.7 If any compounding material is expired, destroy the material according to SOP 3.070, "Destruction of Expired Product and Reagents."

4.3.11.2.8 If waiting for any manufacturer's recommendations, the product for reasons of expiration, recall, or compromise will be placed into quarantine. The labeled "Quarantine" container is located in the office.

4.3.12 A formal inventory shall be conducted annually, or as required by governing State Board of Pharmacy requirements.

4.3.12.1 For API inventory which also includes controlled API' inventory "tare weight will be utilized. The pharmacist will subtract the weight of an empty container (like a vial or pill jar) from the total weight, enabling them to accurately measure the net weight of the medication inside, without including the container's weight in the reading; essentially, it lets them "zero out" the container before adding the medication to ensure precise dosage calculations. Addition options for obtaining the weight of a partial container controlled substance powders as follows:

4.3.12.2 Maintain an emptied bottle for use as an actual tare and label as "for tare weight purposes only"

4.3.12.3 Keep a spreadsheet of size/brand/drug for each API added to inventory with the tare weights as different products are used by the pharmacy so that tare can be subtracted from the total weight of the partial container.

4.3.12.4 Compare the weight of a full unopened container if one is in stock and subtract the weight of the partial. The difference reflects the amount that has been removed from the container.

4.3.12.5 Write the original weight of any new unopened product onto a spreadsheet to allow any of the above options for calculating what is iin a partial container of controlled substance powder. Of note the same premise exists for any powder but has less significance in drug diversion and legal concerns.

Key points about using tare weight in a pharmacy:

- Accuracy:
  - The tare feature is crucial for accurate medication dispensing, as it eliminates potential errors from weighing containers alongside the medication.
- Procedure:
  - Place the empty container on the scale.
  - Press the "tare" button to set the scale to zero, effectively "ignoring" the weight of the container.
  - Add the medication to the container.

- The scale will now display only the weight of the medication.

4.3.13 – Drug Supply Chain Security Act compliance

The FDA provides some degree of exemption for compounding ingredients and for small dispensers (a company with 25 or fewer full-time employees licensed as pharmacists or qualified as pharmacy technicians. See attached FDA guidance.

Current exemption for small dispensers has been extended to November 2026 but based on steps in Policy, Synergy Apothecary will review FDA site at least annually for manufacturers and distributors in active use fand use only DSCSA compliant wholesalers for any commercially available medications

Annually, wholesalers must submit a report to the FDA reporting compliance of the DSCSA. This to be requested Annually

Websites: https://dps.fda.gov/decrs , and https://dps.fda.gov/wdd3plreporting.

These to be checked annually but as an additional safeguard, PIC to be added to email list server with FDA for any letters, advisors and Medwatch concerns. Of note each wholesaler and manufacturer may have differing expiration/renewal dates. Annual review added to PRS software and current suppliers now have added additional support to maintain CofA support, FDA manufacturer and distributor updates.

5.0 References

5.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

5.2 USP Current Version <800> "Hazardous Drugs"

5.3 USP Current Version <797> "Pharmaceutical Compounding – Sterile Preparations" is used for general reference; however, Synergy Apothecary is a non-sterile preparation facility

5.4 SOP 5.050 "Product Quarantine, Storage and Release"

5.5 https://www.fda.gov/drugs/drug-supply-chain-integrity/drug-supply-chain-security-act-dscsa

5.6 Wisconsin Pharmacy Rules and Statutes

5.7 FDA List of compounding drugs that were withdrawn or removed from the market for safety reasons

5.8 https://www.fda.gov/drugs/guidance-compliance-regulatory-information/human-drug-compounding

5.9 NIOSH List of Antineoplastic and Other Hazardous Drugs in Healthcare Settings

5.10 OSHA Technical Manual Controlling Occupational Exposure to Hazardous Drugs

5.11 "Product Receiving" Standard Work

5.12 SOP 6.010 "Handling of Hazardous Drug Compounds"

6.0 Attachments

6.1 Drug Supply Chain Security Act – how to verify wholesaler. (FDA List of compounding drugs that were withdrawn or removed from the market for safety reasons – See most recent copy in printed Policy book – additional information and updates on FDA website

6.2 NIOSH Sample list of drugs that should be handled as hazardous – See forms folder
6.3 Common Flammable Chemicals – See forms folder
6.4 Common Corrosive Chemicals – See forms folder

7.0 SOP History

___ Draft X Final **Creator/Approved by:** Theresa Bergh, RPh, PIC **This policy implemented on:** 11/01/2024	**Annual Policy Review** Original Owner / Date: Theresa Bergh: 11-01-2024 Reviewer / Date: Reviewed and updated on 2/21/25.

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U.S. FOOD & DRUG ADMINISTRATION

Date Issued: July 12, 2024

Subject: DSCSA Exemptions from Certain Requirements Under Section 582 of the FD&C Act for Small Business Dispensers (revised with clarifying edits to June 12, 2024, letter)

The Food and Drug Administration (FDA, Agency, or we) is using authority under section 582(a)(3) of the Food, Drug, and Cosmetic Act (FD&C Act) to grant exemptions for small business dispensers[1] - and, where noted, small business dispensers' trading partners[2] - as outlined in these exemptions, from certain requirements in section 582 of the FD&C Act[3] until November 27, 2026.

In August 2023, FDA announced two compliance policy guidances[4] that explained, among other things, FDA's enforcement policy with respect to: (a) the enhanced drug distribution security requirements[5] in section 582(g)(1) of the FD&C Act; and (b) verification requirements for dispensers regarding suspect or illegitimate product in sections 582(d)(4)(A)(ii)(II) and (d)(4)(B)(iii) of the FD&C Act, that went into effect on November 27, 2023. Together, the compliance policy guidances establish a 1-year stabilization period, from November 27, 2023, through November 27, 2024, to accommodate additional time that trading partners in the pharmaceutical supply chain need to implement, troubleshoot, and mature systems and processes to fully implement the Drug Supply Chain Security Act (DSCSA) enhanced drug distribution security requirements.

Since publishing the 2023 Compliance Policy guidances, FDA has continued to receive comments and feedback from stakeholders and trading partners, particularly small business dispensers, expressing concern with readiness to implement requirements under section 582(g)(1) of the FD&C Act at the conclusion of the stabilization period on November 27, 2024. Specifically, small business dispensers have described challenges related to the time, costs, and resources needed to further develop the robust technologies and processes to enable data exchange, establish business relationships with their trading partners and operationalize business practices. FDA recognizes that small business dispensers may still need additional time beyond November 27, 2024, when the enforcement policy set forth in the 2023 Compliance Policies expires, to focus resources and efforts on refining systems and technological infrastructures. Accordingly, FDA is issuing these exemptions to accommodate the additional time beyond November 27, 2024, that may be needed by small business dispensers to fully transition to interoperable, electronic

[1] Section 582(g)(2)(B)(i) of the FD&C Act specifically refers to agency authority to create alternative timelines for compliance with section 582(g)(1) of the FD&C Act requirements for "small business dispensers with 25 or fewer full-time employees."

[2] *Trading partner* is defined in section 581(23)(A) of the FD&C Act. Although third-party logistics providers are also considered trading partners under section 581(23)(B) of the FD&C Act, they are not subject to the same product tracing requirements of section 582 of the FD&C Act.

[3] Pursuant to section 582(a)(3) of the FD&C Act, FDA has issued guidance on waivers, exceptions, and exemptions from section 582 of the FD&C Act requirements, that includes descriptions of circumstances and processes by which FDA may establish exceptions or exemptions on its own initiative. As noted in that guidance, if FDA establishes an exception or exemption to address a particular issue, it "intends to communicate the information in writing using a method appropriate for the circumstances (e.g., a letter to the affected trading partners or - if an exception or exemption applied to a broad segment of industry - a posting on its website). An exception or exemption that is established by FDA may be limited in duration or valid until further notice from FDA." Consistent with that guidance, we are posting these exemptions on our website.

[4] For more information, see the compliance policy guidances for industry, *Enhanced Drug Distribution Security Requirements Under Section 582(g)(1) of the Federal Food, Drug, and Cosmetic Act — Compliance Policies* (August 2023) and *Wholesale Distributor Verification Requirement for Saleable Returned Drug Product and Dispenser Verification Requirements When Investigating a Suspect or Illegitimate Product — Compliance Policies, Revision 1* (August 2023).

[5] *Enhanced drug distribution security requirements* refer to the requirements for interoperable, electronic, package-level product tracing, including systems and processes, in section 582(g)(1) of the FD&C Act.

product tracing at the package level under the DSCSA. The FDA has determined these exemptions are appropriate to maintain public health and help ensure continued patient access to certain prescription drugs in the United States.

For the purpose of this exemption, a dispenser[6] is considered a small business dispenser if the corporate entity that owns the dispenser has a total[7] of 25 or fewer full-time employees[8] licensed as pharmacists or qualified as pharmacy technicians according to the applicable state board of pharmacy requirements. We believe this definition best incorporates small business pharmacy operations and those who are most in need of additional time to comply with the requirements of section 582(g)(1) of the FD&C Act outlined below.

If a small business dispenser relies on the exemptions outlined here, we recommend communicating such reliance to its trading partners as needed to further facilitate distribution of product without difficulty or delay. The exemptions described herein do not apply to other requirements in section 582 of the FD&C Act.

FDA has determined that the following FD&C Act exemptions for small business dispensers - and, where noted, their trading partners - are appropriate for products they transact with each other from November 27, 2024, until November 27, 2026:

- The requirements under sections 582(d)(4)(A)(ii)(II) and (B)(iii) of the FD&C Act for dispensers to verify the product identifier of the statutorily designated proportion of suspect or illegitimate product in the dispenser's possession or control. Small business dispensers are still obligated to meet all other verification requirements of section 582(d)(4) of the FD&C Act.
- The requirement under section 582(g)(1)(A) of the FD&C Act that the transaction information and the transaction statements be exchanged in a secure, interoperable, electronic manner in accordance with the standards established under the guidance issued pursuant to paragraphs (3) and (4) of section 582(h) of the FD&C Act. Small business dispensers and their trading partners may continue to rely on current methods for providing, capturing, and maintaining transaction information and transaction statements[9] for transactions of product .
- The requirement under section 582(g)(1)(B) of the FD&C Act that the transaction information required to be exchanged include the product identifier at the package level for each package included in the transaction. Small business dispensers and their trading partners may continue exchange transaction information that does not include the product identifier at the package level for each package included in the transaction.
- The requirement under section 582(g)(1)(C) of the FD&C Act that systems and processes for verification of product at the package level, including the standardized numerical identifier, be in accordance with the standards established under the guidance issued pursuant to section 582(a)(2) of the FD&C Act and the guidances issued pursuant to paragraphs (2), (3), and (4) of section 582(h) of the FD&C Act. Small business dispensers and their trading partners may continue to rely on current methods for verification activities
- The requirement under section S82(g)(1)(D) of the FD&C Act for systems and processes necessary to promptly respond with the transaction information and transaction statement for a product upon a request by the Secretary, or other appropriate Federal or State official, in the event of a recall or for the purposes of

(X) we track lots of API in case of recall

[6] See Section 581(3) of the FD&C Act for the definition of *dispenser*.

[7] The total number of employees as of November 27, 2024.

[8] The Internal Revenue Service defines a *full-time employee* as "for a calendar month, an employee employed on average at least 30 hours of service per week, or 130 hours of service per month." For additional information on identifying full-time employees, see https://www.irs.gov/affordable-care-act/employers/identifying-full-time-employees.

[9] Beginning on November 27, 2023, section 582(k)(1) of the FD&C Act effectively ended the requirement for trading partners to provide and receive transaction history.

investigating a suspect product or an illegitimate product. Small business dispensers and their trading partners may continue to rely on current methods to respond to such requests for such information.

- The requirement under section 582(g)(1)(E) of the FD&C Act for systems and processes necessary to promptly facilitate gathering the information necessary to produce the transaction information for each transaction going back to the manufacturer, as applicable (i) in the event of a request by the Secretary, or other appropriate Federal or State official, on account of a recall or for the purposes of investigating a suspect product or an illegitimate product; or (ii) in the event of a request by an authorized trading partner, in a secure manner that ensures the protection of confidential commercial information and trade secrets, for purposes of investigating a suspect product or assisting the Secretary, or other appropriate Federal or State official, with a request described in clause (i). Small business dispensers and their trading partners may use current methods respond to such requests with their relevant transaction information if they directly transacted the product(s) subject to the request.
- The requirement under section 582(g)(1)(F) of the FD&C Act that each person accepting a saleable return have systems and processes in place to allow acceptance of such product and may accept saleable returns only if such person can associate the saleable return product with the transaction information and transaction statement for the product. Small business dispensers' trading partners may use current methods to accept saleable returns.

The exemptions described in this notification are not intended to provide, and should not be viewed as providing, a justification for delaying efforts by small dispensers to implement the enhanced drug distribution security requirements under section 582(g)(1) of the FD&C Act. FDA strongly urges small dispensers to continue their efforts to implement necessary measures to satisfy these enhanced drug distribution security requirements. Small dispensers and their trading partners who utilize these exemptions do not need to submit anything to FDA.

Sincerely,

Michael M. Levy -S Digitally signed by Michael M. Levy -S Date: 2024.07.12 11:08:17 -04'00'

Michael Levy, J.D.
Deputy Director
Office of Compliance
Center for Drug Evaluation and Research
Food and Drug Administration

Attachment 5- 060

Drug Supply Chain Security Act

To verify if a **wholesaler** has completed their **annual report with the FDA**, follow these steps:

1. Check the FDA Drug Establishments Database

- The **FDA's Drug Establishment Registration and Listing System (DRLS)** maintains records of drug wholesalers, manufacturers, and repackagers.
- **Search here:** FDA Drug Establishment Registration Database
- Enter the **wholesaler's name or FEI (Facility Establishment Identifier)** to check their **registration status.**
- Go to this website to check https://dps.fda.gov/decrs

2. Verify in the FDA's Wholesale Distributor & 3PL Database

- If the company is distributing **prescription drugs,** they must be compliant with **DSCSA (Drug Supply Chain Security Act)** regulations.
- **Check their status here:** FDA Wholesale Distributor & 3PL Database
- https://dps.fda.gov/wdd3plreporting

3. Request Proof of FDA Compliance from the Wholesaler

- **Ask for their latest Annual Report submission confirmation** or **FDA Registration Certificate.**
- **Contact the FDA** directly via email: druginfo@fda.hhs.gov or call **1-855-543-3784** for verification.

4. Check the FDA Warning Letters Database

- If the wholesaler has **failed to submit reports or comply with regulations,** they may have received a **warning letter.**
- **Search here:** FDA Warning Letters
- https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters

An official website of the United States government Here's how you know

FDA

Share | Tweet | LinkedIn | Email | Print

Drug Establishments Current Registration Site

New Search

Search Results for *letco medical*

Showing 1 to 1 of 1 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Letco Medical, LLC	3003063918	079891426	RELABEL; REPACK	1316 Commerce Drive NW, Decatur, Alabama (AL) 35601, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Wednesday, Feb 26, 2025

New Search

Fagron/Letco/Humco all one company

Quality Information/Intelligence System (QIS)

Supply Chain

- APIs are sourced only from FDA-registered manufacturers
- Advanced in-house analysis performed in fully- equipped laboratory
- Full compendial testing for each API from each and identification tests on every lot of material
- Identification testing on every repackaged lot, before shipment to customers

Distribution Quality

Our products are held and distributed under the strictest conditions, with 24/7 electronic temperature and humidity monitoring, temperature mapping, USP storage conditions for all product types, validated and temperature warehouses and cold storage. Fagron meets all licensing requirements for each state and is NABP accredited.

Employee Safety

Licens (/s/)

Home Request Support

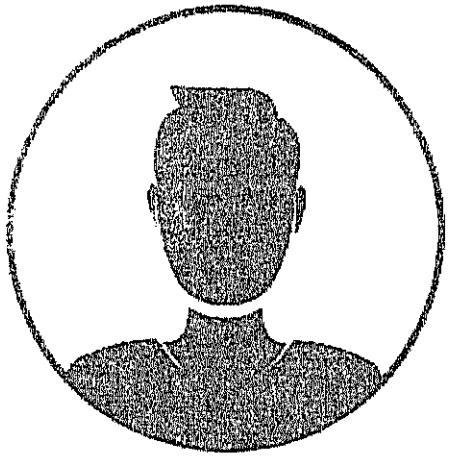
Third Party Document Upload

Application Status Lookup LEAP Login

Provider Login Performance Data

File a Complaint Orders and Disciplinary Actions

License Lookup



DSPS Site Guest User

Credential/License Summary for 2724 - 45

As of December 18, 2024 1:56:41 PM

Name : LETCO MEDICAL, LLC

Credential/License Number : 2724 - 45

Professions : Wholesale Distributor of Prescription Drugs

Location : DECATUR, Alabama - 35601

Credential/License Type : Regular

Status : License is current (Active)

Eligible To Practice : Eligible

Credential Expiration Date : 2026-05-31

Granted Date : 2015-11-04

Multi-State : N

Orders : 0

Specialities :

Other Names :

Orders for 2724 - 45

No Orders Found

Relationships for 2724 - 45

Individual

Licens E (/s/)

Home Request Support

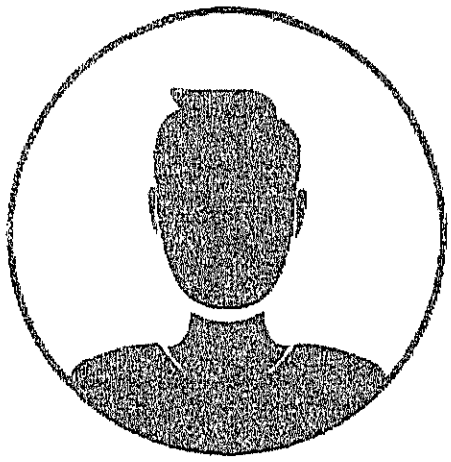
Third Party Document Upload

Application Status Lookup LEAP Login

Provider Login Performance Data

File a Complaint Orders and Disciplinary Actions

License Lookup



DSPS Site Guest User

Credential/License Summary for 2739 - 45 As of December 18, 2024 1:57:20 PM

Name : Fagron Sterile Services, LLC

Credential/License Number : 2739 - 45

Professions : Wholesale Distributor of Prescription Drugs

Location : Wichita, Kansas - 67726

Credential/License Type : Regular

Status : License is current (Active)

Eligible To Practice : Eligible

Credential Expiration Date : 2026-05-31

Granted Date : 2016-01-07

Multi-State : N

Orders : 0

Specialities :

Other Names :

Orders for 2739 - 45

No Orders Found

Relationships for 2739 - 45

Individual

Certificate of Analysis

Fagron personalizing medicine

Product Name	SaltStable LS Advanced	**Manufacturers Information:**	
Item Number	1004499	**Mfg. Batch #**	240232
Inspection Report #	C224-009717	**Ref No.**	2240101369
Batch #	240232	Birchwood Laboratories, Inc.	
Analyzed According to	FAUS	7900 Fuller Road	
Expiration Date	7/31/2026	Eden Prairie, MN 55344	
		USA	

Test Description	Test Result Description	Requirement	Result	Unit	Test Location
Description	Opaque, off-white cream, non-flowable; characteristic odor	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Odor	Characteristic	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
pH	6.0 - 7.5 @ 25ºC	6.0-7.5	6.9	No Unit	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Specific Gravity	@ 25ºC information only, read and report	0.90-1.50	0.97	g/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Viscosity	1000000 - 1400000 @ 25ºC	1,000,000-1,400,000	1,133,333	cP*s	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total aerobic microbial count		0-50	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total yeast and mold count		0-10	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	P. aeruginosa	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	S. aureus	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	B. cepacia	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA

Release Details
Quality Technician: Kendra Borawski
Conclusion Date: 8/16/2024
Conclusion: Approved
This document has been produced electronically from our quality system and is valid without signature.

4200

Certificate of Analysis

HUMCO

Product Name	SaltStable LS Advanced	**Manufacturers Information:**	
		Mfg. Batch #	240232
Item Number	1004499	**Ref No.**	2240101369
Inspection Report #	C224-009717	Birchwood Laboratories, Inc.	
Batch #	240232	7900 Fuller Road	
Analyzed According to	FAUS	Eden Prairie, MN 55344	
Expiration Date	7/31/2026	USA	

Test Description	Test Result Description	Requirement	Result	Unit	Test Location
Description	Opaque, off-white cream, non-flowable; characteristic odor	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Odor	Characteristic	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
pH	6.0 - 7.5 @ 25ºC	6.0-7.5	6.9	No Unit	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Specific Gravity	@ 25ºC information only, read and report	0.90-1.50	0.97	g/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Viscosity	1000000 - 1400000 @ 25ºC	1,000,000-1,400,000	1,133,333	cP*s	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total aerobic microbial count		0-50	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total yeast and mold count		0-10	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	P. aeruginosa	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	S. aureus	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	B. cepacia	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA

Release Details
Quality Technician: Kendra Borawski
Conclusion Date: 8/16/2024
Conclusion: Approved
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Drug Establishments Current Registration Site

New Search

Search Results for *birch*

Showing 1 to 2 of 2 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Birchwood Laboratories LLC	2182825	096488432	MANUFACTURE	7900 Fuller Road, Eden Prairie, Minnesota (MN) 55344, United States (USA)	12/31/2025
Willow Birch Pharma Inc	3009864247	617153924	RELABEL; REPACK	447 County Road 303 Ste B, Taylor, Mississippi (MS) 38673, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Wednesday, Feb 26, 2025

New Search

Facility Name	Facility Type	License Number	License State	License Expiration Date	Reporting Year	Address	Facility Contact Name	Facility Contact Email
ChemRx Pharmacy Services LLC DBA: PharMerica	WDD	039877	US-NY	11-30-2025	2024	12 Interstate Avenue Colonie NY	Susan Reinach	sxr4100@pharmerica.com
Darmerica, LLC DBA: Darmerica, LLC	WDD	2220268	US-FL	05-31-2025	2025	4380 Oakes Rd Ste 800 Davie FL	Kyle Hamza	submission@darmerica.cor
Pharmacy Corporation of America DBA: PharMerica	3PL	02434	US-FL	06-04-2024	2024	4816 Hendron Rd. Groveport OH	Susan Reinach	sxr4100@pharmerica.com
Pharmacy Corporation of America DBA: PharMerica	3PL	94000240A	US-IN	09-30-2024	2024	4816 Hendron Rd. Groveport OH	Susan Reinach	sxr4100@pharmerica.com
Pharmacy Corporation of America DBA: PharMerica	WDD	CSW.0000628	US-CT	06-30-2024	2024	8 Fairfield Blvd. STE. 103 Wallingford CT	Susan Reinach	sxr4100@pharmerica.com
Pharmacy Corporation of America DBA: PharMerica	WDD	PWD-53	US-HI	12-31-2024	2024	1900 Main St. STE.3 Wailuku HI	Susan Reinach	sxr4100@pharmerica.com

Darmerica
4380 Oakes Road, Unit 800
Davie, FL 33314 USA
www.darmerica.com

Certificate of Analysis

Sildenafil Citrate USP

Product Name : Sildenafil Citrate
Mfg. Date : Mar 2024
CAS No. : 171599-83-0
Lot No. : DR8084
Exp. Date : Feb 2029
Batch Qty : 263.16 kg

TESTS	SPECIFICATIONS		RESULTS
Description	White or almost white, slightly hygroscopic, crystalline powder		White, slightly hygroscopic, crystalline powder
Solubility	Slightly soluble in water and in methanol, practically insoluble in hexane		Complies
Identification	IR <197K>		Complies
Limit of Imidazole <621>	≤ 0.10%		< 0.10%
Organic Impurities (HPLC)	Sildenafil Related Compound A	≤ 0.30%	Below Quantification Limit
	Any Other Unspecified Individual Impurity	≤ 0.10%	Below Quantification Limit
	Total Unspecified Impurities	≤ 0.30%	Below Quantification Limit
	Total Impurities	≤ 0.50%	Below Quantification Limit
Water Content (KF) <921> (Method I)	≤ 2.50% w/w		1.40% w/w
Residue on Ignition <281>	≤ 0.10% w/w		0.02% w/w
Assay (On Anhydrous and Solvent-Free Basis) (HPLC) <621>	98.0 – 102.0% w/w		100.4% w/w
Citric Acid Content (Titration) (In-House)	27.5 – 30.5% w/w		28.7% w/w
Residual Solvents	Methanol	≤ 3000 ppm	Not Detected
	Methylene Dichloride	≤ 600 ppm	Not Detected
	Triethyl Amine (GC)	≤ 320 ppm	Below Quantification Limit
X-Ray Diffraction (In-House)	X-Ray diffraction pattern of test sample should match with 2θ value - 8.08, 10.29, 14.40, 19.87, 22.66 ± 0.2.		Complies
Conclusion: The product meets the USP Monograph specifications. Long Term Storage: Store in a sealed container at room temperature. ID Test was confirmed by FT-IR on-site. Distributed by Darmerica.			

Note: Analytical results transcribed from the original COA provided by Amoli Organics (A Division of Umedica Laboratories Pvt. Ltd.) (Luna) (India); Lot No. B24410H021.

Based on the review of above information, the lot stands released.

	Name	Title	Signature	Date
Prepared by	Christina Boykin	Quality Supervisor		05/30/2024
Released by	Faiz Badrudeen	Quality Associate		06/03/2024

DARMERICA

PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

Product Information			
Legend Drug Name, Strength, NDC, Dosage Form, Container Size	Sildenafil Citrate USP - 100 g NDC: 71052-067-01	Lot #DR8084	Total Qty: 300 g
Manufacturer Name and Address	Amoli Organics Pvt Ltd. (Location 1) (LUNA), Block No. 422. ECP Canal Road, Village-Luna, Taluka-Padra, Vadodara, GUJARAT 391440, India		
Legend Drug Name, Strength, NDC, Dosage Form, Container Size	Tadalafil USP - 50 g NDC: 71052-059-08	Lot #: DR7958	Total Qty: 50 g
Manufacturer Name and Address	Malthili Life Sciences Private Limited Plot No. 2, APIIC Industrial Estate, Gajulamandyam Village Renigunta Mandal, Tirupati, Tirupati, Andhra Pradesh 517520, India (IND)		

Transaction Information			
Shipping Date	11/20/2024	**Invoice #**	71040
Seller Name and Address	Darmerica LLC, 4380 Oakes Rd, Unit 800, Davie, FL 33314, USA		
Buyer Name and Address	Synergy Apothecary 10101 W. Innovation Dr, #600 Wauwatosa, WI 53226 USA		

Transaction History	
Shipper Name and Address	Darmerica LLC, 4380 Oakes Rd, Unit 800, Davie, FL 33314, USA; Fl Wholesale License No.: 2220268
Receiver Name and Address	Synergy Apothecary 10101 W. Innovation Dr, #600 Wauwatosa, WI 53226 USA

Transaction Statement
☑ (A) Is authorized as required under the Drug Supply Chain.
☑ (B) Received the product from a person that is authorized as required under the Drug Supply Chain Security Act.
☑ (C) Received transaction in formation and a transaction statement from the prior owner of the product, as required under section 582.
☑ (D) Did not knowingly ship a suspect or illegitimate product.
☑ (E) Had systems and processes in place to comply with verification requirements under section 582.
☑ (F) Did not knowingly provide false transaction information.
☑ (G) Did not knowingly alter the transaction history.

Darmerica LLC

Name of Authenticator: Fabrizio Mora

Signature of Authenticator:

Telephone Number: 321-219-9111

Email address: operations@darmerica.com

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Drug Establishments Current Registration Site

New Search

Dermerica CofA

Search Results for *amoli*

Showing 1 to 2 of 2 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Amoli Organics (A Division of Umedica Laboratories Pvt.Ltd)	3004810446	862234820	ANALYSIS; API MANUFACTURE	Plot 322/4, 40 Shed Area, G.I.D.C. Vapi District, GIDC VAPI, Valsad, GUJARAT 396195, India (IND)	12/31/2025
Amoli Organics (A Division of Umedica Laboratories Pvt.Ltd.)	3007836955	918610077	ANALYSIS; API MANUFACTURE	Block No. 422, ECP Canal Road Village-Luna, Taluka-Padra, Vadodara, Gujarat 391440, India (IND)	12/31/2025

Previous 1 Next

Data Current Through: Tuesday, Feb 25, 2025

New Search

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Drug Establishments Current Registration Site

New Search

Davmenca CofA

Search Results for *maith*

Showing 1 to 3 of 3 entries

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Maithili Life Sciences Private Limited	3017864048	872295061	API MANUFACTURE	Plot No. 2, APIIC Industrial Estate, Gajulamandyam Village Renigunta Mandal, Tirupati, Tirupati, Andhra Pradesh 517520, India (IND)	12/31/2025
Maithri Drugs Private Limited	3012234942	650843621	ANALYSIS; API MANUFACTURE	Sy. No. 205, 222 to 226, IDA Bonthapally, Bonthapally (Village), Gummadidala (Mandal),, Sangareddy District, Telangana 502313, India (IND)	12/31/2025
Maithri Laboratories Private Limited	3007800082	675870897	ANALYSIS; API MANUFACTURE	Sy.No. 10/1 & 14, IDA Gaddapotharam, Gaddapotharam (Village), Jinnaram (Mandal),, Sangareddy District,, Telangana 502319, India (IND)	12/31/2025

Licens E (/s/)

Home Request Support

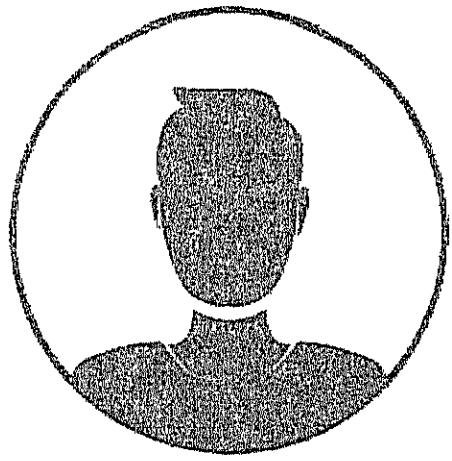
Third Party Document Upload

Application Status Lookup LEAP Login

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File a Complaint Orders and Disciplinary Actions

License Lookup



DSPS Site Guest User

Credential/License Summary for 10053 - 45

As of February 24, 2025 3:03:17 PM

Name : DARMERICA LLC

Credential/License Number : 10053 - 45

Professions : Wholesale Distributor of Prescription Drugs

Location : Davie, Florida - 33314

Credential/License Type : Regular

Status : License is current (Active)

Eligible To Practice : Eligible

Credential Expiration Date : 2026-05-31

Granted Date : 2023-10-17

Multi-State : N

Orders : 0

Specialities :

Other Names :

Orders for 10053 - 45

No Orders Found

Relationships for 10053 - 45

Individual

NABP ACCREDITED

DRUG DISTRIBUTOR

Safeway Distributors Inc (AKA Darmerica)

located at

15851 SW 41st St, Ste 500, Davie, FL 33331

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Carmen A. Catizone, MS, RPh, DPh
Executive Director/Secretary

04/17/2019 - 04/16/2022
Period of Accreditation

Facility Name	Facility Type	License Number	License State	License Expiration Date	Reporting Year	Address	Fa Co Na
						Plattsburgh NY	
MEDISCA Inc.	WDD	5317	US-SC	06-30-2024	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	600-0378	US-SD	12-31-2024	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	0000001188	US-TN	02-28-2025	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	0038334	US-TX	02-09-2025	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	163.0000446	US-VT	07-31-2025	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	PHWH.FX.00055948	US-WA	09-30-2024	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	906-45	US-WI	05-31-2024	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	WD0557518	US-WV	06-30-2024	2024	661 Route 3 Unit C Plattsburgh NY	Be Art
MEDISCA Inc.	WDD	1455	US-WY	06-30-2024	2024	661 Route 3 Unit C Plattsburgh NY	Be Art

Medisca®

CERTIFICATE OF ANALYSIS

VERSAPRO™ CREAM BASE

Batch/Lot Number : 208012

Manufacturing Date : 01/13/2024

Expiration Date : 12/31/2025

CAS: N/A

TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	White, smooth, shiny, viscous cream. Is odorless.	CONFORMS
SPECIFIC GRAVITY	0.96 - 1.10 (25°C)	0.99
pH	4.25 - 5.50 (25°C)	4.82
TOTAL AEROBIC MICROBIAL COUNT <61>	≤ 100 cfu/g	< 10 cfu/g
TOTAL YEAST & MOLD <61>	≤ 10 cfu/g	< 10 cfu/g
ABSENCE OF SPECIFIED MICROORGANISMS <62>	Meets the requirements for the absence of: • Staphylococcus aureus • Pseudomonas aeruginosa • Candida albicans • Bile tolerant gram negative bacteria	CONFORMS
ABSENCE OF SPECIFIED MICROORGANISMS <60>	Meets the requirements for the absence of: • Burkholderia cepacia	CONFORMS
GRAM POSITIVE	Absent.	CONFORMS
PACKAGING AND STORAGE	Keep in well-closed containers at controlled room temperature.	

Lot number has been changed from ZA278 to 208012.

PUBLISHED BY:

PUBLISHED DATE:
03/22/2024

ISSUE DATE:
03/22/2024

The above mentioned product conforms to the manufacturer's specifications.

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk.

All dates in this document are in format mm/dd/yyyy unless otherwise specified

This document has been electronically approved through MEDISCA's Quality Management System.

4212

Englewood LAB
FDA LICENSE/REGISTRATION # 3013020160 | ISO INTERNATIONAL STANDARD 22716:2007

20 CAMPUS RD TOTOWA, NJ 07512 USA
Tel: 201-567-2267 Fax: 201-567-2280

MICROBIOLOGICAL CERTIFICATE OF ANALYSIS

QC LAB - CHAIN OF CUSTODY FORM AND REPORT BULK/FG/WIP — Microbiological Certificate of Analysis — QBK24-00129-001-MCI-001

EWL Micro Lab Reference Number	Product Type: Bulk, FG, WIP	CUSTOMER	PRODUCT NAME	LOT #	BATCH #	PRODUCTION DATE	SIZE QUANTITY	Comments	Test Method
	BULK	MEDISCA	BK102179 / VERSAPRO CREAM BASE (REFORM 3) / 137146	N/A	ZA278	01/13/2024	4 FL.OZ 1 BULK	N/A	USP-60, USP-61, USP-62

Submission By: AL Date : 1-15-24 24
A 1-15-24

Note 1: All Supplier/Vendor Materials that require Micro, CoA must be attached.
Note 2: Requestor must attach product specification sheet.

Microbiology Lab Only: Date Received: 1/15/24 Initial: JR

Test Method:

Microbiological Analysis

No.	TPC	Gram Stain			Results								
	Count (CFU/g or ml)	g-	g+B	g+C	Yeast/Mold Count (CFU/g or ml)	EC	PA	SA	Salmonella	Clostridia	Candida Albicans	BCC	Coliform
1	<10 CFU/g		N A TK 01/20/2024		<10 CFU/g	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☐NG ☑G
2						☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G
3					N A TK 01/20/2024	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☑NG ☐G

Abbreviations: g-: gram-negative; g+B: gram-positive Bacilli; g+C: gram-positive Cocci; TPC: Total Plate Count; TNTC: Too Numerous to Count; EC: E coli; PA: Pseudomonas aeroginosa; SA: Staphylococcus aureus; BCC: B.Cepacia; G= Growth; NG = No Growth

Test Results Recorded by: Initial TK Date: 01/20/2024

Reviewed and Approved by: Initial LC Date : 01/20/2024

Comment (For Microbiology Lab Use Only): MA TK 01/20/2024

englewoodLAB
WWW.ENGLEWOODLAB.COM

20 Campus Road, Totowa, NJ 07512 • Phone: 201-567-2267 • Fax: 201-567-2280

CERTIFICATE OF ANALYSIS

Product: VERSAPRO CREAM BASE (REFORM 3) –MEDISCA FORMULA # RD010919-6
Customer: MEDISCA
Batch Code: ZA278
Formula Code: 170-18249-04 Rev 5
Batch Size: 2,000 KG
Compounding Date: 01/13/2024
2 Year Expiration Date: 01/13/2026

TEST	TEST METHOD (SOP)	SPECIFICATIONS	RESULTS
APPEARANCE	6-006	SMOOTH, SHINY, VISCOUS CREAM TO MATCH STANDARD	T- PASS B-PASS
COLOR	6-006	WHITE TO MATCH STANDARD	T- PASS B- PASS
SCENT	6-005	ODORLESS (NO FRAG. ADDED) TO MATCH STANDARD	T- PASS B- PASS
pH	6-001	4.25 - 5.50 (DIRECT, @ 25°C)	T-4.82 B-4.86
SPECIFIC GRAVITY	6-002	0.96 - 1.10 (PYCNOMETER, @ 25°C)	T-0.99 B-0.99
SOLUBILITY	N/A	PARTIALLY SOLUBLE IN WATER	T-PASS B-PASS
VISCOSITY	6-003	INITIAL: BROOKFIELD RVDV-1/RVT, SPINDLE T-D AT 2.5 RPM FOR 1 MINUTE @25°C 250,000 TO 400,000 CPS *VISCOSITY DIFFERENCE BETWEEN TOP & BOTTOM SAMPLE SHOULD NOT BE GREATER THAN 50,000 CPS*	T-349,000 CPS B-355,300 CPS
			6,300 CPS
		AFTER 24HOURS: BROOKFIELD RVDV-1/RVT, SPINDLE T-D AT 2.5 RPM FOR 1 MINUTE @25°C 250,000 TO 400,000 CPS *VISCOSITY DIFFERENCE BETWEEN TOP & BOTTOM SAMPLE SHOULD NOT BE GREATER THAN 50,000 CPS*	T-360,000 CPS M-383,400 CPS B-380,600 CPS
			20,600 CPS
		(1 WEEK; INFORMATIONAL) BROOKFIELD RVT T-D AT 2.5 RPM FOR 1 MINUTE @ 25C	*381,000 CPS*
MICROBIAL CONTENT TEST	USP <60> USP<61> USP<62>	TOTAL PLATE COUNT (TPC) <100 CFU/G OR ML YEAST & MOLD <10 CFU/G OR ML GRAM NEGATIVE: ABSENT ABSENT OF PATHOGENS INCLUDING: STAPHYLOCOCCUS AUREUS, PSUEDOMONAS AERUGINOSA, CANDIDA ALBICANS, BURKHOLDERIA CEPACIA AND BILE-TOLERANT GRAM - NEGATIVE BACTERIA GRAM POSITIVE:: ABSENT	*PASS (01/20/2024)*
PACKAGING AND STORAGE	N/A	STORE AT CONTROLLED ROOM TEMPERATURE	*INFORMATIONAL ONLY*

Note 1: Samples were tested by an approved Lab.

Results recorded by: Alejandra Lopez Date: 1-21-24

Quality manager or designee Approved by: Juan Cuzmar Date: 1/26/2024

NO. 2770 - 45

EXPIRES: 05/31/2026

The State of Wisconsin
Department of Safety and Professional Services
PHARMACY EXAMINING BOARD

Hereby certifies that

Medisca Inc

was granted a license to practice as a

WHOLESALE DISTRIBUTOR OF PRESCRIPTION DRUGS

in the State of Wisconsin in accordance with Wisconsin Law
on the 27th day of April in the year 2016
The authority granted herein must be renewed each biennium by the granting authority.
In witness thereof, the State of Wisconsin
Pharmacy Examining Board
has caused this certificate to be issued under
the seal of the Department of Safety and Professional Services

DSPS Secretary

Chairperson

Secretary

This certificate was printed on the 6th day of May in the year 2024

4214

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Wholesale Distributor and Third-Party Logistics Provider Reporting

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Search Results for *"top rx"*

Showing 1 to 1 of 1 entries Show 50 entries

Facility Name	Facility Type	License Number	License State	License Expiration Date	Reporting Year	Address	Facility Contact Name	Facility Contact Email
Top Rx, LLC	WDD	2669-45	US-WI	05-31-2024	2025	2950 Brother Boulevard Bartlett TN	John Richardson	j.richardson@toprx.com

Verified as active 5/31/25

Previous 1 Next

Licens ((s))

Home Request Support

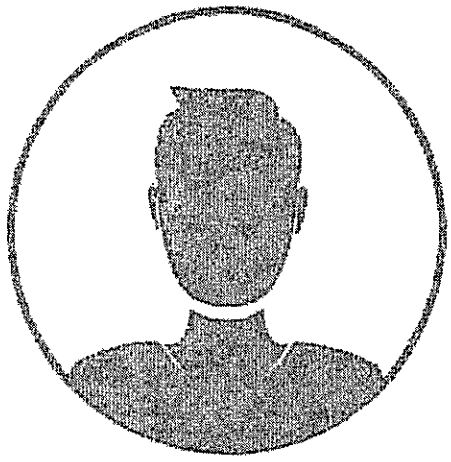
Third Party Document Upload

Application Status Lookup LEAP Login

Provider Login Performance Data

File a Complaint Orders and Disciplinary Actions

License Lookup



DSPS Site Guest User

Credential/License Summary for 2669 - 45

As of December 18, 2024 1:59:54 PM

Name : Top Rx LLC

Credential/License Number : 2669 - 45

Professions : Wholesale Distributor of Prescription Drugs

Location : Bartlett, Tennessee - 38133

Credential/License Type : Regular

Status : License is current (Active)

Eligible To Practice : Eligible

Credential Expiration Date : 2026-05-31

Granted Date : 2015-04-29

Multi-State : N

Orders : 0

Specialities :

Other Names :

Orders for 2669 - 45

No Orders Found

Relationships for 2669 - 45

Individual

NABP ACCREDITED

DRUG DISTRIBUTOR

Top Rx, LLC

located at

2950 Brother Blvd, Bartlett, TN, 38133

This business has met all the drug distributor criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the drug distributor section on the NABP website, located at: www.nabp.pharmacy/programs/drug-distributor/accredited-facilities/.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

02/23/2022 to 02/22/2025

Period of Accreditation

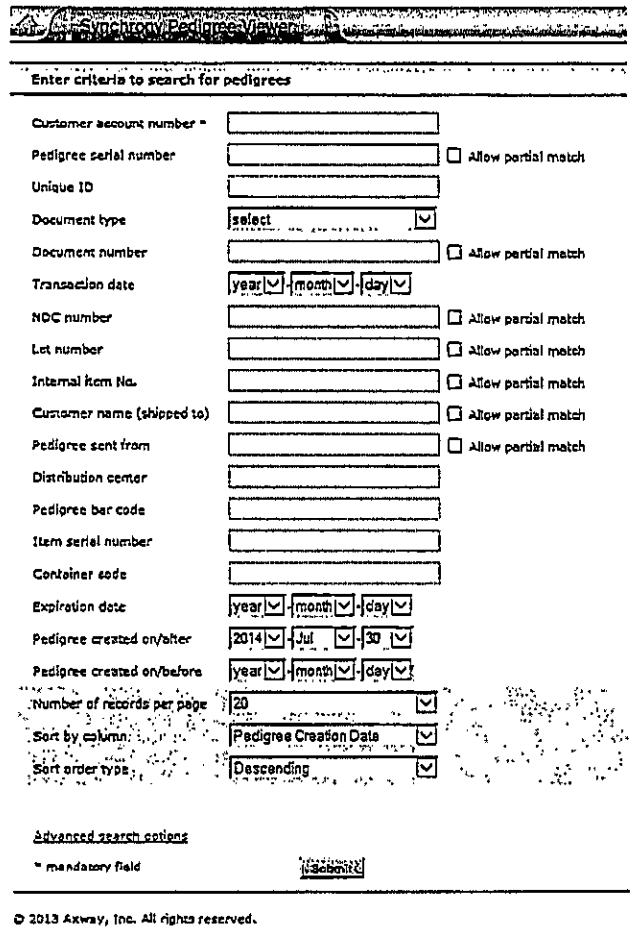
Login ⊕ Sample

All new accounts will have their Pedigree login and password established the next business day. New accounts will use the same login and password scheme as current customers.

result of E-pedigree

Login: Account #
Password: Billing zip Code

Contact Dave Hoffman at pedigree@toprx.net if you encounter any problems.



Once you have successfully logged in, you will see a screen similar to the one above. Enter criteria to match the pedigree(s) you are searching for, and press the "Submit" button at the bottom of the page.

Epedigree samples 1/4

Last sold by	TOP RX LLC
Pedigree serial number	um:uuid:ff410821-e56e-4828-b195-0e6751ccd0bc

MUPIROCIN OINT 2%

Product information

Manufacturer name	TARO		
Drug name	MUPIROCIN OINT 2%		
Strength	2 %	**Dosage form**	OINTMENT
Container size	22 GM	**NDC**	51672131200

TOP RX LLC sent following items to SYNERGY APOTHECARY

Lot number	Quantity	Expiration date
AD66182	4	2026-02-28

Reference No.	Type	Reference date
9633229	Invoice	2024-11-29

History of drug sales and distribution

TOP RX LLC Sells To SYNERGY APOTHECARY

Seller name	TOP RX LLC
Business address	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
Shipping name	TOP RX LLC
Shipping address	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
License number	RT0474217|2669-45
Electronically signed as 'Certified' by	Anne Tetreault Compliance 800-542-8677 a.tetreault@toprx.net www.toprx.com
Electronic signature digest	r0TcB7PUpsKcrGZDOg7x8AEAN3Q=
Invoice Number	9633229
Date	2024-11-29
Transaction	Sale
To authenticate this Sale contact:	
Name	Anne Tetreault
Title	Compliance
Telephone	800-542-8677
E-mail	a.tetreault@toprx.net
Url	www.toprx.com

Recipient name	SYNERGY APOTHECARY
Business address	10101 WEST INNOVATION DR STE 600 WAUWATOSA, WI, 53226, USA
Shipping name	SYNERGY APOTHECARY LLC
Shipping address	10101 WEST INNOVATION DRIVE SUITE 600 WAUWATOSA, WI, 53226, US
License number	

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TARO PHARMACEUTICALS U.S.A.INC Sells To TopRx LLC

2/4

Seller name	TARO PHARMACEUTICALS U.S.A.INC	**Recipient name**	TopRx LLC
Business address	ONE COMMERCE DRIVE CRANBURY, NJ, 08512, USA	**Business address**	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
Shipping name	TARO PHARMACEUTICALS U.S.A.INC	**Shipping name**	TopRx LLC
Shipping address	ONE COMMERCE DRIVE CRANBURY, NJ, 08512, USA	**Shipping address**	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
License number	RT0504870	**License number**	RT0474217
PO Number	8114965	**Date received**	2024-11-22
Date	2024-11-22	**Electronically signed as 'Received' by**	Anne Tetreault 800-542-8677 a.tetreault@toprx.com
Transaction	Sale		
To authenticate this Sale contact:			
Name	TARO PHARMACEUTICALS U.S.A.INC	**Electronic signature digest**	zL2fBwyWmkkBY3/RnFErbSk8QAc=
Telephone	800-544-1449		

Transaction Statement:
Top Rx has complied with each applicable subsection of FDCA Sec. 581(27)(A)-(G).

Direct Purchase Statement:
For generic items, Top Rx purchased this product directly from the manufacturer, an exclusive distributor of the manufacturer, or a repackager that purchased the product directly from the manufacturer. For brand items, Top Rx purchased this product from a distributor who was provided with a Direct Purchase Statement for the item.

Electronically Signed (See electronic signature digest in history of sales above)	Anne Tetreault, Compliance	12-02-2024
Signature(authorized to bind the company)	Print Name and Title	Date

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Last sold by	TOP RX LLC
Pedigree serial number	urn:uuid:3530ef43-ea49-4b99-98dd-dd1a5c83e3a9

ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT

314

Product information

Manufacturer name	HIKMA PHARMACEUTICALS USA		
Drug name	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT		
Strength	108 MCG/ACT	Dosage form	AEROSOL
Container size	6.7 GM	NDC	00054074287

TOP RX LLC sent following items to SYNERGY APOTHECARY

Lot number	Quantity	Expiration date
NS7728	1	2026-02-28

Reference No.	Type	Reference date
9633229	Invoice	2024-11-29

History of drug sales and distribution

TOP RX LLC Sells To SYNERGY APOTHECARY

Seller name	TOP RX LLC
Business address	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
Shipping name	TOP RX LLC
Shipping address	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
License number	RT0474217|2669-45
Electronically signed as 'Certified' by	Anne Tetreault Compliance 800-542-8677 a.tetreault@toprx.net www.toprx.com
Electronic signature digest	fAIKjN75cc0N06egoyJpEeySoBc=
Invoice Number	9633229
Date	2024-11-29
Transaction	Sale
To authenticate this Sale contact:	
Name	Anne Tetreault
Title	Compliance
Telephone	800-542-8677
E-mail	a.tetreault@toprx.net
Url	www.toprx.com

Recipient name	SYNERGY APOTHECARY
Business address	10101 WEST INNOVATION DR STE 600 WAUWATOSA, WI, 53226, USA
Shipping name	SYNERGY APOTHECARY LLC
Shipping address	10101 WEST INNOVATION DRIVE SUITE 600 WAUWATOSA, WI, 53226, US
License number	

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Last sold by	TOP RX LLC
Pedigree serial number	urn:uuid:3530ef43-ea49-4b99-98dd-dd1a5c83e3a9

ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT

Product Information

Manufacturer name	HIKMA PHARMACEUTICALS USA		
Drug name	ALBUTEROL SULFATE INHAL AERO 108 MCG/ACT		
Strength	108 MCG/ACT	**Dosage form**	AEROSOL
Container size	6.7 GM	**NDC**	00054074287

TOP RX LLC sent following items to SYNERGY APOTHECARY

Lot number	Quantity	Expiration date
NS7728	1	2026-02-28

Reference No.	Type	Reference date
9633229	Invoice	2024-11-29

History of drug sales and distribution

TOP RX LLC Sells To SYNERGY APOTHECARY

Seller name	TOP RX LLC
Business address	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
Shipping name	TOP RX LLC
Shipping address	2950 BROTHER BLVD BARTLETT, TN, 38133, USA
License number	RT0474217|2669-45
Electronically signed as 'Certified' by	Anne Tetreault Compliance 800-542-8677 a.tetreault@toprx.net www.toprx.com
Electronic signature digest	fAIKjN75cc0N06egoyJpEeySoBc=
Invoice Number	9633229
Date	2024-11-29
Transaction	Sale
To authenticate this Sale contact:	
Name	Anne Tetreault
Title	Compliance
Telephone	800-542-8677
E-mail	a.tetreault@toprx.net
Url	www.toprx.com

Recipient name	SYNERGY APOTHECARY
Business address	10101 WEST INNOVATION DR STE 600 WAUWATOSA, WI, 53226, USA
Shipping name	SYNERGY APOTHECARY LLC
Shipping address	10101 WEST INNOVATION DRIVE SUITE 600 WAUWATOSA, WI, 53226, US
License number	

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Quality Information/Intelligence System (QIS)

Supply Chain

- APIs are sourced only from FDA-registered manufacturers
- Advanced in-house analysis performed in fully- equipped laboratory
- Full compendial testing for each API from each and identification tests on every lot of material
- Identification testing on every repackaged lot, before shipment to customers

Distribution Quality

Employee Safety

Certificate of Analysis

Fagron personalizing medicine

Product Name	SaltStable LS Advanced	**Manufacturers Information:**	
Item Number	1004499	**Mfg. Batch #**	240232
Inspection Report #	C224-009717	**Ref No.**	2240101369
Batch #	240232	Birchwood Laboratories, Inc.	
Analyzed According to	FAUS	7900 Fuller Road	
Expiration Date	7/31/2026	Eden Prairie, MN 55344	
		USA	

Test Description	Test Result Description	Requirement	Result	Unit	Test Location
Description	Opaque, off-white cream, non-flowable; characteristic odor	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Odor	Characteristic	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
pH	6.0 - 7.5 @ 25ºC	6.0-7.5	6.9	No Unit	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Specific Gravity	@ 25ºC information only, read and report	0.90-1.50	0.97	g/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Viscosity	1000000 - 1400000 @ 25ºC	1,000,000-1,400,000	1,133,333	cP*s	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total aerobic microbial count		0-50	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total yeast and mold count		0-10	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	P. aeruginosa	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	S. aureus	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	B. cepacia	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA

Release Details
Quality Technician: Kendra Borawski
Conclusion Date: 8/16/2024
Conclusion: Approved
This document has been produced electronically from our quality system and is valid without signature.

Certificate of Analysis

HUMCO

Product Name	SaltStable LS Advanced	**Manufacturers Information:**	
		Mfg. Batch #	240232
Item Number	1004499	**Ref No.**	2240101369
Inspection Report #	C224-009717	Birchwood Laboratories, Inc.	
Batch #	240232	7900 Fuller Road	
Analyzed According to	FAUS	Eden Prairie, MN 55344	
Expiration Date	7/31/2026	USA	

Test Description	Test Result Description	Requirement	Result	Unit	Test Location
Description	Opaque, off-white cream, non-flowable; characteristic odor	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Odor	Characteristic	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
pH	6.0 - 7.5 @ 25ºC	6.0-7.5	6.9	No Unit	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Specific Gravity	@ 25ºC Information only, read and report	0.90-1.50	0.97	g/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Viscosity	1000000 - 1400000 @ 25ºC	1,000,000-1,400,000	1,133,333	cP*s	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total aerobic microbial count		0-50	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total yeast and mold count		0-10	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	P. aeruginosa	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	S. aureus	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	B. cepacia	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA

Release Details
Quality Technician: Kendra Borawski
Conclusion Date: 8/16/2024
Conclusion: Approved
This document has been produced electronically from our quality system and is valid without signature.

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Drug Establishments Current Registration Site

New Search

Search Results for *birch*

Showing 1 to 2 of 2 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Birchwood Laboratories LLC	2182825	096488432	MANUFACTURE	7900 Fuller Road, Eden Prairie, Minnesota (MN) 55344, United States (USA)	12/31/2025
Willow Birch Pharma Inc	3009864247	617153924	RELABEL; REPACK	447 County Road 303 Ste B, Taylor, Mississippi (MS) 38673, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Wednesday, Feb 26, 2025

New Search

Darmerica
4380 Oakes Road, Unit 800
Davie, FL 33314 USA
www.darmerica.com

Certificate of Analysis

Sildenafil Citrate USP

Product Name : Sildenafil Citrate
Mfg. Date : Mar 2024
CAS No. : 171599-83-0

Lot No. : DR8084
Exp. Date : Feb 2029
Batch Qty : 263.16 kg

TESTS	SPECIFICATIONS		RESULTS
Description	White or almost white, slightly hygroscopic, crystalline powder		White, slightly hygroscopic, crystalline powder
Solubility	Slightly soluble in water and in methanol, practically insoluble in hexane		Complies
Identification	IR <197K>		Complies
Limit of Imidazole <621>	≤ 0.10%		< 0.10%
Organic Impurities (HPLC)	Sildenafil Related Compound A	≤ 0.30%	Below Quantification Limit
	Any Other Unspecified Individual Impurity	≤ 0.10%	Below Quantification Limit
	Total Unspecified Impurities	≤ 0.30%	Below Quantification Limit
	Total Impurities	≤ 0.50%	Below Quantification Limit
Water Content (KF) <921> (Method I)	≤ 2.60% w/w		1.40% w/w
Residue on Ignition <281>	≤ 0.10% w/w		0.02% w/w
Assay (On Anhydrous and Solvent-Free Basis) (HPLC) <621>	98.0 – 102.0% w/w		100.4% w/w
Citric Acid Content (Titration) (In-House)	27.5 – 30.5% w/w		28.7% w/w
Residual Solvents	Methanol	≤ 3000 ppm	Not Detected
	Methylene Dichloride	≤ 600 ppm	Not Detected
	Triethyl Amine (GC)	≤ 320 ppm	Below Quantification Limit
X-Ray Diffraction (In-House)	X-Ray diffraction pattern of test sample should match with 2θ value - 8.08, 10.29, 14.40, 19.87, 22.66 ± 0.2.		Complies
Conclusion: The product meets the USP Monograph specifications. Long Term Storage: Store in a sealed container at room temperature. ID Test was confirmed by FT-IR on-site. Distributed by Darmerica.			

Note: Analytical results transcribed from the original COA provided by Amoli Organics (A Division of Umedica Laboratories Pvt. Ltd.) (Luna) (India); Lot No. B24410H021.

Based on the review of above information, the lot stands released.

	Name	Title	Signature	Date
Prepared by	Christina Boykin	Quality Supervisor		05/30/2024
Released by	Faiz Badrudeen	Quality Associate		06/03/2024

DARMERICA

PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

Product Information			
Legend Drug Name, Strength, NDC, Dosage Form, Container Size	Sildenafil Citrate USP - 100 g NDC: 71052-067-01	Lot #DR8084	Total Qty: 300 g
Manufacturer Name and Address	Amoli Organics Pvt Ltd. (Location 1) (LUNA), Block No. 422. ECP Canal Road, Village-Luna, Taluka-Padra, Vadodara, GUJARAT 391440, India		
Legend Drug Name, Strength, NDC, Dosage Form, Container Size	Tadalafil USP - 50 g NDC: 71052-059-08	Lot #: DR7958	Total Qty: 50 g
Manufacturer Name and Address	Maithili Life Sciences Private Limited Plot No. 2, APIIC Industrial Estate, Gajulamandyam Village Renigunta Mandal, Tirupati, Tirupati, Andhra Pradesh 517520, India (IND)		

Transaction Information			
Shipping Date	11/20/2024	Invoice #	71040
Seller Name and Address	Darmerica LLC, 4380 Oakes Rd, Unit 800, Davie, FL 33314, USA		
Buyer Name and Address	Synergy Apothecary 10101 W. Innovation Dr, #600 Wauwatosa, WI 53226 USA		

Transaction History	
Shipper Name and Address	Darmerica LLC, 4380 Oakes Rd, Unit 800, Davie, FL 33314, USA; Fl Wholesale License No.: 2220268
Receiver Name and Address	Synergy Apothecary 10101 W. Innovation Dr, #600 Wauwatosa, WI 53226 USA

Transaction Statement
☑ (A) Is authorized as required under the Drug Supply Chain.
☑ (B) Received the product from a person that is authorized as required under the Drug Supply Chain Security Act.
☑ (C) Received transaction in formation and a transaction statement from the prior owner of the product, as required under section 582.
☑ (D) Did not knowingly ship a suspect or illegitimate product.
☑ (E) Had systems and processes in place to comply with verification requirements under section 582.
☑ (F) Did not knowingly provide false transaction information.
☑ (G) Did not knowingly alter the transaction history.

Darmerica LLC

Name of Authenticator: Fabrizio Mora

Signature of Authenticator:

Telephone Number: 321-219-9111

Email address: operations@darmerica.com

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Drug Establishments Current Registration Site

New Search

Dominica CofA

Search Results for *amoli*

Showing 1 to 2 of 2 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Amoli Organics (A Division of Umedica Laboratories Pvt.Ltd)	3004810446	862234820	ANALYSIS; API MANUFACTURE	Plot 322/4, 40 Shed Area, G.I.D.C, Vapi, District, GIDC VAPI, Valsad, GUJARAT 396195, India (IND)	12/31/2025
Amoli Organics (A Division of Umedica Laboratories Pvt.Ltd.)	3007836955	918610077	ANALYSIS; API MANUFACTURE	Block No. 422, ECP Canal Road Village-Luna, Taluka-Padra, Vadodara, Gujarat 391440, India (IND)	12/31/2025

Previous 1 Next

Data Current Through: Tuesday, Feb 25, 2025

New Search

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Drug Establishments Current Registration Site

New Search

Darmenca Cofa

Search Results for *maith*

Showing 1 to 3 of 3 entries

Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Maithili Life Sciences Private Limited	3017864048	872295061	API MANUFACTURE	Plot No. 2, APIIC Industrial Estate,. Gajulamandyam Village Renigunta Mandal, Tirupati, Tirupati, Andhra Pradesh 517520, India (IND)	12/31/2025
Maithri Drugs Private Limited	3012234942	650843621	ANALYSIS; API MANUFACTURE	Sy. No. 205, 222 to 226, IDA Bonthapally, Bonthapally (Village), Gummadidala (Mandal),, Sangareddy District, Telangana 502313, India (IND)	12/31/2025
Maithri Laboratories Private Limited	3007800082	675870897	ANALYSIS; API MANUFACTURE	Sy.No. 10/1 & 14, IDA Gaddapotharam, Gaddapotharam (Village), Jinnaram (Mandal),, Sangareddy District,, Telangana 502319, India (IND)	12/31/2025

Medisca®

CERTIFICATE OF ANALYSIS

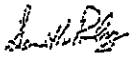
VERSAPRO™ CREAM BASE

Batch/Lot Number :	208012
Manufacturing Date :	01/13/2024
Expiration Date :	12/31/2025
CAS:	N/A

TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	White, smooth, shiny, viscous cream. Is odorless.	CONFORMS
SPECIFIC GRAVITY	0.96 - 1.10 (25°C)	0.99
pH	4.25 - 5.50 (25°C)	4.82
TOTAL AEROBIC MICROBIAL COUNT <61>	≤ 100 cfu/g	< 10 cfu/g
TOTAL YEAST & MOLD <61>	≤ 10 cfu/g	< 10 cfu/g
ABSENCE OF SPECIFIED MICROORGANISMS <62>	Meets the requirements for the absence of: • Staphylococcus aureus • Pseudomonas aeruginosa • Candida albicans • Bile tolerant gram negative bacteria	CONFORMS
ABSENCE OF SPECIFIED MICROORGANISMS <60>	Meets the requirements for the absence of: • Burkholderia cepacia	CONFORMS
GRAM POSITIVE	Absent.	CONFORMS
"PACKAGING AND STORAGE"	Keep in well-closed containers at controlled room temperature.	

Lot number has been changed from ZA278 to 208012.

PUBLISHED BY:



PUBLISHED DATE:

03/22/2024

ISSUE DATE:

03/22/2024

The above mentioned product conforms to the manufacturer's specifications.

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk.

All dates in this document are in format mm/dd/yyyy unless otherwise specified

This document has been electronically approved through MEDISCA's Quality Management System.

4232

Englewood LAB
FDA LICENSE/REGISTRATION # 3013020160 | ISO INTERNATIONAL STANDARD 22716:2007
20 CAMPUS RD TOTOWA, NJ 07512 USA
Tel: 201-567-2267 Fax: 201-567-2280

MICROBIOLOGICAL CERTIFICATE OF ANALYSIS

QC LAB - CHAIN OF CUSTODY FORM AND REPORT BULK/FG/WIP — Microbiological Certificate of Analysis — QBK24-00129-001-MCI-001

EWL Micro Lab Reference Number	Product Type: Bulk, FG, WIP	CUSTOMER	PRODUCT NAME	LOT #	BATCH #	PRODUCTION DATE	SIZE QUANTITY	Comments	Test Method
	BULK	MEDISCA	BK102179 / VERSAPRO CREAM BASE (REFORM 3) / 137146	N/A	ZA278	01/13/2024	4 FL.OZ 1 BULK	N/A	USP-60, USP-61, USP-62

Submission By: AL Date: 1-15-24 29 A 1-15-24

Note 1: All Supplier/Vendor Materials that require Micro, CoA must be attached.
Note 2: Requestor must attach product specification sheet.

Microbiology Lab Only: Date Received: 1/15/24 Initial: JR

Test Method:

Microbiological Analysis

No.	TPC	Gram Stain			Results								
	Count (CFU/g or ml)	g-	g+B	g+C	Yeast/Mold Count (CFU/g or ml)	EC	PA	SA	Salmonella	Clostridia	Candida Albicans	BCC	Coliform
1	<10 CFU/g		N TK 01/20/2024		<10 CFU/g	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☐NG ☑G
2						☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G
3					N TK 01/20/2024	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☑NG ☐G 1/21/24

Abbreviations: g-: gram-negative; g+B: gram-positive Bacilli; g+C: gram-positive Cocci; TPC: Total Plate Count; TNTC: Too Numerous to Count; EC: E coli; PA: Pseudomonas aeruginosa; SA: Staphylococcus aureus; BCC: B.Cepacia; G= Growth; NG = No Growth

Test Results Recorded by: Initial TK Date: 01/20/2024

Reviewed and Approved by: Initial LC Date: 01/20/2024

Comment (For Microbiology Lab Use Only): N/A TK 01/20/2024

englewoodLAB
WWW.ENGLEWOODLAB.COM

20 Campus Road, Totowa, NJ 07512 • Phone: 201-567-2267 • Fax: 201-567-2280

CERTIFICATE OF ANALYSIS

Product: VERSAPRO CREAM BASE (REFORM 3) –MEDISCA FORMULA # RD010919-6
Customer: MEDISCA
Batch Code: ZA278
Formula Code: 170-18249-04 Rev 5
Batch Size: 2,000 KG
Compounding Date: 01/13/2024
2 Year Expiration Date: 01/13/2026

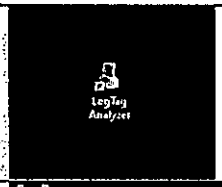
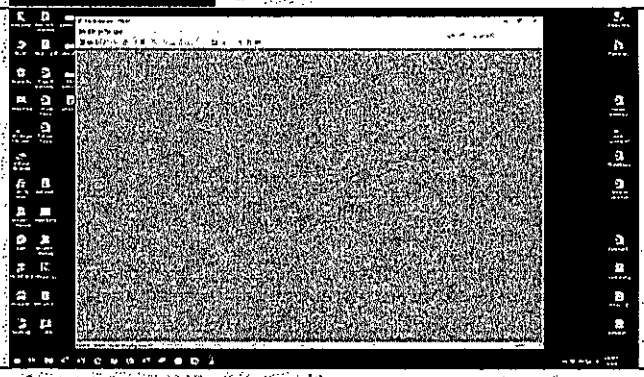
TEST	TEST METHOD (SOP)	SPECIFICATIONS	RESULTS
APPEARANCE	6-006	SMOOTH, SHINY, VISCOUS CREAM TO MATCH STANDARD	T- PASS B-PASS
COLOR	6-006	WHITE TO MATCH STANDARD	T- PASS B- PASS
SCENT	6-005	ODORLESS (NO FRAG. ADDED) TO MATCH STANDARD	T- PASS B- PASS
pH	6-001	4.25 - 5.50 (DIRECT, @ 25°C)	T-4.82 B-4.86
SPECIFIC GRAVITY	6-002	0.96 - 1.10 (PYCNOMETER, @ 25°C)	T-0.99 B-0.99
SOLUBILITY	N/A	PARTIALLY SOLUBLE IN WATER	T-PASS B-PASS
VISCOSITY	6-003	INITIAL: BROOKFIELD RVDV-1/RVT; SPINDLE T-D AT 2.5 RPM FOR 1 MINUTE @25°C 250,000 TO 400,000 CPS *VISCOSITY DIFFERENCE BETWEEN TOP & BOTTOM SAMPLE SHOULD NOT BE GREATER THAN 50,000 CPS*	T-349,000 CPS B-355,300 CPS.
			6,300 CPS
		AFTER 24HOURS: BROOKFIELD RVDV-1/RVT, SPINDLE T-D AT 2.5 RPM FOR 1 MINUTE @25°C 250,000 TO 400,000 CPS *VISCOSITY DIFFERENCE BETWEEN TOP & BOTTOM SAMPLE SHOULD NOT BE GREATER THAN 50,000 CPS*	T-360,000 CPS M-383,400 CPS B-380,600 CPS
			20,600 CPS.
		(1 WEEK: INFORMATIONAL) BROOKFIELD RVT T-D AT 2.5 RPM FOR 1 MINUTE @ 25C	*381,000 CPS.*
MICROBIAL CONTENT TEST	USP <60> USP<61> USP<62>	TOTAL PLATE COUNT (TPC) <100 CFU/G OR ML YEAST & MOLD <10 CFU/G OR ML GRAM NEGATIVE: ABSENT ABSENT OF PATHOGENS INCLUDING: STAPHYLOCOCCUS AUREUS, PSUEDOMONAS AERUGINOSA, CANDIDA ALBICANS, BURKHOLDERIA CEPACIA AND BILE-TOLERANT GRAM - NEGATIVE BACTERIA GRAM POSITIVE: ABSENT	*PASS (01/20/2024)*
PACKAGING AND STORAGE	N/A	STORE AT CONTROLLED ROOM TEMPERATURE	*INFORMATIONAL ONLY*

Note 1: Samples were tested by an approved Lab.

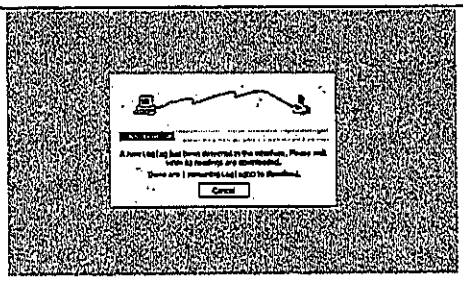
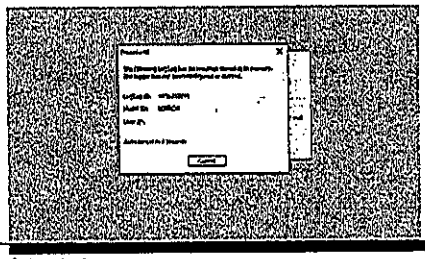
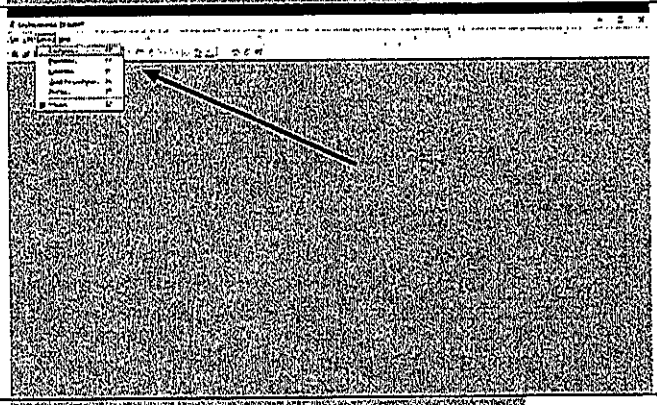
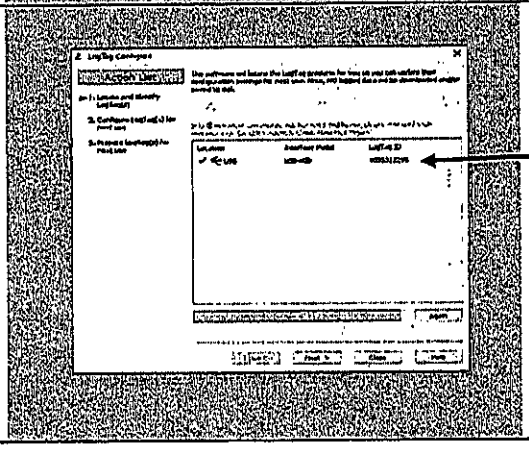
Results recorded by: Alejandra Lopez Date: 1-24-24

Quality manager or designee Approved by: Juan Carrasco Date: 1/26/2024

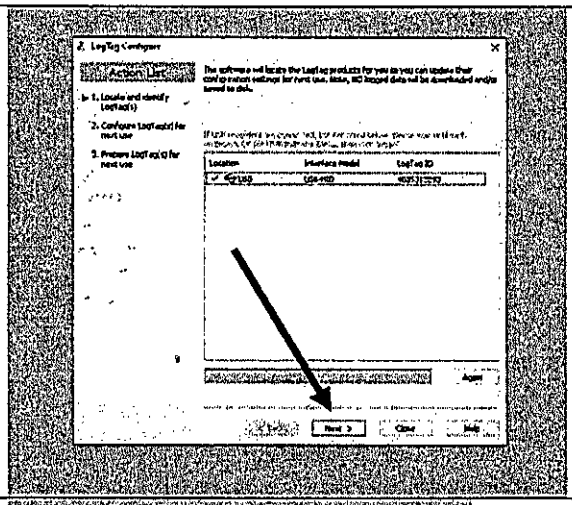
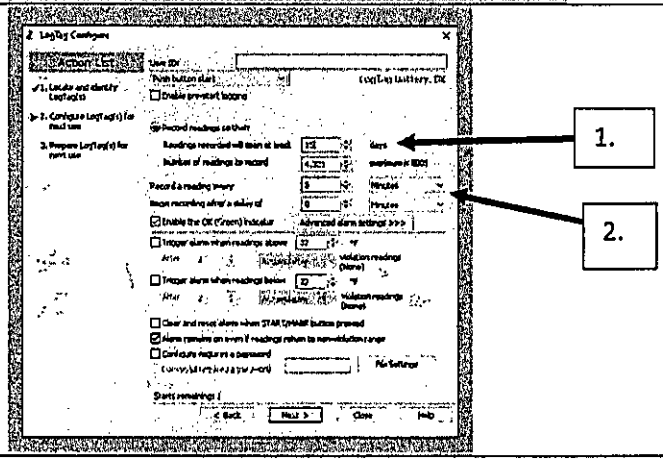
Synergy Apothecary SOP:	LogTag Temperature Recorder		
Trigger:	Semi-annual Receiver compliance check needed		
Done:	Completed test is returned from Receiver		
Applies to:	All Staff	*Rev #:*	0001
Revised By:	Theresa Bergh RPH	*Effective Date:*	11/01/2024
Written By:	Patti Luedtke RPh, Wendy Buehring	*Original Date:*	03/02/2020

	Process Step	Reference	Time
1.	**CONFIGURE LOGTAG** (if LogTag is already configured skip to step 24)		
2.	Double click on LogTag Analyzer icon on computer where software is located.		
3.	LogTag Analyzer window will open on computer		
4.	Take unconfigured LogTag out of red bubble wrap		
5.	Remove protective cover from USB plug-in on the LogTag		
6.	Put LogTag in USB port of computer where software is located. (Note: might need to push it in and jiggle LogTag a bit to get it into the port. This is normal as it is a tight fit.)		

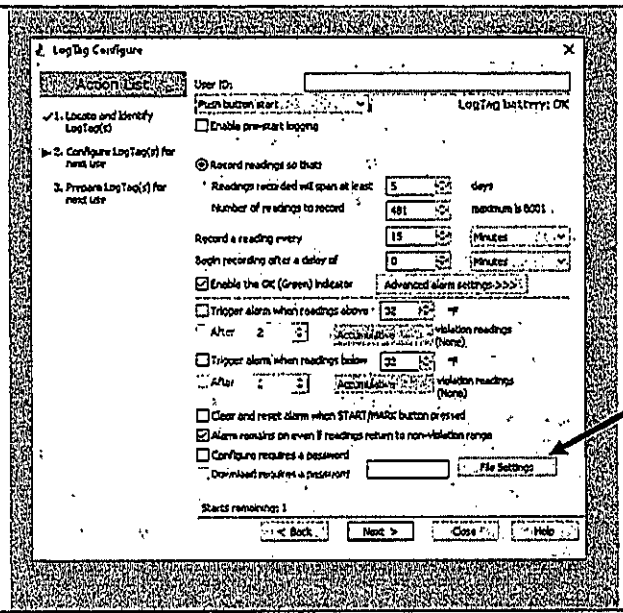
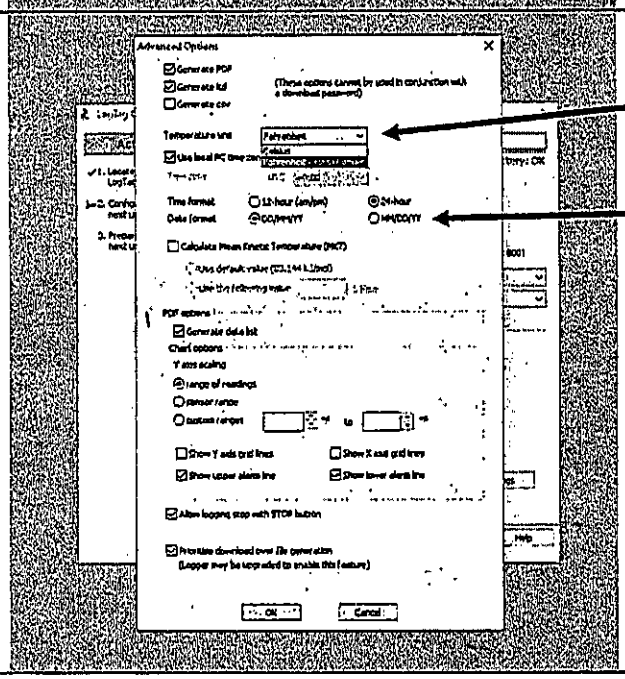
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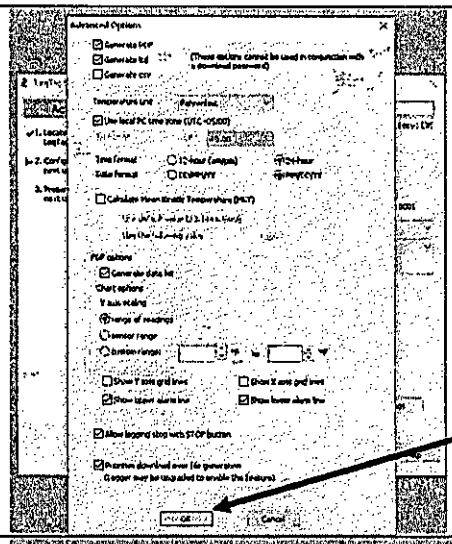
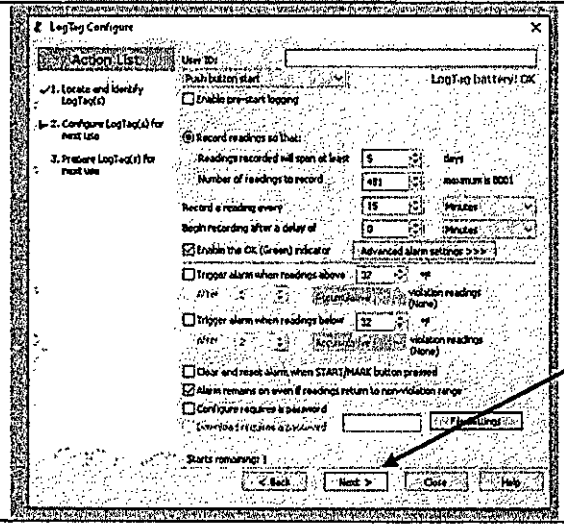
7.	Once the LogTag is in the USB port 2 screens will appear on computer monitor.	 	
8.	Click "LogTag" on top portion of screen, and drag down to "Configure"		
9.	Click LogTag to be configured		

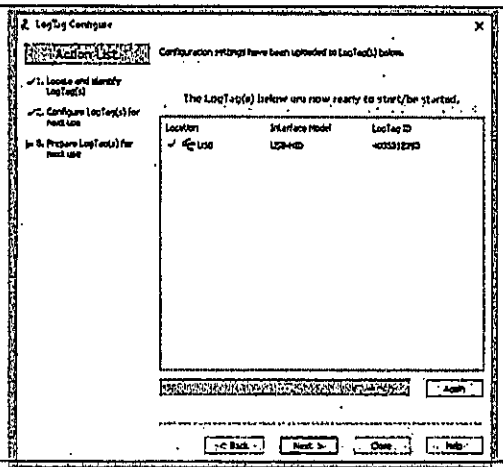
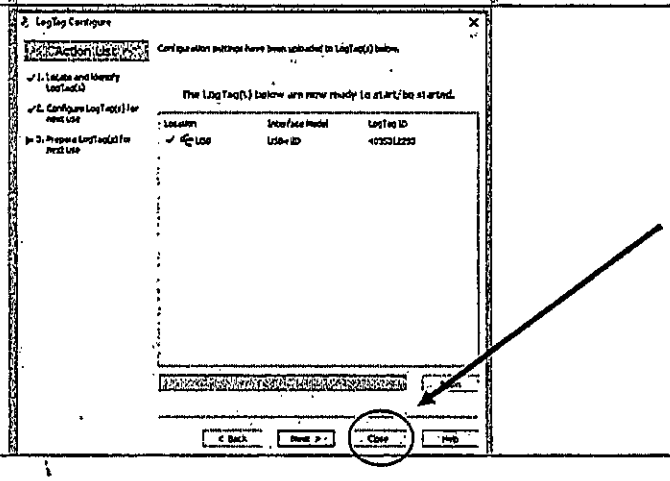
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10.	Click "Next"		
11.	Under "Record readings so that:" section, 1. change days to 15 days 2. change record a reading every 15 minutes		

Synergy Apothecory SOP:	**LogTag Temperature Recorder**		
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12.	Click "File Settings"		
13.	1.Change Temperature unit to be Fahrenheit. 2.Change Date format to be MM/DD/YY		

14.	Click "OK"		
15.	Click "Next"		
16.	As the LogTag is being configured the percentage bar shows when done.		

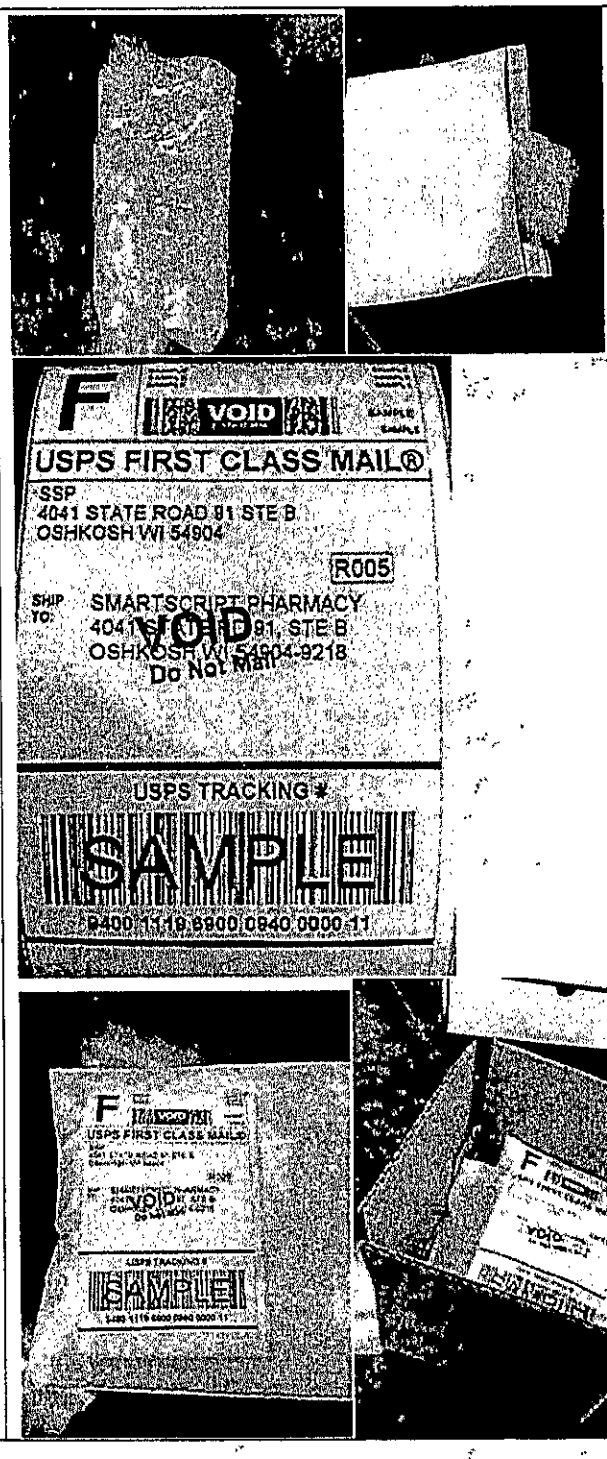
17.	This screen shows when complete.		
18.	Click Close		
19.	Exit the application		
20.	Physically remove LogTag from computer		
21.	Replace cover on the USB port		
22.	**PREPARE MONITOR FOR SHIPPING**		

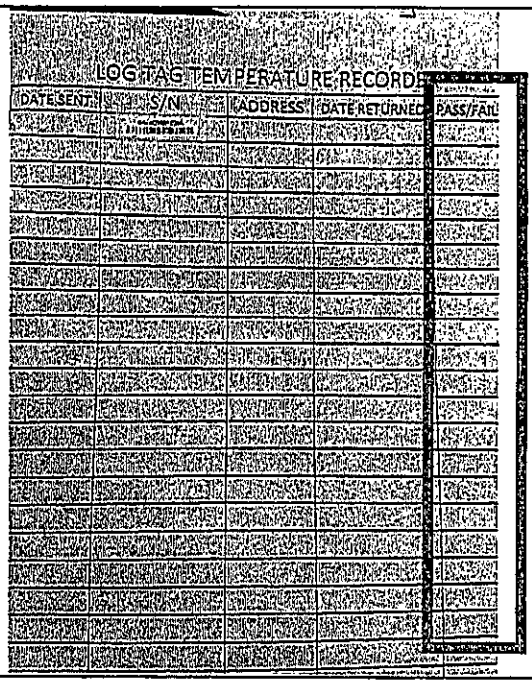
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23.	Peel back film and remove		
24.	Remove extra serial number (S/N) and place on Log Tag Temperature Recorder log. Be sure to log the date sent and address of receiver		

25.	Press Start			

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26.	Wrap log tag temperature recorder in bubble wrap and place is bubble mailer. Create and print shipping label for return of Log Tag to Pharmacy. Stick on bubble mailer and then place in shipping box. ****Be sure to include note for receiver to take bubble wrapped package out of box and place sealed bubble wrap in mail to return to pharmacy. No need for receiver to open package.** **Have address of receiver available as you will seal box in next step. ***	

27.	Seal box with packing tape and take to shipping station to weigh and create shipping label		
28.	Create shipping label with receivers' address, print and stick on box		
29.	When Log Tag Temperature Recorder is returned to the pharmacy, give to the pharmacist to upload information and print off log.		
30.	When log is printed highlight the intervals of 2hrs, 4hrs, 8hrs, 12hrs and 24hrs.		
31.	Mark if temperatures are pass/fail on Log Tag Temperature Recorder		

32.	Staple print outs together and file in P.I projects binder under temperature monitoring		
33.			
34.			
35.			
36.			
37.			
38.			
39.			

LogTag Temperature Recorder Product Shipping Integrity Check Form

PHARMACY STAFF COMPLETE THIS SECTION: Shipping Info	
Date Shipped from Synergy Apothecary:	
Ship Date Temp at Synergy Apothecary:	
Receiver's Ship To Address:	

PHARMACY STAFF COMPLETE THIS SECTION: Product Shipping Integrity Check	
LogTag TEMPERATURE monitor 85ºF indicator results *(device changes temperature that exceeds 85ºF)*	
	= Temperature at 1 hour as indicated on chart
	= Temperature at 2 hours as indicated on chart
	= Temperature at 4 hours as indicated on chart
	= Temperature at 8 hours as indicated on chart
	= Temperature at 12 hours as indicated on chart
	= Temperature at 24 hours or more as indicated on chart
LogTag TEMPERATURE monitor 32ºF indicator results *(device changes temperature that exceeds 32ºF)*	
	= Temperature at 1 hour as indicated on chart
	= Temperature at 2 hours as indicated on chart
	= Temperature at 4 hours as indicated on chart
	= Temperature at 8 hours as indicated on chart
	= Temperature at 12 hours as indicated on chart
	= Temperature at 24 hours or more as indicated on chart
Other Instructions:	
◯ Yes ◯ No	Any shipping heat additive added when shipped to cold climate?
◯ Yes ◯ No	Any shipping ice packs added when shipped to extreme hot climate?
◯ Yes ◯ No	Variance / PI form complete if breach in package integrity?

Pharmacy Staff Signature:		Date Form Completed:	

STAPLE RECEIVER'S FORM to this document

VPI response
Nonsterile
Part 2 of 2

Synergy Apothecary ORIENTATION CHECKLIST

The employee shall be oriented to the pharmacy and the responsibilities and tasks dictated per their job description.

Date	Department/ Procedures Reviewed	Materials/References Used	Initials of Employee	Initials of Dept. Rep.
	Introduction to management and pharmacy staff; signature log, SOPs and SWs	SOPs and SWs		
	Tour of Synergy Apothecary facility	Mentor		
	Review Employee Handbook and payroll packet, including HIPAA signature, orientation plan for 90-day orientation program, hours of operation, benefits, Paycor timecard app and expectations.	Employee Handbook		
	Review of pharmacy goals, practices and applicable SOP's	SOPs		
	Customer Service Philosophy and Best Practices	SOPs		
	Daily job responsibilities (including opening and closing duties), including applicable job description(s)	Mentor		
	I/T Training (Pioneer software and network logins)	Mentor		
	Safety training, including ECPP (Policy 5.025) and Hazardous materials (if applicable)	SOPs		
	USP training	USP 795 Form		
	Calculations Quiz	Form		
	Orientation to designated compounding area and compounding equipment	Form/Mentor		
	Narcotics and controlled substances	SOPs		
	Formulation preparation as appropriate	SOPs and Formulation Worksheets		
	Investigation of Method Deviation – OOS	Potency		
	Quality Assurance/Quality Control Programs	SOPs		
	Fraud-Waste-Abuse and Medicare Part D Compliance Training	PRS program		

Validation of training and applicable Standard Works review shall be completed within 45 days; Orientation period and orientation review shall be completed within 90 days

Signature: _____ *Date:* _____
Employee

Signature: _____ *Date:* _____
Pharmacist-In-Charge

2/11
Neoformat

Synergy Apothecary EMPLOYEE TRAINING RECORD

Hire Date: _____

Employee Name: _____ **Hired Position** _____

Initial Mentor/Trainer Signature: _____

Training Requirement (i.e initial orientation/compounding/safety)	Comments	Completion Date/Initials
Review of SW and orientation checklist		
Handling of meds – components & compounded items – Part 1	Complete "Receiving Chemicals and Devices Form	
Chemical Spill process and Transport of medications/chemicals Part 2	" "	
Cleaning and Sanitizing (office and/or lab areas	Refer to SW and daily logs	
Office procedures/shipping/cleaning		
Batch prepwork and labeling		
Pioneer Rx training (role dependent)	See SW for most common parts of pharmacy	
Understanding of PDMP requirements		

Description of Training: _____

_____

Reviewed By: _____ **Date:** _____

3/11 new format

Synergy Apothecary PERSONNEL TRAINING VERIFICATION
NON-STERILE COMPOUNDING

Name/Role _____ **New Hire or Annual Review**_____

Non-sterile compounding personnel shall be trained on proper compounding techniques and processes necessary to compound nonsterile preparations.

Date	Training Provided	Materials/References Used	Initials of Employee	Initials of Trainer
	USP 795 Test			
	Equipment and room Cleaning			
	Donning and Doffing PPE			
	Scales: leveling, weighing/taring			
	Powder hoods: cleaning, use and technique			
	Troches: Filling by hand			
	Troches: powder filler Base machine			
	Hotplates and Warming ovens			
	Creams: Miller Unguator			

Signature: _____ **Date:** _____
Compounding Staff/Title

Signature: _____ **Date:** _____
Pharmacist-In-Charge

4/11

Staff Training and Validation – Weighing and Mixing

Employee _____ Received reminder list? ☐ Yes ☐ No

Balance (AND Scale, OHAUS EXPLORER Scale and OHAUS ADVENTURER PRO Scale)
Employee experience level with equipment ☐ Beginner ☐ Intermediate ☐ Advanced
Training
1) SOP_____ read for procedure on operating, cleaning, calibrating and maintenance. Date_____
2) Demonstration of procedure on operating, cleaning, calibrating and maintenance performed by supervisor or experienced user. Date _____ Demonstrated by_____
Validation of Training
Staff member was observed by supervisor or experienced user operating, cleaning, calibrating and maintaining equipment per procedure.
Balance level? ☐ Yes ☐ No
Balance calibrated? ☐ Yes ☐ No
Balance tared? (tare recorded, if applicable)? ☐ Yes ☐ No
Chemical scanned (if applicable) and weight recorded/double-checked? ☐ Yes ☐ No
Weight accurate? ☐ Yes ☐ No
Date _____ Observed by _____
Comments:

_____

Powder Hood
Employee experience level with equipment ☐ Beginner ☐ Intermediate ☐ Advanced
Training
1) SOP_____ read for procedure on operating, cleaning, calibrating and maintenance. Date_____
2) Demonstration of procedure on operating, cleaning, calibrating and maintenance performed by supervisor or experienced user. Date _____ Demonstrated by_____
Validation of Training
Staff member was observed by supervisor or experienced user operating, cleaning, calibrating and maintaining equipment per procedure. Date _____ Observed by _____
Hood on and shield in place? ☐ Yes ☐ No
Potential for cross-contamination minimized? ☐ Yes ☐ No
Powder containment maximized? ☐ Yes ☐ No
Hood clean? ☐ Yes ☐ No
Date _____ Observed by _____
Comments:

Mixing in mortar using Principles of Geometric Dilution
Demonstration of procedure performed by supervisor or experienced user.
Date _____ Demonstrated by_____
Validation of Training
Staff member was observed by supervisor or experienced user performing procedure.
Procedure performed accurately? ☐ Yes ☐ No
Date _____ Observed by _____
Comments:

Staff Training and Validation – Weighing and Mixing Reminders 5/4

Powder Containment/Cross-Contamination

1. Hoods must be kept on with the safety shield in place.
2. Powders need to be weighed, mixed to the wet stage or made into capsules in a powder containment hood wearing full garb (including N95 mask). Add eye protection if compounding with hazardous liquids or cleaning with bleach or hazardous chemicals.
3. Cover weigh boats.
4. Blenders/Grinders need to be operated in the powder hood. Tablets need to be crushed in the hood.
5. Troches/Suppositories need to be mixed in hood. Either bring melted base into hood when pouring in powder or move hot plate to hood.
6. Capsule machine, mortars, utensils, weigh boats etc. need to be wet with water before leaving the hood.
7. Close all chemical containers before removing them from the hood. Open one container at a time in hood.
8. Do not store excess chemicals or supplies (including weigh boats or spatulas) in hood.
9. Wash capsule machine plates and thoroughly wipe down capsule machine when active ingredients change.
10. Think about ways to reduce the risk of cross-contamination:

- Best to use a clean utensil for each chemical weighed. If utensil is reused, make sure all surfaces are wiped with isopropyl alcohol and a clean towel or Kleenex. Towels (paper or cloth) and Kleenex must be changed between each chemical. Do not leave scoops in containers.
- Evaluate bulk transfer process. Dipping from large container adds to the risk of cross contamination. Make sure lot numbers match when containers are refilled. Wash containers between lot numbers.
- Syringes left in bottles or rubber-banded to bottle add to risk of cross-contamination.
- Store glassware upside down
- Store utensils, devices, etc. in closed drawers or covered.
- Do not re-use weigh boats.
- Replace chipped spatulas.
- Do not use re-usable brushes to clean powders from hood. Use disposable q-tips or similar.

Compounding

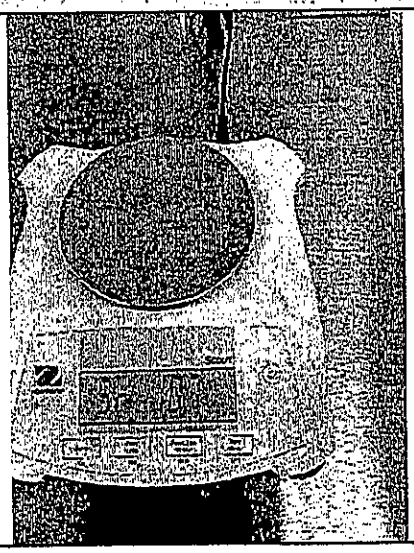
1. Double-check needed on chemicals, weights and volumes if performed by technician. Scanning the chemical into the pharmacy software works for a double check. Make sure all chemicals are scanned. Need double-check on volumes done with camera or by second person.
2. Ensure balance is level.
3. Record tares.
4. Compound one preparation at a time. Clean balance and hood between compounds and right away if a spill occurs using a clean towel or Kleenex. Towels (paper or cloth) and Kleenex are one use.
5. Processes need to be standardized for consistency. Is everyone following the same process?

Principles of Geometric Dilution

Use to ensure uniformity when mixing two or more components.
Select a mortar large enough for the entire quantity.
Add the smallest quantity to mortar. Add an equivalent amount of the next smallest quantity and mix until uniform using pestle. Add a quantity equal to the combined quantities and mix until uniform. Repeat as necessary to mix all components.
Note: A small amount of color is sometimes added to ensure uniform mixing.
Note: When a very small quantity is mixed into a large quantity, the mortar may be coated with a small amount of the large quantity to fill any fissures before adding the small quantity.
Note: Wedgewood or ceramic mortars are a better choice over glass mortars for reducing particle size but tend to trap particles so careful cleaning is needed.

6/11

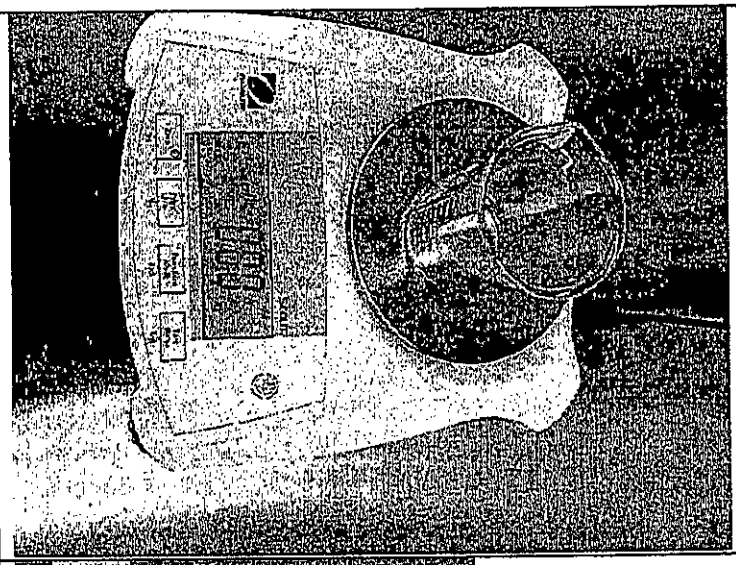
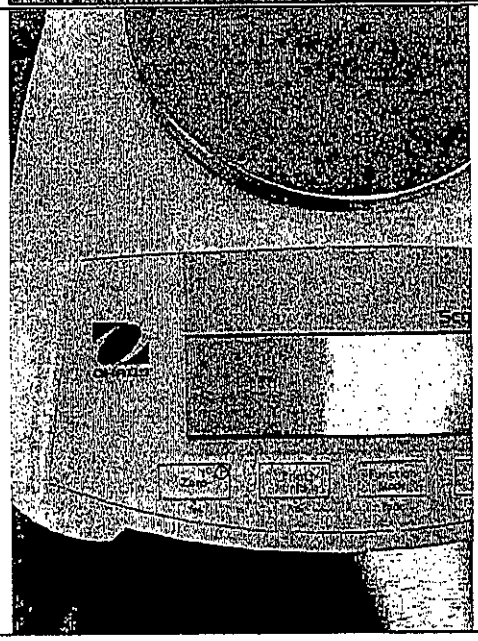
Synergy Apothecary	**OHAUS Scout Scale (Both SPX and SJX Models)**		
Trigger:	**Received prescription orders**		
Done:	**Product ready to go through a final mix**		
Applies to:	**All compounding staff**	*Rev #:*	**0001**
Revised By:	**Theresa Bergh**	*Effective Date:*	**11/01/2024**
Written By:	**Jennifer Beaudoin**	*Original Date:*	**11/01/2024**

1.			
	Clean stainless weigh pan with 70% alcohol and allow to dry. Do as needed between products as any residual powders affect accuracy:		
3.	Turn on scale by pressing power button		
4.			
5.	See attached on calibration process Step 1 – Press and hold Menu til menu is displayed		

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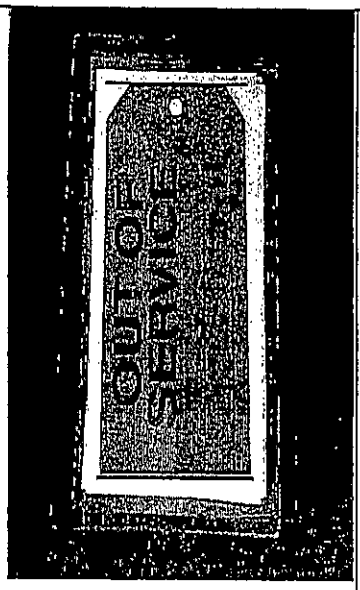
	Step 2. Release the button, display will show (CAL) Step 3 Press Yes to accept (SPAN) will be shown. Step 4 Press Yes to begin span calibration. Zero reading is stored automatically Step 5 Press the specified span calibration mass or press NO to select an alternat weight The display will show (done) if the calibration is successful. The scale is now ready for use.		
6.	Zero out the scale then place appropriately sized weighing container on the scale. Press Tare		

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Trigger:	**Received prescription orders**
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7.	Ensure that scale now reads zero so the appropriate amount of product is weighed		
	Once appropriate amount has been weighed, print label to allow attaching to the compounding document		
9.	Return all parts when ready for reuse.		
10	Daily cleaning: After each prescription and at end of the day. (Approved cleaning solutions 70% alcohol.)		
	Weekly cleaning: Same as daily cleaning		
	Preventative/Required: Clean after each use and at end of the day.		

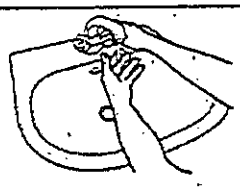
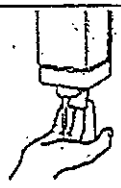
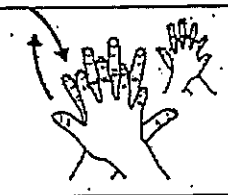
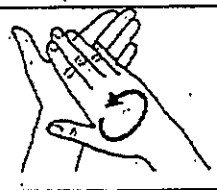
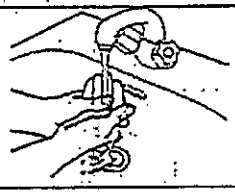
9.11.+

Synergy Apothecary	**OHAUS Scout Scale (Both SPX and SJX Models)**		
Trigger:	**Received prescription orders**		
Done:	**Product ready to go through a final mix**		
Applies to:	**All compounding staff**	*Rev #:*	**0001**
Revised By:	**Theresa Bergh**	*Effective Date:*	**11/01/2024**
Written By:	**Jennifer Beaudoin**	*Original Date:*	**11/01/2024**

13	Defect/Out for repair: If machine has become defective or needs to be repaired, arrange with Pharmacist to ship to repair facility. Place/Tape "Out of Service" card on piece of equipment (preferably the front of the unit) to show it is not usable. Out of Service cards can be found in Lab Equipment Manuals Binder. Out of Service machine should be moved to closet area in main pharmacy until unit can be shipped out for repair. You may need to move extra working equipment to your area. (Check log to see if additional units are available)		
14	Get Equipment Maintenance Log Book and log on the equipment log which machine is going out of service, the date and the reason that it is out of service. When the machine is returned, you will need to get the book out again and log that it was returned/ if it was put back into service and if a repair sheet was included, place a copy of that sheet under the tab of the binder		
15			

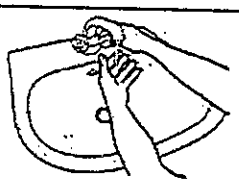
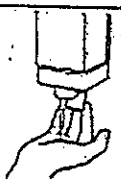
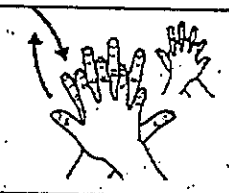
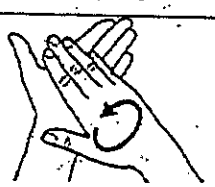
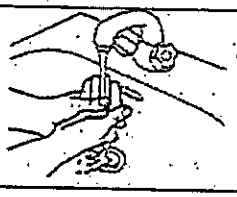
10/11

Synergy Apothecary SOP:	**Proper hand washing protocol.**		
Trigger:	**Per protocol.**		
Done:	**When hands are properly washed**		
Applies to:	**All Staff**	*Rev #:*	**0001**
Revised By:	**Theresa Bergh**	*Effective Date:*	**11/01/2024**
Written By:	**Abigail Tritt**	*Original Date:*	**01/19/2018**

	Process Step	Reference	Time
1.	Hands should be properly washed: - Before start of shift - When leaving the compounding area - Before and after using the restroom - Before and after break - After removing gloves - At end of shift before leaving the clean room facility		
2.	Personnel must remove all makeup and jewelry prior to entering the compounding facility.		
3.	Turn water on to lukewarm.		
4.	Push the sleeves of the gown above the elbows and allow the water to soak your arms from the fingertips to the elbow.		
5.	Apply a liberal amount of hand soap into the palm of the hands. (If necessary, a pick shall be used to thoroughly clean under the fingernails.)		
6.	Assure to wash the "four sides" of the hands and fingertips, paying particular attention to the skin in between each finger. Liberally scrub hands and fingers for at least 30 seconds.		
7.	After each finger has been washed, proceed to clean the forearm, using a circular motion, from the wrist to the elbow. -Apply this process to both hands/arms.		
8.	Once both arms have been thoroughly washed, place arms under the running water to rinse away the soap. Make sure to rinse with the palm of hands remaining upwards so the water always runs from the fingertips to the elbows.		

11/17

Synergy Apothecary SOP:	**Proper hand washing protocol.**		
Trigger:	**Per protocol.**		
Done:	**When hands are properly washed**		
Applies to:	**All Staff**	*Rev #:*	**0001**
Revised By:	**Theresa Bergh**	*Effective Date:*	**11/01/2024**
Written By:	**Abigail Tritt**	*Original Date:*	**01/19/2018**

	Process Step	Reference	Time
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8.	Once both arms have been thoroughly washed, place arms under the running water to rinse away the soap. Make sure to rinse with the palm of hands remaining upwards so the water always runs from the fingertips to the elbows.		

4.050 SOP CLEANING AND MAINTENANCE OF THE NON-STERILE COMPOUNDING AREA (VERSION 1.0)

Synergy Apothecary

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the cleaning the office areas and the non-sterile compounding area.

2.0 SCOPE

2.1 This procedure applies to the Synergy Apothecary non-sterile compounding area under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <795>.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne microbial contamination.

2.3 Area will be immediately cleaned when a splash or suspected contamination has occurred.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that personnel will comply with this procedure.

4.0 DEFINITIONS

4.1 C-2's are medications classified as Controlled II substances.

4.2 IPA- Isopropyl Alcohol 70%

5.0 FREQUENCY

5.1 Office Areas

5.1.1 Weekly (or as needed)

5.1.1.1 Clean countertops/desks
5.1.1.2 Wipe down phones
5.1.1.3 Wipe down office equipment – computer/monitor/keyboards
5.1.1.4 Trash discarded
5.1.1.5 Empty recycling
5.1.1.6 Vacuum all carpeted areas
5.1.1.7 Clean staff refrigerator

5.1.2 Monthly (or as needed)

5.1.2.1 Dust shelves/racks
5.1.2.2 Clean windows and blinds
5.1.2.3 Clean wall hangings

5.2 Non-sterile Compounding Area (Lab 2)

5.2.1 Daily

5.2.1.1 Clean hood(s)
5.2.1.2 Clean Door Handles including pass through
5.2.1.3 Wipe down equipment
5.2.1.4 Clean utensils .
5.2.1.5 Document Temperature and humidity, if out of range, bring to attention of pharmacist or PIC as noted below
5.2.1.6 Fill and start dishwasher if installed (emptied next morning and as needed) plus handwash any glassware that is fragile each day.
5.2.1.7 Clean sink(s)
5.2.1.8 Sweep and mop floors
5.2.1.9 Trash discarded
5.2.1.10 Lab coats to laundry bin

5.2.1.11 Tacky mat refreshed
5.2.1.12 Assess supply needs and restock room as needed.

5.2.2 Weekly

5.2.2.1 Order supplies – note supply needs on clipboard or dry erase board as they arise throughout the week.

5.2.3 Monthly

5.2.3.1 Clean/sanitize drug product refrigerator/freezer
5.2.3.2 Clean/sanitize cabinet exteriors
5.2.3.3 Clean outside and underside of hoods
5.2.3.4 Inventory – controlled substances.

5.2.4 Quarterly

5.2.4.1 Walls, shelves and cabinet exteriors (if any)
5.2.4.2 Ceilings will be inspected for visible soil and cleaned

6.0 EQUIPMENT & SUPPLIES

6.1 Proper gowning protocol placards.
6.2 Mop with disposable cleaning pads labeled for use on floors of non-sterile compounding area.
6.3 Tacky mat (if necessary)
6.4 Paper towels
6.5 Bleach concentrate, Chlorox Hydrogen Peroxide or appropriate cleanser (i.e. quaternary compounds)
6.6 70% isopropyl alcohol (IPA)
6.7 Waste container liners
6.8 Step stool
6.9 Room thermometer
6.10 Room hygrometer

7.0 GENERAL INFORMATION

7.1 Cleaning Solutions

7.1.1 All labs will be cleaned daily with a neutral disinfectant daily, followed by 70% IPA.

7.1.2 Chlorox Hydrogen Peroxide disinfectant solution or a bleach-based solution is used at the end of the day once weekly (possibly a less busy day in the week). The manufacturer's instructions are followed. The surface will be allowed at a **10-minute** contact time. After surfaces are dry, follow up with a clean lint free cloth soaked with 70% IPA

7.1.3 All labs will be mopped daily when compounding occurs with Neutral Floor Cleaner (see SW), typically at the end of the day to allow floor to dry completely

7.1.4 All Lab surfaces are to be cleaned every 6 months with Sporicidin (RTU solution) by spraying lint free rag to decrease splatter. Allow 10-minute contact time to allow best antimicrobial activity. Document the date done on the quarterly portion of the monthly log and carry over the date done and date due to the next log.

8.0 PROCEDURE

8.1 Personnel must gown appropriately for the areas to be cleaned following the appropriate Standard Work for donning PPE.

8.2 Cleaning solutions shall be prepared as needed. – See SW for directions on cleaning solutions if mixing or dilution is required

- 8.2.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs.
- 8.2.2 Disinfectants with no expiration date should be assigned an expiration date of 30 days after opening.

8.3 Except for sanitization of the workbenches, utensils or equipment, cleaning of the non-sterile compounding area is prohibited during compounding operations.

- 8.3.1 Ensure all compounded preparations are completed.
- 8.3.2 The operator must clean and sanitize the exposed work surfaces before and after each batch preparation and immediately should a spill occur.

8.4 The order of cleaning within the non-sterile compounding area is as follows:

- 8.4.1 Hoods (powder hood)
- 8.4.2 Non-sterile compounding area
- 8.4.3 Warehouse storage room

8.5 **Daily requirements (when non-sterile compounding is occurring)**

- **8.5.1 At the beginning of the day:**
  - 8.5.1.1 Check supplies and straighten up the non-sterile compounding area (if necessary).
  - 8.5.1.2 Turn on all necessary equipment and computers.
  - 8.5.1.3 Temperature and humidity readings shall be taken in the non-sterile compounding area as well as drug store and office areas.
    - 8.5.1.3.1 The temperature and humidity in the non-sterile compounding area shall be monitored electronically.
    - 8.5.1.3.2 The humidity should be maintained in the range of 10% to 60% RH.
    - 8.5.1.3.3 The temperature shall be maintained between 68°F to 77°F
    - 8.5.1.3.4 Document results on the Temperature and Humidity Monitoring of the Non-Sterile Compounding Lab – See SOP 4.051
    - 8.5.1.3.5 Record drug product refrigerator/freezer temperature on Maintenance Log in SOP 4.051 – Any excursions out of range to be brought to PIC attention and products assessed for viability. They should be moved to backup working refrigerator. We do have a generator backup.
    - 8.5.1.3.6 Any excursions from the recommended temperature ranges to be brought to the attention of the PIC and HVAC vendor to

be contacted. Compounding activities to be held if needed based on temperature and humidity issues to ensure product quality and employee safety.

8.5.1.4 Clean and sanitize countertops/sinks.

8.5.1.5 Clean and sanitize equipment at start and end of day and with every new compound ingredient and as needed...

8.5.1.6 Clean and sanitize plastic bins used to transport drug preparation before compounding.

8.5.1.7 Once obtained, dishwasher will run at least once daily once installed. Do not use rinsing agent in the dishwasher cycle. Fragile glassware should be washed by hand and rinsed with distilled water, purified water or reverse osmosis water. If reusable compounding utensils are hand washed, they also should be rinsed with the same water quality as glassware.

8.5.1.8 Peel off tacky layer mat (if applicable).

8.5.1.9 Allow all rooms and equipment to air dry before non-sterile compounding resumes.

8.5.2 At the end of the day:

8.5.2.1 Turn off all equipment and computers as required.

8.5.2.2 Sweep and mop the floor with floor cleaning solution – see SW

8.5.2.3 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Lab labelled SOP 4.051.

8.5.2.4 If the task is not relevant to that lab area, write "N/A" in the appropriate location on the form.

8.6 **Weekly requirements**

8.6.1 Includes all the requirements in section 8.5

8.6.2 Order supplies as necessary.

8.6.3 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area Form and Office Area Forms (Attachment 1&2) If the equipment is not in use, write "N/A" in the appropriate location on the form.

8.7 **Monthly requirements**

8.7.1 Includes all requirements in section 8.5

8.7.2 Clean and sanitize the drug product refrigerator/freezer.

8.7.3 Clean outside and underside of hoods/BSC monthly

8.7.4 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area Lab (SOP 4.051) If the equipment is not in use, write "N/A" in the appropriate location on the form. QQ

8.8 **Quarterly requirements**

8.8.1 Wipe down/clean wall panels and cabinet exteriors

8.8.2 Wipe down shelving and bins

8.8.3 Assess ceiling tiles and wipe or replace as needed.

8.8.4 Remove all supplies from the shelving in the non-sterile compounding area and clean and sanitize the shelves.

9.0 Cleaning can be performed as often as needed, but the minimum requirement is at the end of the day after compounding.

10.0 The Pharmacist-in-charge shall ensure the completion of tasks on a daily basis and shall review and sign/date attachment 1&2 at the end of each month. The form shall be retained in a cleaning/maintenance binder. At the end of the month the forms will be scanned to a shared folder.

11.0 REFERENCES

11.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

11.2 SOP 1.050 "General Compounding Technique"

11.3 SOP 3.130 "Required Garb for Non-Sterile Compounding Area"

12.0 ATTACHMENTS

12.1 Office area cleaning and maintenance log – See forms folder

12.2 Temperature and humidity logs – See forms folder

12.3 Non-sterile compounding area cleaning and maintenance log – See forms folder

13.0 SOP History

___ Draft X Final	Annual Policy Review
Approved by:	Original Owner / Date: Theresa Bergh, RPh, PIC / 11-01-24
_____ Theresa Bergh, RPh, PIC	Reviewer / Date:
This policy implemented on: 11/01/2024	

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Equipment/BALANCE MAINTENANCE/REPAIR LOG

Name: LabGard ES BSC **Serial Number: 209207110821** **Model Number: NU 540**

Date out	Reason/Results	Date in
	obtained from previous owner of building	10/31/2024
	Certified by Northern Air Flow	10/31/2024
	Next Maintainence due 4/30/25.	

2/3

BALANCE MAINTENANCE/REPAIR LOG

Name: OHAUS Adventurer **Serial Number: C421156494** **Model Number: AX423**

Date out	Reason/Results	Date in
	Received from Scales Plus after ISO Calibration completed	11/11/2024

SCALESPLUS

CALIBRATION CERTIFICATE

ACCREDITED
CERT #6896.01

S25W30174 Jenna Lane
Waukesha, Wisconsin 53188

Interval: 365 days
Certificate Number: 20988
Scale Name: C421156494
Customer ID: N/A

3/3

Tech ID: SP-0010 17025 Compliant Scale

Scale System		Indicator		Base	
Customer Used Capacity	N/A	Manufacturer	Ohaus	Manufacturer	N/A
Division	0.001 g	Model	AX423	Model	N/A
Location		Serial Number	C421156494	Serial Number	N/A
Class	Unclassified	Programmed Capacity	420.000 g		
Scale Type	Lab	REP#	0		

Tolerance Source: NIST Handbook 44 Tolerance Applied: NIST Handbook Table T.1.1 (0.05%)

Temperature: 68.9 °F Humidity: 52.0 % Relative Work Instruction Used: Scale Test Procedure

Unit of Measure Reported In: g

Shift Test

0.065 g Absolute Tolerance at 130 g Weight Applied

Section	As Found Reading g	As Left Reading g
1)	130.050	129.999
2)	130.050	130.002
3)	130.049	130.001
4)	130.049	130.001
Results	☑ Pass	☑ Pass
Adjusted: Yes	☐ Fail	☐ Fail

Load Test

Weight Applied g	Tolerance +/- g	As Found Reading g	As Left Reading g
0.000	0.001	0.000	0.000
1.000	0.001	1.000	1.000
50.000	0.025	50.020	50.000
130.000	0.065	130.051	129.999
300.000	0.150	300.113	299.998
400.000	0.200	400.151	399.998
Adjusted: Yes		☑ Pass	☑ Pass
		☐ Fail	☐ Fail

Comments:

Tested and adjusted internal calibration on Ohaus balance. Service was performed at Scales Plus in Allendale, Michigan. Expanded Measurement Uncertainty: 0.0027 g

Serial Number(s) of test weight(s) used: SET 7 (Class 1) Due 8/2025
Technician Name(s): Solomon Bosman
Reviewed By: Ron Belden
Calibration Next Due: 11/2025 Form Used: CAL-CERT-GENERAL - Rev Date 03/2014

Date of Calibration: 11/11/2024
Certificate Issue Date: 11/11/2024
Certificate Review Date: 11/11/2024
Equipment Tested on Location: No

1. Test standards used are traceable through the NATIONAL INSTITUTE OF STANDARDS AND TECHNOLOGY to the International System of Units, SI units, and conform to the requirements of NIST Handbook 105-1 Class F, ASTM E617 Class 0, ASTM E617 Class 1, ASTM E617 Class 6.
2. This report shall not be reproduced, except in full, without the permission of Scales Plus. 3. Pass/Fail compliance statements are the opinions of Scales Plus and are based on data from measurements made, procedures utilized, technical training and professional experience. 4. Unless otherwise noted, the above Pass/Fail compliance statements are based on simple acceptance and do not take measurement uncertainty into account. Pass: Error is within or equal to the tolerance limit. Fail: Error is outside the tolerance limit. Results are raw data and are not compensated for uncertainty. Unless otherwise noted, it is the responsibility of the end user to determine if the results meet the requirements for the intended application. 5. Results relate only to the item calibrated. 6. Measurement uncertainty is expressed as expanded measurement uncertainty with a coverage factor of (k=2) for a confidence level of approximately 95%.

4267

nergy Apothecary Non-Sterile Compounding Lab – Cleaning and Maintenance Log "OLD" form with Feb 25 data

nth/Year: Feb 25

#: 102

Cleaning Solution Used: Alcohol 70% daily

Reviewer/Date: 1/2

	Daily														Quarterly						Monthly			
y	Clean Door Handles	Replace Tacky Mat	Room Temp (68°-77°)	Room Humidity (10-60%)	Refrigerator Temp (36°-46°)	Clean Counters/Table	Clean Glassware/Trays/Spatula & PRN	Clean Hood(s) & Scales	Pressure Settings (if applicable)	Clean Sink (start or end of day)	Take Out Trash	Restock Room for Next Day Needs	Sweep & Mop Floor (EOD)	Order Supplies (PRN)	Wipe/Clean Wall Panels & Cabinet Exteriors	Wipe Down Shelving & Bins	Schedule quarterly QA mtg & assess Shred it Bin	Wipe or Replace Ceiling Tiles (PRN)	Clean with sporicidal Q6 mos (write date last done	Review BIN or Outdated CS- Replace per policy	Clean Refrigerator in lab	Monthly Narcotic Inventory and scan previous month log	Check for Outdates/Label anything 3 months or less	Clean under Hood
	SAT																							
	SUN																							
	J	J	69	58	40	J	J	J	N/A	J	J	N/A	BW	–										
	J	J	68	16	40	J	J	J		J	J	N/A		–										
	J	J	70	16	41	J	N/A	J		J	N/A	N/A		–										
	J	J	69	18	41	J	N/A	J		J	J	N/A		–										
	J	J	70	16	40	J	N/A	J		J	J	N/A		–							J	N/A		J
	J	J	69	17	40	J	N/A	J		J	J	N/A	J	–										
	J	J	68	31	43	J	N/A	J		J	J	N/A		–										
	J		69	38	39.6	J	N/A	J		J	J	N/A	–	–										
	J		70	35	40	J	N/A	J		J	J	N/A												
	J		68	35	40	J	N/A	J		J	J	N/A												
	J	J	68	19	40	J	N/A	J		J	J	N/A												
	J	J	68	12	40	J	N/A	J		J	J	N/A		–										
	J	J	69	12	41	J	N/A	J		J	J	N/A		–										
	J	J	69	11	40	J	N/A	J		J	J	N/A		–										
	J	J	69	16	41	J	N/A	J		J	J	N/A												

Due 4/25

Synergy Apothecary Non-Sterile Compounding Lab – Cleaning and Maintenance Log

NOW

Month/Year: _____ **Cleaning Solution Used:** Alcohol 70% daily 2/2

Lab #: _____ **Reviewer/Date:** _____

Q		Daily														Quarterly						Monthly		
Day	Clean Door Handles	Replace Tacky Mat	Room Temp (68°-77°)	Room Humidity (10-60%)	Refrigerator Temp (36°-46°)	Clean Counters/Table	Clean Glassware/Trays/Spatula & PRN	Clean Hood(s) & Scales	Pressure Settings (if applicable)	Clean Sink (start or end of day)	Take Out Trash	Restock Room for Next Day Needs	Sweep & Mop Floor (EOD)	Order Supplies (PRN)	Wipe/Clean Wall Panels & Cabinet Exteriors	Wipe Down Shelving & Bins	Schedule quarterly QA mtg & assess Shred It Bin	Wipe or Replace Ceiling Tiles (PRN)	Clean with sporicidal Q6 mos (write date last done	Review BIN or Outdated CS- Replace per policy	Clean Lab Refrigerator, Clean Hoods Outside & Underside	Monthly Narcotic Inventory and scan previous month log	Check for Outdates/Label anything 3 months or less
1																							
2																							
3																							
4																							
5																							
6																							
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4.050 SOP CLEANING AND MAINTENANCE OF THE NON-STERILE COMPOUNDING AREA (VERSION 1.0)

Synergy Apothecary

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the cleaning the office areas and the non-sterile compounding area.

2.0 SCOPE

2.1 This procedure applies to the Synergy Apothecary non-sterile compounding area under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <795>.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne microbial contamination.

2.3 Area will be immediately cleaned when a splash or suspected contamination has occurred.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-charge shall supervise this procedure and document that personnel will comply with this procedure.

4.0 DEFINITIONS

4.1 C-2's are medications classified as Controlled II substances.

4.2 IPA- Isopropyl Alcohol 70%

5.0 FREQUENCY

5.1 Office Areas

5.1.1 Weekly (or as needed)

5.1.1.1 Clean countertops/desks
5.1.1.2 Wipe down phones
5.1.1.3 Wipe down office equipment – computer/monitor/keyboards
5.1.1.4 Trash discarded
5.1.1.5 Empty recycling
5.1.1.6 Vacuum all carpeted areas
5.1.1.7 Clean staff refrigerator

5.1.2 Monthly (or as needed)

5.1.2.1 Dust shelves/racks
5.1.2.2 Clean windows and blinds
5.1.2.3 Clean wall hangings

5.2 Non-sterile Compounding Area (Lab 2)

5.2.1 Daily

5.2.1.1 Clean hood(s)
5.2.1.2 Clean Door Handles including pass through
5.2.1.3 Wipe down equipment
5.2.1.4 Clean utensils .
5.2.1.5 Document Temperature and humidity, if out of range, bring to attention of pharmacist or PIC as noted below
5.2.1.6 Fill and start dishwasher if installed (emptied next morning and as needed) plus handwash any glassware that is fragile each day.
5.2.1.7 Clean sink(s)
5.2.1.8 Sweep and mop floors
5.2.1.9 Trash discarded
5.2.1.10 Lab coats to laundry bin

5.2.1.11 Tacky mat refreshed
5.2.1.12 Assess supply needs and restock room as needed.

5.2.2 Weekly

5.2.2.1 Order supplies – note supply needs on clipboard or dry erase board as they arise throughout the week.

5.2.3 Monthly

5.2.3.1 Clean/sanitize drug product refrigerator/freezer
5.2.3.2 Clean/sanitize cabinet exteriors
5.2.3.3 Clean outside and underside of hoods
5.2.3.4 Inventory – controlled substances.

5.2.4 Quarterly

5.2.4.1 Walls, shelves and cabinet exteriors (if any)
5.2.4.2 Ceilings will be inspected for visible soil and cleaned

6.0 EQUIPMENT & SUPPLIES

6.1 Proper gowning protocol placards.
6.2 Mop with disposable cleaning pads labeled for use on floors of non-sterile compounding area.
6.3 Tacky mat (if necessary)
6.4 Paper towels
6.5 Bleach concentrate, Chlorox Hydrogen Peroxide or appropriate cleanser (i.e. quaternary compounds)
6.6 70% isopropyl alcohol (IPA)
6.7 Waste container liners
6.8 Step stool
6.9 Room thermometer
6.10 Room hygrometer

7.0 GENERAL INFORMATION

7.1 Cleaning Solutions

7.1.1 All labs will be cleaned daily with a neutral disinfectant daily, followed by 70% IPA.

7.1.2 Chlorox Hydrogen Peroxide disinfectant solution or a bleach-based solution is used at the end of the day once weekly (possibly a less busy day in the week). The manufacturer's instructions are followed. The surface will be allowed at a **10-minute** contact time. After surfaces are dry, follow up with a clean lint free cloth soaked with 70% IPA

7.1.3 All labs will be mopped daily when compounding occurs with Neutral Floor Cleaner (see SW), typically at the end of the day to allow floor to dry completely

7.1.4 All Lab surfaces are to be cleaned every 6 months with Sporicidin (RTU solution) by spraying lint free rag to decrease splatter. Allow 10-minute contact time to allow best antimicrobial activity. Document the date done on the quarterly portion of the monthly log and carry over the date done and date due to the next log.

8.0 PROCEDURE

8.1 Personnel must gown appropriately for the areas to be cleaned following the appropriate Standard Work for donning PPE.

8.2 Cleaning solutions shall be prepared as needed. – See SW for directions on cleaning solutions if mixing or dilution is required

- 8.2.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs.
- 8.2.2 Disinfectants with no expiration date should be assigned an expiration date of 30 days after opening.

8.3 Except for sanitization of the workbenches, utensils or equipment, cleaning of the non-sterile compounding area is prohibited during compounding operations.

- 8.3.1 Ensure all compounded preparations are completed.
- 8.3.2 The operator must clean and sanitize the exposed work surfaces before and after each batch preparation and immediately should a spill occur.

8.4 The order of cleaning within the non-sterile compounding area is as follows:

- 8.4.1 Hoods (powder hood)
- 8.4.2 Non-sterile compounding area
- 8.4.3 Warehouse storage room

8.5 **Daily requirements (when non-sterile compounding is occurring)**

- **8.5.1 At the beginning of the day:**
  - 8.5.1.1 Check supplies and straighten up the non-sterile compounding area (if necessary).
  - 8.5.1.2 Turn on all necessary equipment and computers.
  - 8.5.1.3 Temperature and humidity readings shall be taken in the non-sterile compounding area as well as drug store and office areas.
    - 8.5.1.3.1 The temperature and humidity in the non-sterile compounding area shall be monitored electronically.
    - 8.5.1.3.2 The humidity should be maintained in the range of 10% to 60% RH.
    - 8.5.1.3.3 The temperature shall be maintained between 68°F to 77°F
    - 8.5.1.3.4 Document results on the Temperature and Humidity Monitoring of the Non-Sterile Compounding Lab – See SOP 4.051
    - 8.5.1.3.5 Record drug product refrigerator/freezer temperature on Maintenance Log in SOP 4.051 – Any excursions out of range to be brought to PIC attention and products assessed for viability. They should be moved to backup working refrigerator. We do have a generator backup.
    - 8.5.1.3.6 Any excursions from the recommended temperature ranges to be brought to the attention of the PIC and HVAC vendor to

be contacted. Compounding activities to be held if needed based on temperature and humidity issues to ensure product quality and employee safety.

8.5.1.4 Clean and sanitize countertops/sinks.

8.5.1.5 Clean and sanitize equipment at start and end of day and with every new compound ingredient and as needed...

8.5.1.6 Clean and sanitize plastic bins used to transport drug preparation before compounding.

8.5.1.7 Once obtained, dishwasher will run at least once daily once installed. Do not use rinsing agent in the dishwasher cycle. Fragile glassware should be washed by hand and rinsed with distilled water, purified water or reverse osmosis water. If reusable compounding utensils are hand washed, they also should be rinsed with the same water quality as glassware.

8.5.1.8 Peel off tacky layer mat (if applicable).

8.5.1.9 Allow all rooms and equipment to air dry before non-sterile compounding resumes.

8.5.2 At the end of the day:

8.5.2.1 Turn off all equipment and computers as required.

8.5.2.2 Sweep and mop the floor with floor cleaning solution – see SW

8.5.2.3 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Lab labelled SOP 4.051.

8.5.2.4 If the task is not relevant to that lab area, write "N/A" in the appropriate location on the form.

8.6 Weekly requirements

8.6.1 Includes all the requirements in section 8.5

8.6.2 Order supplies as necessary.

8.6.3 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area Form and Office Area Forms (Attachment 1&2) If the equipment is not in use, write "N/A" in the appropriate location on the form.

8.7 Monthly requirements

8.7.1 Includes all requirements in section 8.5

8.7.2 Clean and sanitize the drug product refrigerator/freezer.

8.7.3 Clean outside and underside of hoods/BSC monthly

8.7.4 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area Lab (SOP 4.051) If the equipment is not in use, write "N/A" in the appropriate location on the form. QQ

8.8 Quarterly requirements

8.8.1 Wipe down/clean wall panels and cabinet exteriors

8.8.2 Wipe down shelving and bins

8.8.3 Assess ceiling tiles and wipe or replace as needed.

8.8.4 Remove all supplies from the shelving in the non-sterile compounding area and clean and sanitize the shelves.

9.0 Cleaning can be performed as often as needed, but the minimum requirement is at the end of the day after compounding.

10.0 The Pharmacist-in-charge shall ensure the completion of tasks on a daily basis and shall review and sign/date attachment 1&2 at the end of each month. The form shall be retained in a cleaning/maintenance binder. At the end of the month the forms will be scanned to a shared folder.

11.0 REFERENCES

11.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

11.2 SOP 1.050 "General Compounding Technique"

11.3 SOP 3.130 "Required Garb for Non-Sterile Compounding Area"

12.0 ATTACHMENTS

12.1 Office area cleaning and maintenance log – See forms folder

12.2 Temperature and humidity logs – See forms folder

12.3 Non-sterile compounding area cleaning and maintenance log – See forms folder

13.0 SOP History

___ Draft X Final	Annual Policy Review
Approved by:	Original Owner / Date: Theresa Bergh, RPh, PIC / 11-01-24
_____ Theresa Bergh, RPh, PIC	Reviewer / Date:
This policy implemented on: 11/01/2024	

1/10

original

Certificate of Analysis

Fagron personalizing medicine

Product Name	SaltStable LS Advanced	**Manufacturers Information:**	
Item Number	1004499	**Mfg. Batch #**	240232
Inspection Report #	C224-009717	**Ref No.**	2240101369
Batch #	240232	Birchwood Laboratories, Inc.	
Analyzed According to	FAUS	7900 Fuller Road	
Expiration Date	7/31/2026	Eden Prairie, MN 55344	
		USA	

Test Description	Test Result Description	Requirement	Result	Unit	Test Location
Description	Opaque, off-white cream, non-flowable; characteristic odor	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Odor	Characteristic	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
pH	6.0 - 7.5 @ 25ºC	6.0-7.5	6.9	No Unit	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Specific Gravity	@ 25ºC information only, read and report	0.90-1.50	0.97	g/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Viscosity	1000000 - 1400000 @ 25ºC	1,000,000-1,400,000	1,133,333	cP*s	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total aerobic microbial count		0-50	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total yeast and mold count		0-10	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	P. aeruginosa	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	S. aureus	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	B. cepacia	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA

Release Details
Quality Technician: Kendra Borawski
Conclusion Date: 8/16/2024
Conclusion: Approved
This document has been produced electronically from our quality system and is valid without signature.

Certificate of Analysis

2/10 HUMCO

manufacturer

Product Name	SaltStable LS Advanced	Manufacturers Information:
Item Number	1004499	Mfg. Batch # 240232
Inspection Report #	C224-009717	Ref No. 2240101369
Batch #	240232	Birchwood Laboratories, Inc.
Analyzed According to	FAUS	7900 Fuller Road
Expiration Date	7/31/2026	Eden Prairie, MN 55344 USA

← manufacturer verified on FDA website

Test Description	Test Result Description	Requirement	Result	Unit	Test Location
Description	Opaque, off-white cream, non-flowable; characteristic odor	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Odor	Characteristic	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
pH	6.0 - 7.5 @ 25ºC	6.0-7.5	6.9	No Unit	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Specific Gravity	@ 25ºC information only, read and report	0.90-1.50	0.97	g/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Viscosity	1000000 - 1400000 @ 25ºC	1,000,000-1,400,000	1,133,333	cP*s	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total aerobic microbial count		0-50	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Total yeast and mold count		0-10	0	CFU/mL	Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	P. aeruginosa	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	S. aureus	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA
Test for specified organism	B. cepacia	Conforms	Conforms		Birchwood Laboratories, Inc. 7900 Fuller Road Eden Prairie, MN 55344 USA

Release Details
Quality Technician: Kendra Borawski
Conclusion Date: 8/16/2024
Conclusion: Approved
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Drug Establishments Current Registration Site

New Search

Search Results for *birch*

Showing 1 to 2 of 2 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Birchwood Laboratories LLC	2182825	096488432	MANUFACTURE	7900 Fuller Road, Eden Prairie, Minnesota (MN) 55344, United States (USA)	12/31/2025
Willow Birch Pharma Inc	3009864247	617153924	RELABEL; REPACK	447 County Road 303 Ste B, Taylor, Mississippi (MS) 38673, United States (USA)	12/31/2025

Previous 1 Next

Data Current Through: Wednesday, Feb 26, 2025

New Search

Darmerica
4380 Oakes Road, Unit 800
Davie, FL 33314 USA
www.darmerica.com

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our original

Certificate of Analysis

Sildenafil Citrate USP

Product Name : Sildenafil Citrate
Mfg. Date : Mar 2024
CAS No. : 171599-83-0

Lot No. : DR8084
Exp. Date : Feb 2029
Batch Qty : 263.16 kg

TESTS	SPECIFICATIONS		RESULTS
Description	White or almost white, slightly hygroscopic, crystalline powder		White, slightly hygroscopic, crystalline powder
Solubility	Slightly soluble in water and in methanol, practically insoluble in hexane		Complies
Identification	IR <197K>		Complies
Limit of Imidazole <621>	≤ 0.10%		< 0.10%
Organic Impurities (HPLC)	Sildenafil Related Compound A	≤ 0.30%	Below Quantification Limit
	Any Other Unspecified Individual Impurity	≤ 0.10%	Below Quantification Limit
	Total Unspecified Impurities	≤ 0.30%	Below Quantification Limit
	Total Impurities	≤ 0.50%	Below Quantification Limit
Water Content (KF) <921> (Method I)	≤ 2.50% w/w		1.40% w/w
Residue on Ignition <281>	≤ 0.10% w/w		0.02% w/w
Assay (On Anhydrous and Solvent-Free Basis) (HPLC) <621>	98.0 – 102.0% w/w		100.4% w/w
Citric Acid Content (Titration) (In-House)	27.5 – 30.5% w/w		28.7% w/w
Residual Solvents	Methanol	≤ 3000 ppm	Not Detected
	Methylene Dichloride	≤ 600 ppm	Not Detected
	Triethyl Amine (GC)	≤ 320 ppm	Below Quantification Limit
X-Ray Diffraction (In-House)	X-Ray diffraction pattern of test sample should match with 2θ value - 8.08, 10.29, 14.40, 19.87, 22.66 ± 0.2.		Complies
Conclusion: The product meets the USP Monograph specifications. Long Term Storage: Store in a sealed container at room temperature. ID Test was confirmed by FT-IR on-site. Distributed by Darmerica.			

Note: Analytical results transcribed from the original COA provided by Amoli Organics (A Division of Umedica Laboratories Pvt. Ltd.) (Luna) (India); Lot No. B24410H021.

Manufacturer Verified

Based on the review of above information, the lot stands released.

	Name	Title	Signature	Date
Prepared by	Christina Boykin	Quality Supervisor	Christina Boykin	05/30/2024
Released by	Faiz Badrudeen	Quality Associate	Faiz Badrudeen	06/03/2024

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Drug Establishments Current Registration Site

New Search

Dermerica CofA

Search Results for *amoli*

Showing 1 to 2 of 2 entries Show 50 entries

Firm Name	FDA Establishment Identifier	DUNS	Business Operations	Address	Registration Expiration Date
Amoli Organics (A Division of Umedica Laboratories Pvt.Ltd)	3004810446	862234820	ANALYSIS; API MANUFACTURE	Plot 322/4, 40 Shed Area, G.I.D.C, Vapi, District, GIDC VAPI, Valsad, GUJARAT 396195, India (IND)	12/31/2025
Amoli Organics (A Division of Umedica Laboratories Pvt.Ltd.)	3007836955	918610077	ANALYSIS; API MANUFACTURE	Block No. 422, ECP Canal Road Village-Luna, Taluka-Padra, Vadodara, Gujarat 391440, India (IND)	12/31/2025

Previous 1 Next

Data Current Through: Tuesday, Feb 25, 2025

New Search

DARMERICA

6/10

PRESCRIPTION (LEGEND) DRUG PEDIGREE
History of Drug Sales and Distributions

Product Information			
Legend Drug Name, Strength, NDC, Dosage Form, Container Size	Sildenafil Citrate USP - 100 g NDC: 71052-067-01	Lot #DR8084	Total Qty: 300 g
Manufacturer Name and Address	Amoli Organics Pvt Ltd. (Location 1) (LUNA), Block No. 422. ECP Canal Road, Village-Luna, Taluka-Padra, Vadodara, GUJARAT 391440, India		
Legend Drug Name, Strength, NDC, Dosage Form, Container Size	Tadalafil USP - 50 g NDC: 71052-059-08	Lot #: DR7958	Total Qty: 50 g
Manufacturer Name and Address	Maithili Life Sciences Private Limited Plot No. 2, APIIC Industrial Estate, Gajulamandyam Village Renigunta Mandal, Tirupati, Tirupati, Andhra Pradesh 517520, India (IND)		

Transaction Information			
Shipping Date	11/20/2024	Invoice #	71040
Seller Name and Address	Darmerica LLC, 4380 Oakes Rd, Unit 800, Davie, FL 33314, USA		
Buyer Name and Address	Synergy Apothecary 10101 W. Innovation Dr, #600 Wauwatosa, WI 53226 USA		

Transaction History	
Shipper Name and Address	Darmerica LLC, 4380 Oakes Rd, Unit 800, Davie, FL 33314, USA; Fl Wholesale License No.: 2220288
Receiver Name and Address	Synergy Apothecary 10101 W. Innovation Dr, #600 Wauwatosa, WI 53226 USA

Transaction Statement
☑ (A) Is authorized as required under the Drug Supply Chain.
☑ (B) Received the product from a person that is authorized as required under the Drug Supply Chain Security Act.
☑ (C) Received transaction in formation and a transaction statement from the prior owner of the product, as required under section 582.
☑ (D) Did not knowingly ship a suspect or illegitimate product.
☑ (E) Had systems and processes in place to comply with verification requirements under section 582.
☑ (F) Did not knowingly provide false transaction information.
☑ (G) Did not knowingly alter the transaction history.

Darmerica LLC

Name of Authenticator: Fabrizio Mora

Signature of Authenticator:

Telephone Number: 321-219-9111

Email address: operations@darmerica.com

Amoli Organics

(A Division of Umedica Laboratories Pvt. Ltd.)

Regd. Office: Plot No. 221, 221/1, G.I.D.C., II[nd] Phase, Vapi - 396195, Dist. Valsad, Gujarat, INDIA.
Factory: Block No. 422, ECP Canal Road, Village - Luna, Ta.- Padra, Dist.-Vadodara. INDIA. Pin Code - 391440.
Phone: +91-2662-811200, E-mail: baroda@amoliindia.com, Website: www.amoliindia.com, CIN: U24231GJ1982PTC141202

7-1/10

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

PRODUCT :	Sildenafil Citrate (SCE) ✓		
Standard For Release :	USP	Mfg. Lic no. :	G/1518

Batch No.:	B24410H021	A.R. No. :	85000017520/02
Batch size :	263.16 Kg	Date of sampling :	31/03/24
Mfg. date :	MAR - 2024	Retest date :	FEB - 2029 ✓

Sr. No.	Test name	Test result	Acceptance criteria	
1.0	Description	White, slightly hygroscopic, crystalline powder.	White or almost white, slightly hygroscopic, crystalline powder.	✓
2.0	Solubility	Slightly soluble in water and in methanol, practically insoluble in hexane.	Slightly soluble in water and in methanol, practically insoluble in hexane.	✓
3.0	Identification by I.R.	Complies	The IR spectrum of the test sample should be concordant with that of working standard.	✓
4.0	Limit of Imidazole	Less than 0.1%	Not more than 0.1 %	✓
5.0	Organic impurities by HPLC			
	a) Sildenafil related compound A	Below Quantification Limit	Not more than 0.3 %	✓
	b) Any other unspecified individual impurities	Below Quantification Limit	Not more than 0.10 %	✓
	c) Total unspecified impurities	Below Quantification Limit	Not more than 0.3 %	✓
	d) Total impurities	Below Quantification Limit	Not more than 0.5 %	✓
6.0	Water content by KF	1.4 % w/w	Not more than 2.5 %	✓
7.0	Residue on ignition	0.02 % w/w	Not more than 0.1 %	✓
8.0	Assay by HPLC (On anhydrous basis and solvent free basis)	100.4 % w/w	Not less than 98.0% and Not more than 102.0%	✓
9.0	Citric acid content by titration	28.7 %	Between 27.5 to 30.5 % w/w	✓

K.B. Mistry 05/10/2024

Date of Approval: 29/04/24

	Prepared by	Checked by	Approved by
Sign / Date	29/04/24	29/04/24	29/04/24
Name :	Ashwin Padhiyar	Mahendra Ravalji	Manish Shah
Designation :	Sr.Officer (QC)	Asst.Manager (QC)	Sr.Manager (QC)

Format No.: QCD/GEN/033/F01-02

Corporate Office : 407, Dalamal House, Jamnalal Bajaj Road, Nariman Point, Mumbai - 400 021 INDIA.
Phone : +91-22-22854715/16/17, (022) 66214715
Email : info@amoliindia.com

Amoli Organics

(A Division of Umedica Laboratories Pvt. Ltd.)

Regd. Office: Plot No. 221, 221/1, G.I.D.C., II[st] Phase, Vapi - 396195, Dist. Valsad, Gujarat, INDIA.
Factory: Block No. 422, ECP Canal Road, Village - Luna, Ta.- Padra, Dist.-Vadodara, INDIA. Pin Code - 391440.
Phone: +91-2662-611200. E-mail: baroda@amolilndia.com, Website:www.amolilndia.com, CIN: U24231GJ1982PTC141202

7-2/10

QUALITY CONTROL DEPARTMENT
CERTIFICATE OF ANALYSIS

PRODUCT :	Sildenafil Citrate (SCE)		
Standard For Release :	USP	Mfg. Lic no. :	G/1518

Batch No.:	B24410H021	A.R. No. :	85000017520/02
Batch size :	263.16 Kg	Date of sampling :	31/03/24
Mfg. date :	MAR - 2024	Retest date :	FEB - 2029

Sr. No.	Test name	Test result	Acceptance criteria	
10.0	Residual solvents			
	Methanol	Not detected	Not more than 3000 ppm	✓
	Methylene dichloride	Not detected	Not more than 600 ppm	✓
11.0	Triethyl amine content by GC	Below Quantification Limit	Not more than 320 ppm	✓
Additional test				
12.0	X- ray Diffraction			
	X- ray Diffraction	Complies	X-ray diffraction Pattern of test sample should be match with 2θ value - 8.08, 10.29, 14.40, 19.87, 22.66 ±0.2	✓

SO No.: 20122

Remarks: **The product complies with USP - 2023 specification.**

Approved / ~~Rejected~~

K.B. Mistry 05/10/2024

Date of Approval: 29/04/24

	Prepared by	Checked by	Approved by
Sign / Date	29/04/24	29/04/24	29/04/24
Name :	Ashwin Padhiyar	Mahendra Ravalji	Manish Shah
Designation :	Sr.Officer (QC)	Asst.Manager (QC)	Sr.Manager (QC)

Format No.: QCD/GEN/033/F01-02

Corporate Office : 407, Dalamal House, Jamnalal Bajaj Road, Nariman Point, Mumbai - 400 021. INDIA.
Phone : +91-22-22854715/16/17, (022) 66214715
Email : info@amolilndia.com

Medisca

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CERTIFICATE OF ANALYSIS

VERSAPRO™ CREAM BASE

Batch/Lot Number : 208012

Manufacturing Date : 01/13/2024

Expiration Date : 12/31/2025

CAS: N/A

TESTS	SPECIFICATIONS	RESULTS
DESCRIPTION	White, smooth, shiny, viscous cream. Is odorless.	CONFORMS
SPECIFIC GRAVITY	0.96 - 1.10 (25°C)	0.99
pH	4.25 - 5.50 (25°C)	4.82
TOTAL AEROBIC MICROBIAL COUNT <61>	≤ 100 cfu/g	< 10 cfu/g
TOTAL YEAST & MOLD <61>	≤ 10 cfu/g	< 10 cfu/g
ABSENCE OF SPECIFIED MICROORGANISMS <62>	Meets the requirements for the absence of: • Staphylococcus aureus • Pseudomonas aeruginosa • Candida albicans • Bile tolerant gram negative bacteria	CONFORMS
ABSENCE OF SPECIFIED MICROORGANISMS <60>	Meets the requirements for the absence of: • Burkholderia cepacia	CONFORMS
GRAM POSITIVE	Absent.	CONFORMS
PACKAGING AND STORAGE	Keep in well-closed containers at controlled room temperature.	

Lot number has been changed from ZA278 to 208012.

PUBLISHED BY:

PUBLISHED DATE:

03/22/2024

ISSUE DATE:

03/22/2024

The above mentioned product conforms to the manufacturer's specifications.

The above test results are a direct transcription of information provided to MEDISCA from the Certificate of Analysis provided by the manufacturer / supplier. Additional testing conducted by MEDISCA is represented by an asterisk.

All dates in this document are in format mm/dd/yyyy unless otherwise specified

This document has been electronically approved through MEDISCA's Quality Management System.

englewoodLAB
WWW.ENGLEWOODLAB.COM

9/10

20 Campus Road, Totowa, NJ 07512 • Phone: 201-567-2267 • Fax: 201-567-2280

CERTIFICATE OF ANALYSIS

Product: VERSAPRO CREAM BASE (REFORM 3) –MEDISCA FORMULA # RD010919-6
Customer: MEDISCA
Batch Code: ZA278
Formula Code: 170-18249-04 Rev 5
Batch Size: 2,000 KG
Compounding Date: 01/13/2024
2 Year Expiration Date: 01/13/2026

TEST	TEST METHOD (SOP)	SPECIFICATIONS	RESULTS
APPEARANCE	6-006	SMOOTH, SHINY, VISCOUS CREAM TO MATCH STANDARD	T- PASS B-PASS
COLOR	6-006	WHITE TO MATCH STANDARD	T- PASS B- PASS
SCENT	6-005	ODORLESS (NO FRAG. ADDED) TO MATCH STANDARD	T- PASS B- PASS
pH	6-001	4.25 - 5.50 (DIRECT, @ 25°C)	T-4.82 B-4.86
SPECIFIC GRAVITY	6-002	0.96 - 1.10 (PYCNOMETER, @ 25°C)	T-0.99 B-0.99
SOLUBILITY	N/A	PARTIALLY SOLUBLE IN WATER	T-PASS B-PASS
VISCOSITY	6-003	INITIAL: BROOKFIELD RVDV-1/RVT, SPINDLE T-D AT 2.5 RPM FOR 1 MINUTE @25°C 250,000 TO 400,000 CPS *VISCOSITY DIFFERENCE BETWEEN TOP & BOTTOM SAMPLE SHOULD NOT BE GREATER THAN 50,000 CPS*	T-349,000 CPS B-355,300 CPS. 6,300 CPS
		AFTER 24HOURS: BROOKFIELD RVDV-1/RVT, SPINDLE T-D AT 2.5 RPM FOR 1 MINUTE @25°C 250,000 TO 400,000 CPS *VISCOSITY DIFFERENCE BETWEEN TOP & BOTTOM SAMPLE SHOULD NOT BE GREATER THAN 50,000 CPS*	T-360,000 CPS M-383,400 CPS B-380,600 CPS 20,600 CPS.
		(1 WEEK: INFORMATIONAL) BROOKFIELD RVT T-D AT 2.5 RPM FOR 1 MINUTE @ 25C	*381,000 CPS*
MICROBIAL CONTENT TEST	USP <60> USP<61> USP<62>	TOTAL PLATE COUNT (TPC) < 100 CFU/G OR ML YEAST & MOLD < 10 CFU/G OR ML GRAM NEGATIVE: ABSENT ABSENT OF PATHOGENS INCLUDING: STAPHYLOCOCCUS AUREUS, PSUEDOMONAS AERUGINOSA, CANDIDA ALBICANS, BURKHOLDERIA CEPACIA AND BILE-TOLERANT GRAM - NEGATIVE BACTERIA GRAM POSITIVE: ABSENT	*PASS (01/20/2024)*
PACKAGING AND STORAGE	N/A	STORE AT CONTROLLED ROOM TEMPERATURE	*INFORMATIONAL ONLY*

Note 1: Samples were tested by an approved Lab.

Results recorded by: Alejandra Lopez Date: 1-24-24

Quality manager or designee Approved by: Juan Cuervo Date: 1/26/2024

Englewood LAB
FDA LICENSE/REGISTRATION # 3013020160 | ISO INTERNATIONAL STANDARD 22716:2007
20 CAMPUS RD TOTOWA, NJ 07512 USA
Tel: 201-567-2267 Fax: 201-567-2280

MICROBIOLOGICAL CERTIFICATE OF ANALYSIS

QC LAB - CHAIN OF CUSTODY FORM AND REPORT BULK/FG/WIP — Microbiological Certificate of Analysis. — QBK24-00129-001-MCI-001

EWL Micro Lab Reference Number	Product Type: Bulk, FG, WIP	CUSTOMER	PRODUCT NAME	LOT #	BATCH #	PRODUCTION DATE	SIZE QUANTITY	Comments	Test Method
	BULK	MEDISCA	BK102179 / VERSAPRO CREAM BASE (REFORM 3) / 137146	N/A	ZA278	01/13/2024	4 FL.OZ 1 BULK	N/A	USP-60, USP-61, USP-62

Submission By: AL Date: 1-15-24 A.1-15-24

Note 1: All Supplier/Vendor Materials that require Micro, CoA must be attached.
Note 2: Requestor must attach product specification sheet.

Microbiology Lab Only: Date Received: 1/15/24 Initial: JR

Test Method:

Microbiological Analysis

No.	TPC	Gram Stain			Results								
	Count (CFU/g or ml)	g-	g+B	g+C	Yeast/Mold Count (CFU/g or ml)	EC	PA	SA	Salmonella	Clostridia	Candida Albicans	BCC	Coliform
1	<10 CFU/g		N A TK 01/20/2024		<10 CFU/g	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☑NG ☐G	☐NG ☐G
2						☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G
3					N A TK 01/20/2024	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☐NG ☐G	☑NG ☐G

Abbreviations: g-: gram-negative; g+B: gram-positive Bacilli; g+C: gram-positive Cocci; TPC: Total Plate Count; TNTC: Too Numerous to Count; EC: E coli; PA: Pseudomonas aeruginosa; SA: Staphylococcus aureus; BCC: B.Cepacia; G= Growth; NG = No Growth

Test Results Recorded by: Initial TK Date: 01/20/2024

Reviewed and Approved by: Initial LC Date: 01/20/2024

Comment (For Microbiology Lab Use Only): MA TK 01/20/2024

3.160 SAFETY PROCEDURES (VERSION 1.0)

Synergy Apothecary

1.0 PURPOSE

1.1 The purpose of this procedure is to establish outlines for safety procedures at Synergy Apothecary.

2.0 RESPONSIBILITY

2.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

2.2 The Pharmacist-in-charge shall be responsible for assuring that all personnel involved in generating, completing or reviewing data are trained in the requirements of this procedure.

2.3 All employees at Synergy Apothecary are responsible for complying with this procedure.

2.4 The Pharmacist-in-charge shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

2.5 The Pharmacist-in-charge is responsible for reviewing the OSHA Standard <29 CFR 1910.1200> Hazard Communication to confirm minimum standards are being met or exceeded by Synergy Apothecary.

2.6 Synergy Apothecary shall develop, implement, and maintain a written hazard communication program for personnel handling or otherwise exposed to chemicals including drugs that represent a health hazard. The written plan shall describe how the criteria specified by OSHA's Hazard Communication Standard will be met.

3.0 DEFINITIONS

3.1 SW – Standard Work

4.0 PROCEDURE

4.1 FREQUENCY

4.1.1 Invariable

4.2 EQUIPMENT & SUPPLIES

4.2.1 Appropriate Safety Data Sheets (SDS)

4.2.2 SW-How to interpret an SDS sheet

4.2.3 OSHA Form 301 – Injury and Illness Incident Report

4.3 GENERAL INFORMATION

4.3.1 N/A

4.4 General Safety

4.4.1 All employees must know the location(s) of first aid kits, eye wash stations, safety showers, change of clothing, fire extinguishers and spill kits.

4.4.2 All employees must be familiar with SDS for materials in use in his or her work area.

4.4.3 Inspect glassware for defects before use. **DO NOT USE DAMAGED GLASSWARE.** If a defect is observed, the glassware must be disposed of properly.

4.4.4 Use only those chemicals for which the quality of the available ventilation system is appropriate.

4.4.5 The work area should be kept clean and free of clutter. Equipment and chemicals must be properly labeled and stored, and the work area must be cleaned upon the completion of an operation and/or at the end of each workday.

4.4.6 SW's are to be followed on spills, donning, and doffing of PPE. Use protective apparel (gloves, goggles, disposable gowns, masks, lab-coats, etc.) as appropriate.

4.4.7 Compliance of The Medical Surveillance plan.

4.4.8 Report all work-related accidents, illnesses and injuries to the Pharmacist-in-charge immediately. If administration of first aid is insufficient, employee must seek medical attention and complete OSHA Form 301 – Injury and Illness Incident Report.

4.4.9 Chemical waste must be disposed of in appropriately labeled containers.

4.4.10 Employees will complete SOP 1.020 Work orders on all equipment malfunctions.

4.5 Chemical Spills

4.5.1 Promptly clean up spills, and properly dispose of, using appropriate protective apparel and equipment. Refer to SDS for specific clean-up instructions.

4.5.2 Hazardous Spills – follow procedure defined in the "Hazardous Spill Clean Up" SW.



4.5.3 Eye Contact – Promptly flush eyes with water for at least 15 minutes and seek medical attention. Refer to SDS for specific eye contact instructions.

4.5.4 Ingestion – Drink large amounts of water. Refer to SDS for specific ingestion instructions.

4.5.5 Skin Contact – Promptly remove any contaminated clothing and flush the affected area with water. Seek medical attention if symptoms persist after washing. Refer to SDS for specific skin contact instructions.

4.6 Hazard Communication Training

4.6.1 The written hazard communication program shall describe how the requirements for labels and other forms of warning, material safety datasheets, and employee information and training are going to be met by the pharmacy. The written program shall also contain the following:

4.6.1.1 A list of the hazardous drugs known to be present in the pharmacy using a chemical name that is referenced on the appropriate SDS.

4.6.1.2 The methods that shall be used to inform personnel of the hazards of non-routine tasks in their work area.

4.6.1.3 The methods that shall be used to inform personnel of other employers of hazards at the pharmacy (i.e. contract janitorial service).

4.6.2 Requirements for labels and other forms of warning

4.6.2.1 The pharmacist or individual receiving hazardous chemicals shall ensure that all containers of hazardous drugs shipped to Synergy Apothecary are appropriately labeled with the identity and warnings of the hazardous drug(s), and the name and address of the chemical manufacturer or distributor.

4.6.2.2 Appropriate hazard warnings shall include words, pictures, symbols, or a combination thereof, and shall provide at least general information

2.050 SOP NON-HAZARDOUS DRUG SPILL CLEAN-UP (Version 1.0)

Synergy Apothecary

1.0 Purpose

1.1 The purpose of this procedure is to establish guidelines for the handling of non-hazardous drug or chemical spills in a safe and efficient manner.

1.2 This procedure applies to all compounding personnel and to the Synergy Apothecary non-sterile compounding area under conditions that meet or exceed state and federal guidelines as outlined by the United States Pharmacopeia <795>

2.0 Responsibility

2.1 The Pharmacist-in-charge or the Quality Control Officer shall supervise this procedure.

2.2 All personnel at Synergy Apothecary are responsible for following this procedure.

2.3 The Pharmacist-in-charge shall be responsible for ensuring that only trained personnel can work in the non-sterile compounding area. No other personnel or patients will be allowed within this area unless wearing appropriate clothing and under strict supervision.

2.4 All personnel shall be responsible for chemical non-hazardous drug spills and shall be cleaned up immediately and appropriately. Personnel involved in the spill shall be given priority, and the spill shall be contained to the immediate vicinity of the spill. Follow SW named Non-Hazardous spill clean-up.

2.5 All personnel must notify The Pharmacist-in-charge immediately if a spill occurs during delivery, and the driver shall fill out an Incident Report Form upon returning to Synergy Apothecary.

3.0 Definitions

3.1 MSDS – Material Safety Data Sheet

3.2 NIOSH – National Institute for Occupational Safety and Health

3.3 BSC – Biological Safety Cabinet

3.4 SW- Standard Work

4.0 Procedure

4.1 Whenever a non-hazardous drug spill occurs, follow SW Non-Hazardous Spill Clean Up.

4.2 The three categories of spills discussed in this procedure are:

- 4.2.1 Small spills
- 4.2.2 Large spills
- 4.2.3 Spills during delivery

4.3 Small Spills

- 4.3.1 Small spills are categorized as those less than 5mL or 5g inside of the hood.

4.4 Large Spills

- 4.4.1 Large spills are categorized as those larger than 5mL or 5g or a spill that extends outside of the hood.

4.4.2 For large spills, follow Non-Hazardous Spill Clean Up SW.

4.5 Spill During Delivery

4.5.1 Small spills and large spills shall be cleaned up per Product Receiving SW.

4.6 The BSC cannot be used until it has been properly cleaned and sanitized.

4.6.1.1 Only qualified personnel shall remove the HEPA filter grid from the BSC, if this is needed and product that was spilled to be disclosed to person/company replacing the filter.

4.6.1.2 The unit must be certified by an outside consulting company prior to use if new filter is placed.

5.0 References

5.1 Local, State and Federal laws

5.2 SOP 5.020 "Patient Satisfaction

5.3 USP <795>

6.0 Attachments

6.1 N/A

7.0 SOP History

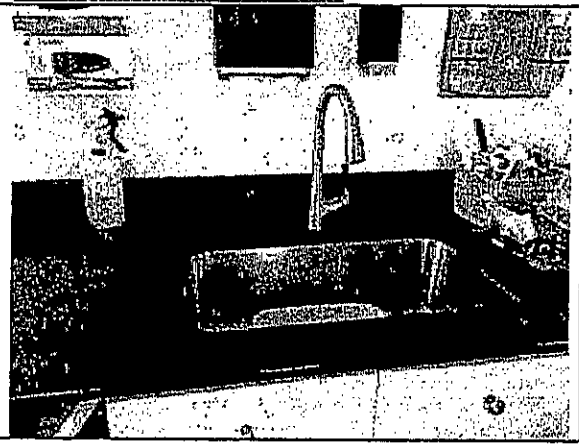
___ Draft X Final	Annual Policy Review
Approved by: Theresa Bergh, RPh, PIC **This policy implemented on:** 02-21-2025	Original Owner / Date: Theresa Bergh, RPh, PIC / 02-21-2025 Reviewer / Date:

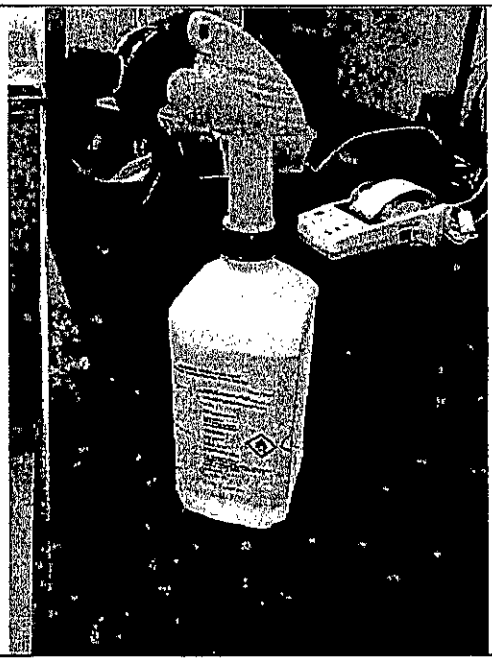
Remainder of this page intentionally left blank

Synergy Apothecary SOP:	**Non-Hazardous Spill Clean Up**		
Trigger:	**When a non-hazardous drug/product is spilled**		
Done:	**When the spill is cleaned up**		
Applies to:	**All Staff**	*Rev #:*	**0005**
Revised By:	**Theresa Bergh**	*Effective Date:*	**02/12/2025**
Written By:	**Wendy Buehring**	*Original Date:*	**11/01/2024**

	Process Step	*Reference*	*Time*
1.	There are three types of spills: when a spill occurs, cease all compounding and assess the situation. • Is the spill contained within the hood -proceed to step 2 • Has the spill contaminated an area outside of the hood but the drug has not penetrated your PPE -proceed to steps 3-13 • Are you personally contaminated where the drug has penetrated through your PPE? Proceed to steps 14-23		
2.	If a spill is contained in the hood • clean up the entire spill as you would clean the hood (see SW for cleaning hoods) • discard in the trash then close up the bag and start a new trash bag.		
3.	If a spill contaminates an area outside of the hood and has not penetrated your PPE, holler SPILL" loud enough to notify other staff that their help is needed to contain the spill (if needed) • An office personnel member/or a second person in the lab, at this time, will proceed to the Lab door and will obtain "Wet floor signs if needed" to avoid any employee an-up. -There is a spill kit that includes all necessary spill kit to clean the spill, Note, it might be labelled as HD spill kit but it's still appropriate to use for non-HD.		

4.	The compounder will remove the outer gloves and dispose of them directly into the spill. (This is to ensure you do not track the chemical/medication any further than necessary.) • Pinch the outside of the first glove about an inch below the cuff and pull down toward your fingers • Insert one finger from your first hand under the cuff of the second hand's glove that you are removing and push off toward your fingers.	 	
5.	Remove the blue disposable gown turning it inside out and rolling it into a ball. Dispose of the gown directly into the spill. (This is to ensure you do not track the chemical/medication any further than necessary.)		
6.	Inspect yourself for any signs of contamination that has penetrated through your PPE. (Seeing none, proceed to next step)		
7.	Re-don the proper PPE using the spill kit that your coworker will bring in with them once they have donned the proper PPE (located just outside Lab 2 door in the white Hazardous Spill Kit or the kit)		

8.	Clean the spill and dispose of everything in the bag provided in the spill kit. • Use water to wet the spill and the disposable towels to wipe up the contaminates. • Decontaminate all surfaces three times using 70% alcohol and a lint free cloth.			
9.	Remove your PPE (following the SW: Doffing PPE used for non-Hazardous Compounding) and place into the bag provided in the spill kit. This includes the shoe covers. Dispose of the bag into the trash unless sharp objects are involved then place in plastic box or bin before disposing of.			
10.	Wash hands following the SW for Proper Hand Washing			

11.	Re-don your non-hazardous PPE following the SW: Donning PPE for nonhazardous Materials	SW: Donning PPE for Non-hazardous Materials	
12.	Proceed to do a final cleaning of the area and allow it to dry and air out. This includes: • wiping the surrounding area, counters, cabinets, and any other equipment with 70% alcohol and a lint free cloth. • Washing any equipment with soap and water that can go into the sink. • Mopping the floor and using WET FLOOR signs		
13.	Resume operation in Lab • Proceed to step 21		
14.	If the spill contaminates an area outside of the hood and has penetrated the compounder's PPE, holler SPILL CONTAMINATED" loud enough to notify other staff that a has occurred, and someone has been contaminated. **Note: at this time multiple things will happen at the same time • An office personnel member/or a second person in the lab, at this time, will proceed to the Lab 2 door and will turn the "Caution Wet Floor" sign around to notify the remainder of the staff that there is a HD spill. This person will then don with the proper attire () to assist with the spill clean-up taking over for the compounder		

	who was contaminated (so they can decontaminate themselves). This person will also take the spill kit into the lab for clean-up following steps 7-14 -A non-contaminated personnel member will set up the shower and set out the clean set of scrubs (		
15.	Remove all PPE and contaminated clothing immediately this includes any clothing under your PPE (following the SW: Doffing for non-Hazardous Drug Preparation) and dispose of everything directly into the spill or double bagged garbage.		
16.	If drug has splashed directly in the eyes, the eyes must be immediately flushed with water or an eye wash solution for at least five minutes and if necessary, seek medical attention immediately. • Provide comfort cares/first aid as needed example: provide moist gauze to cover eyes post flushing. • Make sure to document all cares provided on the incident report form		
17.	Cover with the two lab coats provided by staff and proceed directly to the shower located in the warehouse area. • After shower, dress with the new scrubs provided		
18.	If medical attention is required management will determine if the incident is a minor or a major incident.		

	• Pull a copy of the incident report and the SDS form from the SDS binder for the chemical/medication spilled and send with coworker for the medical professionals to reference.		
19.	For a minor incident: • provide first aid/comfort measures as needed using the first aid kit • If further medical attention is needed, a member of management will drive the injured coworker to seek professional assistance taking a copy of the SDS form and the incident form with them. Management will stay with the injured coworker to ensure all paperwork is completed and to answer any additional questions.		
20.	For a major incident: • Call 911 and follow their instructions until help arrives • Offer comfort measures until medical assistance arrives. (Example: if eyes have been flushed, provide with saline soaked gauze to keep eyes moist) • A member of management will meet the injured coworker at the facility they are being taken to with copies of the SDS forms and an incident report form and will remain with them to ensure all forms are completed and to provide additional information as needed.		
21.	Write out an incident report located in the "Forms" active folder for chemical exposure. (Printed copies are also located in the SDS binder)		

Synergy Apothecary EMPLOYEE TRAINING RECORD

Hire Date: _____

Employee Name: _____ **Hired Position** _____

Initial Mentor/Trainer Signature: _____

Training Requirement (i.e initial orientation/compounding/safety)	Comments	Completion Date/Initials
Review of SW and orientation checklist		
Facility review		
Pioneer Rx training (role dependent)		
Math Calculations		
Office procedures/shipping/cleaning		
Batch prepwork and labeling		
Chemical Spill Kit		



Description of Training: _____

_____

Reviewed By: _____ **Date:** _____

NEW FORMAT 2/21/25

updated default labels with software provider

See comparison of green highlighted areas

OLD Format →

Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed

SYNERGY APOTHECARY LLC
10101 W INNOVATION DR, STE 600
MILWAUKEE, WI 53226-4824 (833) 504-2966

0010026 02/11/2025 [redacted]

Sildenafil 60mg Troche

ONE TROCHE BUCCALLY ONE HOUR PRIOR TO SEXUAL ACTIVITY AS NEEDED. MAX ONE DOSE PER DAY.

NDC: COMPOUND Qty 20

REFILL (02) TIMES AT 20 UNTIL 01/28/2026

LOT; AL-Test010825 BUD-Discard After 07/07/2025 Rph: TB

Sildenafil 60mg Troche

Lot: AL-Test010825 BUD-Discard After 07/07/25

Single Use Only Not For Resale

Buccal Store at Room Temp

Synergy Apothecary Ph: (833) 504-2966



Caution: Federal law prohibits transfer of this drug to any person other than patient for whom prescribed

SYNERGY APOTHECARY LLC
10101 W INNOVATION DR, STE 600
MILWAUKEE, WI 53226-4824 (833) 504-2966

0010026 02/11/2025 [redacted]

Sildenafil 60mg Troche

ONE TROCHE BUCCALLY ONE HOUR PRIOR TO SEXUAL ACTIVITY AS NEEDED. MAX ONE DOSE PER DAY.

NDC: COMPOUND Qty 20

REFILL (02) TIMES AT 20 UNTIL 01/28/2026

AL-Test010825 EXP: 07/07/2025 Rph: TB

3 in x 1.5 in

Item:360120

Sildenafil 60mg Troche

Lot: AL-ST020625 Exp: 08/04/25

Single Use Only Not For Resale

Buccal Store at Room Temp

Synergy Apothecary Ph: (833) 504-2966



Logged Formula Worksheet

2/25/2025 11:17 AM

L8

Synergy Apothecary LLC
10101 W Innovation Dr, Ste 600
Milwaukee, WI 53226-4824
(833) 504-2966

Diclofenac 3%/Gabapentin 6% Cream

Flavor:
Qty Made: 100.000 GM
Date Made: 12/13/2024
Lot #: 8
Alternate Lot #: AL-121324
Beyond Use Date: 1/12/2025
Pharmacist: Bergh, Theresa
Technician:

DEA Schedule: 0
Alternate ID:

Pricing calculations from the log

Estimated Price:	$33.19		
Ingredient Cost:	$16.82		
Additional Cost:	$0.00		
Time Cost:	$10.00	Minutes to Make:	20.00
Profit:	$6.37		

Ingredient	DEA Schedule	Qty Used		QS (Balance)	Actual Cost	Date
1 Diclofenac Sodium Powder Lot: DR7543 Exp. Date: 05/2026 NDC: 71052-0112-05 Barcode Checked: ☐	0	3.300	GM	☐ _____	$0.98	11/26/2024
2 Gabapentin Powder Lot: DR7969 Exp. Date: 07/2027 NDC: 71052-0176-05 Barcode Checked: ☐	0	6.600	GM	☐ _____	$2.63	11/26/2024
3 Versapro Cream Base Lot: Exp. Date: NDC: 38779-2529-08 Barcode Checked: ☐	0	100.100	GM	☑ _____	$13.21	2/24/2025

Linked Prescriptions:

Rx Number	Rf	Date Filled	Date Written	Patient Name	Qty	Expiration Date
10006	0	12/13/2024	12/3/2024	[redacted]	100.00000	12/3/2025

Log Instructions & Notes

Beyond Use Date: 30 days

BUD reference: USP <795>

References : USP, non sterile compounding training book, Contemporary Pharmacy Practice and Compounding or Applied Pharmaceutics in Contemporary Compounding

Compounding Directions:
1. Don appropriate garb for non-sterile compounding. This product is not hazardous
(Hazardous compounding requires full garb, including N95 mask, eye protection if using liquid or powders)
2. Measure/Weigh all active ingredients with analytical balance under powder containment hood and print to scale or computer for validation of weighed components.
3. Transfer into appropriate size EMP jar on a pretared scale for the jar weight. Mix to wet stage with appropriate wetting agent if needed.
4. Weigh and combine transdermal absorption base on pretared balance that also contains the active powder ingredients and add to the prorated amounts to allow for compounding waste during mixing.
5. Using the EMP, mix according to the preprogrammed jar size. Remove the jar while keeping the lid and blade on the machine.
6. Once mixed, transfer contents of the jar to the Three Roll/Ointment Mill at 15/13 roller setting for 1 cycle. After going through the Mill, transfer the compound back into the EMP jar.
7. Repeat mixing in the EMP using the jar lid and blade that are still attached for one more cycle.to ensure lack of grittiness and consistent mixing quality
8. Package in appropriate sized dispensing device taking care to prime any air so it is ready for patient use.
9. Use appropriate technique to reduce cross-contamination in each step.

STORAGE CONDITIONS - Store at controlled room temperatue 68-77 degrees F, (20-25 degrees C). Store in a tightly closed container. Protect from Light

Formula Calculations *** does this prepopulate for diffenent assays?

Results of Quality Control Tests:

Confirm consistency: Is compound smooth (grit test) Pass _____ Fail _____
Visual Inspection: Expected color is white: Pass _____ Fail _____

3.010 SOP PERFORMANCE IMPROVEMENT PROGRAM (Version 1.0)

Synergy Apothecary

OLD & policy portion related to recall

1.0 Purpose

1.1 The purpose of this procedure is to outline a performance improvement (PI) program at Synergy Apothecary.

1.2 This procedure applies to all aspects of the preparation and dispensing of compounded preparations and commercially manufactured medications at Synergy Apothecary.

1.3 The satisfaction and safety of our patients is of the utmost importance. With that in mind, Synergy Apothecary will utilize the resources given to them to assess the quality of our procedures and our final product (dispensed prescriptions). Adverse Drug Events (ADE) will be reported to FDA's Med-watch system. The pharmacists shall report of QREs to the Institute for Safe Medication Practice (www.ISMP.org) a nationally recognized PSO.

1.4 The purpose of this procedure is to establish requirements for corrective and preventative action (CAPA).

1.5 This procedure applies to all CAPAs that might result from analyzing processes, customer complaints, and audit reports.

2.0 Responsibility

2.1 The Pharmacist-in-charge is responsible for designating the individual who will function as the compliance control officer. Refer to the posted "Authorization Approval Form" for the current Pharmacist-In-Charge and designated compliance control officer information.

2.2 The compliance control officer shall supervise the PI program and shall document that all personnel will comply with this procedure.

2.3 All personnel at Synergy Apothecary are responsible for complying with the established policies and procedures (SOPs).

2.4 The Quality Control officer will complete quarterly PI report and present to Synergy Apothecary owners. Report will include PI activities, customer and provider complaints, results from outside reviews and any pending disciplinary actions. The PI report will be discussed at staff meetings.

3.0 Definitions

3.1 Compounding – The preparing, mixing, assembling, packaging and labeling of a drug in accordance with a licensed practitioner's prescription under an initiative based on the practitioner/patient/pharmacist/ compounder relationship in the course of professional practice

3.2 PM – Preventive Maintenance

3.3 Performance Improvement (PI) – A state of control sufficient to result in a safe and effective product achieved by utilization of mechanisms for monitoring, evaluating, correcting and improving activities and operational systems

3.4 Microbial Control – The result of a system of microbiological evaluations, controls and actions sufficient to prevent contamination of preparations

3.5 CAPA – Corrective and Preventative Action

3.6 Corrective Action – Action taken to eliminate the cause of a detected nonconformity

3.7 Preventative Action – Action taken to prevent a nonconformity

3.8 OOS – Out of specification

3.9 EM- Equipment Maintenance

3.10 PDSA – Plan-Do-Study-Adjust

4.8.6.4 Equipment employed for compounding shall be inspected, cleaned and validated at appropriate times to ensure the accuracy and reliability of equipment performance is maintained.

4.8.7 Destruction and Recall

4.8.7.1 Expired, contaminated or otherwise unsuitable compounding preparations or materials shall be immediately removed from compounding preparation areas and stored under quarantine until disposed.

4.8.7.2 Refer to recall policy in SOP 3.080

4.8.8 MEDICATION ERRORS

4.8.8.1 Upon discovery of a medication error, the following procedure will be utilized:

4.8.8.1.1 The error will be brought to the attention of the pharmacist and the prescriber is to be informed of the medication error.

4.8.8.1.2 The pharmacist will work to determine if there was any harm caused to the patient due to the error. * Example: If the wrong drug was dispensed, was it taken by the patient? If so, could this do harm to the patient?

4.8.8.1.3 The error will be rectified as necessary and seen fit by the pharmacist. *Example: Correcting wrong quantity or wrong drug dispensed.

4.8.8.2 The error will be reported using the appropriate report.

4.8.8.3 The following information will be submitted:

4.8.8.3.1 Patient name, gender and date of birth

4.8.8.3.2 Event date, event type (medication event), event subtype (medication error), error type (wrong drug, wrong dose etc.), and error description

4.8.8.3.3 Intervention performed, suspected cause of error and whether or not patient and/or physician was notified

4.8.8.3.4 Location of event

4.8.8.3.5 Reporter description of event, reporter name and position

4.8.8.4 On a quarterly basis (Jan, Apr, July, Oct), all medication errors submitted will be reviewed by the managing pharmacist.

4.8.8.5 Based on possible patterns seen upon reviewing the quarterly reports, the managing pharmacist will adjust pharmacy procedures and workflow as needed. The managing pharmacist may also need to address issues with specific staff members as needed.

4.8.9 PATIENT SATISFACTION

4.8.9.1 On a yearly basis, the pharmacy staff will make available to patients a survey in either written or electronic form in order to determine patient satisfaction with the service provided by the pharmacy. Goals: Number of surveys returned 25%, Returned scores average 85% satisfaction.

4.8.6.4 Equipment employed for compounding shall be inspected, cleaned and validated at appropriate times to ensure the accuracy and reliability of equipment performance is maintained.

4.8.7 Destruction and Recall

4.8.7.1 Expired, contaminated or otherwise unsuitable compounding preparations or materials shall be immediately removed from compounding preparation areas and stored under quarantine until disposed.

4.8.7.2 Refer to recall policy in SOP 3.080

new verbiage of policy for recall med error subpath

4.8.8 MEDICATION ERRORS

4.8.8.1 Upon discovery of a medication error, the following procedure will be utilized:

4.8.8.1.1 The error will be brought to the attention of the pharmacist, and the prescriber is to be informed of the medication error. The prescriber will be contacted immediately in the case of harm or potential harm to the patient. If error does not cause imminent harm or risk, the prescriber is to be contacted the next business day. The patient will be advised upon discovery to stop taking that medication.

4.8.8.1.2 The pharmacist will work to determine if there was any harm caused to the patient due to the error. * Example; If the wrong drug was dispensed, was it taken by the patient? If so, could this do harm to the patient?

4.8.8.1.3 The error will be rectified as necessary and seen fit by the pharmacist. *Example: Correcting wrong quantity or wrong drug dispensed.

4.8.8.1.4 Additional clarification is that a medication error DOES include dispensing of a correctly labeled medication that was later found to be prepared out of specifications or labelled incorrectly during batch compounding. Follow Policy 3.080 recall process on process of recall and patient plus prescriber notifications.

4.8.8.2 The error will be reported using the appropriate report.

4.8.8.3 The following information will be submitted:

4.8.8.3.1 Patient name, gender and date of birth

4.8.8.3.2 Event date, event type (medication event), event subtype (medication error), error type (wrong drug, wrong dose etc.), and error description

4.8.8.3.3 Intervention performed, suspected cause of error and whether or not patient and/or physician was notified

4.8.8.3.4 Location of event

4.8.8.3.5 Reporter description of event, reporter name and position

4.8.8.4 On a quarterly basis (Jan, Apr, July, Oct), all medication errors submitted will be reviewed by the managing pharmacist.

4.13 Goals will be set at time of initiation of PI plan.

5.0 References

6.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

6.2 USP Current Version <1075> "Good Compounding Practices"

6.3 USP Current Version <800> "Hazardous Drugs"

6.4 SOP 1.020 "Work Orders"

6.5 Appropriate State Pharmacy Practice Act Regulations

6.0 Attachments

6.1 Quality Related Event PDSA form – See forms folder

7.0 SOP History

___ Draft X Final **Approved by:** _____ Theresa Bergh, RPh, PIC **This policy implemented on:** 11/01/2024	**Annual Policy Review** Original Owner / Date: Theresa Bergh, RPh, PIC / 11-01-24 Reviewer / Date: Revised on 2/24/25

3.080 SOP RECALL OF COMPOUNDED, COMMERCIALLY MANUFACTURED, AND NON-DRUG PRODUCTS (VERSION 1.0)

Synergy Apothecary

OLD

1.0 Purpose

1.1 The purpose if this procedure is to establish requirements for recalling compounded, commercially available, or non-drug products in the event a problem is encountered or suspected with the product.

2.0 Responsibility

2.1 This procedure applies to all personnel at Synergy Apothecary.

2.2 The QCO (Quality Control Officer) shall supervise this procedure and document that all personnel responsible for compounding will comply with this procedure.

3.0 Definitions

3.1 QCO-Quality Control Officer

3.2 PDSA – Plan-Do-Study-Act

4.0 Procedure

4.1 **EQUIPMENT & SUPPLIES**

4.1.1 Formulation compounding worksheet

4.1.2 Test results from third party laboratory (if applicable)

4.1.3 Applicable records (lot numbers, facility name, patient names, etc.)

no mention of MD here Initials

4.2 In the event that a product is suspected or confirmed to have caused patient harm, was compounded incorrectly, or needs to be recalled for any other reason, all facilities and/or patients that received the product must be notified according to the following criteria:

4.2.1 If the recall is deemed critical either by recall definition or pharmacist discretion, the patient will be notified by phone before the end of the work day.

4.2.2 If the recall is deemed non-critical by recall definition or pharmacist discretion, the patient will be notified by formal letter sent out by the end of the week.

4.2.3 If the recall is defined as "not to patient level" there is no need to notify the patient and the pharmacy will keep record of the recall.

4.2.4 If any time or material is exhausted in the process of notifying patients, the manufacturer will be contacted for reimbursement.

4.3 A comprehensive list of all lot numbers affected shall be retrieved using all available data devices (formulation records, testing results, retained samples, hard copy files, etc.), refer to the standard work on product recall. Pioneer Rx has a process for tracking reporting of all batch numbers and lot numbers.

4.4 The nature of the recall shall be explained by the Quality Control Officer and a request will be made to check the affected lot numbers.

4.5 A formal recall letter (Attachment 1) shall be written, detailing the nature of the recall, affected lot numbers, and dates of dispensing to the facility and/or the patient. This letter will be sent via certified mail and the verification of receipt will be attached to the copy of the letter kept by the pharmacy.

4.6 The Quality Control Officer (QCO) shall ensure that all products that were dispensed are accounted for and/or that no harm was done to patients. The QCO shall complete the recall record (Attachment 2)

Remainder of this page left intentionolly blank

3.080 SOP RECALL OF COMPOUNDED, COMMERCIALLY MANUFACTURED, AND NON-DRUG PRODUCTS (VERSION 1.0)

Synergy Apothecary

1.0 Purpose

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4.1 EQUIPMENT & SUPPLIES

4.1.1 Formulation compounding worksheet

4.1.2 Test results from third party laboratory (if applicable)

4.1.3 Applicable records (lot numbers, facility name, patient names, etc.)

new verbiage

4.2 In the event that a product is suspected or confirmed to have caused patient harm, was compounded incorrectly, or needs to be recalled for any other reason, all facilities and/or patients that received the product must be notified according to the following criteria:

4.2.1 If the recall is deemed critical either by recall definition or pharmacist discretion, the patient AND prescriber will be notified by phone before the end of the workday.

4.2.2 If the recall is deemed non-critical by recall definition or pharmacist discretion, the patient will be notified by formal letter sent out by the end of the week and the prescriber will be informed via phone, fax or email by the end of the week. It would be preferable to alert prescribers all at once if multiple patients under there care are involved a recall and provide a HIPPA compliant list of their patients that might be affected.

4.2.3 If the recall is defined as "not to patient level" there is no need to notify the patient and the pharmacy will keep record of the recall. A prescriber is not involved at this level

4.2.4 If any time or material is exhausted in the process of notifying patients, the manufacturer will be contacted for reimbursement if possible.

4.3 A comprehensive list of all lot numbers affected shall be retrieved using all available data devices (formulation records, testing results, retained samples, hard copy files, etc.), refer to the standard work on product recall. Pioneer Rx has a process for tracking reporting of all batch numbers and lot numbers.

4.4 The nature of the recall shall be explained by the Quality Control Officer and a request will be made to check the affected lot numbers.

4.5 A formal recall letter (Attachment 1) shall be written, detailing the nature of the recall, affected lot numbers, and dates of dispensing to the facility and/or the patient. This letter will be sent via certified mail and the verification of receipt will be attached to the copy of the letter kept by the

pharmacy. A copy of this letter can also be provided to any prescribers that were involved in the recall to better understand the information that patients were provided.

4.6 The Quality Control Officer (QCO) shall ensure that all products that were dispensed are accounted for and/or that no harm was done to patients. The QCO shall complete the recall record (Attachment 2)

4.7 Synergy Apothecary will require all recalled products, if pharmaceutical is in patient's home, if deemed necessary, be returned to Synergy Apothecary via prepaid delivery devices.

4.8 Upon receipt of recalled product, Synergy Apothecary will quarantine the product for further analytical testing and evaluation of process malfunctions.

4.9 Any deficiencies shall be addressed, problems shall be resolved and/or investigated, and a formal explanation of the outcome of the recall will be documented.

4.10 Any training and/or education required to prevent the process deficiencies from occurring in the future will be initiated immediately. This will be documented in a PDSA form.

4.11 A copy of the recall notice, recall letter, investigation, quarantine records, and PDSA will be placed in the PI Projects binder under the recall tab.

4.12 If the event of a patient-level recall of a compounded drug sent to the State of Oregon, PIC will notify the Oregon Board of Pharmacy within 10 working days. This would include any other state that requires notification.

5.0 ATTACHMENTS

5.1 Recall Letter Template – See forms folder

5.2 Recall Record – See forms folder

6.0 REFERENCES

6.1 N/A

7.0 SOP History

3.130 SOP REQUIRED GARB FOR NON-STERILE COMPOUNDING AREA (Version 1.0)

Synergy Apothecary

1.0 PURPOSE

1.1 The purpose of this procedure is to establish gowning requirements for entering the non-sterile compounding area

1.2 This procedure applies to all non-sterile compounding personnel at Synergy Apothecary.

2.0 RESPONSIBILITY

2.1 The Pharmacist-in-charge shall supervise this procedure or document that another staff member has been designated to complete the task.

2.2 The Pharmacist-in-charge shall be responsible for assuring that all personnel involved in generating, completing or reviewing data are trained in the requirements of this procedure. The PIC will make the final decision on personnel being excluded from being assigned to the compounding room as it relates to rashes, recent tattoos, oozing sores, conjunctivitis and active respiratory infections.

2.3 All employees at Synergy Apothecary are responsible for complying with this procedure.

3.0 DEFINITIONS

3.1 SW-Standard Work

4.0 PROCEDURE

4.1 This procedure shall be performed upon entering the non-sterile compounding area.

4.2 Traffic flow through the non-sterile compounding area must be minimized during compounding.

4.3 Materials that shed particles such as cardboard or wood products shall not enter the non-sterile compounding area. All items entering the non-sterile compounding area should be removed from shipping cartons and stored properly.

4.4 All compounding staff are required to wear own scrubs. These must be freshly laundered and changed daily. Before entering the compounding area, compounding personnel must remove any items that are not easily cleanable and that might interfere with garbing. At a minimum, personnel must: • Remove personal outer garments (e.g., bandanas, coats, hats, jackets) • Remove all hand, wrist, and other exposed jewelry, including piercings that could interfere with the effectiveness of garbing or hand hygiene (e.g., watches, rings that may tear gloves) • Remove earbuds or headphones

1.1 The designated person(s) may permit accommodations as long as the quality of the environment and CNSP will not be compromised.

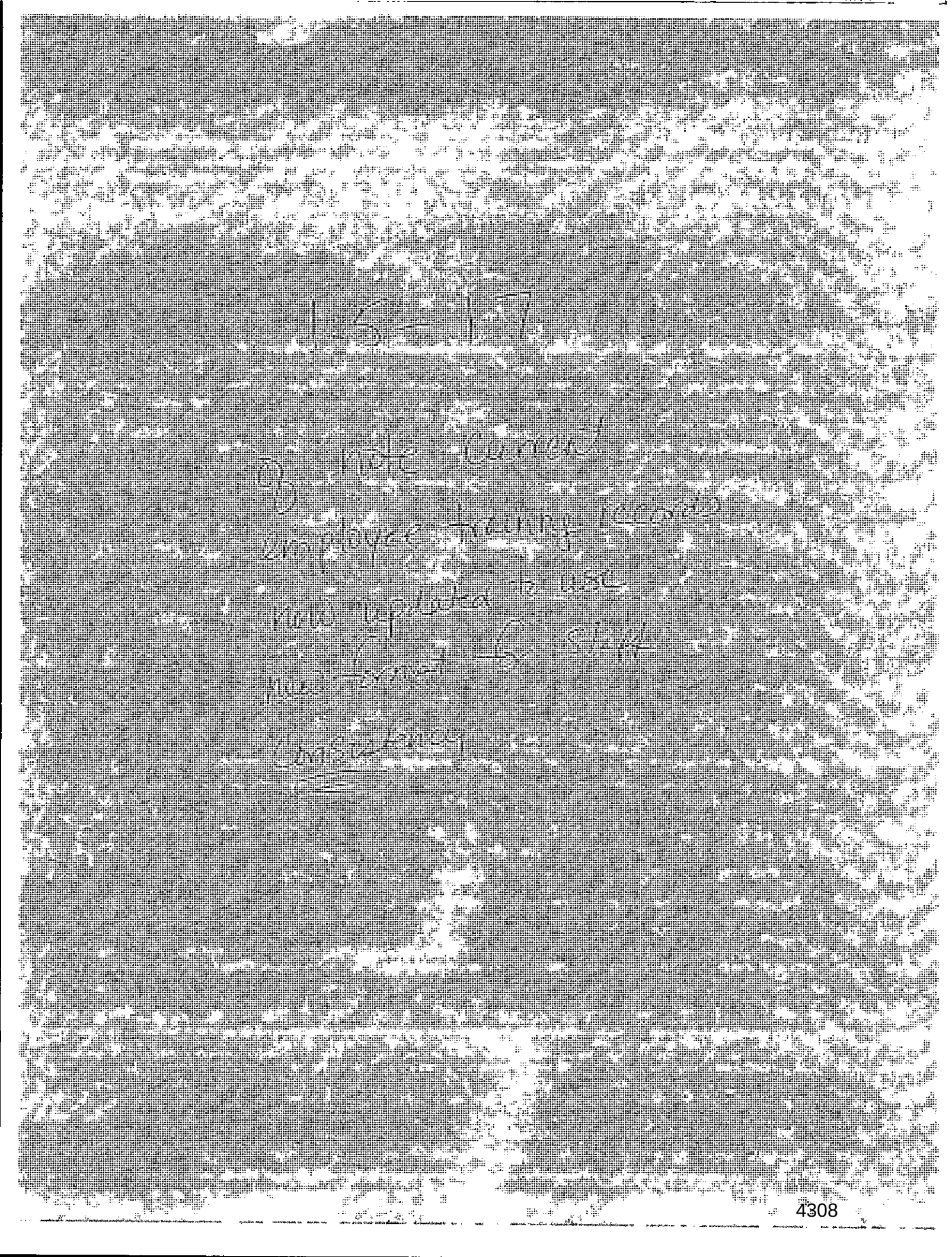
1.2 SW for donning Hazardous and Non-hazardous.

1.2.1.1.1 Prior to entering the compounding area, all personnel, or supervised visitors, must don hair covers and either shoe covers or dedicated shoes. Shoe covers must fit completely over the shoe pair.

1.2.1.1.2 All gloves must be wiped with alcohol and allowed to dry or replaced before beginning compounding a CNSP with a different component or when other objects were touched (i.e pens, keyboards, scanners) to minimize the risk of cross contamination with other CSNPs. Any concern of contamination or glove intregity requires changing to new non-sterile gloves.

5.0 REFERENCES

5.1 USP Current Version <795>, "Pharmaceutical Compounding – Non-Sterile Preparations"



OLD FORMAT

Synergy Apothecary EMPLOYEE TRAINING RECORD

Hire Date: 11/20/24

Employee Name: [redacted] Hired Position PIC

Initial Mentor/Trainer Signature: N/A

Training Requirement (i.e initial orientation/compounding/safety)	Comments	Completion Date/Initials
①Safety ②orientation ③Math test ④Scale ⑤795 Test ⑤ gowning / handwashing	renewed during staffing	11/20/24 11/20/24

Description of Training: _____

Reviewed By: [redacted] Date: 11/20/24

Name [redacted]

Rewritten based on updated formatting

Synergy Apothecary PERSONNEL TRAINING VERIFICATION NON-STERILE COMPOUNDING

Non-sterile compounding personnel shall be trained on proper compounding techniques and processes necessary to compound nonsterile preparations.

Date	Training Provided	Materials/References Used	Initials of Employee	Initials of Trainer
11/20/24	USP 795 Test	USP 795 + P&P documents	J	N/A
2/21/25	Equipment and room Cleaning	SW + Policy review		
2/21/25	Donning and Doffing PPE	SW + Policy review		
2/21/25	Scales: leveling, weighing/taring	SW + policy review		
2/21/25	Powder hoods: cleaning, use and technique	SW + policy review		
2/21/2	Troches: Filling by hand	SW + Policy/MFR's		
2/21/25	Troches: powder filler Base machine	SW + policy		
2/21/25	Hotplates and Warming ovens	SW + policy		
12/13/24	Creams: Miller Unguator	per watching portube video + training by Wendy via video at SSP		

Signature: [redacted] **Date:** 2/21/25
Compounding Pharmacist

Signature: I am PIC **Date:** 2/21/25
Pharmacist-In-Charge

Synergy Apothecary EMPLOYEE TRAINING RECORD

Hire Date: 11/20/24 = opening date - salaried starting 1/1/25

Employee Name: [redacted] **Hired Position** PIC

Initial Mentor/Trainer Signature: —

Training Requirement (i.e initial orientation/compounding/safety)	Comments	Completion Date/Initials
Review of SW and orientation checklist		2/21/25
Handling of meds – components & compounded items – Part 1	Complete "Receiving Chemicals and Devices Form	2/21/25
Chemical Spill process and Transport of medications/chemicals Part 2	" "	2/21/25
Cleaning and Sanitizing (office and/or lab areas	Refer to SW and daily logs	2/21/25
Office procedures/shipping/cleaning		2/21/2
Batch prepwork and labeling		2/21/25
Pioneer Rx training (role dependent)	See SW for most common parts of pharmacy	2/21/25
Understanding of PDMP requirements		2/21/25

Description of Training: Note this is reformatting of initial training log

Reviewed By: (PIC) [redacted] **Date:** 2/21/25

Synergy Apothecary PERSONNEL TRAINING VERIFICATION
NON-STERILE COMPOUNDING

Name/Role _____ **New Hire or Annual Review**_____

Non-sterile compounding personnel shall be trained on proper compounding techniques and processes necessary to compound nonsterile preparations.

Date	Training Provided	Materials/References Used	Initials of Employee	Initials of Trainer
	USP 795 Test			
	Equipment and room Cleaning			
	Donning and Doffing PPE			
	Scales: leveling, weighing/taring			
	Powder hoods: cleaning, use and technique			
	Troches: Filling by hand			
	Troches: powder filler Base machine			
	Hotplates and Warming ovens			
	Creams: Miller Unguator			

Signature: _____ **Date:** _____
Compounding Staff/Title

Signature: _____ **Date:** _____
Pharmacist-In-Charge

Synergy Apothecary EMPLOYEE TRAINING RECORD

Hire Date: _____

Employee Name: _____ **Hired Position** _____

Initial Mentor/Trainer Signature: _____

Training Requirement (i.e initial orientation/compounding/safety)	Comments	Completion Date/Initials
Review of SW and orientation checklist		
Handling of meds – components & compounded items – Part 1	Complete "Receiving Chemicals and Devices Form	
Chemical Spill process and Transport of medications/chemicals Part 2	" "	
Cleaning and Sanitizing (office and/or lab areas	Refer to SW and daily logs	
Office procedures/shipping/cleaning		
Batch prepwork and labeling		
Pioneer Rx training (role dependent)	See SW for most common parts of pharmacy	
Understanding of PDMP requirements		

Description of Training: _____

_____

Reviewed By: _____ **Date:** _____

4ZZZ

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #[redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 03566		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	☐ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: TC Script LLC

Physical Address: 8275 N. Pima Rd, Suite 1

City: Scottsdale State: AZ Zip: 85258-4054

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 855-584-6189 Toll Free # (NAC 639.708, NRS 639.23286): 855-584-6189

Fax: 855-578-1691 Contact Email: tc_script@mercalis.com

Website: N/A

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): James Bataoel

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23620

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: James Bataoel	NV Pharmacist Registration #: 23620
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: North Carolina

Parent Company (if any): Mercalis Inc.

Corporation/Organization Name: TC Script LLC

Mailing Address: 8275 N. Pima Rd, Suite 1

City: Scottsdale State: AZ Zip: 85258

Telephone: 855-584-6189 Email: TC_Script@mercalis.com

Contact Person Name: James Bataoel

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Vice President & Secretary (title) for TC Script LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Michele Peters

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/9/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Michele Peters hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Vice President & Secretary (title) for TC Script LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 9th day of April, 2025

Sherri O McCraw

Notary Public

SHERRI O. MCCRAW
NOTARY PUBLIC
Wake County
North Carolina
My Commission Expires 9-16-29

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michele Peters

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/9/25

Date

Board Use Only	Date Received: 4/15/25	Amount: [redacted]

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Illinois at Chicago College of Pharmacy		08/95-05/99	
Address	City	State	Zip
833 S Wood St., MC 874, 161 PHARM	Chicago	IL	60612
Diploma/Degree obtained, if any			
PharmD			

School Name		From - To (MM/YY – MM/YY)	
University of Illinois Urbana-Champaign		08/91-05/95	
Address	City	State	Zip
901 W Illinois St	Urbana	IL	61801
Diploma/Degree obtained, if any			
Bachelor of Science - Biology			

School Name		From - To (MM/YY – MM/YY)	
St Patrick High School		08/88-05/91	
Address	City	State	Zip
5900 W Belmont Ave	Chicago	IL	60634
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: TC Script LLC

Pharmacy/Wholesaler License # (if applicable): PH03566

Physical Address: 8275 N. Pima Rd, Suite 1

City: Scottsdale State: AZ Zip: 85258

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 855-584-6189 Website: N/A

Licensing Company Email: tc_script@mercalis.com

Section 2: Personal Information

First: James Middle: R. Last: Bataoel

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
TC Script LLC			01/22-Current	
Business Address		**City**	**State**	**Zip**
8275 N. Pima Rd, Suite 1		Scottsdale	AZ	85258
Phone	**Title**		**Number of Employed Hours**	
855-584-6189	Director of Pharmacy		40 hrs/week	
Description of Duties				
PIC, Clinical, Governance, Regulatory & Compliance				

Business Name			From - To (MM/YY – MM/YY)	
Walmart Pharmacy			09/11-12/21	
Business Address		**City**	**State**	**Zip**
4435 W Anthem Way		Phoenix	AZ	85086
Phone	**Title**		**Number of Employed Hours**	
623-551-6320	Pharmacy Manager		40 hrs/week	
Description of Duties				
PIC, Pharmacist on Duty, Patient Clinical Management, Patient Compliance				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/04/2003		Arizona	Phoenix	Maricopa
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
2003-18-PHR		Arizona State Board of Pharmacy		
Reason/Charge				
Dispensed a compounded medication with the incorrect strength.				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
James R. Bataoel		Consent Agreement and Order for Probation		
Name of Business/Industry/Entity				
The Apothecary Shop of Phoenix				

Provide explanation below:

On March 4, 2003, I, James R. Bataoel, was the Pharmacist on duty at The Apothecary Shop of Phoenix, 1300 N. 12th Street, Ste 355, Phoenix, AZ 85006. I dispensed a compounded medication with the incorrect strength. I did not look closely enough at the 'bottle for injection' upon dispensing. The medication was a compounded prostaglandin injection for erectile dysfunction. The medication was dispensed at 1000mcg/ml when it should have been dispensed at 20mcg/ml. The Pharmacy Manager discovered the error the following day and advised the patient. The patient was informed to come back to the Pharmacy to receive the correct medication. He was told to discard the incorrectly dispensed medication.

On September 2, 2003 the patient submitted a "Consumer Complaint Report" to the Arizona State Board of Pharmacy.

On January 9, 2004, I entered into a "Consent Agreement and Order for Probation" with The Arizona State Board of Pharmacy, accepting responsibility for the error.

I was placed on probation for a period of six (6) months and was ordered to attend and complete a Continuing Education class on prescription compounding. I paid a civil penalty of $250.00 and was not allowed to serve as a preceptor Pharmacist or a Pharmacist-In-Charge during the probation period.

I completed all requirements and was released from the probation period on August 12, 2004 during The Arizona State Board of Pharmacy Board Meeting in Prescott, AZ.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/10/2025

Date

I, James R. Bataoel, **certify that as the designated representative for**

TC Script LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. ✓ I am at least 21 years of age;
3. ✓ I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. ✓ I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. ✓ I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. ✓ I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. ✓ I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

James R. Bataoel

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/10/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

James R. Bataoel

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/10/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Arizona, ss. County of Maricopa

I, JAMES R BATAOEL, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

4/10/2025

Date

Subscribed and Sworn to before me this 10th day of April.

Notary Public Signature

CYTLYALY NEDEL OCHOA
Notary Public - Arizona
Maricopa County
Commission # 644432
My Comm. Expires Nov 20, 2028

(Seal)

TC Script LLC
8275 N. Pima Rd, Suite 1
Scottsdale, AZ 85258

March 28, 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Pkwy, Ste 206
Reno, NV 89521

RE: Explanation of Pharmacy License Discipline

Dear Sir or Madam,

On March 4, 2003, I, James R. Bataoel, was the Pharmacist on duty at The Apothecary Shop of Phoenix, 1300 N. 12th Street, Ste 355, Phoenix, AZ 85006. I dispensed a compounded medication with the incorrect strength. I did not look closely enough at the 'bottle for injection' upon dispensing. The medication was a compounded prostaglandin injection for erectile dysfunction. The medication was dispensed at lO00mcg/ml when it should have been dispensed at 20mcg/ml. The Pharmacy Manager discovered the error the following day and advised the patient. The patient was informed to come back to the Pharmacy to receive the correct medication. He was told to discard the incorrectly dispensed medication.

On September 2, 2003, the patient submitted a "Consumer Complaint Report" to the Arizona State Board of Pharmacy.

On January 9, 2004, I entered into a "Consent Agreement and Order for Probation" with The Arizona State Board of Pharmacy, accepting responsibility for the error.

I was placed on probation for a period of six (6) months and was ordered to attend and complete a Continuing Education class on prescription compounding. I paid a civil penalty of $250.00 and was not allowed to serve as a preceptor Pharmacist or a Pharmacist-In-Charge during the probation period.

I completed all requirements and was released from the probation period on August 12, 2004, during The Arizona State Board of Pharmacy Board Meeting in Prescott, AZ.

Sincerely,

[redacted]

James R. Bataoel
Pharmacist in Charge
Director of Pharmacy- Clinical, Governance, Regulatory & Compliance

2003-18-H

04 JAN 12 AM 10: 36

BEFORE THE ARIZONA STATE BOARD OF PHARMACY

In the Matter of:

James R. Bataoel Holder of License No. 12255 For the Practice of Pharmacy In the State of Arizona, Respondent	Case Number 2003-18-PHR **CONSENT AGREEMENT AND ORDER FOR PROBATION**

TO: James R. Bataoel
[redacted]
Phoenix, Arizona [redacted]

RECITALS

In the interest of a prompt and judicious settlement of this case, consistent with the public interest, statutory requirements and responsibilities of the Arizona State Board of Pharmacy ("Board"), and under A.R.S. § 32-1928, *et seq.* and 41-1092(F)(5), James R. Bataoel, holder of license number 12255 to practice pharmacy in the State of Arizona ("Respondent"), and the Board enter into the following Recitals, Finding of Fact, Conclusions of Law and Order ("Consent Agreement") as the final disposition of this matter.

1. Respondent has read and understands this Consent Agreement as set forth herein, and has had the opportunity to discuss this Consent Agreement with an attorney. Respondent voluntarily enters into this Consent Agreement for the purpose of avoiding the expense and uncertainty of an administrative hearing.

2. Respondent understands that he has a right to a public administrative hearing concerning the above-captioned matter, at which administrative hearing he could present evidence and cross-examine witnesses. By entering into this Consent Agreement, Respondent freely and voluntarily relinquishes all rights to such an administrative hearing, as well as all rights of rehearing, review, reconsideration, appeal, judicial review or any other administrative and/or judicial action, concerning the matters set forth herein.

Respondent affirmatively agrees that this Consent Agreement shall be irrevocable.

3. Respondent understands that this Consent Agreement or any part of the agreement may be considered in any future disciplinary action against him.

4. Respondent understands that this Consent Agreement does not constitute a dismissal or resolution of other matters currently pending before the Board, if any, and does not constitute any waiver, express or implied, of the Board's statutory authority or jurisdiction regarding any other pending or future investigation, action or proceeding. Respondent understands that acceptance of this Consent Agreement does not preclude any other agency, subdivision or officer of this state from instituting any other civil or criminal proceedings with respect to the conduct that is the subject of this Consent Agreement.

5. Respondent understands that this Consent Agreement deals with Board Investigation Case No. 2003-18-H involving allegations of unprofessional conduct against Respondent. The investigation into these allegations against Respondent shall be concluded upon the Board's adoption of this Consent Agreement.

6. All admissions made by Respondent in this Consent Agreement are made solely for the final disposition of this matter, and any related administrative proceedings or civil litigation involving the Board and Respondent. Therefore, any admissions made by Respondent in this Consent Agreement are not intended for any other use, such as in the context of another regulatory agency proceedings, or civil or criminal proceedings, whether in the State of Arizona or in any other state or federal court.

7. Respondent acknowledges and agrees that, upon signing this Consent Agreement and returning this document to the Board's Executive Director, Respondent may not revoke his acceptance of the Consent Agreement or make any modifications to the document, regardless of whether the Consent Agreement has been issued by the Board's Executive Director. Any modification to this original document is ineffective and void unless mutually approved by the parties in writing.

8. Respondent understands that the foregoing Consent Agreement shall not become effective unless and until adopted by the Board and signed by its Executive Director.

9. Respondent understands and agrees that if the Board does not adopt this Consent

Agreement, he will not assert as a defense that the Board's consideration of this Consent Agreement constitutes bias, prejudice, prejudgment or other similar defense.

10. Respondent understands that this Consent Agreement is a public record that may be publicly disseminated as a formal action of the Board, and shall be reported as required by law to the National Practitioner Data Bank and the Healthcare Integrity and Protection Data Bank.

11. Respondent understands that any violation of this Consent Agreement constitutes unprofessional conduct under A.R.S. §32-1927(A)(17)([t]he licensee violated a formal order, terms of probation, a consent agreement or a stipulation issued or entered into by the board or its executive director pursuant to this chapter) and may result in disciplinary action under A.R.S. § 32-1927.

DATED: 12/20/03

James R. Bataoel

Reviewed and Approved as to form:

By: _____
(Insert Name of Attorney, if any), Esq.
Attorney for Respondent

FINDINGS OF FACT

By stipulation of the parties, this Consent Agreement is entered into for final disposition of the matters described therein. Respondent admits to the following Finding of Fact:

12. The Board possesses jurisdiction over the subject matter and over Respondent as a licensee of the Board, under A.R.S. § 32-1901, *et seq.*

13. The Board is the duly constituted authority for the regulation and control of the practice of pharmacy in the State of Arizona.

14. Respondent is the holder of License No. 12255 for the practice of pharmacy in the State of Arizona. Respondent was engaged in the practice of pharmacy and was the only pharmacist on duty at Apothecary Shop of Phoenix, located at 1300 N. 12th Street, Suite 555, Phoenix, Arizona on March

4, 2003.

15. On or about March 4, 2003, Respondent admits that he incorrectly compounded and/or assumed responsibility for compounding and dispensed alprostidil 1000 mcg/ml injection pursuant to prescription number 176235 that was written for PGE 1, 20 mcg/ml injection, to patient M.G.

16. On or about March 4, 2003, Respondent dispensed alprostidil 1000 mcg/ml injection that had expired on January 31, 2003.

17. The parties waive all further findings of fact.

CONCLUSIONS OF LAW

18. The Board is the duly constituted authority for the regulation and control of the practice of pharmacy in the State of Arizona, under A.R.S. § 32-1901, *et seq.*

19. The conduct and circumstances described above regarding Respondent constitute violations of A.A.C. R4-23-402(A)(6)(8)&(11) to wit:

> A.A.C. R4-23-402(A)(6)(8)&(11) A pharmacist or a graduate intern or pharmacy intern under the supervision of a pharmacist shall perform the following professional practices in dispensing a prescription medication from a prescription order:
>
> (6). Verify that a dosage is within proper limits;
>
> (8). Compound, mix, combine, or otherwise prepare and package prescription medication needed to dispense individual prescription orders.
>
> (11). Make a final accuracy check on the completed prescription medication and manually initial the finished label;

20. The conduct and circumstances described above regarding Respondent constitute unprofessional conduct under A.R.S. § 32-1927(A)(10) and A.R.S. § 32-1927(B)(1)(2):

> **A.R.S. §32-1927(A)(10)** The license of any pharmacist, pharmacy intern, or graduate intern may be revoked or suspended or a pharmacist or intern may be placed on probation by the board if:
>
> 10. The licensee is found by the board to be guilty of violating any Arizona or federal law, rule or regulation relating to the manufacture and distribution of drugs, devices or the practice of pharmacy.
>
> **A.R.S. §32-1927(B)(1)&(2)** The license of any pharmacist or intern may be revoked or suspended or the pharmacist, pharmacy intern, or graduate intern may be placed on probation or censured and a civil penalty of not more than one thousand dollars for each offense may be imposed by the

board if the licensee:

1. Is found by the Board to be guilty of dispensing a different drug or brand of drug in place of the drug or brand of drug ordered or prescribed without the express permission in each case of the orderer, or in the case of a prescription order, the medical practitioner. The conduct prohibited by this paragraph does not apply to substitutions authorized pursuant to section 32-1963.01.

2. Is found by the board, or is convicted in a federal or state court, of having violated federal or state laws or administrative rules pertaining to marijuana, prescription-only drugs, narcotics, dangerous drugs or controlled substances.

ORDER

Based upon the above Findings of Fact and Conclusions of Law and under the authority granted to the Board under A.R.S. § 32-1928, 41-1092.07(F)(5), and A.A.C. R4-23-104(G),

IT IS HEREBY ORDERED that:

21. License No. 12255, which was issued to Respondent for the practice of pharmacy in the State of Arizona, is hereby placed on **PROBATION** for a period of six (6) months upon adoption of this Consent Agreement by the Board. The **PROBATION** is subject to the following conditions:

22. Respondent shall attend and complete a Continuing Education class on prescription compounding.

23. Respondent shall pay all fees and complete all Continuing Education requirements to maintain Pharmacist License number 12255 throughout the term of **PROBATION**.

24. Respondent shall not serve as a preceptor pharmacist nor as a pharmacist in charge throughout the term of **PROBATION**.

25. Respondent shall obey all federal and state laws and rules governing the practice of pharmacy.

26. Respondent shall pay a civil penalty of two hundred and fifty dollars ($250.00) to the Board within sixty 60 days of the date of this Order. Payment shall be by a certified check or a cashier's check.

27. If Respondent violates this Order in any way or fails to fulfill the requirements of this Order, the Board, after giving the Respondent notice and the opportunity to be heard, may revoke,

suspend or take other disciplinary action against the Respondent. The issue at such hearing will be limited solely to whether this Board Order has been violated.

28. Respondent shall appear before the Board at a regularly scheduled Board meeting on or after July 14, 2004 to request that the probation imposed by this order be terminated.

DATED AND EFFECTIVE this 20th **day of** January **, 2003.**

ARIZONA STATE BOARD OF PHARMACY

SEAL

By _____
Hal Wand, Executive Director
Arizona State Board of Pharmacy

ORIGINAL of the foregoing
filed this 20th day of January
2003, with:

Arizona State Board of Pharmacy
4425 W. Olive Avenue, Suite 140
Glendale, Arizona 85302

COPY of the foregoing mailed by
US Certified Mail #
this 21st day of January, 2003, to:

James R. Bataoel
[redacted]

Copy of the foregoing mailed
this 21st day of January, 2003, to:

[Name of Attorney Respondent]
XXXXXXXXXXXX
XXXXXXXXXXXX

Roberto Pulver
Assistant Attorney General
1275 W. Washington, CIV/LES
Phoenix, Arizona 85007
Attorney for the State

X Elaine C Nissen
Board Operations

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Kansas		08/96-05/00	
Address	City	State	Zip
1450 Jayhawk Blvd	Lawrence	KS	66045
Diploma/Degree obtained, if any			
Master of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Iowa State University		08/89-05/93	
Address	City	State	Zip
3410 Beardshear Hall	Ames	IA	50011
Diploma/Degree obtained, if any			
Bachelor's of Business Administration			

School Name		From - To (MM/YY – MM/YY)	
Kennedy High School		08/86-05/89	
Address	City	State	Zip
4545 Wenig Rd NE	Cedar Rapids	IA	52401
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site TC Script LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03566

Physical Address 8275 N. Pima Rd, Suite 1

City Scottsdale State AZ Zip 85258

Mailing Address (if different from physical address) Same as above

City _____ State _____ Zip _____

Telephone 855-584-6189 Website N/A

Licensing Company Email tc_script@mercalis.com

Section 2: Personal Information

First Scott Middle Richard Last Dulitz

Alias(es, nicknames, name changes, etc.) N/A

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
TC Script LLC			07/22 - Present	
Business Address		**City**	**State**	**Zip**
8275 N. Pima Rd, Suite 1		Scottsdale	AZ	85258
Phone	**Title**			
855-584-6189	President			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
TrialCard			10/21 - 07/22	
Business Address		**City**	**State**	**Zip**
2250 Perimeter Park Dr., Ste 300		Morrisville	NC	27560
Phone	**Title**			
855-584-6189	President & Chief Strategy Officer			
Description of Duties				
Partnership with existing management team				

Business Name			From - To (MM/YY – MM/YY)	
TrialCard			12/18 - 10/21	
Business Address		**City**	**State**	**Zip**
2250 Perimeter Park Dr., Ste 300		Morrisville	NC	27560
Phone	**Title**			
855-584-6189	Chief Strategy Officer & Head of Corporate Development			
Description of Duties				
General Manager and P&L owner of several of TrialCard's acquired companies. Also lead corporate & product strategy, mergers & acquisitions, sell-side and buy-side corporate development and enterprise sales & marketing.				

Business Name			From - To (MM/YY – MM/YY)	
TrialCard			11/17 - 11/18	
Business Address		**City**	**State**	**Zip**
2250 Perimeter Park Dr., Ste 300		Morrisville	NC	27560
Phone	**Title**			
855-584-6189	Senior Vice President, Enterprise Strategy & Corporate Development			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
TrialCard			6/17 – 10/17	
Business Address		**City**	**State**	**Zip**
2250 Perimeter Park Dr., Ste 300		Morrisville	NC	27560
Phone	**Title**			
855-584-6189	Senior Vice President, Product Innovation			
Description of Duties				
Responsible for a new product life-cycle management and development across all the TrialCard's product and service lines. (i.e. HUB, Patient Affordability, technology solutions, etc.)				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
TrialCard			11/15 - 05/17
Business Address	**City**	**State**	**Zip**
2250 Perimeter Park Dr., Ste 300	Morrisville	NC	27560
Phone	**Title**		
855-584-6189	Division Vice President, TC Market Access		

Description of Duties

Business development and product strategy for TrialCard's Market Access service lines of reimbursement HUB's, nursing & adherence, and patient assistance programs.

Business Name			From - To (MM/YY – MM/YY)
Taiho Oncology Inc			09/14 - 10/15
Business Address	**City**	**State**	**Zip**
101 Carnegie Center, Suite 101	Princeton	NJ	08540
Phone	**Title**		
609-750-5300	Director, Market Access Programs & Professional Relations		

Description of Duties

Led the strategic design and implementation of limited specialty pharmacy network and fully integrated patient support program for a colorectal cancer oral oncolytic.

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
N/A			
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see the attached explanation.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4-11-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Scott Dulitz

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4-11-2025

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake

I, Sherri O. McCraw, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

4-11-2025

Date

Subscribed and Sworn to before me this 11th day of April.

Sherri O. McCraw

Notary Public Signature

SHERRI O. MCCRAW
NOTARY PUBLIC
Wake County
North Carolina
My Commission Expires 9-16-29

(Seal)

TC Script LLC
17255 N 82nd Street, Ste 130
Scottsdale, AZ 85255

To whom it may concern,

In the pharmacy application, questions were asked about litigation involving me or companies for which I have worked, including TC Script, LLC. While I, personally, have not been involved in any litigation involving any company with which I have worked, almost every company of any size has been involved in some sort of litigious activity, most frequently with regard to employment matters.

TC Script's parent company, Mercalis Inc., has been involved in similar litigation as well as litigation involving some of the other services we offer – both as plaintiff and defendant. However, no litigation with any regulatory or compliance concern has named either Mercalis or TC Script as a party. There has been no litigation or other regulatory investigation involving either Mercalis or TC Script regarding patient safety or non-compliance with regulations. There has been no litigation or enforcement activity that has had or had the potential to have any impact on the services Mercalis or TC Script provides.

TC Script prides itself on ensuring strict compliance with all applicable regulations and ensuring exceptional patient care.

I trust this addresses any concerns you may have.

[redacted]

Scott Dulitz
President

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: TC Script LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): PH03566

Physical Address: 8275 N. Pima Rd, Suite 1

City: Scottsdale State: AZ Zip: 85258

Mailing Address (if different from physical address): Same as above

City: State: Zip:

Telephone: 855-584-6189 Website: N/A

Licensing Company Email: tc_script@mercalis.com

Section 2: Personal Information

First: Margaret Middle: Michele Last: Peters

Alias(es, nicknames, name changes, etc.): Williams, Atchison

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Univ. of Memphis		8/95 - 5/98	
Address	City	State	Zip
3720 Alumni Center	Memphis	TN	38152
Diploma/Degree obtained, if any			
J.D.			

School Name		From - To (MM/YY – MM/YY)	
UNC Charlotte		8/89 - 9/93	
Address	City	State	Zip
9201 University City Blvd.	Charlotte	NC	28223
Diploma/Degree obtained, if any			
BS Business Administration, BA History			

School Name		From - To (MM/YY – MM/YY)	
Richmond Senior High School		08/86-06/89	
Address	City	State	Zip
838 N US Highway 1	Rockingham	NC	28379
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/25 - present	[redacted]			
01/19-03/25				
10/16-01/19				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Mercalis Inc.			04/15 - Present	
Business Address	**City**		**State**	**Zip**
2250 Perimeter Park Dr, Ste 300	Morrisville		NC	27560
Phone	**Title**			
919-845-0774	General Counsel & Chief Compliance Office; Director			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
TC Script LLC			08/18 - Present	
Business Address	**City**		**State**	**Zip**
8275 N. Pima Rd, Suite 1	Scottsdale		AZ	85258
Phone	**Title**			
855-584-6189	Vice President & Secretary			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 5. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Please see the attached explanation.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/9/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michele Peters

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/1/25

Date

Please have this section completed in the presence of a Notary Public.

State of North Carolina, ss. County of Wake

I, Michele Peters, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

4/9/25

Date

Subscribed and Sworn to before me this 9th day of April

Sherri O. Mccraw

Notary Public Signature

SHERRI O. MCCRAW
NOTARY PUBLIC
Wake County
North Carolina
My Commission Expires 9-16-29

(Seal)

Docusign Envelope ID: 5D281935-324C-4920-956A-7D2B1EFAD956

September 27, 2024

To whom it may concern,

In the pharmacy application, questions were asked about litigation involving me or companies for which I have worked, including TC Script, LLC. While I, personally, have not been involved in any litigation involving any company with which I have worked, almost every company of any size has been involved in some sort of litigious activity, most frequently with regard to employment matters.

TC Script's parent company, Mercalis Inc., has been involved in similar litigation as well as litigation involving some of the other services we offer – both as plaintiff and defendant. However, no litigation with any regulatory or compliance concern has named either Mercalis or TC Script as a party. There has been no litigation or other regulatory investigation involving either Mercalis or TC Script regarding patient safety or non-compliance with regulations. There has been no litigation or enforcement activity that has had or had the potential to have any impact on the services Mercalis or TC Script provides.

TC Script prides itself on ensuring strict compliance with all applicable regulations and ensuring exceptional patient care.

I trust this addresses any concerns you may have.

Sincerely,

[redacted]

M. Michele Atchison
General Counsel & Chief Compliance Officer

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: TC Script LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): 1080

Physical Address: 8275 N. Pima Rd, Suite 1

City: Scottsdale State: AZ Zip: 85258-4054

Mailing Address (if different from physical address): Same as physical address

City: State: Zip:

Telephone: 855-584-6189 Website: N/A

Licensing Company Email: tc_script@mercalis.com

Section 2: Personal Information

First: Robert Middle: Austin Last: Truckenmiller, Jr.

Alias(es, nicknames, name changes, etc.): N/A

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Central Florida		08/03 - 08/05	
Address	City	State	Zip
4000 Central Florida Blvd	Orlando	FL	32816
Diploma/Degree obtained, if any			
Master of Business Administration (MBA)			

School Name		From - To (MM/YY – MM/YY)	
University of Central Florida		08/97 - 08/00	
Address	City	State	Zip
4000 Central Florida Blvd	Orlando	FL	32816
Diploma/Degree obtained, if any			
Bachelor of Science in Business Administration (BSBA)			

School Name		From - To (MM/YY – MM/YY)	
Castle High School		08/92 - 05/93	
Address	City	State	Zip
3344 Hwy 261	Newburgh	IN	47630
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Forest Park High School		08/91 - 05/92	
Address	City	State	Zip
1440 Michigan St.	Ferdinand	IN	47532
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY	
Southridge High School		08/90 - 05/91	
Address	City	State	Zip
1110 S Main St.	Huntingburg	IN	47542
Diploma/Degree obtained, if any			
High School			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
11/23 - current				
From - To (MM/YY – MM/YY)				
08/21 - 11/23				
From - To (MM/YY – MM/YY)				
12/16 - 08/21				
From - To (MM/YY – MM/YY)				
01/08 - 11/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
South Fork High School		08/89 - 05/90	
Address	**City**	**State**	**Zip**
10000 SW Bulldog Way	Stuart	FL	34997
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
PharmaCord			01/25 - present	
Business Address		**City**	**State**	**Zip**
150 Hilton Drive		Jeffersonville	IN	47130
Phone	**Title**			
502-805-3530	CEO			
Description of Duties				
Strategic leadership of PharmaCord's business model, including innovation, operational excellence and patient-centric solutions.				

Business Name			From - To (MM/YY – MM/YY)	
GSK			06/21 - 01/25	
Business Address		**City**	**State**	**Zip**
2929 Walnut St.		Philadelphia	PA	19104
Phone	**Title**			
1-888-825-5249	Senior Vice President of Market Access and US Vaccines Business Units			
Description of Duties				
Led GSK US Market Access and US Vaccines Business Units.				

Business Name			From - To (MM/YY – MM/YY)	
EMD Serono			07/16 - 09/21	
Business Address		**City**	**State**	**Zip**
200 Pier 4 Blvd		Boston	MA	02210
Phone	**Title**			
1-800-283-8088	Senior Vice President of Market Access			
Description of Duties				
Business Unit head for Oncology, HIV, and Fertility teams.				

Business Name			From - To (MM/YY – MM/YY)	
Davita Kidney Care Specialty Pharmacy			01/16 - 07/16	
Business Address		**City**	**State**	**Zip**
1234 Lakeshore Dr.		Coppell	TX	75019
Phone	**Title**			
972-538-8100	Vice President of Market Access			
Description of Duties				
Lead integration of Davita Specialty Pharmacy and Rx Partners IDN.				

Business Name			From - To (MM/YY – MM/YY)	
UCB			08/05 - 01/16	
Business Address		**City**	**State**	**Zip**
1950 Lake Park Dr.		Smyrna	GA	30080
Phone	**Title**			
770-970-7500	Head of UCB Market Access Operations			
Description of Duties				
Overseeing various teams including market access strategy, account management, channel and trade relations, field access and reimbursement, and health outcomes, value and access strategy.				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
N/A				
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # N/A. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

April 1, 2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert, Truckenmiller, Jr.

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

April 1, 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Indiana, ss. County of Clark

I, Robert Truckenmiller, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

April 1, 2025

Date

Subscribed and Sworn to before me this 1st day of April.

Suzannah R Clark

Notary Public Signature

Suzannah R Clark
Notary Public Seal State of Indiana
Clark County
Commission Number NP0742768
My Commission Expires 8/3/2030

...diana
...42768
...xpires 8/3/2030

(Seal)

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

DEMOGRAPHICS

AZ permit# :	AZ Permit Exp.Date :	Business Name :
Y007803	10/31/2025	TC Script LLC

Address :

8275 N Pima Road, Suite 1

Zip :	City :	State :
85258	Scottsdale	AZ

Phone :	Fax :	Email :
(855) 584-6189	(855) 578-1691	james.batoel@mercalis.com

Inspection Date :	PIC :	Pic License Exp Date :
09/19/2024	James Bataoel	10/31/2025

DEA # :	DEA # Exp. date :	Inspection Reviewed With :
FT9699910	11/30/2024	James Batoel

Reviewers License# :	Inspection type :
S012255	Relocation

Inspection Conducted By :

Dennis Waggoner

ACTIVITIES

1	Nonsterile Compounding	☐ YES	☑ NO
2	Nonsterile Hazardous Compounding	☐ YES	☑ NO
3	Sterile Compounding	☐ YES	☑ NO
4	Sterile Hazardous Compounding	☐ YES	☑ NO

Hospital Facility Data

# Licensed Beds	DHS License #

PHARMACY DEPARTMENT

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

1	Size/Personnel R4-23-609(A); R4-23-655(B)(C); R4-23-670 to 675 Total space of approximately 16,000sqft includes Front End/Cubicle Operations area of 2,316sqft, pharmacy fulfillment area of 5,973sqft and warehouse area of 3,135sqft.	☑ S	☐ C/P ☐ U ☐ N/A
2	Shelves R4-23-609(A); R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A) Fixtures and equipment to be moved from current location.	☑ S	☐ C/P ☐ U ☐ N/A
3	Design-efficient, safe pharmacy practice R4-22-609(A); R4-23-655(C); R4-23-672(A); R4-23-673(A)(B); R4-23-674(A)(3); R4-23-675(A)	☑ S	☐ C/P ☐ U ☐ N/A
4	Counter R4-23-609(B); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A) Fixtures and equipment to be moved from current location.	☑ S	☐ C/P ☐ U ☐ N/A
5	Aisles R4-23-609(C); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A) Fixtures and equipment to be moved from current location.	☑ S	☐ C/P ☐ U ☐ N/A
6	Consultation area R4-23-609(D) Mail Order only.	☐ S	☐ C/P ☐ U ☑ N/A
7	Enclosed (barrier) R4-23-609(F); R4-23-655(D); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675	☑ S	☐ C/P ☐ U ☐ N/A
8	Entry doors R4-23-609(F); R4-23-610(B); R4-23-655(D); R4-23-657(A)(2); R4-23-672(A)(F)(2); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	☑ S	☐ C/P ☐ U ☐ N/A
9	Lighting R4-23-609(G); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)	☑ S	☐ C/P ☐ U ☐ N/A

S = SATISFACTORY C/P = NEED TO COMPLETE OR PROVIDE U = UNSATISFACTORY N/A = NOT APPLICABLE

10	Temperature controlled/Ventilation	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(G); R4-23-655(E); R4-23-656(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
11	Working counter barrier	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(H)
12	Receiving/checking area	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(E); R4-23-655(E); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
13	Opening for Rx receipt when closed	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-610(F)
14	Walls	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
15	Ceilings	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
16	Windows	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
17	Floors	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
18	Restroom Two restroom areas within suite.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(4)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	Sink (hot and cold running water)	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-611(A)(9); R4-23-656(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
20	Nonsterile compounding area	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-410(E)

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SECURITY

1	Controlled substances	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(E); R4-23-657(A)(1); R4-23-658(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	No controlled substances to be received, stocked or dispensed initially.		
2	Pharmacist access	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-609(F); R4-23-610(B); R4-23-657(A)(1); R4-23-671(B)(1); R4-23-672(A)(B)(F); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Only a pharmacist can unlock the suite and disarm the alarm. Employee access then controlled by badge reader.		
3	Additional pharmacy drug storage areas	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-609(G)(2); R4-23-655(E); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
4	Filled Rx medication storage	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-610(G); R4-23-673(E); R4-23-674(C); R4-23-675(C)
5	Remote drug storage (hospitals)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-654(D); R4-23-672(C)

PHARMACY LIBRARY

1	Pharmacology or Toxicology reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Fixtures and equipment to be moved from current location.		
2	Therapeutics reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Fixtures and equipment to be moved from current location.		
3	Drug compatibility reference	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
	Fixtures and equipment to be moved from current location.		

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4	Drug product equivalency reference	☑ S	☐ C/P	☐ U	☐ N/A
	R4-23-612(A)(9); R4-23-656(1); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)				
	Fixtures and equipment to be moved from current location.				
5	Sterile products reference	☐ S	☐ C/P	☐ U	☑ N/A
	R4-23-612(A)(9); R4-23-656(1); R4-23-670(B)(6); R4-23-672(A); R4-23-673(C); R4-23-675(A)				
6	Policy and procedure manual-pharmacy operations	☑ S	☐ C/P	☐ U	☐ N/A
	R4-23-610(A); R4-23-653(A); R4-23-658(A); R4-23-671(E); R4-23-672(A)(G); R4-23-673(G); R4-23-674(F); R4-23-675(D)				
	Fixtures and equipment to be moved from current location.				
7	Policy and procedure manual-technicians	☑ S	☐ C/P	☐ U	☐ N/A
	R4-23-610(A); R4-23-653; R4-23-672(A)(G); R4-23-673(C); R4-23-674(F); R4-23-675(D)				
	Fixtures and equipment to be moved from current location.				
8	Policy and procedure manual-automation	☐ S	☐ C/P	☐ U	☑ N/A
	R4-23-614; R4-23-615; R4-23-616; R4-23-654(D); R4-23-701.02; R4-23-701.04				
	No automation initially.				
9	Policy and procedure manual-compounding	☐ S	☐ C/P	☐ U	☑ N/A
	R4-23-410; R4-23-670				
	No compounding.				
10	Arizona statutes/rules	☑ S	☐ C/P	☐ U	☐ N/A
	R4-23-612(A)(8); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)				
	Fixtures and equipment to be moved from current location.				
11	Current antidote/drug interaction information	☑ S	☐ C/P	☐ U	☐ N/A
	R4-23-612(A)(12); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)				
	Fixtures and equipment to be moved from current location.				

12 Poison Control # displayed

☑ S ☐ C/P ☐ U ☐ N/A

R4-23-612(A)(13); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

Stickers and magnets provided.

PHARMACY EQUIPMENT/FORMS

1 Refrigerator

☑ S ☐ C/P ☐ U ☐ N/A

R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670; R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

Fixtures and equipment to be moved from current location.

2 Freezer

☑ S ☐ C/P ☐ U ☐ N/A

R4-23-609(G)(1); R4-23-612(A)(1); R4-23-656(4); R4-23-670(B)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

Fixtures and equipment to be moved from current location.

3 Computer-security/data storage

☑ S ☐ C/P ☐ U ☐ N/A

R4-23-408

Fixtures and equipment to be moved from current location.

4 Computer-patient profiles

☑ S ☐ C/P ☐ U ☐ N/A

R4-23-408(B)(3)

Fixtures and equipment to be moved from current location.

5 Computer-single drug usage report

☑ S ☐ C/P ☐ U ☐ N/A

R4-23-408(B)(4)

Fixtures and equipment to be moved from current location.

6 Computer-pharmacist log book/hard copy print out

☑ S ☐ C/P ☐ U ☐ N/A

R4-23-408(C)(4)

Fixtures and equipment to be moved from current location.

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7	Prescription label ARS 32-1963.01; ARS 32-1968; R4-23-612(A)(10); R4-23-658(D)(1)(2); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)(D); R4-23-701.01(2); R4-23-703(C) Fixtures and equipment to be moved from current location.	☑ S	☐ C/P	☐ U	☐ N/A	
8	Federal transfer labels R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2) Fixtures and equipment to be moved from current location.	☑ S	☐ C/P	☐ U	☐ N/A	
9	Warning labels R4-23-612(A)(10); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A); R4-23-701.01(2) Fixtures and equipment to be moved from current location.	☑ S	☐ C/P	☐ U	☐ N/A	
10	Written patient information R4-23-402(C)(4); R4-23-402(I)	☑ S	☐ C/P	☐ U	☐ N/A	
11	Consultation log R4-23-402(G)	☐ S	☐ C/P	☐ U	☑ N/A	
12	Federal medication guides 21 CFR part 208	☑ S	☐ C/P	☐ U	☐ N/A	
13	Hospital IV label R4-23-658	☐ S	☐ C/P	☐ U	☑ N/A	
14	Generic Rx blanks R4-23-402(A); R4-23-407(D) Fixtures and equipment to be moved from current location.	☑ S	☐ C/P	☐ U	☐ N/A	
15	Immunization administration recordkeeping R4-23-411(F)	☐ S	☐ C/P	☐ U	☑ N/A	

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16	Schedule V register	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(2)
17	Methamphetamine precursor sales log	☐ S ☐ C/P ☐ U ☑ N/A	ARS 32-1977
18	Red C stamp	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(11); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
19	CSPMP reporting	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-502
20	Graduates Fixtures and equipment to be moved from current location.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(3); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
21	Mortar & Pestle Fixtures and equipment to be moved from current location.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(4); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
22	Steel spatulas Fixtures and equipment to be moved from current location.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
23	Rubber (nonmetallic) spatula Fixtures and equipment to be moved from current location.	☑ S ☐ C/P ☐ U ☐ N/A	R4-23-612(A)(5); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
24	Approved Rx balance	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)

25	Weights for Rx balance	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(6); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
26	Ointment tile	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-612(A)(7); R4-23-672(A); R4-23-673(C); R4-23-674(A)(3); R4-23-675(A)
27	Automated storage and distribution system (patient access)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(2)
28	Automated storage and distribution system (hospital)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-614(A)(B)(1)(3); R4-23-654(D)
29	Mechanical storage and counting device	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-615
30	Mechanical counting device	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-616
31	Emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02
32	Automated emergency drug supply units (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.02(E)
33	Automated dispensing system (LTC)	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-701.04

STERILE PRODUCT COMPOUNDING AREA/EQUIPMENT:

1	Size	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)
2	Dedicated to compounding sterile products	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(1); R4-23-656(5)

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3	Isolated from other pharmacy functions	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(2)
4	Restricts entry/access	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(3)
5	Free from unnecessary disturbances airflow	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(4)
6	Nonporous and cleanable floor	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
7	Nonporous and cleanable walls	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
8	Nonporous and cleanable ceiling	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(5)
9	Environment ISO 7	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(A)(6)
10	Hood ISO 5	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-670(B)
11	Prep area ISO 7/ISO 8	☐ S ☐ C/P ☐ U ☑ N/A	R4-23-110; R4-23-670(E)(F)

NOTES

Anticipated move beginning October 11, 2024 with first day of operations on October 14, 2024.

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520 Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749
http://www.azpharmacy.gov

Receipt Date: 10/23/2023
Receipt Number: 2023165569
Receipt Amount $: 480.00

Pharmacy - Limited Service

Mail Order

	PERMIT NO	**EXPIRES**
	Y007803	**10/31/2025**
Issued to :	TC Script LLC TC Script LLC 8275 N. PIMA RD SUITE 1 SCOTTSDALE, AZ 85258	TC Script LLC 8275 N. PIMA RD SUITE 1 SCOTTSDALE, AZ 85258

Kam Gardin
EXECUTIVE DIRECTOR

ARIZONA STATE BOARD OF PHARMACY
P.O. Box 18520
Phoenix, AZ 85005
602-771-ASBP (2727)
FAX: 602-771-2749

WALLET CARD

NAME : TC Script LLC
LICENSE NUMBER : Y007803
EXPIRES : 10/31/2025

http://www.azpharmacy.gov

- **Your license must be available for inspections during business hours.**
- **Permit holder(s) must display permit in the location to which it is issued.**
- **Please note it is your responsibility to keep this license/permit current.**

Important Information

LICENSE HOLDER (pharmacist, intern, technician, technician-trainee)

- Holder of this license number, printed above, is authorized in accordance with A.A.C. R4-23-201(A), A.A.C. R4-23-301(A) or A.A.C R4-23-1101(A), to perform the duties associated within their profession. By holding this license, the licensee agrees to comply with state & federal law.
- You are required by law to notify the Board of any home address and/or employment change within 10 business days

PERMIT HOLDER (pharmacy, non-prescription retailer (OTC), wholesale, manufacture, CMG, DME)

- Holder of this permit number, printed above, is authorized to conduct business according to the classification specified in A.R.S. § 32-1908(A); A.A.C. R4-23-601 and A.A.C. R4-23-607. By holding this permit, the permittee agrees to comply with state & federal law
- In-state pharmacy, wholesaler & manufacture permit holder(s) who plan to remodel or move locations, must submit a change-of-location/remodel form within 30 days prior to move/remodel. In-state non-prescription (OTC), compressed medical gas (CMG) & DME providers who plan to move locations must notify the board within 10 business days of move.
- Out-of-State permit holders must notify the Board of location changes, in writing, within 10 business days of move. A revised copy of your state permit shall be submitted to the Board, when available.
- Permits are non-transferable. Ownership changes of more than 30% require that a new application be submitted to the Board.

Arizona State Board of Pharmacy

Physical Address: 1110 W. Washington St., Suite 260, Phoenix, AZ 85007
Mailing Address: P.O. Box 18520, Phoenix, AZ 85005
(P): 602-771-2727 (F): 602-771-2749 www.azpharmacy.gov

CERTIFICATION OF ARIZONA STATE BOARD OF PHARMACY PERMIT FOR THE ENTITY LISTED BELOW :

This document is not a license/registration/permit but serves as the primary source of verification.

Name :	TC Script LLC
Address :	8275 N. Pima Rd Suite 1 Scottsdale AZ 85258
Registration No :	Y007803
Permit Type :	Pharmacy
Sub Type :	Limited Service
Date Issued :	10/02/2018
Expiration Date :	10/31/2025
Status :	OPEN
Discipline :	No

Kam Gandhi

Executive Director
Arizona State Board of Pharmacy

Date: 04/04/2025

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-15-2024

TC SCRIPT LLC
TC SCRIPT LLC
8275 N PIMA RD
STE 1
SCOTTSDALE, AZ 85258

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2027	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-15-2024

TC SCRIPT LLC
TC SCRIPT LLC
8275 N PIMA RD
STE 1
SCOTTSDALE, AZ 85258

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

NORTH CAROLINA
Department of the Secretary of State

CERTIFICATE OF EXISTENCE
(Limited Liability Company)

I, ELAINE F. MARSHALL, Secretary of State of the State of North Carolina, do hereby certify that

TC SCRIPT LLC

is a limited liability company duly formed, and existing under the laws of the State of North Carolina, having been formed on 14th day of August, 2018

I FURTHER certify that, as of the date of this certificate, (i) the said limited liability company is not dissolved under the terms of its articles of organization, (ii) the said limited liability company's articles of organization are not suspended for failure to comply with the Revenue Act of the State of North Carolina, (iii) that said limited liability company is not administratively dissolved for failure to comply with the provisions of the North Carolina Limited Liability Company Act, (iv) that this office has not filed any decree of judicial dissolution, articles of dissolution, articles of merger, or articles of conversion for said limited liability company.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed my official seal at the City of Raleigh, this 1st day of April, 2025.

Elaine F. Marshall

Secretary of State

Scan to verify online.

Certification# 123067487-1 Reference# 22650777- Page: 1 of 1
Verify this certificate online at https://www.sosnc.gov/verification



TC Script LLC
8275 N. Pima Rd, Suite 1
Scottsdale, AZ 85258

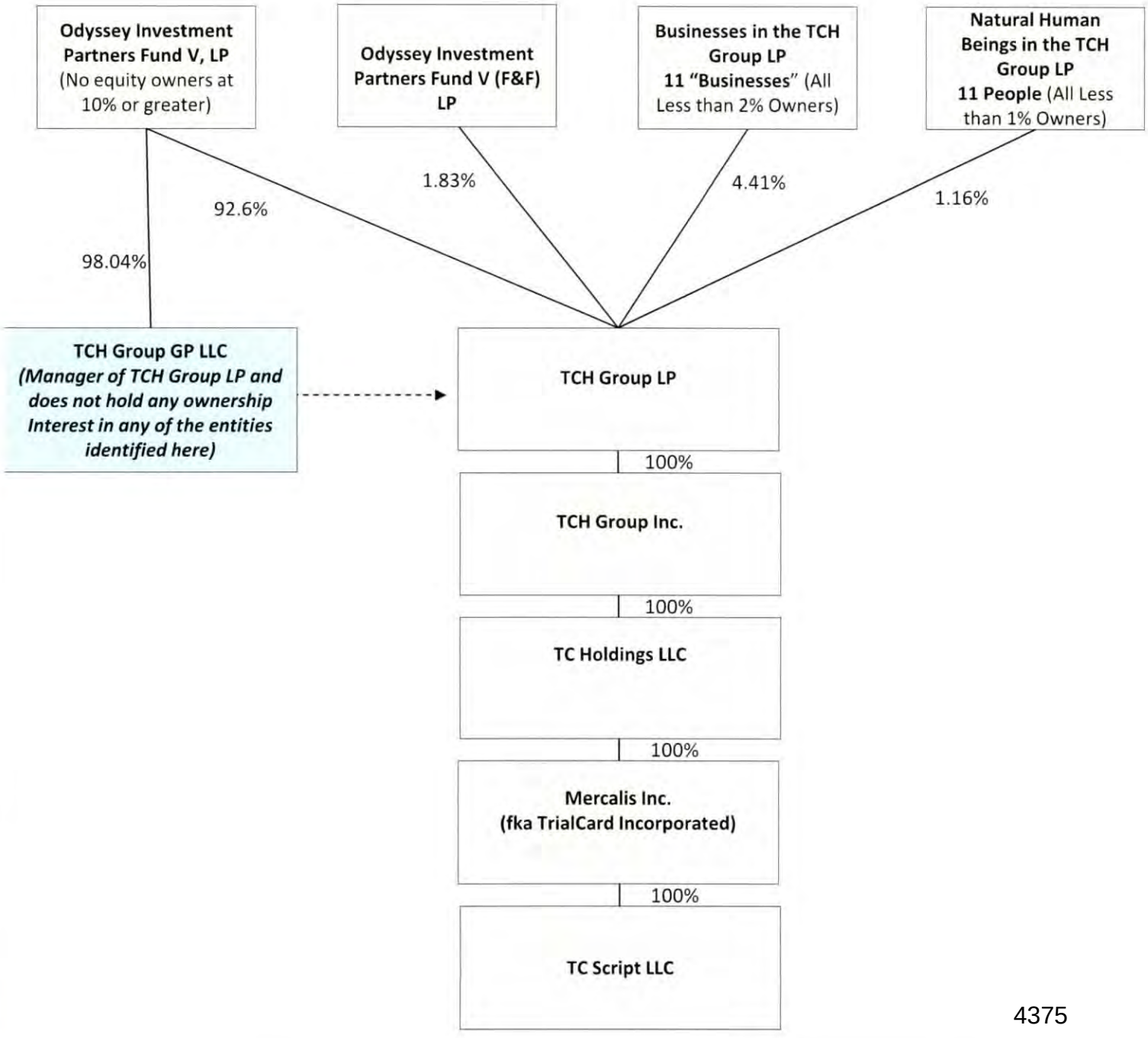
Owner of TC Script LLC:
Mercalis Inc.
2250 Perimeter Park Dr #300
Morrisville, NC 27560
919-845-0774
FEIN: 52-2251120
100% Owner

Officers TC Script LLC:
Robert Truckenmiller, Chief Executive Officer
2250 Perimeter Park Dr #300
Morrisville, NC 27560
855-584-6189

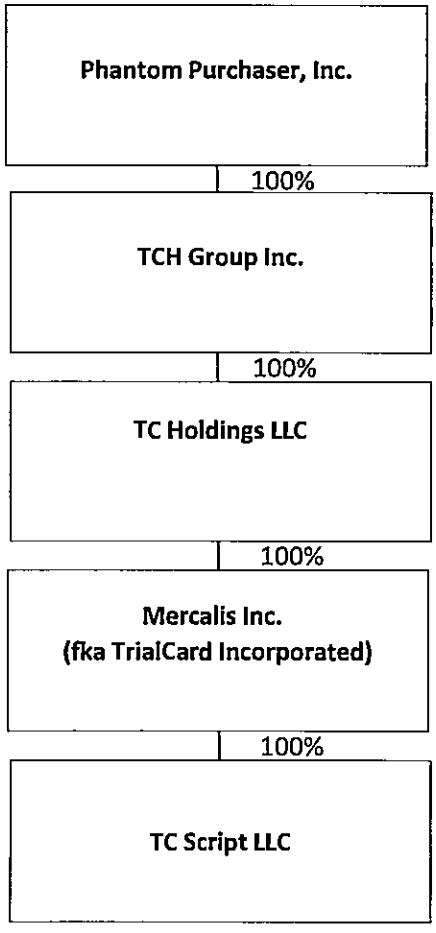
Scott Dulitz, President
2250 Perimeter Park Dr #300
Morrisville, NC 27560
855-584-6189

Michele Peters, Vice President & Secretary
2250 Perimeter Park Dr #300
Morrisville, NC 27560
855-584-6189

Pre-Close Organization Chart



Post-Close Organization Chart



4AAAA

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02913	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: FT3066594 ☒ Non-sterile Compounding ☐ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☐ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Triad Rx Buyer LLC dba Triad Rx

Physical Address: 26258 Pollard Road

City: Daphne State: AL Zip: 36526

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 251-380-7630 Toll Free # (NAC 639.708, NRS 639.23286): 855-288-0135

Fax: 251-621-9914 Contact Email: [redacted]

Website: https://www.triadrx.us/

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Robert Roberts

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21165

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Robert Roberts	NV Pharmacist Registration #: 21165
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): LT Pharmacy Holdco 1 LLC

Corporation/Organization Name: Triad Rx Buyer LLC

Mailing Address: 317 6th Ave Ste 400

City: Des Moines State: IA Zip: 50309

Telephone: 515-231-7664 Email: [redacted]

Contact Person Name: Jonathan Lensing

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President (title) for Triad Rx Buyer LLC dba Triad Rx (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Jonathan Lensing

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/8/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Jonathan Lensing hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the President (title) for Triad Rx Buyer LLC dba Triad Rx (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT

[redacted]

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 8th day of March, 2025

Thea Amsden

Notary Public

NOTARIAL SEAL NEVADA
THÉA AMSDEN
Commission Number 221444
My Commission Expires
March 15, 2026

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Lensing

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

3/8/25
Date

Board Use Only	Date Received: 3/12/25	Amount: [redacted]

CONFIDENTIAL/EXEMPT FROM
FREEDOM OF INFORMATION ACT AND
SIMILAR STATE REQUESTS

Ownership Information

Ownership & Leadership of Applicant Entity - NV License # PH02913

Applicant: **Triad Rx Buyer LLC DBA Triad Rx**
26258 Pollard Road, Daphne, AL 26526

Ownership: The Applicant entity is wholly owned (100%) by LT Pharmacy Holdco 1 LLC

Officers of Triad Rx Buyer LLC
Jonathan Lensing - President

Ownership & Leadership of LT Pharmacy Holdco 1 LLC

Ownership: LT Pharmacy Holdco 1 LLC is wholly owned (100%) by LT Pharmacy Holdco 2 LLC

Officers of LT Pharmacy Holdco 1 LLC
Jonathan Lensing - President
Christian Williams - Secretary and Treasurer

Ownership & Leadership of LT Pharmacy Holdco 2 LLC

Ownership: LT Pharmacy Holdco 2 LLC is wholly owned (100%) by OpenLoop Health, Inc.

Officers of LT Pharmacy Holdco 2 LLC
Jonathan Lensing - President
Christian Williams - Secretary and Treasurer

Leadership of OpenLoop Health Inc.

Officers of OpenLoop Health Inc.
Jonathan Lensing - CEO
Christian Williams - COO
Rob Levy - CFO
Kate Lyon - Secretary

Board of Directors for OpenLoop Health Inc :
Jack P. Berkowitz
Jon Lensing
Ryan Morley
Ferdinand Martignetti

Please see the attached pre- and post-closing Corporate Organization chart for reference.

Post-Close Ownership Organizational Chart



Licensed Entity

Officers:

- President - Jon Lensing

Pre-Close Ownership Organizational Chart

Triad Rx, Inc.

FEIN 45-4212279

Ownership & Officers:
- 100% Owner - David Lindsey
- President - David Lindsey
- Vice President - Tara Morris

Delaware

The First State

I, KRISTOPHER E. KNIGHT, ACTING SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "TRIAD RX BUYER, LLC" IS DULY FORMED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-SECOND DAY OF JANUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "TRIAD RX BUYER, LLC" WAS FORMED ON THE THIRTEENTH DAY OF DECEMBER, A.D. 2024.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL TAXES HAVE BEEN ASSESSED TO DATE.

Kristopher E. Knight, Acting Secretary of State

10036831 8300

SR# 20250217803

Authentication: 202753935

Date: 01-22-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

DISCIPLINARY HISTORY NARRATIVE

TRIAD RX, INC.

Status Summary

- **All disciplinary proceedings have been concluded, and all known investigations closed.**

- **Documentation, including disciplinary complaints, corrective action plans and responses, dispositive pharmacy board orders, and related correspondence are enclosed without exhibits.**

- **All Triad's licenses and permits have remained in good standing at all times.**

Texas Disciplinary Proceeding
(Original – Concluded 2018)

Triad Rx, Inc. ("Triad") holds Texas Pharmacy License #28003 issued by the Texas State Board of Pharmacy (the "TSBP") in 2012. In late 2015, the TSBP adopted rule amendments, effective September 1, 2016, requiring nonresident pharmacies such as Triad to employ a pharmacist-in-charge (a "PIC") who holds a pharmacist license from the TSBP.

On December 15, 2015, the TSBP issued a letter notifying nonresident PICs of this rule change. On June 15, 2016, the TSBP issued a second letter reminding nonresident pharmacy owners of the new PIC-licensing requirement. Both TSBP letters contained the following language "all pharmacy renewal applications submitted on or after September 1, 2016 must include the name and Texas pharmacist license number of the [PIC]...."

Triad's PIC (mis)interpreted this language to mean that TSBP would exercise enforcement discretion with regard to this new requirement so long as a TSBP-licensed PIC was listed on the renewal application next-following the new rule's September 1, 2016 effective date. Accordingly, on February 23, 2017, Robert R. Roberts, III, Triad's PIC, was issued Texas Pharmacist License No. 60196—well in advance of the expiration (and therefore prospective renewal) of Triad's then-current TSBP license.

In March 8, 2018, the TSBP issued a preliminary notice of intent to take disciplinary action (the "Texas Proceeding"), alleging that Triad had operated without a TSBP-licensed PIC from September 1, 2016 through February 22, 2017, in violation of the new rule codified in 22 Tex. Admin. Code § 291.103 (2017).

On April 4, 2018, Triad executed an Agreed Board Order #K-17-005, thereby agreeing to pay an administrative penalty in the amount of $1,000 but without admitting or denying the truth of TSBP's allegations. On May 23, 2018, Triad received notice that the TSBP had taken final agency action in accepting and adopting the Agreed Board Order. Triad self-reported the outcome in writing to the pharmacy regulatory authorities for all other states where Triad holds a pharmacy license within 30 days thereafter.

Triad paid the penalty and retains its Texas license. Triad's PIC did not face any sanction from the TSBP under his Texas pharmacist license.

First Alabama Disciplinary Proceeding
(Derivative – Concluded 2018)

This was derivative of the Texas Proceeding.

Triad is located in Alabama, so Triad's self-reporting of the Texas Proceeding outcome obviously extended to the Alabama Board of Pharmacy (the "ALBP").

In July 2018, the ALBP disclosed its intent to institute disciplinary proceedings against Triad's community pharmacy license. This was a "sister state" action: there were no new facts or substantive allegations in the statement of charges—alleged culpability was to be derived solely from the by-then-concluded matter in Texas described above. In other words, Alabama sought to take disciplinary action and assess a fine against Triad as an Alabama licensee based solely on the fact that another state had previously taken disciplinary action against Triad.

Further, none of the substantive alleged violations—the most recent having occurred over 2 years before the ALBP initiated proceedings, and Triad having passed onsite inspection from ALBP at least twice in that interval—had any direct factual or legal nexus with the State of Alabama, other than the fact that Triad happens to be situated in Alabama.

Triad ultimately signed a consent order to pay a $3,000 fine (triple the amount assessed by the affected State of Texas) because—despite the duplicative nature of the proceedings—the ALBP (technically) had the power to take the disciplinary action in question. This matter was concluded in September 2018.

Maine Disciplinary Proceeding
(Derivative – Concluded 2019)

This was derivative of the Texas Proceeding.

As discussed, Triad self-reported the Texas Proceeding outcome in writing to the pharmacy regulatory authorities for all other states where Triad holds a pharmacy license, including the State of Maine. Maine law, specifically 10 M.R.S. s. 8003-G(2)(C), requires such self-reporting within ten (10) days of final agency action.

Unfortunately for Triad, the Agreed Board Order in the Texas Proceeding was signed on May 1, 2018, but not mailed until May 15; and Triad did not receive it until May 23—well beyond Maine's 10-day deadline.

Accordingly, on July 10, 2019, the State of Maine Board of Pharmacy accepted a Consent Agreement resolving the allegation that Triad had violated 10 M.R.S. s. 8003-G(2)(C) under the following terms: (i) Triad agreed to accept a reprimand and to pay a civil penalty in the amount of $250.00, and (ii) the Maine Board agreed to renew Triad's Maine license.

FDA Warning Letter
(CMS Case #569659)
(Original – Concluded 2023)

Timeline & Summary

- July 2017 – FDA inspected Triad's facility and made observations—all pertaining to sterile compounding.
- July-August 2017 – Triad took immediate and comprehensive corrective action, and requested a reinspection.
- February 2019 – FDA issued a public warning letter 18 months later without any further discussion or acknowledgment.
- October 2019 – FDA replied to Triad's response, claiming that Triad had addressed some, but not all, of the issues, leaving the Warning Letter open until Triad's next inspection.
- July 2021 – Triad ceased all sterile compounding operations.
- December 2022 – FDA conducted a followup inspection.
- May 2023 – FDA notified Triad that the Warning Letter had been closed out, acknowledging that the concerns raised in the Warning Letter had been addressed

Factual Background

1. FDA Inspection, 483, & Triad's Response

On July 17-21, 2017, FDA conducted an onsite inspection of Triad's pharmacy located at 26258 Pollard Road, Daphne, Alabama and licensed by the Board (the "pharmacy"). At the conclusion of that inspection, FDA issued a Form 483 (the "483" – enclosed) describing the inspector's observations. On August 3, 2017, Triad submitted a response to the 483 (the ("483 Response" – enclosed without exhibits) detailing Triad's completed and anticipated corrective actions—and requesting reinspection and/or dialogue.

2. FDA Warning Letter & Triad's Response

FDA did not request a meeting, send a letter or email, make a phone call, or otherwise express dissatisfaction with Triad's 483 Response; and in fact, Triad received no communication from FDA at all for approximately eighteen (18) months—when FDA issued the (public) Warning Letter dated February 5, 2019 (the "Warning Letter").[1]

This course of conduct, although certainly within FDA's discretion, is completely at odds with FDA's stated purpose in issuing 483s in the first instance: "To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration." See 483 at p.4.

Aside from the frustration at FDA having elected to issue the Warning Letter after ignoring Triad's 483 response for a year-and-a-half, Triad was also surprised that FDA placed majority emphasis in the Warning Letter on "ineligible products,"[2] an issue that does not appear **anywhere** in the 483.

In fact, FDA's inspector verbally advised at inspection closeout that he had been instructed through chain of command **not** to include "ineligible products" in 483s issued to 503A pharmacies like Triad, as long as those pharmacies understood the need to "voluntarily" express their willingness to comply with then-interim FDA policy guidance for 503A pharmacies compounding

[1] https://www.fda.gov/ICECI/EnforcementActions/WarningLetters/ucm631101.htm

[2] See Warning Letter, Section B. ("Failure to Meet the Conditions of Section 503A"); Section C. ("Unapproved New Drug Products" and "Misbranded Drug Products"); Section D. ("Corrective Actions").

from bulk drug substances—so as to avoid a warning letter or other regulatory escalation.

Triad naively so "volunteered" in its 483 Response, opening itself to FDA's unprincipled issuance of the Warning Letter, and the resulting deluge of regulatory fallout.

Triad responded to the Warning Letter even more comprehensively than to the 483, painstakingly documenting and detailing each step, each aspect of each particular corrective action. Triad's substantive response to the Warning Letter ("Warning Letter Response" – enclosed without exhibits) is therefore incorporated by reference.

3. FDA Reply & (Eventual) Closeout

On October 18, 2019 FDA replied to Triad's response with the enclosed untitled letter, claiming that Triad had addressed some, but not all, of the issues raised in the Warning Letter.

After nearly **five-and-a-half years**, on December 5-8, 2022, FDA conducted a followup inspection.

By the enclosed letter dated May 3, 2023, FDA notified Triad that, based on the findings of the December 2022 inspection, the Warning Letter had been closed out, acknowledging that the concerns raised in the Warning Letter had been addressed.

Second Alabama Disciplinary Proceeding
(Derivative – Concluded 2022)

Timeline

- July 2021 – Triad ceased **all** sterile compounding operations—for purely business reasons: decreased demand (COVID pandemic), diminishing margins, and rising operational costs (product and environmental testing, inspection/certifications, and regulatory burden).
- May 2022 – ALBOP filed its enclosed complaint in based **solely** on the contents of FDA's 2019 Warning Letter.
- July 2022 – Triad settled with ALBOP effective July 19, 2022 and agreed to pay a fine.

Summary

This was derivative of the Warning Letter, and contained no new allegations. The Consent Order from ALBOP is enclosed.

Wisconsin Disciplinary Proceeding
(Derivative – Concluded 2024)

This was derivative of the (second) Alabama Proceeding, which, in turn, was predicated solely on the issuance of the Warning Letter in 2019.

In September 2023, the Wisconsin Pharmacy Examining Board (the "WPEB") notified Triad of an investigation based on the (second) Alabama proceeding from 2021-22, and eventually initiated disciplinary proceedings (the "Wisconsin Proceeding").

This was another "sister state" action: no new facts or substantive allegations in the

statement of charges—alleged culpability was to be derived solely from Triad's dispensing of sterile compounded preparations to Wisconsin patients—in 2016-17.

Triad ultimately signed a stipulation to pay a $5,000 fine. This matter was concluded in March 2024.

TEXAS STATE BOARD OF PHARMACY

May 15, 2018

TRIAD RX, INC.
C/O ROBERT ROBERTS RPH
PHARMACIST-IN-CHARGE
26258 POLLARD ROAD
DAPHINE, AL 36526

RE: In the Matter of Triad Rx, Inc.

Dear Mr. Roberts:

Enclosed is a copy of Agreed Board Order (ABO) #K-17-055 that was entered by the Texas State Board of Pharmacy (TSBP) concerning the above-referenced matter. TSBP entered this Order on May 1, 2018. The requirements and conditions of the enclosed Order and matters relating to the Order are discussed below.

ADMINISTRATIVE PENALTY (FINE)

Under the terms of this Order, Triad Rx, Inc. (pharmacy license #28003) must pay an administrative penalty (fine) of $1,000.00. **This fine is due on or before August 29, 2018.** Please make your cashier's check or money order payable to the "Texas State Board of Pharmacy" and submit to the TSBP office by the due date. Please include your ABO number (#K-17-055) on the cashier's check or money order. **Note:** TSBP will **not** accept partial payments. You must submit payment for the full amount by the due date.

LICENSE RENEWAL APPLICATIONS

Prior to the next expiration date of pharmacy license #28003, the pharmacy will complete a license renewal application for the Texas State Board of Pharmacy. This application will require a pharmacy representative to answer the question:

> "Has the PHARMACY, THE PHARMACY'S owner or any officer or partner (if the pharmacy is owned by a corporation or partnership) been the subject of any professional disciplinary action or are any such actions pending against you by a regulatory authority within the last 36 months?..."

As a result of the entry of ABO #K-17-055, Triad Rx, Inc. must answer "yes" to this question for 36 months from the date of the termination of all sanctions. Consequently, a Triad Rx, Inc. representative must answer "yes" to this question on any renewal applications submitted beginning May 1, 2018, and ending August 29, 2021.

If you have any questions about this Order, please contact Carissa Garcia, Enforcement Specialist, at (512) 305-8054.

Sincerely,

Robert Rivera
Enforcement Program Manager

RR: cg

Enclosure: Agreed Board Order #K-17-055

c: Triad Rx, Inc.
Matt McDonald
Corporate President
26258 Pollard Road
Daphne, AL 36526

AGREED BOARD ORDER #K-17-055

RE: IN THE MATTER OF
TRIAD RX, INC.
(PHARMACY LICENSE #28003)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28003 issued to Triad Rx, Inc. (Respondent), 26258 Pollard Road, Daphne, Alabama 36526.

By letter dated March 8, 2018, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2017), in that allegedly:

COUNT

On or about September 1, 2016, through on or about February 22, 2017, Triad Rx, Inc., 26258 Pollard Road, Daphne, Alabama 36526, was engaged in the operation of a non-resident pharmacy engaged in sterile compounding in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated March 8, 2018, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Matt McDonald, Corporate President, on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2017), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2018).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st day of May, 2018.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

Matt McDonald, Corporate President
On behalf of Triad Rx, Inc.

APPROVED AS TO FORM:

Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

S:\Attorneys\PNLs 0118 - 1218\Triad RX, Inc\Case Prep\Triad Rx Inc._MOABO_641851.docx

AGREED BOARD ORDER #K-17-055

RE: IN THE MATTER OF
TRIAD RX, INC.
(PHARMACY LICENSE #28003)

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

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And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS _____ day of _____, _____.

_____
MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

_____
Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

_____
Matt McDonald, Corporate President
On behalf of Triad Rx, Inc.

APPROVED AS TO FORM:

_____
Kerstin Arnold, General Counsel
Texas State Board of Pharmacy

S:\Attorneys\PNLs 0118 - 1218\Triad RX, Inc\Case Prep\Triad Rx Inc._MOABO_641851.docx

IN THE MATTER OF:	)	BEFORE THE ALABAMA STATE
	)	
TRIAD RX INC.	)	BOARD OF PHARMACY
	)	
Permit No. 113869	)	CASE NO: 18-L-0066
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Triad Rx Inc. listed above (hereinafter referred to as "Triad") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement, which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Triad, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds Triad has violated the provisions of the Alabama Pharmacy Practice Act based upon the conduct set forth in Counts One and Two of the Statement. Count Three shall be dismissed with prejudice.

2. Triad shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days from the effective date of the Consent Order, which is the date it is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Triad attempt to discharge the same.

3. Triad expressly waives its rights pursuant to the Alabama Pharmacy

Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Triad further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. That Triad agrees that any future violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

5. By execution of this Consent Order, Triad hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

6. Triad acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Triad acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 10th day of September, 2018.

Triad Rx Inc.

BY: _____

ITS: PRESIDENT

_____

Robert F. Jernigan, Attorney for
Triad Rx Inc.

DONE this the 18 day of September, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: _____

David Darby, R.Ph., President

_____

James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
TRIAD RX INC.	)	**BOARD OF PHARMACY**
	)	
Permit No. 113869	)	**CASE NO: 18-L-0066**
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Triad Rx Inc.
26258 Pollard Road
Daphne, Alabama 36526

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on September 18, 2018 at 8:00a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Triad Rx Inc. should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Triad Rx Inc. has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of an Agreed Board Order by the Texas State Board of Pharmacy on May 1, 2018 attached hereto as Exhibit "A" and/or operating a non-resident sterile compounding pharmacy in violation of Texas rules in that the pharmacy was not under the supervision of a pharmacist in charge licensed as a pharmacist in Texas as more fully set out in the

above referenced Order.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(6) based upon any or all of the allegations of the preceding Counts.

Further, pursuant to the provisions of Code of Alabama, (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et. seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-

examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 16th day of July, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

AGREED BOARD ORDER #K-17-055

RE: **IN THE MATTER OF TRIAD RX, INC. (PHARMACY LICENSE #28003)**

BEFORE THE TEXAS STATE BOARD OF PHARMACY

On this day came on to be considered by the Texas State Board of Pharmacy (Board) the matter of pharmacy license number 28003 issued to Triad Rx, Inc. (Respondent), 26258 Pollard Road, Daphne, Alabama 36526.

By letter dated March 8, 2018, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced evidence indicating that Respondent may have violated:

Sections 562.101(f); and 565.002(a)(3) of the Texas Pharmacy Act, TEX. OCC. CODE ANN. Title 3, Subtitle J (2015); and

Section 291.103 of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2017), in that allegedly:

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On or about September 1, 2016, through on or about February 22, 2017, Triad Rx, Inc., 26258 Pollard Road, Daphne, Alabama 36526, was engaged in the operation of a non-resident pharmacy engaged in sterile compounding in violation of Texas State Board of Pharmacy Rules, in that the pharmacy was not under the supervision of a pharmacist-in-charge licensed as a pharmacist in Texas.

By letter dated March 8, 2018, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal administrative hearing. By signing this Order, Matt McDonald, Corporate President, on behalf of Respondent, neither admits nor denies the truth of the matters previously set out in this Order, and agrees that the Board has jurisdiction in this matter and waives the right to informal conference, notice of hearing, formal administrative hearing, and judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

ORDER OF THE BOARD

THEREFORE, PREMISES CONSIDERED, the Board does hereby ORDER that:

(1) Respondent shall pay an administrative penalty of one thousand dollars ($1,000) due one hundred twenty (120) days after the entry of this Order.

(2) Failure to comply with any of the requirements in this Order constitutes a violation and shall be grounds for further disciplinary action. The requirements of this Order are subject to the Texas Pharmacy Act, TEX. OCC. CODE ANN., Title 3, Subtitle J (2017), and Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2018).

And it is so ORDERED.

THIS ORDER IS A PUBLIC RECORD.

SIGNED AND ENTERED ON THIS 1st **day of** May, **2018**.

MEMBER, TEXAS STATE BOARD OF PHARMACY

ATTEST:

Allison Vordenbaumen Benz, R.Ph., M.S.
Executive Director/Secretary
Texas State Board of Pharmacy

APPROVED AS TO FORM AND AGREED TO:

[redacted]
On behalf of Triad Rx, Inc.

APPROVED AS TO FORM:

Kristin Arnold, General Counsel
Texas State Board of Pharmacy

STATE OF MAINE
DEPARTMENT OF PROFESSIONAL
AND FINANCIAL REGULATION
OFFICE OF PROFESSIONAL & OCCUPATIONAL REGULATION
COMPLAINT DIVISION
35 STATE HOUSE STATION
AUGUSTA, MAINE
04333-0035

Janet T. Mills
Governor

Anne L. Head
Commissioner

August 2, 2019

Matt McDonald
Triad Rx Inc
26258 Pollard Rd
Daphne, AL 36526-4250

Re: Complaint No. 2019-PHA-15662 Triad Rx Inc

Dear Mr. McDonald:

Enclosed please find the fully executed consent agreement between Triad Rx, Inc., the Maine Board of Pharmacy, and the Office of the Attorney General in the above referenced matter.

This letter also acknowledges receipt of your fine payment in the amount of $250.00. Your fine is paid in full. As all conditions of the consent agreement have been fulfilled, this complaint file is now closed.

Please feel free to contact our office at (207) 624-8696 with any questions.

Sincerely,

Complaint Division

Enclosure

cc: Meagan Damon, Senior Consumer Assistant Specialist
Geraldine L. Betts, Board Administrator
Jessica Gowell, Professional Licensing Supervisor

STATE OF MAINE
BOARD OF PHARMACY

IN RE:	)	
	)	
TRIAD RX, INC.	)	CONSENT AGREEMENT
	)	
Complaint No. 2019-PHA-15662	)	

PARTIES

This document is a Consent Agreement regarding the pending application of TRIAD RX, INC., for the renewal of its mail order pharmacy license. The parties to this Consent Agreement are: Triad Rx, Inc. ("Triad "), the Maine Board of Pharmacy ("the Board"), and the Office of the Maine Attorney General ("the Attorney General"). This Consent Agreement is entered into pursuant to 10 M.R.S. § 8003(5-A).

STATEMENT OF FACTS

1. Since March 30, 2018, Triad has been licensed in Maine as a mail order pharmacy with a registered location of 26258 Pollard Road, Daphne, Alabama (license number **MO40002052**).

2. On May 1, 2018, the Texas State Board of Pharmacy imposed discipline against Triad's Texas pharmacy license (#28003) pursuant to Agreed Board Order #K-17-055, which found that Triad engaged in the practice of sterile compounding while not under the supervision of a pharmacist in charge who was licensed as a pharmacist in Texas and imposed an administrative penalty of $1,000.00.

3. Triad failed to report this disciplinary action to the Board within 10 days as required by 10 M.R.S. § 8003-G(2)(C).

4. On June 25, 2018, Triad reported to the Board for the first time that it had been assessed a penalty by the Texas Board of Pharmacy.

5. Pursuant to 10 M.R.S. § 8003(5-A)(A)(11) and 10 M.R.S. § 8003-G(2)(C), the Board may deny, refuse to renew, suspend, or revoke a license and impose other discipline for failing to report a license disciplinary action to the Board within 10 days of that action.

6. At its meeting on March 7, 2019, the Board reviewed the above information and voted to preliminarily deny Triad 's application for renewal of its license to be a mail order pharmacy. In lieu of the denial, the Board also voted to offer Triad this Consent Agreement. Unless Triad either requests, in writing, a hearing regarding the appeal of the preliminary denial within thirty (30) days of receipt of the Notice of Preliminary Denial, or accepts this Consent Agreement by signing and dating it and returning it to Complaint Division, 35 State House Station, Augusta, ME 04333, by **July 20, 2019,** the preliminary denial of Triad's application for licensure as a mail order pharmacy will become final.

COVENANTS

7. Triad admits to the facts above and admits that such conduct constitutes grounds for denial of or refusal to renew its license and for the imposition of discipline pursuant to 10 M.R.S. §§ 8003(5-A)(A)(11), and 10 M.R.S. § 8003-G(2)(C) for failing to report disciplinary action taken against a license in another jurisdiction within 10 days after the action was taken.

8. As discipline for the violation admitted to in paragraph 7 above, Triad agrees to accept the following DISCIPLINARY ACTION:

a) A REPRIMAND; and

b) A CIVIL PENALTY in the amount of two hundred fifty dollars ($250.00), payment of which shall be made by certified check or money order payable to the "Treasurer, State of Maine" and delivered to Complaint Division, Maine Department of Professional and Financial Regulation, 35 State House Station, Augusta, Maine 04333, and must be submitted with the signed Consent Agreement;

9. Violation of any of the terms or conditions of this Consent Agreement by Triad shall constitute grounds for discipline, including but not limited to modification, suspension, or revocation of licensure or the denial of licensure or re-licensure.

10. The Board and Triad agree that no further agency action will be initiated against its license by the Board based upon the specific violations admitted to herein, except or unless Triad fails to comply with the terms and conditions of this Consent Agreement. The Board may however consider the conduct described above as evidence of a pattern of misconduct if other allegations are brought against Triad and this Consent Agreement will be admitted into evidence in any future adjudicatory hearing involving Triad. The Board may also consider the fact that discipline was imposed by this Consent Agreement in determining appropriate discipline in any further complaints against Triad.

11. This Consent Agreement is not appealable and is effective until modified or rescinded by the parties hereto.

12. The Board and the Attorney General may communicate and cooperate regarding any matter related to this Consent Agreement.

13. Upon receipt of the signed Consent Agreement and the civil penalty payment, the Board will renew Triad's license contingent upon it meeting all other eligibility criteria.

14. This Consent Agreement is a public record within the meaning of 1 M.R.S. § 402 and will be available for inspection and copying by the public pursuant to 1 M.R.S. § 408-A.

15. Nothing in this Consent Agreement shall be construed to affect any right or interest of any person not a party hereto.

16. Triad acknowledges by its duly authorized representative's signature hereto that it has had an opportunity to consult with an attorney before executing this Consent Agreement, that it executes this Consent Agreement voluntarily, and that it agrees to abide by all terms and conditions set forth herein.

DATED: 7/10/19

TRIAD RX, INC.

By: _____

Print Name: MATT L. MCDONALD

Title: PRESIDENT

DATED: 7/22/2019

_____

JOSEPH BRUNO, R.Ph., PRESIDENT
Maine Board of Pharmacy

DATED: 8/1/2019

_____

ANDREW L. BLACK
Assistant Attorney General

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	07/17/2017-07/21/2017
	FEI NUMBER 3013497126

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Matthew L. McDonald, Owner	
FIRM NAME Triad Rx, Inc.	STREET ADDRESS 26258 Pollard Road
CITY, STATE, ZIP CODE, COUNTRY Daphne, AL 36526	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM (I) (WE) OBSERVED:

OBSERVATION 1
Cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically, the nonwoven wipers used to clean the ISO 5 area are not sterile.

OBSERVATION 2
The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, a lyophilizer and a portable dehumidifier are located in the clean room (ISO 7) adjacent to the ISO 5 area.

OBSERVATION 3
Inadequately or un-protected product intended to be sterile was observed to be exposed to lower than ISO 5 quality air.

Product Going to Work

Specifically, drug products intended to be lyophilized are sterile filtered in the ISO 5 area, partially stoppered, and then transferred to the lyophilizer (ISO 7 area) via unprotected/uncovered trays.

OBSERVATION 4
Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, perform aseptic processing in the ISO 5 area. The operator did not always disinfect or change gloves before reentering the ISO 5 area after retrieving materials or discarding waste in the ISO 7 area. The following lots were produced without adequate glove disinfection/changes:

-Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Brandon C. Helbmeier, Investigator	07/21/2017

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	07/17/2017-07/21/2017
	FEI NUMBER 3013497126

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Matthew L. McDonald, Owner	
FIRM NAME Triad Rx, Inc.	STREET ADDRESS 26258 Pollard Road
CITY, STATE, ZIP CODE, COUNTRY Daphne, AL 36526	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs

-Sermorelin Acetate 3mg/GHRP-6 3mg, Lyophilized, lot 07172017@24

OBSERVATION 5
Personnel engaged in aseptic processing were observed with exposed hands, wrists, legs, hair, or mouth.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, enter the ISO 5 area with bare hands then put on sterile gloves and proceed with aseptic processing. The following lots were produced:

-Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25
-Sermorelin Acetate 3mg/GHRP-6 3mg, Lyophilized, lot 07172017@24

OBSERVATION 6
Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, move a vacuum pump from the ISO 7 area to the ISO 5 area without first disinfecting the equipment.

OBSERVATION 7
Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, place hands and arms over open glass vials during aseptic filling of the following products:

-Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25
-Sermorelin Acetate 3mg/GHRP-6 3mg, Lyophilized, lot 07172017@24

OBSERVATION 8
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
404 BNA Dr., Bldg. 200, Ste. 500 Nashville, TN 37217-2597 (615)366-7801 Fax:(615)366-7802	07/17/2017-07/21/2017
	FEI NUMBER 3013497126

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Matthew L. McDonald, Owner	
FIRM NAME Triad Rx, Inc.	STREET ADDRESS 26258 Pollard Road
CITY, STATE, ZIP CODE, COUNTRY Daphne, AL 36526	TYPE ESTABLISHMENT INSPECTED Producer of Sterile and Non-sterile Drugs

Specifically, your firm's batch sizes for injectable drug products range in volume from 10 ml to 4,500 ml and from 1 vial to 500 vials. However, the last media fill performed only consisted of 6 -10 ml vials. Additionally, media fills previously performed do not simulate all steps for lyophilized products including but not limited post filtration manipulations, transfer, and lyophilization.

OBSERVATION 9

The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.

Specifically, your firm uses a prepared bleach water solution that consists of 30 ml of 5.25% sodium hypochlorite mixed with 1 liter of sterile water for irrigation. However, your firm has not established an effective contact time for this concentration/strength and the contact time is not currently monitored by your firm.

***DATES OF INSPECTION**

07/17/2017, 07/18/2017, 07/19/2017, 07/21/2017

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE	EMPLOYEE(S) NAME AND TITLE (Print or Type)	DATE ISSUED
		Brandon C. Hellmeier, Investigator	07/21/2017

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

Matthew L. McDonald
President

26258 Pollard Road
Daphne, Alabama 36526
Telephone: 251-380-7630
Facsimile: 251-380-7631

August 3, 2017

Via Facsimile (615-366-7802) and FedEx Overnight
U.S. Food and Drug Administration
New Orleans District
404 BNA Dr., Bldg. 200, Ste. 500
Nashville, TN 37217-2597

RE: Triad Rx, Inc. – FEI No. 3013497126
Response to FDA Form 483 Issued 7/21/2017

To Whom It May Concern:

This responds to the July 21, 2017 FDA Form 483 (the "483") issued to Triad Rx, Inc., FEI Number 3013497126 ("Triad") containing findings from FDA's July 17-21 inspection (the "inspection") of Triad's compounding pharmacy (described as a "[p]roducer of Sterile and Non-sterile Drugs") located at 26258 Pollard Road, Daphne Alabama (the "facility" or "establishment").

Background

As a small business undergoing our first post-Compounding Quality Act ("CQA") inspection by FDA, Triad values the input of FDA's inspector, Investigator Brandon C. Heitmeier, who demonstrated commendable efficiency, subject matter expertise, communications skill, and professionalism throughout the inspection.

Triad takes this process seriously and views the inspection, our interactions with Investigator Heitmeier during the inspection, the 483, and this response as opportunities for improving Triad's performance and understanding of its considerable responsibilities in protecting public health, safety, and welfare from unsafe products.

As a 503A compounding pharmacy, we are committed to compliance with USP standards and view this interaction as an opportunity to improve quality through ever-greater compliance.

Summary of Analysis

Triad has investigated the issues raised in the 483 in an effort to evaluate potential implications for product safety concerns, including an evaluation of the necessity for issue-specific exploratory and corrective responses, together with more general measures necessary to prevent recurrence of these and similar nonconformities.

We concluded that (i) immediate action is (and will be) required to respond to potential safety concerns over identified nonconformities in the compounding process, and (ii) comprehensive corrective and/or preventative action is (and will be) required to prevent similar (and other) nonconformities and otherwise to sustain compliance over the longer term.

We believe that we understand FDA's concerns, have identified compliance opportunities, and formulated and begun implementing action plans that we believe will successfully eliminate or rectify these issues.

Discussion

OBSERVATION 1

Cleaning pads or wipes used in the ISO 5 area are not sterile.

Specifically, the nonwoven wipes used to clean the ISO 5 area are not sterile.

RESPONSE TO OBSERVATION 1

1. **Context**

Going into the inspection, Triad's routine cleaning practice was to sterilize the wipes by soaking in alcohol for the validated duration before introducing the wipes into the ISO 5 environment for cleaning purposes.

Triad internalized this Observation, researched pharmacy compounding best practices, reviewed its policies and procedures ("P&Ps"), examined its compounding and environmental testing records, and concluded that corrective action would be warranted to reduce the risk of contaminated product even further.

2. **Immediate and Long-Term Corrective Actions**

Triad has purchased sterile cleaning pads for use in the ISO 5 area and replaced the non-sterile wipes. Triad has revised its P&Ps applicable to cleaning the ISO 5 area to incorporate the requirement for using sterile cleaning materials, and conducted training on the revised procedure with all pharmacists and technicians involved in sterile compounding. (Revised procedure and training records attached as composite Exhibit 1.)

OBSERVATION 2
The ISO-classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

Specifically, a lyophilizer and a portable dehumidifier are located in the clean room (ISO 7) adjacent to the ISO 5 area.

RESPONSE TO OBSERVATION 2

We have investigated (and believe that we understand) FDA's concerns, identified compliance opportunities, and formulated and begun implementing action plans that should successfully eliminate or rectify FDA's issues of concern.

- **Immediate Corrective Action**

Triad has removed the portable dehumidifier from the ISO 7 clean room and will continue to carefully monitor humidity in the ISO areas.

- **Medium- to Long-Term Corrective Action**

Triad has consulted with Simplex Isolation Systems and is in the process of developing a practical solution to FDA's concerns over the lyophilizer's presence in the ISO 7 environment. We have determined that the equipment in question may be moved to a place in the room that is the maximum distance from the ISO 5 work area. Furthermore, we are able to modify the area with a clear vinyl curtain to isolate the area where the lyophilizer is located from all other areas in the room. Additionally, the exposed part of the equipment, which was the most concerning to the inspector, will be located adjacent to the vented wall of the cleanroom, limiting exposure to any part of the room, or any other adjacent areas of filtered air.

Triad will remain diligent in its environmental surface and air testing to ensure the safety of our patients. Triad has followed strict environmental and/or sterile product procedure applicable to all medications prepared in the ISO 5 area and conducted training on the revised procedure with all pharmacists and technicians involved in sterile compounding, and will continue to do so in accordance with USP 797 requirements. (Procedure and diagram of proposed cleanroom layout attached as composite Exhibit 2.)

OBSERVATION 3
Inadequately or un-protected product intended to be sterile was observed to be exposed to lower than ISO 5 quality air.

Specifically, drug products intended to be lyophilized are sterile filtered in the ISO 5 area, partially stoppered, and then transferred to the lyophilizer (ISO 7 area) via unprotected/uncovered trays.

RESPONSE TO OBSERVATION 3

We have investigated (and believe that we understand) FDA's concerns, identified compliance opportunities, and formulated and begun implementing action plans that should successfully eliminate or rectify this issue.

Triad has consulted with Simplex Isolation Systems and is in the process of developing a practical solution to FDA's concerns over the workflow between the ISO 5 and ISO 7 environments. As discussed in Observation 2, the ISO 5 area created by the new curtain will be extended to allow direct access to the lyophilizer's chamber and controls without any unsealed product leaving the ISO 5 environment.

Triad will remain diligent in its sterility, fungal, and pyrogen testing of any products that are compounded to be lyophilized, to ensure the safety of our patients. Triad has followed or exceeded USP 797's requirements for testing all of its sterile products for potency and sterility, and will continue to do so with diligence, in accordance with USP 797 requirements.

Once the new curtain is in place, Triad will adopt a new sterile product procedure applicable to all medications prepared in the ISO 5 area to be placed in the lyophilizer and will conduct training on the revised procedure with all pharmacists and technicians involved in sterile compounding. (See Exhibit 2.)

OBSERVATION 4
Personnel were observed touching equipment or other surfaces located outside the ISO 5 area with gloved hands and then proceeding with aseptic processing without changing or sanitizing gloves.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, perform aseptic processing in the ISO 5 area. The Operator did not always disinfect or change gloves before reentering the ISO 5 area after retrieving materials or discarding waste in the ISO 7 area. The following lots were produced without adequate glove disinfection/change:

-Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25
-Sermorelin Acetate 3mg/GHRP-6 3mg Lyophilized, lot 07172017@24

RESPONSE TO OBSERVATION 4

We have investigated (and believe that we understand) FDA's concerns, identified compliance opportunities, and formulated and begun implementing action plans that should successfully eliminate or rectify this issue.

Triad has reviewed its P&Ps and training records relative to aseptic handling of clean room items and confirmed that the observed behavior is not consistent with Triad's P&Ps and training standards. Triad has conducted an in-service training for all personnel involved in aseptic procedures to reinforce the correct procedure for disinfection and re-disinfection of gloves and equipment upon leaving and re-entering the ISO 5 area. (Training records attached as Exhibit 4.)

Further, Triad will increase testing frequency for the implicated lots by 100% of USP 797 requirements—to 20 vials of each—in an attempt to control for any potential contamination.

OBSERVATION 5
Personnel engaged in aseptic processing were observed with exposed hands, wrists, legs, hair, or mouth.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, enter the ISO 5 area with bare hands then put on sterile gloves and proceed with aseptic processing. The following lots were produced:

-Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25

-Sermorelin Acetate 3mg/GHRP-6 3mg Lyophilized, lot 07172017@24

RESPONSE TO OBSERVATION 5

We have investigated (and believe that we understand) FDA's concerns, identified compliance opportunities, and formulated and begun implementing action plans that should successfully eliminate or rectify this issue.

Triad has reviewed its P&Ps and has noted that, consistent with long-standing professional pharmacy practice standards, Triad's procedure for aseptic gloving in the clean room did not prohibit initial gloving in the ISO 5 environment. Triad has adopted a revised procedure applicable to aseptic gloving that requires the initial donning of sterile gloves in the ISO 7 area and IPA to be applied to the gloves' outer surface before entering the ISO 5 area. We have also conducted an in-service training on the new procedure for all personnel involved in aseptic procedures. (Revised procedure and training records attached as composite Exhibit 5). We especially valued Investigator Heitmeier's input concerning the importance of not allowing any exposed skin in the ISO 5 environment.

Further, Triad will increase sterility testing frequency for the implicated lots by 100% of USP 797's requirements—to 20 vials of each—in an attempt to control for any potential contamination.

OBSERVATION 6
Equipment, materials, and/or supplies are not disinfected prior to entering the aseptic processing areas.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, move a vacuum pump from the ISO 7 area to the ISO 5 area without first disinfecting the equipment.

RESPONSE TO OBSERVATION 6

Triad has reviewed its P&Ps and training records applicable to the disinfecting of gloves and equipment moving between ISO 7 and ISO 5 environments, and confirmed that the observed behavior is not consistent with Triad's P&Ps and training standards. Triad has conducted an in-service training for all personnel involved in aseptic procedures to reinforce the correct procedure for disinfection and re-disinfection of gloves and equipment upon leaving and re-entering the ISO 5 area. (See Exhibit 4.)

OBSERVATION 7
Personnel were observed conducting aseptic manipulations or placing equipment/supplies in an area that blocked the movement of first pass air around an open unit, whether before or after it is filled with sterile product.

Specifically, on 07/17/2017, I observed clean room operator, with initials GW, place hands and arms over open glass vials during aseptic filling of the following products:

-Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, lot 07172017@25

-Sermorelin Acetate 3mg/GHRP-6 3mg Lyophilized, lot 07172017@24

RESPONSE TO OBSERVATION 7

In these instances, a tray of smaller items was being filled with sterile solution. Triad has reviewed its P&Ps for ISO 5 aseptic manipulations, including, without limitation, techniques for applicable to filling multiple liquid units under laminar flow, and identified room for improvement. The drug formulation worksheet reflecting the procedure for producing sterile products compounded using a similar process has been revised to reflect the need to keep unfilled vials covered while the compounder is filling the tray in order to minimize the risk of unclean air flowing over the vials. Triad has conducted an in-service training for all personnel involved in aseptic procedures (Revised procedure and training records attached as Exhibit 5).

Further, Triad will increase sterility testing frequency for the implicated lots by 100% of USP 797's requirements—to 20 vials of each—in an attempt to control for any potential contamination.

OBSERVATION 8
Media fills were not performed that closely simulate aseptic production operations incorporating, as appropriate, worst-case activities and conditions that provide a challenge to aseptic operations.

Specifically, your firm's batch sizes for injectable drug products range in volume from 10 ml to 4,500 ml and from 1 vial to 500 vials. However, the last media fill performed only consisted of 6 – 10 ml vials. Additionally, media fills previously performed do not simulate all steps for lyophilized products including but not limited post filtration manipulations, transfer, and lyophilization.

RESPONSE TO OBSERVATION 8

We have investigated (and believe that we understand) FDA's concerns, identified compliance opportunities, and formulated and begun implementing action plans that should successfully eliminate or rectify this issue.

Again, Triad has reviewed its P&Ps and has noted that, consistent with long-standing professional pharmacy practice standards, we were under the impression that Triad's procedure for conducting Media Fills for High Risk Procedures met USP 797's requirements for this assessment. After discussing this with Investigator Heitmeier, we realized the importance conducting a more complex procedure for this assessment, especially in light of his other concerns of the equipment we regularly use for compounding. We have revised this procedure for all personnel involved in aseptic procedures also conducted an in-service training on the new procedure, which includes a more complex process with more fills and incorporates the lyophilizer. (Revised procedure and training records attached as composite Exhibit 5).

OBSERVATION 9
The use of sporicidal agents in the cleanrooms and/or ISO 5 area is inadequate or infrequent.

Specifically, your firm uses a prepared bleach water solution that consists of 30 ml of 5.25% sodium hypochlorite mixed with 1 liter of sterile water for irrigation. However, your firm has not established an effective contact time for this concentration/strength and that contact time is not currently monitored by your firm.

RESPONSE TO OBSERVATION 9

Triad has reviewed its P&Ps for preparing and documenting its use of sporicidal agents and has conducted an in-service training for all personnel involved in these procedures. The formulation has been adjusted to a concentration that is accepted in the industry for sporicidal activity (100 ml of 5.25% sodium hypochlorite mixed with 1 liter of sterile water for irrigation, in contact for 5 minutes), and documentation of use for sporicidal agents and length of contact time has been added to the pharmacy cleaning logs. (Revised formulation, pharmacy log sheet example, and training records attached as composite Exhibit 9.)

Conclusion

Triad welcomes this opportunity to improve patient safety through open and cooperative dialogue with FDA. We are prepared to undertake all actions necessary to achieve complete and comprehensive resolutions to all the concerns identified in the 483—or any other concerns FDA may have. In particular, Triad is committed to raising the level of its compliance under the CQA and related regulations. Triad's P&Ps have been updated to require monthly reviews of FDA publications to ensure that no article in 503A Categories 2 (Bulk Drug Substances that Raise Significant Safety Risks) or 3 (Bulk Drug Substances Nominated Without Adequate Support – including, without limitation, melatonin or GHRP-2 or -6) is inadvertently included as an active ingredient in compounded products.

Triad hopes that FDA will, in reviewing this response, have an opportunity to provide feedback, particularly if we are headed in a wrong direction.

Unless otherwise instructed, we will update this response monthly to:

- Incorporate any FDA feedback; and
- Track progress on long-term action items where solutions were still under development.

Please feel free to contact me with questions or concerns, or in my absence, Rob R. Roberts, III, Triad's pharmacist-in-charge. Or you may our general counsel, Robert Jernigan (251-753-2652).

Sincerely,

Matthew L. McDonald
President

Matthew L. McDonald
President & CEO
26258 Pollard Road
Daphne, Alabama 36526
(251) 581-9189 – Office
(251) 626-9999 – Facsimile
[redacted]

February 28, 2019

CMS Case #5699659

Via FedEx and Email Attachment (ORAPHARM2_Responses@fda.hhs.gov)
U.S. Food and Drug Administration
Office of Pharmaceutical Quality Operations, Division II
Attn: Mr. John W. Diehl, Director, Compliance Branch
4040 N. Central Expressway, Ste. 300
Dallas, TX 75204

RE: Triad Rx, Inc. – FEI No. 3013497126
Response to FDA Warning Letter Dated 02/05/2019
CMS Case #5699659

Dear Director Diehl:

This responds to the February 5, 2019 warning letter (the "Warning Letter" or the "Letter" – CMS Case #5699659) issued to Triad Rx, Inc., FEI Number 3013497126 ("Triad") concerning (i) the findings from FDA's July 17-21 inspection (the "inspection") of Triad's compounding pharmacy (described as a "[p]roducer of Sterile and Non-sterile Drugs") located at 26258 Pollard Road, Daphne Alabama (the "facility" or "establishment") as set forth in the July 21, 2017 FDA Form 483 (the "483"); and (ii) Triad's August 3, 2017 response to the 483 (the "Response").

Triad provides the following additional submittals:

Exhibit	Description	Bates No(s).
A	Vinyl Curtain Packing List	000001
B	Clean Room Curtain Photo 1 of 2	000002
C	Clean Room Curtain Photo 2 of 2	000003
D	Clean Room Certification Report 3-19-2018	000004-000007
E	Formula Worksheet – Sermorelin	N/A[1]
F	Formula Worksheet – TestCypProp	N/A
G	USP Control Certification Reports 8-2018	000010-000052
H	USP Control Certification Reports 02-2019	000053-000122
I	Clean Room Modification Photo (Lyophilizer) 1 of 5	000123
J	Clean Room Modification Photo (Lyophilizer) 2 of 5	000124
K	Clean Room Modification Photo (Lyophilizer) 3 of 5	000125
L	Clean Room Modification Photo (Lyophilizer) 4 of 5	000126
M	Clean Room Modification Photo (Lyophilizer) 5 of 5	000127
N	SOP 7.007.3 Media Fill for High Risk Compounding	000128-000131
O	High Risk Level Media-Fill Challenge Log Sheet (for SOP 7.007:3)	000132

[1] Exhibits E and F lack labeled Bates Numbers, as the files were generated from Triad's pharmacy compounding software program, protected from post-export editing. Bates Numbers 000008-000009 are therefore omitted.

Exhibit	Description	Bates No(s).
P	Sterile Cleaning Pads – Invoice, Spec Sheets & COAs	000133-000140
Q	SOP 1.088 Drug and Chemical Selection	000141-000143
R	In-Service Documentation 8-02-2017	000144
S	SOP 2.016 Personnel Training and Evaluation in Aseptic Compounding	000145-000147
T	SOP 4.011 Cleaning and Maintenance of the Cleanroom Facility	000148-000155
U	Clean Room Service Report 10-25-2017	000156-000159
V	Clean Room Service Report 4-26-2018	000160-000163
Z	Triad Clean Room Layout Diagram	000164

Responses to Corrective Action Items

Triad also provides narrative commentary in an effort to provide FDA with sufficient basis to evaluate Triad's proposed corrective actions, as described in Warning Letter, Section D (entitled "Corrective Action"):

Corrective Action Item #1

In your response, you indicated that you have "Consulted with Simplex Isolation Systems" and provided a copy of the diagram of the proposed cleanroom layout where "the ISO 5 are created by the new curtain will be extended to allow direct access to the lyophlizer's chamber and controls without any unsealed product leaving the ISO 5 environment." However, you did not provide any detailed plans of construction or timeframe regarding the facility modification of the ISO 5 or the ISO 7 areas.

Response to Corrective Action Item #1

Triad consulted with Simplex Isolation Systems, and completed the installation of a vertical curtain compartmentalizing the work area of the clean room that includes the lyophilizer into an ISO 5 area, in mid- to late August 2017 . (See Exhibits A, B, and C). This creates an environment in which mobilization of products that need to be placed into the lyophilizer may remain in ISO 5 controlled air while doing so. A diagram of the clean room layout, including an illustration of the ISO 5 corridor created by the vinyl curtain, is also attached. (See Exhibit Z).

Triad's clean room has passed multiple environmental tests and certifications since the inspection (See Exhibits D, G, H, U, and V). Further, all sterile products compounded at the facility have passed lot-level sterility testing at a third-party analytical laboratory (examples available upon request).

Corrective Action Item #2

In your response, you indicated that you have revised "the drug formulation worksheet" to reflect "the need to keep unfilled vials covered while the compounder is filling the tray in order to minimize the risk of unclean air flowing over the vials." However, you did not provide "the drug formulation worksheet" or any other documents reflecting the revised procedures to support this corrective action."

Response to Corrective Action Item #2

In this instance—described in Observation 7 from the 483—a tray of smaller items was being filled with sterile solution. Upon discussion with FDA's inspector, Triad revised its procedure as set forth in the applicable standard drug formulation worksheets to reflect the need to keep unfilled vials covered while the compounder is filling the tray in order to minimize the risk of unclean air from flowing over the vials. Triad also reviewed and revised its procedures for aseptic handling of clean room items, and conducted in-service training for all personnel involved in aseptic procedures.

Triad acknowledges that its Response to the 483 did not include examples of the revisions to Triad's standard drug formulation worksheets, an oversight that Triad hopefully corrects by attaching Exhibits E and F. However, we respectfully submit that "other documents reflecting the revised procedures" were, in fact, included, specifically: revised procedure and training records attached as Exhibit 7 to Triad's Response. These items are also enclosed as Exhibits R, S, and T.

Corrective Action Item #3

In your response, you indicated that you can modify the cleanroom with a "clear vinyl curtain to isolate the area where the lyophilizer is located" and the "exposed part" of the lyophilizer "will be located adjacent to the vented wall of the cleanroom, limiting exposure to any part of the room." However, you did not provide any detailed plans or timeline of construction within the ISO 5 or the ISO 7 areas. Furthermore, it is unclear if your firm evaluated whether the "vinyl curtain" is considered a difficult to clean surface and whether a "vented wall" between an ISO 5 are and unclassified space could potentially introduce contamination directly in the aseptic processing areas.

Response to Corrective Action Item #3

Triad installed the curtain and completed in stages the related repositioning of equipment and reconfiguring of workflow described in the Response in mid- to late August 2017.

Triad considered whether the vinyl curtain would constitute a difficult-to-clean surface, and concluded that, based on the curtain's size, shape, and composition, the curtain would not pose any significant degree of additional difficulty as regards cleaning processes. The curtain installed is an AirBlock strip system comprised of overlapping individual 36" segments of heavy-gauge vinyl "designed to hang straight and maintain overlaps."[2] Given the thickness and relatively short length and of each individual segment, pharmacy personnel can place tension on the bottom of each segment so as to achieve the desired surface-to-surface contact during wiping/cleaning evolutions.

Triad did evaluate the potential for contamination posed by placing the lyophilizer as close as possible to a wall with a vent, and concluded that the risk of contamination did not exceed that of any other exterior vent in an ISO 5 area. Triad also made sure to test the air quality effects of so placing the lyophilizer inside the curtained ISO 5 corridor to ensure no significant threat to the quality of air in any

[2] https://simplex.is/products/modular-cleanrooms/softwall-enclosures/airblock/. Specifications for the curtain's composition material may be found here: https://simplex.is/assets/tech_sheets/SIM_TDS_ClearMaterial.pdf.

critical areas of the clean room. (See Exhibit G – Comments p.12; Exhibit H, Comments p.13; Exhibits U & V).

However, given the theoretical risk of eventual microbial colonization going undetected in or on the lyophilizer's potentially problematic components (exhaust ports/vents, fan blades/shafts/motors, exposed interior recesses, etc.), Triad decided to take additional steps in furtherance of protecting air quality. Triad has modified the ISO 5 area by installing a custom cutout in the clean room wall so that such potentially problematic components are not exposed within to the ISO 5 environment. (See Exhibit I, J, K, L, and M). This latest modification was completed in February 2019.[3]

Triad evaluated the safety of excluding the potentially problematic components from the ISO 5 environment by placing them in the immediately adjacent unclassified space, and concluded that the risk of contamination did not exceed that of any other exterior vent in an ISO 5 area. Triad also made sure to test the air quality effects of this reconfiguration to ensure no significant threat to the quality of air in any critical areas of the clean room. (See Exhibit H, Comments p.12-13).

Corrective Action Item #4

In your response, you indicated that you have revised your media fill procedure which includes a "more complex process with more fills and incorporates the lyophilizer". However, your revised media fill procedures reference only thirty 5ml vials which do not simulate operations incorporating the worst-case activities and conditions.

Response to Corrective Action Item #4

Triad has reviewed its procedures for media fills and has modified the media fill procedure to replicate a more complex manipulation: filling at least one hundred 10mL vials, incorporating non-sterile commercially available Tryptic Soy Broth, and using the lyophilizer. (See Exhibits N & O).

Corrective Action Item #5

In your response, you indicated that you have purchased "sterile cleaning pads" for use in the ISO 5 area to replace the non-sterile wipes. However, you did not provide a receipt or a certificate of analysis of the sterile "cleaning pads" purchased or the starting date of their use within your facility.

Triad purchased sterile cleaning pads as indicated in the 483 Response and began using these pads on August 1, 2017. The pads are TrueCare Biomedix—sterile gamma irradiated to a 10-6 Sterility Assurance level—for use in the pharmacy's ISO 5 areas. (See Exhibit P).

Response Regarding Section 503A Bulk Compounding

Triad believes that it understands FDA's concerns regarding which compounding bulk substances Triad, as a traditional, compounding and retail pharmacy dispensing medications on a patient-specific

[3] Please note that the enclosed clean room diagram (Exhibit Z) predates the February 2019 modification.

basis, may compound so as to stay within the parameters established by section 503A. To that end, Triad has (i) ceased compounding active ingredients identified as "ineligible drug products" in the Warning Letter, and (ii) revised its procedures in an effort to exclude, not just 503A category 2 or 3 bulk drug substances, but all bulk drug substances that (i) are not the subject of an applicable USP or NF monograph, (ii) are not a component of an FDA-approved drug, and (iii) do not appear on the 503A bulks list. (See Exhibit Q).

We would welcome any pre-inspection feedback FDA might provide, and otherwise look forward to collaborating in the process of achieving greater compliance in the interest of patient safety.

Sincerely,

Matthew L. McDonald
President & CEO
Triad Rx, Inc.

cc: Susan Alverson, Pharm.D. (via U.S. Mail)
Executive Secretary, Alabama Board of Pharmacy
P.O. Box 381988
Birmingham, AL 35238-1988



October 18, 2019

Case #: 569659

RESPONSE LETTER

VIA UPS

Matthew L. McDonald, Owner
Triad Rx, Inc.
26258 Pollard Road
Daphne, Alabama 36526

Mr. McDonald:

This letter acknowledges receipt of your letter dated February 28, 2019, in which you responded to FDA's warning letter (ref: WL# CMS Case 569659) dated February 5, 2019.

We address below your responses to the violations identified in the warning letter.

Overall, it appears your response is inadequate as it appears incomplete. Regarding the insanitary conditions listed on page 3 of our February 5, 2019, Warning Letter, it appears your firm did not directly respond to examples: #3-4, #6-7, and #9-11. It appears your firm responded to page 4-5, section D of the Warning Letter, which correlate to examples #1-2, #5, and #8, of the insanitary conditions listed on page 3. Referring to pages 2-4 of your February 28, 2019 response (Response to Corrective Action Item #1 and #3), the response appears to correlate with insanitary condition #1 on page 3 of our Warning Letter.

We acknowledge your firm purchased and installed, during August 2017, a "Custom Cleanroom Soft Wall." The installation included a redesign of your firm's work area to include the lyophilizer within the ISO 5 area and conducted cleanroom certification tests after installation. Your response did not include written procedures regarding the cleaning of the soft wall; however, your response states "...pharmacy personnel can place tension on the bottom of each segment so as to achieve the desired surface-to-surface contact during wiping/cleaning evolutions." Your response did not address how your firm ensured the quality of in-process and finished drug products produced during the bracketed timeframes when these physical modifications were being conducted.

U.S. Food & Drug Administration
Office of Pharmaceutical Quality Operations, Division II
4040 N. Central Expressway, Suite 300
Dallas, Texas 75204
www.fda.gov

Referring to page 3 of your February 28, 2019, response, "Response to Corrective Action Item #2" appears to correlate with insanitary condition #2 on page 3 of our Warning Letter. It does not appear your firm responded directly to the insanitary condition cited in the Warning Letter. Formulation worksheets provided with your response as examples of corrective action, state at Step 10 and/or 11, generally: when working with a tray of multiple vials, carefully expose one row at a time for the next 2 steps to prevent interruption of air flow over open vials. However, your written procedure and training documents provided do not appear to address the practice specifically.

Referring to page 4 of your February 28, 2019, response, "Response to Corrective Action Item #4" appears to correlate with insanitary condition #5 on page 3 of our Warning Letter. We note your submission of a revised written procedure "Media Fill for High Risk Compounding Triad Rx Inc." that addresses media fill for high-risk compounding and requires 100 to 483, 10 ml vials, which, according to the procedure reflects the typical batch size range produced by your firm and incorporates the use of the lyophilizer. However, it does not appear the procedure was revised comprehensively to reflect the change made to the number of vials to be filled and tested as stated in your response and referenced in the procedure at step #4-5. Additional inconsistencies regarding the procedure, include: step #6 refers to drawing 30 ml of medium with 30 vials produced; and step #14 only requires the incubation of 10 randomly selected vials.

Referring to page 4 of your February 28, 2019, response, "Response to Corrective Action Item #5" appears to correlate with insanitary condition #8 on page 3 of our Warning Letter. It appears your firm responded adequately and began using sterile cleaning pads on August 1, 2017.

The Agency will verify the adequacy of your corrective actions during the next inspection.

If you have further questions regarding this letter, please contact Rebecca A. Asente, Compliance Officer, via (504) 846-6104 or Rebecca.Asente@fda.hhs.gov.

Sincerely,

John W. Diehl -S3

John W. Diehl, M.S
Director, Compliance Branch
Office of Pharmaceutical Quality Operations,
Division II

CC:

Susan Alverson, Executive Secretary
Alabama Board of Pharmacy
P.O. Box 381988
Birmingham, Alabama 35238-1988

U.S. FOOD & DRUG ADMINISTRATION

May 3, 2023

VIA Electronic Mail
Return Confirmation Requested

Matt McDonald, Owner
Triad Rx, Inc.
26258 Pollard Rd.
Daphne, AL 36526-4250

Dear Mr. McDonald:

The U.S. Food and Drug Administration (FDA) has completed an evaluation of your firm's corrective actions in response to our warning letter [WL 569659 Issued February 5, 2019]. We acknowledge that your firm no longer produces sterile drug products. Based on our evaluation, it appears that you have adequately addressed the violations contained in this warning letter.

You are expected to take all necessary steps to ensure compliance with the Federal Food, Drug, and Cosmetic Act and FDA's implementing regulations. This letter will not preclude any future regulatory action should violations be observed during a subsequent inspection or through other means.

Sincerely,

Ronda R. Loyd-jones.-S Digitally signed by Ronda R. Loyd-jones.-S Date: 2023.05.07 12:11:50 -07'00'

Ronda R. Loyd-Jones
Director, Compliance Branch
Office of Pharmaceutical Quality Operations, Division II

U.S. Food and Drug Administration
Office of Pharmaceutical Quality Operations, Division II
1201 Main Street, Suite 7200
Dallas, Texas 75202
www.fda.gov

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
TRIAD RX INC.	)	**BOARD OF PHARMACY**
	)	
Community Pharmacy	)	**CASE NO: 19-L-0137**
Permit Number: 113869	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Triad Rx Inc. which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that Triad Rx Inc. has violated the provisions of law based upon the conduct set out in Counts One through Six of the Statement.

2. Triad Rx Inc. shall pay an administrative fine in the amount of Fifteen Thousand Dollars ($15,000.00) within thirty (30) days of the effective date of this Consent Order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Triad Rx Inc. attempt to discharge the same.

3. Triad Rx Inc. expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and

Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Triad Rx Inc. further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, Triad Rx Inc. hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. Triad Rx Inc. acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against Triad Rx Inc.'s permit, including, but not limited to revocation.

6. Triad Rx Inc. acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Triad Rx Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of their attorney.

DONE this the 7th of July, 2022.

TRIAD RX INC.

BY: _____

ITS: PRESIDENT

_____

Robert F. Jernigan
Attorney for Triad Rx Inc.

DONE this the 19 of July, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: _____
Chris Phung, R.Ph., President

By: _____
James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 645
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE**
TRIAD RX INC.	)	**BOARD OF PHARMACY**
	)	
Community Pharmacy	)	**CASE NO: 19-L-0137**
Permit Number: 113869	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Triad Rx Inc.
26258 Pollard Road
Daphne, Alabama 36526

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on July 19, 2022 at 8:00 a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Triad Rx Inc. should not be revoked, suspended or placed on probation or a monetary penalty imposed based upon any or all of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) in that you violated 503(a) of the FDCA as set out in a Warning Letter dated February 5, 2019 attached hereto as Exhibit "A", to include any or all of the following:

(a) Using bulk drug substances which were not the subject of an applicable USP or NF monograph, were not components of an FDA approved human

drug and which did not appear on the 503A bulks list. An example of such is set out and described in Section B of the referenced Warning Letter.

(b) Violations of the FDCA Adulterated Drug Product, eleven (11) examples of the same being set out and described in Section C of the referenced Warning Letter.

(c) Compounding Unapproved New Drug Products as set out and described in Section C of the referenced Warning Letter.

(d) Your ineligible drug products compounded were misbranded as set out and described in Section C of the referenced Warning Letter.

The Board alleges that each and every violation is a separate and distinct offense.

COUNT TWO

Violating Code of Alabama, (1975), § 34-23-33(6) based upon any or all of the allegations of Count One above and/or the deficiencies noted by the FDA in your response to the Warning Letter as set out with particularly in Section D.

COUNT THREE

Violating Code of Alabama, (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(a) based upon any or all of the allegations of Count One above.

COUNT FOUR

Violating Code of Alabama, (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(b) based upon any or all of the allegations of Count One above.

COUNT FIVE

Violating Code of Alabama, (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT SIX

Violating Code of Alabama, (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(f) based upon any or all of the allegations of Count One above.

Further, pursuant to the provisions of Code of Alabama, (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et. seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT SEVEN

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

Notice is further given that in the event you are found guilty of the allegations contained in any or all of the preceding Counts contained in this Statement of Charges and Notice of Hearing, the Board may consider in assessing punishment the Consent

Order entered by the Board on September 18, 2018, said document being attached hereto and made a part hereof as Exhibit "B".

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 4th day of May, 2022.

ALABAMA STATE BOARD OF PHARMACY

By: Donna C. Yeatman
Executive Secretary

EXHIBIT "A"

WARNING LETTER

Triad Rx, Inc

MARCS-CMS 569659 – FEB 05, 2019

Recipient:

Matthew L. McDonald

Owner

Triad Rx, Inc

26258 Pollard Road

Daphne, AL 36526

United States

Issuing Office:

Division of Pharmaceutical Quality Operations II

4040 North Central Expressway, Suite 300

Dallas, TX 75204-3128

United States

February 5, 2019

CMS Case #569659

WARNING LETTER

VIA UPS EXPRESS

Matthew L. McDonald, Owner Triad Rx, Inc.

26258 Pollard Road

Daphne, AL 36526

Dear Mr. McDonald:

From July 17, 2017, to July 21, 2017, a U.S. Food and Drug Administration (FDA) investigator inspected your facility, Triad Rx, Inc., located at 26258 Pollard Road, Daphne, AL 36526. During the inspection, the investigator noted that drug products you produced failed to meet the conditions of section 503A of the Federal Food, Drug, and Cosmetic Act (FDCA) [21 U.S.C. § 353a] for exemption from certain provisions of the FDCA. The investigator noted serious deficiencies in your practices for producing sterile drug products, which put patients at risk.

FDA issued a Form FDA 483 to your firm on July 21, 2017. FDA acknowledges receipt of your facility's response, dated August 3, 2017. Based on this inspection, it appears that you produced drug products that violate the FDCA.

A. Compounded Drug Products Under the FDCA

Section 503A of the FDCA describes the conditions under which human drug products compounded by a licensed pharmacist in a State licensed pharmacy or a Federal facility, or a licensed physician, qualify for exemptions from three sections of the FDCA: compliance with current good manufacturing practices (CGMP) (section 501(a)(2)(B)); labeling with adequate directions for use (section 502(f)(1)); and FDA approval prior to marketing (section 505) [21 U.S.C. §§ 351(a)(2)(B), 352(f)(1) and 355(a)].1 Receipt of valid prescriptions for individually- identified patients is one of the conditions for the exemptions under section 503A.

In addition, for a compounded drug product to qualify for the exemptions under section 503A, bulk drug substances used to compound it must: (I) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, be components of drugs approved by the Secretary; or (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on a list developed by the Secretary through regulation ("503A bulks list") (section 503A(b)(1)(A)(i) of the FDCA).

B. Failure to Meet the Conditions of Section 503A

During the inspection, the FDA investigator noted that drug products produced by your firm failed to meet the conditions of section 503A. For example, the investigator noted your firm compounded drug products using GHRP-2, GHRP-6, and chromium picolinate. Drug products compounded using GHRP-2, GHRP-6, and chromium picolinate are not eligible for the exemptions provided by section 503A(a), because these bulk drug substances are not the subject of an applicable USP or NF monograph, are not a component of an FDA-approved human drug, and do not appear on the 503A bulks list.2

Therefore, you compounded drug products that do not meet the conditions of section 503A and are not eligible for the exemptions in that section from the FDA approval requirement of section 505 of the FDCA, the requirement under section 502(f)(1) of the FDCA that labeling bear adequate directions for use, and the requirement of compliance with CGMP under section 501(a)(2)(B) of the FDCA. In the remainder of this letter, we refer to your drug products that do not qualify for exemptions under section 503A as the "ineligible drug products."

Specific violations are described below.

C. Violations of the FDCA Adulterated Drug Products

The FDA investigator noted that drug products intended or expected to be ster... were prepared, packed, or held under insanitary conditions, whereby they may have become contaminated with filth or rendered injurious to health, causing your drug products to be adulterated under section 501(a)(2)(A) of the FDCA. For example:

1. Partially stoppered vials of product intended to be sterile were observed to be exposed to lower than ISO 5 quality air during production while being transferred into the lyophilizer.

2. Personnel were observed conducting aseptic manipulations that blocked the movement of first pass air over and around open vials.

3. The (b)(4) testing of the (b)(4) was not conducted per the manufacturer's specification.

4. The ISO classified areas have difficult to clean, particle-generating, or visibly dirty equipment or surfaces.

5. The media fills were not performed under the most challenging or stressful conditions. Therefore, there is a lack of assurance that your firm can aseptically produce drug products within your facility.

6. You re-used isopropyl alcohol (IPA) bottles containing (b)(4) IPA for disinfecting ISO 5 areas without assurance that the bottles remained sterile after multiple uses and can adequately prevent the spread of contamination in the ISO 5 area.

7. Personnel engaged in aseptic processing were observed with exposed hands and wrists in the ISO 5 area.

8. Cleaning pads or wipes used in the ISO 5 area were not sterile.

9. Personnel were observed touching equipment or other surfaces located outside of the ISO 5 area with gloved hands and then proceeding with aseptic processing in the ISO 5 area without changing or sanitizing gloves.

10. Equipment used for aseptic processing was not disinfected prior to entering the ISO 5 processing area.

11. Your firm's preparation and contact time of the sporicidal agent used in the cleanrooms and ISO 5 areas was not adequate for its intended use.

Unapproved New Drug Products

You do not have any FDA-approved applications on file for the ineligible drug products that you compounded.3 Under sections 505(a) and 301(d) of the FDCA [21 U.S.C. § 331(d)], a new drug may not be introduced into or delivered for introduction into interstate commerce unless an application approved by FDA under section 505 of the FDCA is in effect for the drug. Marketing of these products, or other applicable products, without an approved application violates these provisions of the FDCA.

Misbranded Drug Products

The ineligible drug products you compounded are intended for conditions not amenable to self- diagnosis and treatment by individuals who are not medical practitioners; therefore, adequate directions for use cannot be written so that a layman can use these products safely for their intended uses. Consequently, their labeling fails to bear adequate directions for their intended uses.4 Accordingly, these ineligible drug products are misbranded under section 502(f)(1) of the FDCA. The introduction or delivery for introduction into interstate commerce of these products therefore violates section 301(a) of the FDCA. It is also a prohibited act under section 301(k) of the FDCA to do any act with respect to a drug, if such act is done while the drug is held for sale after shipment in interstate commerce and results in the drug being misbranded.

D. Corrective Actions

We have reviewed your firm's response to the Form FDA 483.

Regarding the insanitary condition observations in the Form FDA 483, we cannot fully evaluate the adequacy of the following corrective actions described in your response because you did not include sufficient information or supporting documentation:

1. In your response, you indicated that you have "consulted with (b)(4)" and provided a copy of the diagram of the proposed cleanroom layout where "the ISO 5 area created by (b)(4) to allow direct access to the lyophilizer's chamber and controls without any unsealed product leaving the ISO 5 environment." However, you did not provide any detailed plans of construction or timeframe regarding the facility modification of the ISO 5 or the ISO 7 areas. Furthermore, it is unclear if your firm will continue to produce lyophilized product while construction is underway.

2. In your response, you indicated that you have revised "the drug formulation worksheet" to reflect "the need to keep unfilled vials covered while (b)(4) in order to minimize the risk of unclean air flowing over the vials." However, you did not provide "the drug formulation worksheet" or any other documents reflecting the revised procedures to support this corrective action.

3. In your response, you indicated that you can modify the cleanroom "(b)(4) the area where the lyophilizer is located" and the "exposed part" of the lyophilizer "will be located (b)(4), limiting exposure to any part of the room." However, you did not provide any detailed plans or timeline of construction within the ISO 5 or the ISO 7 areas. Furthermore, it is unclear if your firm evaluated whether the "(b)(4)" is considered a difficult to clean surface and whether a "(b)(4)" between an ISO 5 area and unclassified space could potentially introduce contamination directly in the aseptic processing areas.

4. In your response, you indicated that you have revised your media fill procedure which includes a "more complex process with (b)(4) and (b)(4) the lyophilizer". However, your revised media fill procedures reference only (b)(4) which do not simulate production operations incorporating the worst-case activities and conditions.

5. In your response, you indicated that you have purchased "sterile cleaning pads" for use in the ISO 5 area to replace the non-sterile wipes. However, you did not provide a receipt or a certificate of analysis of the sterile "cleaning pads" purchased or the starting date of their use within your facility.

In addition, our review of your batch records collected during the inspection revealed that your (b)(4) testing for your L-Carnitine 250mg/ml injectable product was performed for (b)(4) with volumes of (b)(4) and (b)(4), but the batch quantity made was (b)(4). Therefore, the (b)(4) volume is not adequate for the quantity of drug product (b)(4).

Please be aware that section 501(a)(2)(A) of the FDCA concerning insanitary conditions applies regardless of whether drug products you compound meet the conditions of section 503A, including that bulk drug substances used to compound must: (I) comply with the standards of an applicable USP or NF monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (II) if such a monograph does not exist, be components of drugs approved by the Secretary; or (III) if such a monograph does not exist and the drug substance is not a component of a drug approved by the Secretary, appear on 503A bulks list.

In addition, regarding issues related to the conditions of section 503A of the FD.A, your corrective actions appear partially adequate. In your response you state: "Triad's P&Ps have been updated to require (b)(4) reviews of FDA publications to ensure that no [nominated] article in 503A Categories 2 (Bulk Drug Substances that Raise Significant Safety Risks) or 3 (Bulk Drug Substances Nominated Without Adequate Support including, without limitation, GHRP-2 or -6) is inadvertently included as an active ingredient in compounded products." However, you did not state how your firm will ensure that other ineligible bulk drug substances that do not appear in the categories you referenced in your letter would not be used in compounding. An example bulk drug substance that is not the subject of an applicable USP or NF monograph, a component of an FDA-approved drug, and does not appear in category 2 or 3 of the interim 503A bulks list is chromium picolinate.

Should you continue to compound and distribute drug products that do not meet the conditions of section 503A, the compounding and distribution of such drugs would be subject to the new drug approval requirement, the requirement to label drug products with adequate directions for use, and the drug CGMP regulations. Before doing so, you must comply with the requirements of section 505, 502(f)(1), and 501(a)(2)(B).

In addition to the issues discussed above, you should note that CGMP requires the implementation of quality oversight and controls over the manufacture of drugs, including the safety of raw materials, materials used in drug manufacturing, and finished drug products. *See* section 501 of the FDCA. If you choose to contract with a laboratory to perform some functions required by CGMP, it is essential that you select a qualified contractor and that you maintain sufficient oversight of the contractor's operations to ensure that it is fully CGMP compliant. Regardless of whether you rely on a contract facility, you are responsible for assuring that drugs you produce are neither adulterated nor misbranded. [*See* 21 CFR 210.1(b), 21 CFR 200.10(b)].

FDA strongly recommends that your management undertake a comprehensive assessment of operations, including facility design, procedures, personnel, processes, maintenance, materials, and systems. In particular, this review should assess your aseptic processing operations. A third party consultant with relevant sterile drug manufacturing expertise should assist you in conducting this comprehensive evaluation.

E. Conclusion

The violations cited in this letter are not intended to be an all-inclusive statement of violations at your facility. You are responsible for investigating and determining the causes of the violations identified above and for preventing their recurrence or the occurrence of other violations. It is your responsibility to ensure that your firm complies with all requirements of federal law, including FDA regulations.

You should take prompt action to correct the violations cited in this letter. Failure to promptly correct these violations may result in legal action without further notice, including, without limitation, seizure and injunction.

Within fifteen working days of receipt of this letter, please notify this office in writing of the specific steps that you have taken to correct violations. Please include an explanation of each step being taken to prevent the recurrence of violations, as well as copies of related documentation. If you do not believe that the products discussed above are in violation of the FDCA, include your reasoning and any supporting information for our consideration. If you cannot complete corrective action within 15 working days, state the reason for the delay and the time within which you will complete the correction.

Your written notification should refer to the Warning Letter Number above (**CMS Case #569659**). Please address your reply to John W. Diehl, Director, Compliance Branch, at the FDA address provided on bottom of first page of this letter. Additionally, please submit a signed copy of your response on your firm's letterhead via

e-mail to ORAPHARM2_Response...@fda.hhs.gov. (mailto:ORAPHARM2_Re...nses@fda.hhs.gov)

If you have questions regarding the contents of this letter, please contact Rebecca A. Asente, Compliance Officer, via (504) 846-6104 or Rebecca.asente@fda.hhs.gov. (mailto:Rebecca.asente@fda.hhs.gov)

Sincerely,

/S/

Monica R. Maxwell

Program Division Director

Office of Pharmaceutical Quality Operations,

Division II

CC: Susan Alverson, Executive Secretary

Alabama Board of Pharmacy

P.O. Box 381988

Birmingham, AL 35238-1988

---

1 We remind you that there are conditions other than those discussed in this letter that must be satisfied to qualify for the exemptions in section 503A of the FDCA.

2 On June 9, 2016, FDA issued a final guidance titled, *Interim Policy on Compounding Using Bulk Drug Substances Under Section 503A of the Federal Food, Drug, and Cosmetic Act*. This guidance describes FDA's interim regulatory policy for State-licensed pharmacies, Federal facilities, and licensed physicians that compound human drug products using bulk drug substances that do not otherwise meet the conditions of section 503A(b)(1)(A)(i) while the 503A bulks list is being developed. Specifically, the guidance sets out the conditions under which FDA does not intend to take action against a State-licensed pharmacy, Federal facility, or licensed physician for compounding a drug product using a bulk drug substance that is not the subject of an applicable USP or NF monograph or a component of an FDA-approved drug, until the substance is identified in a final rule as included or not included on the 503A bulks list. These conditions include that the substance may be eligible for inclusion on the 503A bulks list, was nominated with adequate support for FDA to evaluate it, and has not been identified by FDA as a substance that appears to present significant safety risks pending further evaluation. GHRP-2 andGHRP-6 were nominated, but not with adequate support for FDA to evaluate these substances. Chromium picolinate was not nominated. For additional information, see the guidance at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf. (http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM469120.pdf)

3 The specific products made by y . firm are drugs within the meaning of s. .on 201(g) of the Act, [21 U.S.C. § 321(g)] because they are intended for use in the diagnosis, cure, mitigation, treatment, or prevention of diseases and/or because they are intended to affect the structure or any function of the body. Further, they are "new drugs" within the meaning of section 201(p) [21 U.S.C. 321(p)] of the FDCA because they are not generally recognized as safe and effective for their labeled uses.

4 Your ineligible drug products are not exempted from the requirements of section 502(f)(1) of the FDCA by regulations issued by the FDA (see, e.g., 21 CFR 201.115).

More Warning Letters (/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters)

¬XHIBIT "B"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
TRIAD RX INC.	)	**BOARD OF PHARMACY**
	)	
Permit No. 113869	)	**CASE NO: 18-L-0066**
	)	

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against Triad Rx Inc. listed above (hereinafter referred to as "Triad") which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act. These allegations with particularity are set out in the Statement, which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975) §41-22-12(f), the Board through its counsel and Triad, through its counsel, engaged in negotiations and as a result, the matters at issue were resolved informally by the parties who agreed to the entry of this Consent Order which includes the following terms:

1. The Board finds Triad has violated the provisions of the Alabama Pharmacy Practice Act based upon the conduct set forth in Counts One and Two of the Statement. Count Three shall be dismissed with prejudice.

2. Triad shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days from the effective date of the Consent Order, which is the date it is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall Triad attempt to discharge the same.

3. Triad expressly waives its rights pursuant to the Alabama Pharmacy

Practice Act, the Alabama Administrative Procedures Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), § 20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. Triad further waives any objection to the attorney for the Board preparing, drafting or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. That Triad agrees that any future violation of the Alabama Pharmacy Practice Act, the rules and regulations of the Alabama State Board of Pharmacy or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against its license.

5. By execution of this Consent Order, Triad hereby releases the Board, its members, agents, representatives, servants and employees from any and all liability, claims, damages, fees or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

6. Triad acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions and contents of the same. Triad acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and is signing this Consent Order on the advice of its attorney.

DONE this the 10th day of September, 2018.

Triad Rx Inc.

BY: _____

ITS: President

_____

Robert F. Jernigan, Attorney for
Triad Rx Inc.

DONE this the 17 day of September, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: _____
David Darby, R.Ph., President

_____

James S. Ward,
Attorney for the Alabama State
Board of Pharmacy

OF COUNSEL:
WARD & COOPER, LLC
2100A Southbridge Parkway
Suite 580
Birmingham, AL 35209
(205) 871-5404

EXHIBIT "A"

IN THE MATTER OF:	)	**BEFORE THE ALABAMA STATE**
	)	
TRIAD RX INC.	)	**BOARD OF PHARMACY**
	)	
Permit No. 113869	)	**CASE NO: 18-L-0066**
	)	

STATEMENT OF CHARGES AND NOTICE OF HEARING

TO: Triad Rx Inc.
26258 Pollard Road
Daphne, Alabama 36526

Pursuant to the provisions of Code of Alabama (1975), § 34-23-34 and § 34-23-92(12) and Code of Alabama (1975), § 41-22-12, you are hereby notified and requested to appear before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on September 18, 2018 at 8:00a.m., at the State Board of Pharmacy Conference Room, 111 Village Street, Birmingham, Alabama 35242, and from time to time thereafter as may be required by the Board for the purpose of a hearing to determine why the permit to operate Triad Rx Inc. should not be revoked, suspended or placed on probation or a monetary penalty imposed in that it is alleged that Triad Rx Inc. has been guilty of the following, to-wit:

COUNT ONE

Violating Code of Alabama (1975), § 34-23-33(2) based upon the entry of an Agreed Board Order by the Texas State Board of Pharmacy on May 1, 2018 attached hereto as Exhibit "A" and/or operating a non-resident sterile compounding pharmacy in violation of Texas rules in that the pharmacy was not under the supervision of a pharmacist in charge licensed as a pharmacist in Texas as more fully set out in the

above referenced Order.

COUNT TWO

Violating Code of Alabama (1975), § 34-23-33(13) in that you violated Board Rule 680-X-2.22(2)(d) based upon any or all of the allegations of Count One above.

COUNT THREE

Violating Code of Alabama (1975), § 34-23-33(6) based upon any or all of the allegations of the preceding Counts.

Further, pursuant to the provisions of Code of Alabama, (1975), § 20-2-53 and § 41-22-12, you are hereby notified and requested to appear before the Board at the aforesaid time and place and from time to time thereafter as may be requested by the Board for the purpose of a hearing to determine why your registration to manufacture, dispense or distribute controlled substances enumerated in Schedules II, III, IV and V of the Alabama Uniform Controlled Substances Act, Code of Alabama (1975), § 20-2-1, et. seq., issued pursuant to Code of Alabama (1975), § 20-2-52, should not be suspended or revoked in that it is alleged that you have been guilty of the following:

COUNT FOUR

Violating Code of Alabama (1975), § 20-2-54(a)(4) by violating the provisions of Code of Alabama (1975), § 34-23-1 et seq., said violation being based upon the allegations contained in any or all of the preceding Counts of this Statement of Charges and Notice of Hearing.

At the aforesaid time and place and from time to time thereafter as may be directed by the Board, you may be represented by an attorney, if you so desire, cross-

examine all witnesses who testify against you and present such evidence in your own behalf in response to these charges as you consider necessary and appropriate.

Dated this the 16th day of July, 2018.

ALABAMA STATE BOARD OF PHARMACY

By: Susan Alverson
Secretary

EXHIBIT "A"

AGREED BOARD ORDER #K-17-055

RE: IN THE MATTER OF
[redacted]
(PHARMACY PERMIT #[redacted])

BEFORE THE TEXAS STATE
BOARD OF PHARMACY

On this day [redacted] is considered by the Texas State Board of Pharmacy (Board) the matter of [redacted] issued to Triad Rx, Inc. (Respondent), 26258 Pollard Road, [redacted].

By letter dated March 6, 2018, the Board gave preliminary notice to Respondent of its intent to take disciplinary action. This action was taken as a result of an investigation which produced [redacted] that Respondent may have violated:

Section [redacted] of the Texas Pharmacy Act, TEX. OCC. CODE ANN. [redacted] (West 2012), and

Section [redacted] of the Texas Pharmacy Board Rules, 22 TEX. ADMIN. CODE (2017), to [redacted].

COUNT

On or about [redacted] through on or about February 22, 2017, Triad Rx, Inc., 26258 Pollard [redacted] was engaged in the [redacted] of a non-resident pharmacy [redacted] Rules, in that [redacted] under the supervision of a pharmacist [redacted] licensed as a pharmacist in Texas.

By letter dated March 6, 2018, Respondent was notified that the matters previously set out in this Order could be disposed of without the scheduling of an informal conference or a formal adjudicative hearing. By signing this Order, Matt McDonald, Corporate President, on behalf of Respondent, [redacted] admits the truth of the matters previously set out in this Order, and agrees [redacted] in this matter and [redacted] the right to informal conference, [redacted] judicial review of this Order.

The parties acknowledge that this Order resolves the allegations set forth herein, and agree to the terms and conditions set forth in the ORDER OF THE BOARD below.

[redacted]

(1) [redacted]

(2) [redacted]

[redacted]
[redacted]
Page 3

And it is so [redacted].

[redacted]

SIGNED AND [redacted] this 1st day of May, 2018.

[redacted]

ATTEST:

[redacted]

APPROVED AS TO [redacted] AGREED TO:

[redacted]

APPROVED AS TO [redacted]:

[redacted]

[redacted]

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	FINAL DECISION AND ORDER
TRIAD RX, INC. RESPONDENT.	:	ORDER0019890

Division of Legal Services and Compliance Case No. 22 PHM 120

The parties to this action for the purpose of Wis. Stat. § 227.53 are:

Triad Rx, Inc.
Daphne, AL 36526

Wisconsin Pharmacy Examining Board
P.O. Box 8366
Madison, WI 53708-8366

Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190
Madison, WI 53707-7190

The parties in this matter agree to the terms and conditions of the attached Stipulation as the final disposition of this matter, subject to the approval of the Pharmacy Examining Board (Board). The Board has reviewed this Stipulation and considers it acceptable.

Accordingly, the Board in this matter adopts the attached Stipulation and makes the following Findings of Fact, Conclusions of Law, and Order.

FINDINGS OF FACT

1. Triad Rx, Inc. (Respondent), is licensed in the state of Wisconsin as an Out-of-State Pharmacy, having license number 774-43, first issued on May 29, 2012, and current through May 31, 2024. Respondent's most recent address on file with the Wisconsin Department of Safety and Professional Services (Department) is in Daphne, Alabama 36526.

2. At all times relevant to this proceeding, Respondent was an Out-of-State Pharmacy located in Daphne, Alabama (Facility).

3. On August 19, 2022, Respondent notified the Department of a disciplinary action taken against Respondent by the Alabama Board of Pharmacy (Alabama Board).

4. In 2017 the FDA conducted an inspection at Respondent's facility. In 2019, the FDA issued a warning letter to Respondent for using ineligible drug products in compounding. The ineligible products were intended for conditions not amenable to self-diagnosis and treatment by individuals who were not medical practitioners. Respondent did not alert the Board to the warning letter.

5. Some of the medications which were referenced by the FDA in their warning letter as using ineligible products included Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized, Sermorelin Acetate 3mg/GHRP-2 3mg Lyophilized, L-Carnitine 250 mg/ml, and Chromium Picolinate.

6. Following the FDA inspection, Respondent shipped Sermorelin Acetate 9mg/GHRP-2 9mg Lyophilized to Wisconsin on 11 occasions, and L-Carnitine 250 mg/ml to Wisconsin on five occasions.

7. Respondent did not report the FDA warning letter to the Board because "(i) it was published on FDA's website and does not constitute final agency action, (ii) none of the allegations in the Warning Letter involved or implicated patient harm of any kind; (iii) [Respondent] did not consider the Warning Letter to describe any pharmacy practices constituting a realistic danger to the health, safety, or welfare of a patient or the public."

8. On July 7, 2022, the Alabama Board issued a consent order ordering Respondent to pay a $15,000 fine based upon findings that the Respondent used bulk drug substances which were not the subject of an applicable USP or NF monograph, were not components of an FDA approved human drug, and which did not appears on the 503A bulks list. Further, Respondent violated the FDCA Adulterated Drug Product on at least eleven occasions, compounded unapproved new drug products, and misbranded the unapproved compounded drug products.

9. In resolution of this matter, Respondent consents to the entry of the following Conclusions of Law and Order.

CONCLUSIONS OF LAW

1. The Board has jurisdiction to act in this matter pursuant to Wis. Stat. § 450.10(1) and is authorized to enter into the attached Stipulation pursuant to Wis. Stat. § 227.44(5).

2. By the conduct described in the Findings of Fact, Respondent committed unprofessional conduct by engaging in an any pharmacy practice which constitutes a danger to the health, welfare, or safety of patient or public including but not limited to, practicing in a manner which substantially departs from the standard of care ordinarily exercised by a pharmacist which harmed or could have harmed a patient pursuant to Wis. Admin. Code § Phar 10.03(2).

3. By the conduct described in the Findings of Fact, Respondent committed unprofessional conduct by failing to report to the Pharmacy Examining Board any pharmacy practice which constitutes a danger to the health, safety or welfare of patient or public pursuant to Wis. Admin. Code § Phar 10.03(7).

4. As a result of the above violations, Respondent is subject to discipline pursuant to Wis. Stat. § 450.10(1)(b)(1), and subject to a forfeiture pursuant to Wis. Stat. § 450.10(2).

ORDER

1. The attached Stipulation is accepted.

2. Respondent is REPRIMANDED.

3. Within ninety (90) days from the date of this Order, Respondent shall pay a forfeiture in the amount of $5,000.

4. Within ninety (90) days from the date of this Order, Respondent shall pay COSTS of this matter in the amount of $820.00. If costs are not paid within ninety (90) days from the date of this Order, interest shall accrue at the statutory rate of 12% per annum, pursuant to Wis. Stat. § 440.22(2).

5. Any requests, petitions, payments of forfeitures or costs (made payable to Department of Safety and Professional Services), and other information required by this Order shall be submitted to:

Department Monitor
Division of Legal Services and Compliance
Department of Safety and Professional Services
P.O. Box 7190, Madison, WI 53707-7190
Telephone (608) 266-2112; Fax (608) 266-2264
DSPSMonitoring@wisconsin.gov

Respondent may also submit this information online at: https://dspsmonitoring.wi.gov.

6. In the event Respondent violates any term of this Order, Respondent's license (number 774-43) or Respondent's right to renew its license, may, in the discretion of the Board or its designee, be SUSPENDED, without further notice or hearing, until Respondent has complied with the terms of the Order. The Board may, in addition and/or in the alternative refer any violation of this Order to the Division of Legal Services and Compliance for further investigation and action.

7. This Order is effective on the date of its signing.

WISCONSIN PHARMACY EXAMINING BOARD

By: John Weitekamp
A Member of the Board

2/29/2024
Date

STATE OF WISCONSIN
BEFORE THE PHARMACY EXAMINING BOARD

IN THE MATTER OF DISCIPLINARY PROCEEDINGS AGAINST	:	
	:	STIPULATION
TRIAD RX, INC., RESPONDENT.	:	ORDER0019890

Division of Legal Services and Compliance Case No. 22 PHM 120

Triad Rx, Inc. (Respondent), and the Division of Legal Services and Compliance, Department of Safety and Professional Services, stipulate as follows:

1. This Stipulation is entered into as a result of a pending investigation by the Division of Legal Services and Compliance. Respondent consents to the resolution of this investigation by Stipulation.

2. Respondent understands that by signing this Stipulation, Respondent voluntarily and knowingly waives the following rights:

- the right to a hearing on the allegations against Respondent, at which time the State has the burden of proving those allegations by a preponderance of the evidence;
- the right to confront and cross-examine the witnesses against Respondent;
- the right to call witnesses on Respondent's behalf and to compel their attendance by subpoena;
- the right to testify on Respondent's own behalf;
- the right to file objections to any proposed decision and to present briefs or oral arguments to the officials who are to render the final decision;
- the right to petition for rehearing; and
- all other applicable rights afforded to Respondent under the United States Constitution, the Wisconsin Constitution, the Wisconsin Statutes, the Wisconsin Administrative Code, and other provisions of state or federal law.

3. Respondent is aware of Respondent's right to seek legal representation and has been provided an opportunity to obtain legal counsel before signing this Stipulation.

4. Respondent agrees to the adoption of the attached Final Decision and Order by the Wisconsin Pharmacy Examining Board (Board). The parties to the Stipulation consent to the entry of the attached Final Decision and Order without further notice, pleading, appearance or consent of the parties. Respondent waives all rights to any appeal of the Board's order, if adopted in the form as attached.

5. If the terms of this Stipulation are not acceptable to the Board, the parties shall not be bound by the contents of this Stipulation, and the matter shall then be returned to the Division

of Legal Services and Compliance for further proceedings. In the event that the Stipulation is not accepted by the Board, the parties agree not to contend that the Board has been prejudiced or biased in any manner by the consideration of this attempted resolution.

6. The parties to this Stipulation agree that the attorney or other agent for the Division of Legal Services and Compliance and any member of the Board ever assigned as an advisor in this investigation may appear before the Board in open or closed session, without the presence of Respondent, for purposes of speaking in support of this agreement and answering questions that any member of the Board may have in connection with deliberations on the Stipulation. Additionally, any such advisor may vote on whether the Board should accept this Stipulation and issue the attached Final Decision and Order.

7. Respondent is informed that should the Board adopt this Stipulation, the Board's Final Decision and Order is a public record and will be published in accordance with standard Department procedure.

8. Respondent is further informed that should the Board adopt this Stipulation, the Board's Final Decision and Order will be reported as required by the National Practitioner Databank (NPDB) Guidebook and as otherwise required by any licensure compact or any other state or federal law.

9. The Division of Legal Services and Compliance joins Respondent in recommending the Board adopt this Stipulation and issue the attached Final Decision and Order.

[redacted]

Triad Rx, Inc., Respondent
Daphne, AL 36526
License No. 774-43

16 Feb. 2024
Date

Brian Juech

Brian J. Juech, Prosecuting Attorney
Department of Safety and Professional Services
Division of Legal Services and Compliance
P.O. Box 7190
Madison, WI 53707-7190

2/19/2024
Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Triad Rx Buyer LLC dba Triad Rx

Pharmacy/Wholesaler License # (if applicable) PH02913

Physical Address 26258 Pollard Road

City Daphne State AL Zip 36526

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 251-380-7630 Website https://www.triadrx.us/

Licensing Company Email stacey@triadrx.com

Section 2: Personal Information

First Robert Middle Reyburn Last Roberts, III

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Mississippi		05/12/94	
Address	**City**	**State**	**Zip**
PO Box 1848	University	MS	
Diploma/Degree obtained, if any			
BS in Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
present				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Triad Rx			2/12-present	
Business Address		**City**	**State**	**Zip**
26258 Pollard Road		Daphne	AL	36526
Phone	**Title**		**Number of Employed Hours**	
251-380-7630	Pharmacist-in-Charge		40/week	

Description of Duties

Ensuring compliance and regulations, observing safe and timely prescription filling and dispensing

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/11/25

Date

I, Robert Reyburn Roberts, III, **certify that as the designated representative for**

Triad Rx Buyer LLC dba Triad Rx,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. RR I am at least 21 years of age;
3. RR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. RR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. RR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. RR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. RR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Robert Roberts III

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Roberts III

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

2/11/25

Date

Please have this section completed in the presence of a Notary Public.

State of Alabama, ss. County of Baldwin

I, Robert Roberts III, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

2/11/25

Date

Subscribed and Sworn to before me this 11th day of February.

Mariia Kostiukova

Notary Public Signature

MARIIA KOSTIUKOVA
NOTARY PUBLIC
ALABAMA - STATE AT LARGE
My Commission Expires April 27, 2027

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Triad Rx Buyer LLC dba Triad Rx

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH02913

Physical Address 26258 Pollard Road

City Daphne State AL Zip 36526

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 251-380-7630 Website https://www.triadrx.us/

Licensing Company Email stacey@triadrx.com

Section 2: Personal Information

First Jonathan Middle Nguyen Last Lensing

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Calvin University		08/2012-05/2016	
Address	City	State	Zip
3201 Burton St SE	Grand Rapids, MI	MI	49546
Diploma/Degree obtained, if any			
BS			

School Name		From - To (MM/YY – MM/YY)	
Pella Christian High School		08/2008-05/2012	
Address	City	State	Zip
300 Eagle Lane	Pella	IA	50219
Diploma/Degree obtained, if any			
GED			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/24- Present	[redacted]			
12/22-05/24				
07/20-12/22				
08/16-05/20				
05/13-08/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
OpenLoop Health, Inc		12/19-present	
Business Address	**City**	**State**	**Zip**
317 6th Ave Ste 400	Des Moines,	IA	50309
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Lensing

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/8/25

Date

Please have this section completed in the presence of a Notary Public.

State of Iowa, ss. County of Polk

I, Jonathan Lensing, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/8/25

Date

Subscribed and Sworn to before me this 8th day of March, 2025.

Thea Amsden

Notary Public Signature

THÉA AMSDEN
Commission Number 221444
My Commission Expires
March 15, 2026

(Seal)

DEMOGRAPHICS

Not Licensed

AL License Number	DEA Number	Status
113869	FT3066594	Closed - Compliant
Supervising Pharmacist	**Supervising Pharmacist-License**	**Supervising Pharmacist Email**
ROBERT REYBURN ROBERTS	12683	ROB@TRIADRX.COM
Pharmacist Assisting	**Pharmacist Assisting License**	**Pharmacist Assisting Email**
SARAH WADE SIEFERT	16775	sarah.siefert@gmail.com
Inspection Type	**Inspection Date**	**Inspector Name**
Routine	12/27/2023	cshaw

Case Number

SEE SEPARATE USP 795 NON-STERILE INSPECTION REPORT

ADDRESS INFORMATION

Address 1 : 26258 POLLARD ROAD
Address 2 :
City : DAPHNE
State / Zip : AL 36526

REQUIREMENT

Pharmacy space and layout 16 sq. ft counter space; 24 sq ft if 2 or more pharmacists.	Yes	No	N/A	
Non-sterile compounding pharmacy.				34-23-71
Reference Books or online data: Facts and Comparisons.	Yes	No	N/A	
All required licenses and permits are displayed prominently	Yes	No	N/A	
				34-23-70(b)
Private consultation area available.	Yes	No	N/A	
				680-X-2-.27
Is the method used to collect patient signatures to approve or refuse pharmacist counseling HIPAA compliant? (Signatures should not be visible to other customers)	Yes	No	N/A	
Pharmacy Staff makes verbal offer to counsel on each new prescription.	Yes	No	N/A	
				680-x-2-.21
Access to pharmacy (keys or code) with pharmacist only.	Yes	No	N/A	
				680-X-2-.11
Designated Key Holder (List Name) (Approval Form must be posted in pharmacy)	Yes	No	N/A	
				680-X-2-.11
Refrigerator is clean, temperature between 2 – 8 degrees C, or 36-46 degrees F.	Yes	No	N/A	
Continuously monitored. Alerts if out of range.				
Only drug related products stored in refrigerator.	Yes	No	N/A	

Prescription area is clean and orderly. Minimal chance to confuse orders. ☑ Yes ☐ No ☐ N/A

Daily, Weekly, and monthly cleaning log maintained.

Drugs in date; ☑ Yes ☐ No ☐ N/A

34-23-9

Drugs purchased from reputable sources. ☑ Yes ☐ No ☐ N/A

34-23-32-1

Do you provide prescriptions to patients in a Skilled Nursing Facility (SNF) and/or Intermediate Care Facility (ICF)? ☐ Yes ☑ No ☐ N/A

TECHNICIANS

Pharmacy technicians: supervised, registered, have name tag. ☑ Yes ☐ No ☐ N/A

34-23-131

Pharmacist:technician ratio of 1:2, 1:3 if one tech is certified. ☑ Yes ☐ No ☐ N/A

Pharmacy technician manual: may use www//albop.com ☑ Yes ☐ No ☐ N/A

680-X-2-.14(5)

Technicians have been trained in all assigned tasks. ☑ Yes ☐ No ☐ N/A

680-X-2-.14(5)

Are technicians prevented from processing/receiving prescriptions before a pharmacist arrives or after the pharmacist leaves? ☑ Yes ☐ No ☐ N/A

Does a pharmacist verify all work performed by technicians and document this verification? ☑ Yes ☐ No ☐ N/A

CONTROLS/MONITORED MEDICATIONS

Pharmacy connected to NPLEX if selling ephedrine pseudoephedrine products (Those selling by prescription only, do not have to submit to database) ☐ Yes ☐ No ☑ N/A

By prescription only.

20-2-190

Pharmacy is reporting to PDMP
(Pharmacies should be uploading every day)
(Should be uploading a zero balance even if no CS filled) ☑ Yes ☐ No ☐ N/A

20-2-213

Controlled Substance Inventory (Date of Last Inventory) ☑ Yes ☐ No ☐ N/A

01/15/2023

680-X-3-.08

PRESCRIPTIONS

refills limited to prescriber's orders. ☑ Yes ☐ No ☐ N/A

Record keeping of prescriptions (initials, number, date, label, notes compounding notes) ☑ Yes ☐ No ☐ N/A

680-X-2-.05 680-X-2-.14

all controlled substance prescriptions shall bear full name and address of the patient along with date, drug, strength, dosage form, quantity, directions for use, and name, address and registration number of practitioner.	Yes	No	N/A

DRUG RETURN

Pharmacy takes back non-controlled medication from patients for destruction.	Yes	No	N/A
Pharmacy takes back controlled medication from patients for destruction.	Yes	No	N/A
Quarantined all out-dated medications (both prescription and OTC)? Note: This includes compounding supplies and items in the refrigerator.	Yes	No	N/A

COMPOUNDING

Have a separate, clean area for any compounding (only compounding equipment, orderly, clean)	Yes	No	N/A
A separate USP 795 inspection was conducted.		34-23-152	
Compounding area has washable counter, floors, ceiling, shelves.	Yes	No	N/A
Sink with potable hot and cold water, sink clean, available to hand washing before compounding.	Yes	No	N/A
Prescription Balance/scale and Weights, , Technical Equipment commensurate with its level of practice.	Yes	No	N/A
		680-X-2-.04	
Purified water used for compounding or reconstitution	Yes	No	N/A
Last time calibrated balance or scale Date: _____	Yes	No	N/A
		34-23-153	
Prepares a compounding record with each compound which includes amount of each ingredient, lot number and expiration date.	Yes	No	N/A
		34-23-156	
Master Formula and compounding instructions available for commonly used formulas.	Yes	No	N/A
Compounding of hazardous drugs follows USP 800.	Yes	No	N/A
Any staff who compound hazardous drugs have been trained and have signed an informed consent.	Yes	No	N/A

AUTOMATED FILLING DEVICES

Are you able to identify brand name, or generic name & manufacturer; strength; lot number; expiration date; or an internal control number which references the manufacturer and lot number used for medications placed into all cells in automated dispensing machines ?	Yes	No	N/A
Pharmacy is not equipped.			
Does pharmacist verify technician filling of automated dispensing machines?	Yes	No	N/A

Alabama State Board of Pharmacy

2026

This is to certify:

Triad Rx Inc.
26258 Pollard Road
Daphne, AL 36526

Permit Number:

113869

Is Duly Licensed as a:

Community Pharmacy

Specialty Services:

Non-Sterile Compounding

Supervising Pharmacist

Robert Reyburn Roberts
12683

IN COMFORMITY WITH THE PROVISIONS OF ACT #205, GENERAL ACTS OF ALABAMA, 1966 SPECIAL SESSION, AND RULES AND REGULATIONS OF THE BOARD. THIS CERTIFICATE MUST BE CONSPICIOUSLY DISPLAYED AND EXPIRE ON THE LAST DAY OF

December 2026

THIS IS YOUR RECEIPT FOR FEE PAID AS REQUIRED BY LAW
THIS PERMIT IS NOT TRANSFERRABLE

Donna C. Yeatman
EXECUTIVE SECRETARY

2026

Alabama State Board of Pharmacy

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE

Controlled Substance Number:

CS113869

Business Activity:

Community Pharmacy

Schedules:

II, III, IV, V

The Controlled Substance Act of 1971 reads in part as follows:
Section 304 (Revocation and Suspension of the Registration.)

(a) A registration under Section 303 to manufacture, distribute, or dispense a controlled substance may be suspended or revoked by the Certifying Boards upon a finding that the registrant:

(1) Has furnished false or fraudulent material information in any application filed under this Act,

(2) Has been convicted of a felony under any State or Federal law relating to any controlled substance or

(3) Has had his Federal registration suspended or revoked to manufacture, distribute, or dispense controlled substances

(4) Has violated the provisions Act 205 (al-a32) Code of Alabama 1940 (Recomp. 1958)

Date Issued: **02/16/2012**

Expiration Date: **12/31/2026**

Triad Rx Inc.
26258 Pollard Road
Daphne, AL 36526

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-03-2023

TRIAD RX INC
26258 POLLARD RD
DAPHNE, AL 36526

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-03-2023

TRIAD RX INC
26258 POLLARD RD
DAPHNE, AL 36526

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

ALABAMA

BOARD OF PHARMACY

The Alabama Board of Pharmacy certifies that it maintains the information for the credential verification function of this website, as well as performing hourly updates to the information represented. Therefore, the website is a secure and primary source of credential verification information, as authentic as a direct inquiry to the Board.

Triad Rx Inc.

Pharmacy

Permit Status:

Active

Permit #:

113869

Issued Date:

02/16/2012

Expire Date:

12/31/2026

Classification:

Community

Discipline on File:

Yes

Facility Information

Address:

26258 Pollard Road
Daphne, AL 36526

Supervising Pharmacist:

Robert Reyburn Roberts

Pharmacy Phone:

251-380-7630

Pharmacy Email:

maria@triadrx.com

Services:

Controlled Substance Registration

Status:

Active

Number:

CS113869

Issued Date:

02/16/2012

Expire Date:

12/31/2026

Public Records

11f8aef47d904fbab21035994959a46e9202018.pdf
09/28/2024

529bb5d1201942a896fb727729ada12a7192022.pdf
09/28/2024

Information loaded from this database is current as of 3/10/2025 3:34:26 PM

4BBBB

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Y

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☐ New Pharmacy	■ Retail/Community	■ Retail/Community
■ Out-of-Nevada	■ Ownership Change*	☐ Hospital (# beds _____)	■ Dangerous drugs
	☐ Location Change *	☐ Internet	■ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.)	☐ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			■ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #: PH 04209		☐ Hospital
			☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Truepill NY LLC

Physical Address: 850 3rd Ave., Ste. 404

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): See above

City: _____ State: _____ Zip: _____

Telephone: 518-692-3362 Toll Free # (NAC 639.708, NRS 639.23286): 855-687-8369

Fax: _____ Contact Email: compliance@truepill.com

Website: https://www.truepill.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Michelle Lynne Meyer

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 23766

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Michelle Lynne Meyer	NV Pharmacist Registration #: 23766
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: New York

Parent Company (if any): Postmeds, Inc.

Corporation/Organization Name: Truepill NY LLC

Mailing Address: 850 3rd Ave. Ste. 404

City: Brooklyn State: NY Zip: 11232

Telephone: 518-692-3362 Email: compliance@truepill.com

Contact Person Name: Artiom Solovei

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility – MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Co-Manager (title) for Truepill NY LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Paul Greenall

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/5/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Paul Greenall hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Co-Manager (title) for Truepill NY LLC (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

CALIFORNIA
JURAT
ATTACHED

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 5 day of March, 2025, by Paul Greenall,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

M. DEMERS
COMM. # 2378608
SAN JOAQUIN COUNTY
NOTARY PUBLIC-CALIFORNIA
MY COMMISSION EXPIRES
OCTOBER 15, 2025

(Seal) Signature

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/5/25

Date

Board Use Only	Date Received: 3/13/25	Amount: [redacted]

List of Officers

Paul Greenall - [redacted]

Aaron Wurst - [redacted]

03/28/2025

TRUEPILL NY LLC
POST-RESTRUCTURE
ORGANIZATIONAL CHART

This organizational chart was prepared by Truepill, Inc.'s Legal Team and may not be distributed to third parties without prior approval. For further information, please reach out to entities@truepill.com

Truepill NY LLC
3121 Diablo Ave.
Hayward, CA 94545

STATE OF NEW YORK

DEPARTMENT OF STATE

Certificate of Status

I, WALTER T. MOSLEY, Secretary of State of the State of New York and custodian of the records required by law to be filed in my office, do hereby certify that upon a diligent examination of the records of the Department of State, as of the date and time of this certificate, the following entity information is reflected:

Entity Name:	TRUEPILL NY LLC
DOS ID Number:	5501126
Entity Type:	DOMESTIC LIMITED LIABILITY COMPANY
Entity Status:	EXISTING
Date of Initial Filing with DOS:	02/25/2019
Statement Status:	CURRENT
Statement Due Date:	02/28/2025

No information is available from this office regarding the financial condition, business activity or practices of this entity.

WITNESS my hand and official seal of the Department of State, at the City of Albany, on January 13, 2025 at 02:52 P.M.

WALTER T. MOSLEY
Secretary of State

Brendan C. Hughes

BRENDAN C. HUGHES
Executive Deputy Secretary of State

Authentication Number: 100007277909 To Verify the authenticity of this document you may access the Division of Corporation's Document Authentication Website at http://ecorp.dos.ny.gov

POSTMEDS, INC. DBA TRUEPILL DISCIPLINARY SUMMARY

California resident license PHY 60061

California old resident license numbers: PHY 58585, PHY 56100

Illinois Board of Pharmacy

The Illinois Board issued the pharmacy (non-resident license #054.022249) a Consent Order of Discipline effective **August 8, 2024** resolving alleged violations of the Illinois Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Illinois State Board of Pharmacy.

Alaska Board of Pharmacy

The Alaska Board issued the pharmacy (non resident license #166601) a Consent Order of Discipline effective **February 15, 2024** resolving alleged violations of the Alaska Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Alaska State Board of Pharmacy.

Pennsylvania Board of Pharmacy

The Pennsylvania Board issued the pharmacy (non resident license #NP000931) a Consent Order of Discipline effective **November 7, 2023** resolving alleged violations of the Pennsylvania Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,500 administrative fine to the Pennsylvania State Board of Pharmacy.

Alabama Board of Pharmacy

The Alabama Board issued the pharmacy (non resident license #114861) a Consent Order of Discipline dated **June 6, 2023**. The Pharmacy has resolved alleged violations of the Alabama Pharmacy Practice Act through entry of a Consent Order with the Alabama State Board of Pharmacy on June 8, 2023. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,000 administrative fine to the Alabama State Board of Pharmacy.

Kansas Board of Pharmacy

The Kansas Board of Pharmacy issued the pharmacy (non resident license #22-117859) an amended Summary Order effective **February 8, 2023.** The pharmacy did not report the change of ownership in a timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy (non resident license #PHY.007761-NR) a Consent Order of Discipline dated **May 11, 2022.** The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated **March 8, 2022.** The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on **March 30, 2022** that its non-resident license (#MO40002429) was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license (#MO40003167) on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a letter of admonishment CI 2019 84877 dated **January 23, 2020,** concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a modified citation and fine CI 2019 78633 dated **June 16, 2020,** with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a citation and fine order of abatement CI 2020 89223 dated **August 25, 2021,** with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

PENDING MATTERS

The following Actions are currently pending or threatened against the Company. The below Actions are currently subject to ongoing discussions, negotiations, and developments.

California Board of Pharmacy

California CI 2024 105307: On August 9, 2024, the California State Board of Pharmacy sent notice of a pending citation along with information on contesting or appealing. Truepill is in process of requesting an informal hearing to contest the citation.

South Carolina Board of Pharmacy

South Carolina 2022-49: On May 3, 2023, Postmeds agreed in principle to a proposed consent order with the South Carolina Board of Pharmacy to resolve inaccuracies in prior ownership information provided to the Board. The agreement would be categorized as a public reprimand but would not be a public document and would not be reported to the National Practitioner Data Bank. The negotiated fine was $30,000. The South Carolina Board of Pharmacy has not finalized this consent order or initiated formal disciplinary proceedings.

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

IN RE: The Application of POSTMEDS INC DBA TRUEPILL, 054-app-4237687	APPLICANT.	)))	Case No. 2023-00783

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Nicholas V. Gallo, and Applicant POSTMEDS INC ("Applicant"), by its attorney Marc N. Wagner, hereby agree to the following:

STIPULATIONS

On or about August 22, 2022, Applicant submitted to the Department a change of ownership application (the "application") for Illinois licensed pharmacy license no. 054.022350.

On or about June 16, 2020, the California State Board of Pharmacy issued Applicant a disciplinary modified citation and fine ("California Citation and Fine") under case no. 2017-78633 for Applicant filling prescriptions issued to Applicant by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. The California Citation and Fine constitutes grounds for disciplinary action against Applicant on the authority of the Illinois Pharmacy Practice Act ("Act") at 225 ILCS 85/30(a)(8) as the grounds for action in the California Citation and Fine are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/4(g).

On or about August 25, 2021, the California State Board of Pharmacy issued Applicant a disciplinary citation and fine order of abatement ("California Citation and Fine Order of Abatement") under case no. 2020-89223 for, including but not limited to, Applicant storing dangerous drugs in temperatures exceeding the recommended storage temperatures. The California Citation and Fine Order of Abatement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8)

as the grounds for action in the California Citation and Fine Order of Abatement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/3(d)(12).

On or about March 8, 2022, Applicant and the North Carolina Board of Pharmacy entered into a Consent Order of Discipline for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The North Carolina Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the North Carolina Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via the Act's Administrative Rules ("Rules") at 68 IAC 1330.780(a)(1).

On or about May 11, 2022, Applicant and the Louisiana Board of Pharmacy entered into a disciplinary Consent Agreement ("Louisiana Agreement") under case no. 21-0456 for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The Louisiana Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Louisiana Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.780(a)(1).

On or about February 15, 2024, Applicant and the Board of Pharmacy for the State of Alaska entered into a disciplinary Consent Agreement ("Alaska Agreement") under case no. 2022-000434 for, including but not limited to, Applicant failing to disclose prior disciplines from another state within the required timeframe. The Alaska Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Alaska Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.40(c).

Pursuant to 68 IAC 1130.300(a) the following factor is considered in aggravation: (a) the presence of multiple adverse actions taken by other states against Applicant.

Pursuant to 68 IAC 1130.300(b) the following factors are considered in mitigation: (a) Applicant has cooperated with the Department in its investigation; and (b) Applicant has no prior disciplinary history with the Department.

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Applicant has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, to contest any charges brought and present mitigating evidence, and to administrative review of any order resulting from a hearing. Applicant knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Secretary or the Secretary's designee or the Board. Applicant acknowledges that it has entered into this Consent Order freely and of Applicant's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Applicant acknowledges that the Department attorney may be requested to communicate with the Board or the Secretary or the Secretary's designee in furtherance of the approval of this Consent Order. Applicant acknowledges that this Consent Order will be presented to the Secretary or the Secretary's designee. If this Consent Order is not approved, Applicant waives any right to raise any prejudice resulting from the Secretary or the Secretary's designee's consideration of this Consent Order. Applicant understands that this Consent Order is not effective unless and until it is adopted by the Secretary or the Secretary's designee. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Applicant and the Department agree, in order to resolve this case, that the Applicant be permitted to enter into a Consent Order with the Department providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Nicholas V. Gallo, and Applicant, by its attorney Marc N. Wagner, agree:

A. Applicant's Illinois licensed pharmacy license no. 054.022350 shall be issued with a Reprimand.

B. Applicant shall pay a five-thousand-dollar ($5,000.00 USD) disciplinary fine within sixty (60) days of the effective date of this Consent Order.

C. All fines issued pursuant to this Consent Order are to be paid by personal check, company check, cashier's check, or personal money order. Said monetary instrument(s) shall be made payable to "Illinois Department of Financial and Professional Regulation," clearly indicate on the face of the monetary instrument the case number of 2023-00783 as well as license no. 054.022350, and be mailed to the following address:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section - Fines
P.O. Box 7086
Springfield, IL 62791-7086

D. Prior to the satisfaction of subsections B and C, above, Applicant shall not violate any state or federal law, rule, or regulation concerning controlled substances or the practice of wholesale drug distribution.

E. Applicant agrees that any violation of this Consent Order permits the Secretary or Secretary's designee to issue an Order forthwith mandating the automatic, indefinite, and immediate suspension of Applicant's license for a minimum period of twelve (12) months. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. In the event that Applicant(s) contest(s) in writing (by the filing with the Department within thirty (30) days the effective date of the suspension, a Petition complying with the Department's Rules of Practice in Administrative Hearings) the factual basis underlying said suspension, then Applicant(s) shall be afforded a hearing on the merits in accordance with the Department's Rules of Practice in Administrative Hearings, 68 Ill. Admin. Code 1110/et seq.

F. Applicant acknowledges that this Consent Order is a public disciplinary action and will be made available to the public. It will be reported to all applicable reporting databases.

G. This Consent Order is a final administrative order. This Consent Order shall become effective upon the signature of the Secretary or the Secretary's designee below unless otherwise stated herein.

Signatures on the following page

July 12, 2024
Date

Department Attorney – Nicholas V. Gallo

7/11/2024 | 1:39 PM PDT
Date

DocuSigned by:
Laura Peterson
Applicant – POSTMEDS INC
By: General Counsel, Truepill Inc. - Laura Peterson

7/11/2024 | 5:00 PM CDT
Date

DocuSigned by:
Lee Rosebush
Applicant's Attorney – Lee H. Rosebush

7/12/24
Date

Illinois State Board of Pharmacy Member

The foregoing Consent Order is approved in full.

DATED THIS 8th day of August, 2024.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY MARIO TRETO, JR.

Mario Treto, Jr. Secretary
Illinois Department of Financial and Professional Regulation

Case No. 2023-00783
Application No.: 054-app-4237687

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. doing business as (Dba) TRUEPILL)
Respondent)
Case No. 2022-000434

CONSENT AGREEMENT

IT IS HEREBY AGREED by the Department of Commerce, Community and Economic Development, Division of Corporations, Business and Professional Licensing (Division) and TRUEPILL (Respondent) as follows:

1) **Licensure.** Respondent is currently registered as an Out-of-State Pharmacy in the State of Alaska and holds License number #166601. This license was first issued on 08/27/2020 and will lapse unless renewed by 06/30/2024.

2) **Admission/Jurisdiction.** Respondent admits and agrees that the Board of Pharmacy has jurisdiction over the subject matter of their license in Alaska and over this Consent Agreement.

3) **Admission/Facts.** Respondent admits to the following facts:

a) On September 25, 2017, Staff Pharmacist working for TRUEPILL, Curtis Ancar, received a disciplinary order from the California Board of Pharmacy for failure to exercise corresponding responsibility and excessive furnishing of controlled substances.

b) On January 24, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for failure to provide documentation substantiating completion of continuing education and knowingly making or signing a document with false information.

c) On December 16, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for furnishing and dispensing dangerous drugs without a prescription and dispensing on order of nurse practitioner (or person of similar status).

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

d) On January 23, 2020, the California Board of Pharmacy issued a letter of admonishment to Respondent for shipping a prescription to the wrong address and shipping two prescriptions with the wrong return address.

e) On June 16, 2020, the California Board of Pharmacy issued a modified citation and fine CI 2019 78633 with the fine amount of $0.00 for receiving prescriptions by prescribers that were not licensed or have not entered into procedures with supervising physicians.

f) On April 08, 2022, Respondent submitted an Out-of-State Pharmacy Registration Ownership Change Application from license no. 166601 to license no. 193858 (now withdrawn) to the Division. Professional Fitness Question #1 was marked "Yes" indicating disciplinary actions had been issued against their license as listed above in sections a) through e).

g) Subsequent background investigation revealed Respondent failed to disclose the abovementioned 2017, 2019, and 2020 licensing actions from the California Board of Pharmacy on previous State of Alaska applications for TRUEPILL (formerly DBA Postmeds, Inc.) for licenses 137655 and 166601 dated June 08, 2018, August 06, 2020, and August 27, 2020.

h) Respondent admits that as a result of the above facts, grounds exist for possible suspension, revocation, or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.261(a)(1), AS 08.80.261(a)(6), AS 08.80.261(a)(9), AS 08.80.261(a)(11)(12)(14), 12 AAC 52.920(a)(13), and 52.920(a)(14)(c).

4) **Formal Hearing Process.** It is the intent of the parties to this Consent Agreement to provide for the compromise and settlement of all issues addressed in Paragraph 3 (above) that could be raised by an Accusation to revoke, suspend, or impose disciplinary sanctions against Respondent's license through a formal hearing process.

5) **Waiver of Rights.** Respondent understands they have the right to consult with an attorney of their own choosing and has a right to an administrative hearing on the facts in this case. Respondent understands and agrees that by signing this Consent Agreement, Respondent is waiving their rights to counsel and to a hearing. Further, Respondent understands and agrees that they are relieving the Division of any burden it has of proving the facts admitted above. Respondent further understands and agrees that by signing this Consent Agreement they are voluntarily and knowingly giving up their right to present oral and documentary evidence, to present rebuttal evidence, to cross-examine witnesses against Respondent, and to appeal the Board's decision to Superior Court.

6) **Effect of Non-Acceptance of Consent Agreement.** Respondent and the Division agree that this Consent Agreement is subject to the approval of the Board. They agree that, if the Board rejects this Consent Agreement, it will be void, and an Accusation may be filed. If this Consent Agreement is rejected by the Board, it will not constitute a waiver of Respondent's right to a hearing on the matters alleged in an Accusation and the admissions contained herein will have no effect. Respondent agrees that, if the Board rejects this Consent Agreement, the Board may decide the matter after a hearing, and its consideration of this Consent Agreement shall not alone be grounds for claiming that the Board is biased against Respondent, that it cannot fairly decide the case, or that it has received ex parte communication.

7) **Consent Agreement, Decision, and Order.** Respondent agrees that the Board has the authority to enter into this Consent Agreement and to issue the following Decision and Order.

PROPOSED DECISION AND ORDER

IT IS HEREBY ORDERED that any license issued to Respondent by the Board shall be subject to the following terms and conditions:

A. Violation of Agreement

If Respondent fails to comply with any term or condition of this Consent Agreement, the Division may enforce this agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of this agreement. In addition, any suspended portion of the civil fine will be immediately due.

If Respondent's license is suspended under this paragraph, as provided above, they will be entitled to a hearing, on an expedited basis, regarding the issue of the suspension. If Respondent's license is suspended, they will continue to be responsible for all license requirements pursuant to AS 08.80.

Respondent shall maintain an active license for the entire duration of this Consent Agreement. If the Respondent lets their license lapse, and after receiving adequate notice from the Board fails to correct the problem, the failure to maintain active licensure will be considered a violation of this Consent Agreement.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

B. Respondent Address

It is the responsibility of the Respondent to keep the Board's agent advised, in writing, at all times of their current mailing address, physical address, telephone number, current employment and any change in employment.

Failure to provide notice of any changes within 10 calendar days will constitute grounds for suspension of his or her license in accordance with paragraph 'B' above.

C. Compliance with Laws

Respondent shall obey all federal, state and local laws governing their license.

D. Authorization

Within 10 calendar days of a request by the Board agent, Respondent will sign all authorizations necessary for the release of information required by this Consent Agreement.

E. Good Faith

All parties agree to act in good faith in carrying out the stated intentions of this Consent Agreement.

F. Address of the Board

All required reports or other communication concerning compliance with this Consent Agreement shall be addressed to:

Attn: Holly Handley, Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8124 Fax (907) 269-8195

G. Civil Fine

Respondent shall pay a fine of five thousand dollars ($5,000.00). This civil fine is due within 180 days of the adoption of this agreement and is payable to the "State of Alaska" in cash, certified check, or money order or via credit card.

All payments required by this Consent Agreement shall be addressed to:

Erika Prieksat, Chief Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

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IT IS HEREBY FURTHER ORDERED that this Decision and Order shall take effect immediately upon its adoption by the Board of Pharmacy and is a public record of the Board of Pharmacy and the State of Alaska. The State may provide a copy of it to any person or entity, professional licensing board, federal, state, or local government, or other entity making a relevant inquiry.

The action taken by the Board of Pharmacy in this Consent Agreement will be reported to the National Association of Boards of Pharmacy (NABP) and the National Practitioner Data Bank (NPDB) other entities as required by law.

DATED this 5 day of October 2023, at Anchorage, Alaska.

JULIE SANDE, COMMISSIONER

By: DocuSigned by: Erika Prieksat 34F98CE5F1DF48C...

Erika Prieksat, Chief Investigator for
Sylvan Robb, Director
Division of Corporations, Business and
Professional Licensing

I, TRUEPILL, have read the Consent Agreement, understand it, and agree to be bound by its terms and conditions.

DATED: 20th November 2023 Joseph Alexander Cipriani

SUBSCRIBED AND SWORN TO before me this 20th day of November, 2023, at Newport News, Virginia, Virginia.

(city) (state)

SEAL
Winston Ndow
REGISTRATION NUMBER
8040550
COMMISSION EXPIRES
February 28, 2027

Notary Public in and for Virginia.
(state)

Winston Ndow
Notary Printed Name

Notarized online using audio-video communication

My commission expires: 02/28/2027

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. dba TRUEPILL)
)
Respondent)
Case No. 2022-000434

ORDER

The Board of Pharmacy for the State of Alaska, having examined the Consent Agreement and Proposed Decision and Order, Case No. 2022-000434, Respondent, license number #166601, adopts the Consent Agreement and Decision and Order in this matter.

This Consent Agreement takes effect immediately upon signature of this Order in accordance with the approval of the Board of Pharmacy.

The Division may enforce the Consent Agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of the Consent Agreement.

DATED this 15th day of February, 2024, at Anchorage, Alaska.

Board of Pharmacy

By: Ashley Schaber
Chairperson

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**	
vs.	**Case Nos.** **21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**	

NOTICE

Formal disciplinary action has been filed against you. You may lose your license, certificate, registration or permit to practice your profession or occupation. You may be subject to civil penalties of up to $10,000 for each violation, and the imposition of costs of investigation.

If you wish to defend against the charges in the attached order to show cause or to present evidence to mitigate any penalty that may be imposed, the procedures for doing so are explained in the Order to Show Cause.

You have the right to retain an attorney. Although you may represent yourself without an attorney, you are advised to seek the help of an attorney. You also have the right to have an interpreter provided should you request one.

All proceedings are conducted under the Administrative Agency Law and the General Rules of Administrative Practice and Procedures.

You are directed to respond to the charges by filing a written answer within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. IF YOU DO NOT FILE AN ANSWER, DISCIPLINARY ACTION MAY BE TAKEN AGAINST YOU WITHOUT A HEARING. Any answer submitted in this matter must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:	**By Facsimile:**	**By E-mail:**
Prothonotary Department of State 2601 N Third St PO Box 2649 Harrisburg, PA 17105-2649	(717)772-1892	ra-prothonotary@pa.gov

You must also send or email a separate copy of your answer and any other pleadings or documents related to this case to the prosecuting attorney named in the Order to Show Cause.

Prothonotary Filed On:
May 10 2023 02:10 PM
Department of State

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

ORDER TO SHOW CAUSE

AND NOW, this 10th day of May 2023, **PostMeds Inc** ("Respondent") is hereby ORDERED TO SHOW CAUSE why the Pennsylvania State Board of Pharmacy ("Pennsylvania Board"), upon consideration of the Factual Allegations and the applicable law, should not suspend, revoke or otherwise restrict Respondent's registration, impose a civil penalty, or impose the costs of investigation. This action is brought pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and 63 Pa.C.S. Chapter 31 ("Chapter 31"); and will be conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704, Chapter 31, and the General Rules of Administrative Practice and Procedure ("GRAPP"), 1 Pa. Code §§ 31.1-35.251.

IT IS FURTHER ORDERED that Respondent file an Answer to this Order to Show Cause in writing within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, in accordance with Rule 35.37 of GRAPP, 1 Pa. Code § 35.37, *as amended.*

FACTUAL ALLEGATIONS

1. Respondent holds the following registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania: registration no. NP000931.

DOS Prothonotary.
May 10 2023

2. Respondent's registration was originally issued on July 3, 2017, and it is currently set to expire on August 31, 2023.

3. Absent further action by the Pennsylvania Board, the Respondent's registration may be renewed or reactivated upon the filing of the appropriate documentation and payment of the necessary fees.

4. At all times pertinent to the Factual Allegations, Respondent held a registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania.

5. Respondent's last known address on file with the Board is: 3131 Diablo Ave, Hayward, CA 94545.

COUNT ONE

6. Paragraphs 1 through 5 are incorporated by reference.

7. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of North Carolina.

8. On or about March 8, 2022, the State of North Carlina Board of Pharmacy ("North Carolina Board"), by way of Consent Order of Discipline, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of North Carolina because Respondent failed to report a restructuring of ownership to the North Carolina Board.

9. In the March 8, 2022 Consent Order of Discipline, the North Carolina Board voided Respondent's permit from the time it was issued until the time the restructuring began and approved Respondent's change of ownership application as a successor permit.

10. A true and correct copy of the North Carolina Board's March 8, 2022 Consent Order of Discipline is attached as **EXHIBIT A** and is incorporated by reference.

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11. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Louisiana.

12. On or about May 11, 2022, the State of Louisiana Board of Pharmacy ("Louisiana Board"), by way of Consent Agreement at Louisiana Board Case Number 21-0456, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Louisiana because Respondent failed to report a restructuring of ownership to the Louisiana Board.

13. In the May 11, 2022 Consent Agreement, the Louisiana Board imposed a ten thousand dollar ($10,000.00) fine, two hundred fifty dollars ($250.00) in administrative costs, and three hundred twenty-four dollars and forty-eight cents ($324.48) in investigative costs.

14. A true and correct copy of the Louisiana Board's May 11, 2022 Consent Agreement, Louisiana Board Case Number 21-0456, is attached as **EXHIBIT B** and is incorporated by reference.

15. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Kansas.

16. On or about January 20, 2023, the State of Kansas Board of Pharmacy ("Kansas Board"), by way of Amended Summary Order at Kansas Board Case Number 22-183, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Kansas because Respondent failed to report a restructuring of ownership to the Kansas Board and failed to report disciplinary actions from North Carolina, Alabama, and California which also pertained to a failure to report a restructuring of ownership to each respective Board.

17. In the January 20, 2023 Amended Summary Order, the Kansas Board imposed a three thousand five hundred dollar ($3,500.00) fine.

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18. A true and correct copy of the Kansas Board's January 20, 2023 Amended Summary Order, Kansas Board Case Number 22-183, is attached as **EXHIBIT C** and is incorporated by reference.

19. Based upon the foregoing Factual Allegations, the Pennsylvania Board is authorized to suspend or revoke, or otherwise restrict Respondent's nonresident pharmacy registration under section 4.1(e) of the Act, 63 P.S. §§ 390-4.1(e); or impose a civil penalty under section 63 Pa.C.S. § 3108(b)(4), and/or impose the costs of investigation under 63 Pa.C.S. § 3108(b)(5), because Respondent violated the Act at section 4.1(g), 63 P.S. § 390-4.1(g), in that Respondent had a permit to conduct a pharmacy suspended or revoked or the nonresident pharmacy was otherwise disciplined by the proper licensing authority of another state.

PENALTIES

If the Pennsylvania Board finds that the Factual Allegations are true and correct, and determines that it has the authority to suspend or revoke the Respondent's registration, the Pennsylvania Board may, in its discretion, impose one or more of the following penalties:

- The revocation, suspension or other restriction of any licenses, certifications, registrations, permits or other authorizations to practice a profession held by Respondent in the Commonwealth of Pennsylvania, or the imposition of any other disciplinary or corrective action that the Act authorizes the Board to impose.
- The imposition of a civil penalty of up to ten thousand dollars ($10,000.00) for each and every violation of the Act. Where criminal proceedings are a basis for a violation of the Act, each count for which the Respondent was convicted may be considered a separate violation of the Act.

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PROCEDURES

All proceedings are conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704; Chapter 31; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§ 31.1-35.251. **RESPONDENT IS HEREBY ORDERED TO FILE A WRITTEN ANSWER TO THIS ORDER TO SHOW CAUSE WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE.** The Answer shall specifically admit or deny each of the Factual Allegations made herein, and shall set forth the facts and state concisely the matter of law upon which Respondent relies. If Respondent fails to file an Answer within the time allowed herein, the Factual Allegations may be deemed admitted, and the Pennsylvania Board will issue an Order which may impose penalties as set forth above.

If Respondent desires a formal administrative hearing, at which Respondent may defend against the allegations in the Order to Show Cause or to present evidence in mitigation of any penalty which may be imposed upon Respondent or any of Respondent's licenses, certifications, registrations, permits or other authorizations to practice a profession, a written request for hearing must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. **IF RESPONDENT FAILS TO FILE A WRITTEN REQUEST FOR HEARING WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE, RESPONDENT WILL BE DEEMED TO HAVE WAIVED HIS OR HER RIGHT TO A HEARING AND FINAL JUDGMENT MAY BE ENTERED WITHOUT A HEARING.**

If a hearing is scheduled, Respondent will be notified of the specific time and place of the hearing. The hearing will be held before the Board or its duly designated Presiding Officer, in

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accordance with Section 35.185 of GRAPP, 1 Pa. Code § 35.185. Respondent may appear, with or without counsel, offer testimony or other evidence on his or her behalf, and confront and cross-examine the Commonwealth's witnesses.

Answers, requests for hearings, preliminary motions, protests, petitions to intervene, or any other pleading must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

Also, you must send or e-mail a separate copy of any documents submitted in this matter to the prosecuting attorney named below at:

By Mail:
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521

By E-mail:
gmasser@pa.gov

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Notices and petitions to intervene must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, unless in extraordinary circumstances for good cause shown, a later filing is authorized by the agency.

BY ORDER:
DEPARTMENT OF STATE

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DATE: 05.10.2023

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STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Trucpill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

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Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

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PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

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2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

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transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

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Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Rather

Title: General Counsel

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STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

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EXHIBIT B

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LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

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La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

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Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

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SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

Harry J. Philips Jr.

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R McKay

Marty R. McKay
Hearing Officer for the Board

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BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

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Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

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7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

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that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

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registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

DOS Prothonotary:
May 10 2023

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS. 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

4535

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave.
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

DOS Prothonotary:
May 10 2023

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

CERTIFICATE OF SERVICE

I, Glenn P. Masser, hereby certify that I have this 11th day of May 2023 caused a true and correct copy of the foregoing Notice and Order to Show Cause to be served upon all parties of record in this proceeding in accordance with the requirements of Rule 33.31 of the General Rules of Administrative Practice and Procedure, 1 Pa. Code § 33.31 (relating to service by the agency).

CERTIFIED MAIL, ELECTRONIC RETURN RECEIPT REQUESTED AND FIRST-CLASS MAIL, POSTAGE PREPAID:

PostMeds Inc
3121 Diablo Ave
Hayward, CA 94545
9171.9690.0935.0253.8568.95

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P. O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DOS Prothonotary
May 10 2023

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IN THE MATTER OF:	)	
POSTMEDS INC. dba TRUEPILL and/or TRUEPILL f/k/a POSTMEDS INC.	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
Non-Resident Pharmacy Permit Number: 114861	)	**CASE NO: 22-L-0114**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** has violated the provisions of law set out in the Statement.

2. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama

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Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** further waives any objection to the attorney for the Board preparing, drafting, or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees, or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.'s** permit, including, but not limited to revocation.

6. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions, and contents of the same. **PostMeds Inc. dba Truepill and/or**

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Truepill f/k/a PostMeds Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 6th of June, 2023.

PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.

BY: Donny Simkin
Donny Simkin

ITS: General Counsel, Truepill, Inc.

James Hoover
Counsel for **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.**

DONE this the 8th of JUNE, 2023.

ALABAMA STATE BOARD OF PHARMACY

By:
Robert M. Colburn, Jr., R. Ph., President

Jennifer Muro Neumann,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[*Remainder of page intentionally left blank; signature page to follow.*]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a)On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b)On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c)On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021	TOTAL AMOUNT OF FINE(S): $5,000.00

PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021

COPY

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold

Virginia Herold
Executive Officer
Board of Pharmacy

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination	Citation without a fine
Bus. & Prof. Code § 4174	Dispensing on order of nurse practitioner or person of similar status.	Citation without a fine

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	TOTAL AMOUNT OF FINE(S): $0.00

PAYMENT OF FINE(S) DUE BY: July 16, 2020

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Truepill NY LLC

Pharmacy/Wholesaler License # (if applicable): PH04209

Physical Address: 850 3rd Ave, Ste 404

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 518-692-3362 Website:

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Michelle Middle: Lynne Last: Meyer

Alias(es, nicknames, name changes, etc.): Jennings

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Eastchester High School			09/05-06/09	
Address		City	State	Zip
2 Stewart Place		Eastchester	NY	10709
Diploma/Degree obtained, if any				
High School Degree				
School Name			From - To (MM/YY – MM/YY)	
Northeastern University			09/09-05/15	
Address		City	State	Zip
360 Huntington Ave		Boston	MA	02115
Diploma/Degree obtained, if any				
PharmD				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
04/23-Present				
From - To (MM/YY – MM/YY)				
02/19-04/23				
From - To (MM/YY – MM/YY)				
02/16-02/19				
From - To (MM/YY – MM/YY)				
05/15-02/16				
From - To (MM/YY – MM/YY)				
09/14-05/15				
From - To (MM/YY – MM/YY)				
09/12-08/14				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name		From - To (MM/YY – MM/YY)	
Truepill NY LLC		07/20-Present	
Business Address	**City**	**State**	**Zip**
850 3rd Ave Suite 404	Brooklyn	NY	11201
Phone	**Title**	**Number of Employed Hours**	
518-692-3362	Pharmacist in Charge	8320	
Description of Duties			
Oversee pharmacists, technicians and overall operations.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
10/31/2016	04/21/2018	NY	Yonkers	

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
3605270	New York Board of Pharmacy

Reason/Charge
Minor & Technical Violation

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity
CVS Pharmacy

Provide explanation below:

In October 2016 the New York Board of Pharmacy imposed a $500 fine for an alleged minor and technical violation which was not contested for settlement purposes.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/11/25

Date

I, Michelle Meyer, **certify that as the designated representative for**

Truepill NY LLC,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. MM I am at least 21 years of age;
3. MM I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. MM I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. MM I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. MM I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. MM I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Michelle Meyer

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/11/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michelle Meyer

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/11/25

Date

Please have this section completed in the presence of a Notary Public.

State of NY, ss. County of Kings

I, Michelle Meyer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/11/25

Date

Subscribed and Sworn to before me this 11 day of March 2025

Notary Public Signature

SAJID PATEL
NOTARY PUBLIC STATE OF NEW YORK
No. 01PA6318967
Qualified in Kings County
Expires: February 09, 2027

SAJID PATEL
NOTARY PUBLIC STATE OF NEW YORK
No. 01PA6318967
(Seal)
Qualified in Kings County
Expires: February 09, 2027

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK / ALBANY, NY 12234

OFFICE OF THE PROFESSIONS
DIVISION OF PROFESSIONAL LICENSING SERVICES
Public Information Unit
Tel. (518) 474-3817 EXT: 330
Fax (518) 473-0578
E-mail: DPLSDSU@NYSED.GOV

STATE OF NEW YORK)
SS:
COUNTY OF ALBANY)

In accordance with the **Civil Practice Law and Rules Article 45**, I, Sandra Barsallo, Education Credentials Specialist 1 in the Division of Professional Licensing Services of the New York State Education Department, have caused this certificate to be prepared. I certify that I have legal custody of the official original records of the Division of Professional Licensing Services and I attest that the attached are true, complete and correct copies of the original documents in our files relating to the licensure of MICHELLE LYNNE MEYER aka MICHELLE LYNNE JENNINGS.

Witness my hand and the seal of the New York State Education Department this 9 March, 2022.

Sandra Barsallo, Education Credentials Specialist 1
Professional Licensing Services

DATED
03/09/2022

THE STATE EDUCATION DEPARTMENT / THE UNIVERSITY OF THE STATE OF NEW YORK

OFFICE OF PROFESSIONAL DISCIPLINE, PROSECUTIONS DIVISION
ONE GATEWAY PLAZA, 3RD FLOOR, PORT CHESTER, NEW YORK 10573
Tel.: (914) 934-7554
Fax: (914) 934-7607

Re: Michelle Lynne Jennings, R.Ph. File # 3605270
License # 060799

VIOLATIONS COMMITTEE STATEMENT

TO: The New York State Office of Professional Discipline
The New York State Board of Pharmacy

I wish to settle and dispose of the misconduct allegations which are pending against me, to wit: committing unprofessional conduct (On October 31, 2016, while employed and on duty as the only pharmacist at the CVS Pharmacy, [redacted], New York, I had the assistance of four pharmacy technicians) in violation of Section 6509(9) of the Education Law and in specific violation of Section 29.7(a)(21)(ii)(a) of the Rules of the Board of Regents (8 NYCRR). For the purposes of settlement I do not contest said allegations. I understand that this settlement will be a matter of public record. My check in the sum of $500.00, payable to the order of "New York State Education Department," is enclosed.

[redacted]
Signature

4/11/18
Date

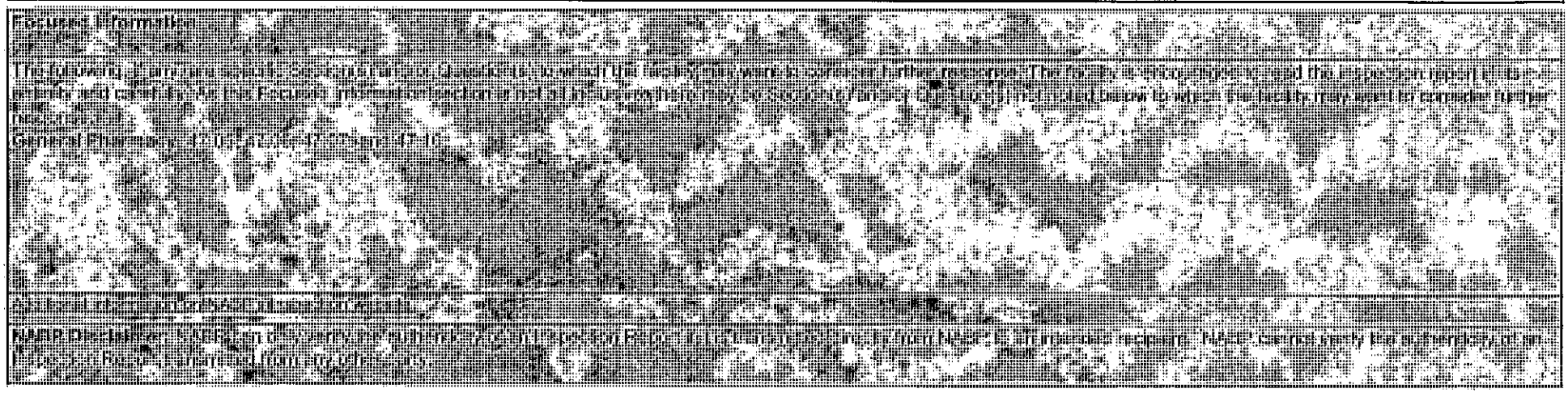
a/k/a MICHELLE LYNNE JENNINGS

:ds

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Business e-Profile ID:	1489518		Inspection Information
Legal Business Name:	Truepill NY LLC	Conference Call Date:	N/A
Doing Business As (DBA):	Truepill	Start Time: 24-hour format (13:00)	N/A
Address:	850 3rd Ave Ste 404	End Time: 24-hour format (13:00)	N/A
City:	Brooklyn	Onsite Inspection Date(s):	9/5/2024
State:	New York	Start Time(s): 24-hour format (13:00)	9:25
Zip Code:	11232	End Time(s): 24-hour format (13:00)	11:11
Telephone number:	518-692-3362	Inspector Name(s):	Amanda Harding, PharmD, BCSCP
Toll free number:	855-910-8606	Inspection performed by (NABP, State, etc):	NABP
Fax number:	718-499-3362	Observer Name/Affiliation (if applicable):	N/A
Website:	www.truepill.com	Observer Name/Affiliation (if applicable):	N/A



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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday			x
Monday	9:00	18:00	
Tuesday	9:00	18:00	
Wednesday	9:00	18:00	
Thursday	9:00	18:00	
Friday	9:00	18:00	
Saturday	10:00	17:00	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Pharmacist in Charge	Michelle Meyer	michelle.meyer@truepill.com	1109326
Nonsterile Designated person(s)	N/A	N/A	N/A
Sterile Designated person(s)	N/A	N/A	N/A
Hazardous Designated person(s)	N/A	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current (Y/N)
1	Michelle Meyer	PIC	Y
2	Stacey Chen	RPH	Y
3	Min Hua Liao	RPH	Y
4	Stephanie Pel	RPH	Y
5	Tramaine Yzer	Tech	N/A
6	Jonise Hammond	Tech	N/A
7	Tahitti Tapia	Tech	N/A
8	Anabel Herreros	Tech	N/A
9	Haidee Goya	Tech	N/A
10	Ferdinand Seda	Warehouse associate	N/A

If more than 10, list the first 10 below, then list the title and number (eg: 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present. 1 RPH, 2 Techs, 3 Inventory Specialists, and 1 Warehouse associate were also present during the inspection.

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Business Licensure Information for State of Residence and Federal

(board of pharmacy, state controlled substance, DEA, FDA, etc)

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number & Expiration Date
New York State Board of Pharmacy	Truepill NY LLC	Pharmacy	037429 exp 7/31/2025
Drug Enforcement Administration	Truepill NY LLC	Controlled Substance - Pharmacy	FT8664648 exp 11/30/2025

Inspector Notes: List states in which Non-Resident licenses are held. Pharmacy is licensed in all states except MA which does not currently require licensure. Pharmacy acts as a fulfillment pharmacy contracted to provide prescriptions from patients or clients of Vetcove, Eli Lilly, Twenty Eight Health and Wisp. The pharmacy primarily dispenses veterinary prescription for clients of veterinary clinics that work with Vetcove. The Eli Lilly patients are part of program to dispense Zepbound. The pharmacy also provides patient care outreach and follow up for hepatitis and lupus specialty patients that receive the specialty medications from the Truepill pharmacy located in CA. The pharmacy is staffed 24 hours a day weekdays and from 10 am to 5 pm on Saturdays and Sundays. The pharmacy is only open to the public during the listed hours.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description

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Type(s) of practice Type "X" for all that apply		Type(s) of practice Type "X" for all that apply	
Traditional retail		Central Fill/Processing/Shared Services	
Open to the Public	X	Nuclear Pharmacy	
Closed Door		Specialty Pharmacy	X
Drive-through window		White bagging/ clear bagging	
Mail- in state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	Outsourcing Facility	
Mail- out of state (eg prescriptions are mailed through USPS or through common carrier) *See table below*	X	FDA Registered Drug Establishment (eg Manufacturer, repackager, relabeler)	
Local Delivery (if out of state describe in note)		Wholesale Distributor	
Veterinary Pharmacy (occasionally dispenses prescriptions for animals)	X	Provide prescription drugs for "Office Use" (eg distributes)	
Institutional (hospital or correctional facility)		Handles Medical Marijuana	
Long-Term Care (nursing home, residential care)		Nonsterile Compounding	
Investigational Drugs, Clinical Trials/Research		Nonsterile Hazardous Drug Compounding	
Telepharmacy		Sterile Compounding	
Internet Pharmacy		Sterile Hazardous Drug Compounding	

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Compounded Nonsterile Preparations (CNSPs) Type "X" for all that apply		Compounded Sterile Preparations (CSPs) Type "X" for all that apply	
CNSPs with controlled substance(s)		CSPs with controlled substance(s)	
CNSPs with vitamins or nutritional supplements		CSPs with vitamins or nutritional supplements (includes total parenteral nutrition)	
CNSPs sold to other pharmacies - If so, list to whom – instate, out of state, under common ownership/shared services – central fill agreement, and state if patient specific or distributed		CSPs sold to other pharmacies - If so, list to whom - in state, out of state, under common ownership/shared services - central fill agreement, and state if patient specific or distributed	
Patient specific (compounded preparation labeled for an individually identified patient):		**Patient specific** (compounded preparation labeled for an individually identified patient):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
Distributed (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):		**Distributed** (compounded preparation leaves the pharmacy without a patient-specific label eg non patient-specific):	
CNSPs for animals		CSPs for animals	
CNSPs for human patients		CSPs for human patients	
CNSPs to practitioners for office use		CSPs to practitioners for office use	
CNSPs to hospitals, clinics, or surgery centers		CSPs to hospitals, clinics, or surgery centers	

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Types of CNSPs:		Categories of CSPs:	
Aqueous		Category 1 CSPs	
Nonaqueous		Category 2 CSPs	
Specific types:		Category 3 CSPs	
Solid oral preparations		Types of CSPs:	
Liquid oral preparations		Allergenic extracts	
Otic preparations		Allergenic extracts in addition to prescription patient sets	
Rectal preparations		Immediate Use	
Vaginal preparations		Proprietary bag and vial systems	
Topical preparations		Blood derived or other biological material (eg autologous serum)	
Nasal and sinus preparations		Sterile injections/ sterile infusions	
Other (please list):		Ophthalmic dosage forms	
		Baths and soaks for live organs and tissues	
		Implants/Pellets	
		Other (please list):	

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Facility Size in Square Feet *(can be approximated)* and Number of PECs		Personnel	
Total Pharmacy size:	11286	Total Pharmacists:	10
Nonsterile Compounding Room size:	N/A	Number of Compounding Pharmacists:	0
Nonsterile Compounding powder hoods number:	N/A	Total Student Interns:	1
Nonsterile Hazardous Drugs (HD) Compounding Room size:	N/A	Total Technicians:	15
Nonsterile HD Compounding CVE/BSC/CACI hoods number:	N/A	Number of Compounding Technicians:	0
Sterile Compounding Ante Room size:	N/A	Of technicians, how many are nationally certified?	0
Sterile Compounding Clean/Buffer Room size:	N/A	Of technicians, how many are techs-in-training?	0
Sterile Compounding Number LAFW hoods/areas:	N/A	Total Other Unlicensed Personnel:	10 Warehouse associates
Sterile Compounding Number BSC hoods:	N/A	Ratio #Technician(s) : #Pharmacist(s) present at time of inspection:	7:5
Sterile Compounding Number CAI/CACI hoods:	N/A	If multiple compounding suites are present under this licensed location (eg outsourcing facilities or hospital health systems), describe in notes other spaces where compounding occurs (eg location name, approximate size of space, and number and type of PECs:	N/A
Negative Pressure Sterile HD Room size:	N/A		
Sterile HD Compounding Number of BSC hoods:	N/A		
Sterile HD Compounding Number of CACI hoods:	N/A		

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Indicate the drug name, dosage or strength, and the size of the CSP sample obtained for testing. (N/A if no sample)	N/A
Indicate the areas/rooms of the pharmacy entered to perform the CSP inspection. If the inspector did not fully garb and enter buffer room(s), indicate reason.	NA

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	2500	Total Orders Distributed/day:	0
% Veterinary Prescriptions	95%	% Veterinary Orders	0%
% Controlled Substance Prescriptions	0%	% Controlled Substance Orders	0%
% Nonsterile Compounded Prescriptions	0%	% Nonsterile Compounded Orders	0%
% Sterile Compounded Prescriptions	0%	% Sterile Compounded Orders	0%
% Hazardous Drugs (HD) Prescriptions	<10%	% Hazardous Drugs (HD) Orders	0%

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Definitions: DISPENSE means to provide a prescription drug or compounded preparation pursuant to a patient-specific prescription. DISTRIBUTE means to provide a prescription drug or compounded preparation to a prescriber, another pharmacy, or health care entity for office use or stock and is NOT patient-specific, is not labeled with the patient name at the pharmacy.

States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Alabama (AL)	19923	0	from 11/1/2022 - 8/15/2024
Alaska (AK)	334	0	from 11/1/2022 - 8/15/2024
Arizona (AZ)	8294	0	from 11/1/2022 - 8/15/2024
Arkansas (AR)	1227	0	from 11/1/2022 - 8/15/2024
California (CA)	25762	0	from 11/1/2022 - 8/15/2024
Colorado (CO)	12916	0	from 11/1/2022 - 8/15/2024
Connecticut (CT)	19584	0	from 11/1/2022 - 8/15/2024
Delaware (DE)	6014	0	from 11/1/2022 - 8/15/2024
District of Columbia (DC)	4598	0	from 11/1/2022 - 8/15/2024
Florida (FL)	71784	0	from 11/1/2022 - 8/15/2024
Georgia (GA)	45649	0	from 11/1/2022 - 8/15/2024
Hawaii (HI)	670	0	from 11/1/2022 - 8/15/2024
Idaho (ID)	4891	0	from 11/1/2022 - 8/15/2024
Illinois (IL)	17354	0	from 11/1/2022 - 8/15/2024
Indiana (IN)	7482	0	from 11/1/2022 - 8/15/2024
Iowa (IA)	2674	0	from 11/1/2022 - 8/15/2024
Kansas (KS)	3903	0	from 11/1/2022 - 8/15/2024
Kentucky (KY)	9897	0	from 11/1/2022 - 8/15/2024
Louisiana (LA)	7447	0	from 11/1/2022 - 8/15/2024
Maine (ME)	9507	0	from 11/1/2022 - 8/15/2024
Maryland (MD)	41816	0	from 11/1/2022 - 8/15/2024
Massachusetts (MA)	39247	0	from 11/1/2022 - 8/15/2024
Michigan (MI)	11552	0	from 11/1/2022 - 8/15/2024
Minnesota (MN)	2365	0	from 11/1/2022 - 8/15/2024
Mississippi (MS)	2979	0	from 11/1/2022 - 8/15/2024
Missouri (MO)	10570	0	from 11/1/2022 - 8/15/2024
Montana (MT)	2396	0	from 11/1/2022 - 8/15/2024

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States to which the pharmacy mails/delivers prescription drugs and volume dispensed, and volume distributed per day (or week or month):
Note: if not available, request information be sent to VPP and note that information was requested in grid.

State	Volume Dispensed	Volume DISTRIBUTED	/day, week, month
Nebraska (NE)	3179	0	from 11/1/2022 - 8/15/2024
Nevada (NV)	1202	0	from 11/1/2022 - 8/15/2024
New Hampshire (NH)	11077	0	from 11/1/2022 - 8/15/2024
New Jersey (NJ)	43325	0	from 11/1/2022 - 8/15/2024
New Mexico (NM)	1121	0	from 11/1/2022 - 8/15/2024
New York (NY)	113050	0	from 11/1/2022 - 8/15/2024
North Carolina (NC)	84180	0	from 11/1/2022 - 8/15/2024
North Dakota (ND)	166	0	from 11/1/2022 - 8/15/2024
Ohio (OH)	17575	0	from 11/1/2022 - 8/15/2024
Oklahoma (OK)	6284	0	from 11/1/2022 - 8/15/2024
Oregon (OR)	3918	0	from 11/1/2022 - 8/15/2024
Pennsylvania (PA)	90994	0	from 11/1/2022 - 8/15/2024
Rhode Island (RI)	10111	0	from 11/1/2022 - 8/15/2024
South Carolina (SC)	33911	0	from 11/1/2022 - 8/15/2024
South Dakota (SD)	278	0	from 11/1/2022 - 8/15/2024
Tennessee (TN)	18712	0	from 11/1/2022 - 8/15/2024
Texas (TX)	137350	0	from 11/1/2022 - 8/15/2024
Utah (UT)	4814	0	from 11/1/2022 - 8/15/2024
Vermont (VT)	12205	0	from 11/1/2022 - 8/15/2024
Virginia (VA)	57207	0	from 11/1/2022 - 8/15/2024
Washington (WA)	6792	0	from 11/1/2022 - 8/15/2024
West Virginia (WV)	5191	0	from 11/1/2022 - 8/15/2024
Wisconsin (WI)	9832	0	from 11/1/2022 - 8/15/2024
Wyoming (WY)	940	0	from 11/1/2022 - 8/15/2024
Other			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Truepill NY LLC dba Truepill
e-Profile ID: 1489518
Inspection Date: 9/5/2024

		Observation	Notes
General Pharmacy			
1.00	Is the PIC (or pharmacy manager/director) present for the inspection? *If no, list the pharmacist on duty.*	Yes	
2.00	Is the PIC employed full-time at the pharmacy? *List the number of hours worked per week onsite.*	Yes	at least 40 hours
3.00	Are there any other businesses located at this address? *If yes, note type of business and name.*	No	
4.00	Does the pharmacy have any other websites? *Provide list of other names/URLs.*	No	
4.01	Does the pharmacy hold .pharmacy verification?	Yes	
5.00	Do any other websites link to the pharmacy website (such as a provider, or other affiliate)? *If yes, list.*	No	
6.00	Does the pharmacy allow patients to securely enter/update profile and medical information through the website (such as through a secure patient portal)?	No	Patients or clients have account with pharmacy's client. All communication goes through the pharmacy's client.
7.00	Are patients able to order or refill prescriptions through the website? *If yes, describe.*	No	
8.00	Are photographs allowed during the inspection (no PHI)?	Yes	None taken
9.00	**List of additional personnel interviewed as part of the inspection, including name and title:**		Stacey Chen, RPH; Min Hua Liao, RPH

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Facility Name: Truepill NY LLC dba Truepill

e-Profile ID: 1489518

Inspection Date: 9/5/2024

		Observation	Notes
Types of Practice Additional Questions: If any part of a question is no, enter "No" and explain the observation.			
10.00	If the pharmacy mails or delivers filled prescriptions (patient specific, labeled with patient name when it leaves the pharmacy), are any of the deliveries to a provider or facility for administration to the patient? *If yes, indicate volume or percentage of deliveries going to a provider or facility in this state, and volume or percentage of deliveries going to a provider or facility in other states.*	No	
11.00	Does the pharmacy provide prescription products to a provider or facility for "office use" (not pursuant to a prescription received prior to delivery, not patient specific, not labeled with the patient name)? *If yes, indicate volume or percentage provided to a provider or facility within this state, and volume or percentage provided to a provider or facility in other states.*	No	
12.00	Does the pharmacy provide prescription products to providers or facilities (including other pharmacies) as a wholesale distributer (sold to the provider or facility for their use, administration, or providing/dispensing to patients)?	No	Intracompany transfers in rare situations to another Truepill pharmacy location.
13.00	If yes, is the percentage of product distributed at wholesale to providers or facilities within this state less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	
14.00	If yes, is the percentage of product distributed at wholesale to providers or facilities in other states less than 5%? *Indicate actual percentage and if the percentage is based on number of units, number of prescriptions, dollar volume of total sales or dollar volume of prescription sales.*	N/A	

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Truepill NY LLC dba Truepill

e-Profile ID: 1489518

Inspection Date: 9/5/2024

		Observation	Notes
General Operations and Licensure	**If any part of a question is no, enter "No" and explain the observation.**		
15.00	Are pharmacy licenses, permits, and registrations (state, controlled substance, DEA, etc) posted in customers' view and current? *If no, provide details such as closed-door pharmacy, expired licenses, etc.*	Yes	Posted in front lobby area
16.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	Initial inspection 7/25/2019, NY BOP does not routinely inspect
17.00	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies were noted.
18.00	Does the pharmacy hold ANY wholesale, distributor, or manufacturer licenses? *Document information in the license grid above for Resident State and in the Notes for Non-Resident States.*	No	
19.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
20.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
21.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
22.00	Does the pharmacy have any additional restrictions, limitations, or waivers with regards to any federal licenses or registrations (FDA, DEA, etc)? *If yes, note the agency and additional item.*	No	DEA settlement agreement from inspection of CA Truepill location.

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Verified Pharmacy Program® Inspection Form

General Pharmacy Inspection

The information and comments obtained in the Nonsterile Compounding, Sterile Compounding Inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Truepill NY LLC dba Truepill
e-Profile ID: 1489518
Inspection Date: 9/5/2024

		Observation	Notes
23.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	DEA went to CA location not on site in NY
24.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
25.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	URAC Specialty (exp 4/1/2026) and Mail Order (exp 2/1/2026), NABP Digital Pharmacy
26.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold? *Provide a list and the reasons for such.*	No	
27.00	Does the pharmacy perform patient lab testing such as blood glucose tests, cholesterol tests, etc? *Verify that the lab director is current (usually the PIC is the lab director named). If yes, record the Clinical Laboratory Improvement Amendments (CLIA) waiver information, expiration date, and the name of lab director listed.*	N/A	
28.00	Does the pharmacy maintain all required records, including but not limited to prescription files and invoices on site? *Record how long records are kept. If not on site, where?*	Yes	Most records maintained electronically. Paper invoices kept on site for at least 7 years.
28.01	Are written and verbal prescriptions (reduced to writing) kept on site for the entire retention period? *If not, explain including how long they are stored on site?*	Yes	
28.02	Are electronic prescriptions (such as fax, e-scripts) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic
28.03	Are all dispensing records (such as refills, verifications, DUR overrides) kept on site for the entire retention period? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic
28.04	Are there systems in place to prevent a pharmacy record from being deleted after the prescription has been dispensed? *Describe how they are kept (electronically or printed and kept in hard copy).*	Yes	Electronic record that cannot be deleted.

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28.05	If record are stored off site are they secure in a HIPAA compliant manner and readily retrievable?	N/A	
29.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	Keep at least 7 years
	Personnel **If any part of a question is no, enter "No" and explain the observation.**		
30.00	Are all pharmacist, pharmacy intern, and pharmacy technician (if applicable) licenses or registrations with the board current and in good standing? *Describe how this is documented.*	Yes	Corporate HR does primary source verification, annual primary source verification
31.00	Is there a process for periodic verification of validity of licenses? *Describe the process.*	Yes	Corporate HR does primary source verification, annual primary source verification
32.00	If pharmacists are providing patient services that require additional training or certification, are they appropriately trained and certified? *(Immunization, CPR, MTM, etc.). Mark NA if no patient services that require additional training/certification. If yes, list certifications and if current?*	N/A	
33.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Mark N/A if not required by resident state. Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	4:1; the pharmacy usually staffs 2:1
	Facility and Security **If any part of a question is no, enter "No" and explain the observation.**		
34.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	Pharmacy alarmed and access controlled through badge access. PIC and facilities team get call if security system alarmed.
35.00	Are Schedule II controlled substances secured in a locked cabinet or safe? *If not, describe how controlled substances are secured or stored.*	N/A	Pharmacy no longer stocks controlled substances. There is an empty safe on site.
36.00	Are there contingency plans in the event the pharmacy cannot be secured? *Describe how the drug products will be secured and handled.*	Yes	Operations would be moved to another Truepill pharmacy and pharmacy would be secured.

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37.00	Is the pharmacy clean and sanitary, and is there appropriate space for the prescription volume? *Look for clutter, or crowded counters or stacks of prescriptions to be checked. If no, document with photo.*	Yes	
37.01	Is the working area well lit and free of tripping hazards? *If no, document with photo.*	Yes	
37.02	Is there a sink with hot and cold running water?	Yes	
37.03	If the pharmacy destroys prescription products on site (such as expired, damaged, recalled, etc), do they appropriately document the destruction? *View destruction logs. Mark NA if no destruction on site.*	N/A	
37.04	Does the pharmacy return prescription products to the manufacturer, distributor, or send to a reverse distributor for destruction? *If yes, indicate name of reverse distributor used.*	Yes	Returns through Inmar monthly
37.05	Does the pharmacy have a hazardous waste handling and collection system? For example, empty bottles that contained chemotherapy medications or warfarin, or hazardous drug compounding waste. *If yes, indicate how often the bin is emptied/collected and the vendor used.*	Yes	Stericycle, when needed
38.00	Does the pharmacy have a private area for patient counseling and providing patient services? *Describe.*	Yes	Rarely will patients come to pharmacy. Limited access into pharmacy and can speak privately in entrance/lobby area.
39.00	Is temperature in the drug storage area maintained to provide controlled room temperature of 20° to 25°C (68° to 77 °F), or more restrictive if warranted by specific drug product storage requirements? *Describe. Record the temperature at the time of inspection.*	Yes	Temperature 72° F during inspection.
39.01	Is temperature monitoring in place to detect any excursions (24/7) by continuous monitoring or retroactive detection using min/max? Temperature records are maintained. *If yes, describe the process*	Yes	Continuous monitoring for USP range by SmartSense.

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39.02	Are excursion action plans in place including evaluating excursion effects on drug product integrity?	Yes	
40.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes	
41.00	Does the pharmacy have a process for how the refrigerator temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	Yes	Continuous monitoring for USP range by SmartSense. Excursions are notified via app to the cell phones; records are maintained electronically for an indefinite period.
41.01	Is the temperature in the refrigerator within the USP range (2°-8°C or 36°-46 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the refrigerator at the time of inspection.*	Yes	Storage refrigerator: 5.7° C; staging refrigerator: 40.7° F
42.00	Does the pharmacy have a process for how the freezer temperature is monitored for excursions 24/7? *If yes, describe the process. Indicate range. How are excursions detected? How long are records maintained?*	N/A	No drug storage only gel packs. Monitored through SmartSense
42.01	Is the temperature in the freezer within the USP range (between −25° to −10°C or −13° to 14 °F) or as specified by FDA approved labeling for drug product storage? *Record the temperature of the freezer at the time of inspection.*	N/A	
43.00	Are there contingency plans in the event of power outage or refrigerator/freezer failure? *Describe process.*	Yes	Refrigerators on generator backup
44.00	Are there contingency plans in the event of heating or air conditioning failure? *Describe processes.*	Yes	Contract through the landlord to service HVAC system
45.00	Is there a plan of action if there are any temperature or humidity excursions to determine if the integrity of the products has been compromised?	Yes	
46.00	Does the pharmacy utilize any automated apparatuses for prescription processing/counting (such as robotics, Baker cells, etc)? *List numbers and types.*	Yes	Two Parata Max machines, one Parata Mini and seven Kirby Lester counting machines
46.01	If yes, do they have and follow policies and procedures addressing cross-contamination and identification of drug products?	Yes	

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		Observation	Notes
Product Receipt and Inventory	**If any part of a question is no, enter "No" and explain the observation.**		
47.00	Does the pharmacy have a documented process for establishing sources (vendors) of prescription drugs? *Describe.*	N/A	This is a corporate process, pharmacy unable to independently order.
47.01	Does the pharmacy purchase all prescription drugs directly from the manufacturer?	No	Some are purchased from manufacturer: American Regent Animal Health, Boehringer Ingelheim Animal Health, Ceva Animal Health, Creative Science, Elanco US, Lintbells, Merck Animal Health, Neogen Corporation, Pet Honest, RX Vitamins, UltiMed, Vetoquinol USA, VetriMax, VetriScience, Virbac, Zoetis
47.02	Does the pharmacy purchase (obtain) prescription drugs from other pharmacies? *If yes, list pharmacy source information, and circumstances leading to the purchase.*	Yes	Intracompany transfers in rare situations to another Truepill pharmacy location.
47.03	Does the pharmacy purchase (obtain) prescription drugs from wholesale distributors (non-manufacturer sources)? *List non-manufacturer sources.*	Yes	Bloodworth Wholesale Drugs, Clipper Distributing Co, McKesson, Vedco, Vet Brands International. Most drugs used for human patients purchased from McKesson.
47.04	Does the pharmacy require wholesale distributor sources to purchase prescription drugs directly from the manufacturer? *If yes, how is this verified?*	N/A	Corporate process, pharmacy does not place orders.
47.05	Does the pharmacy purchase drugs from wholesale distributors that purchased the drug from other wholesale distributors? *If yes, Describe the due diligence steps to determine the source's legitimacy and legitimacy of the drugs sold by the vendor. (For instance, does the pharmacy examine transaction histories and limit the number of movements of drugs between wholesale distributors, and look for pharmacies in the supply chain?)*	Unknown	Corporate process, pharmacy does not place orders. Corporate inventory team sets up contracts and orders on behalf of the pharmacy.
47.06	Does the pharmacy determine that all sources listed on transaction histories have requisite state licensing? *If yes, describe the process.*	No	Corporate process. Pharmacy can access the information if necessary but reviewed at corporate level since pharmacy does not independently order.
47.07	Does the pharmacy determine that all sources listed on transaction histories have reported to FDA's Wholesale Distributor database? *If yes, describe the process.*	No	Corporate process. Pharmacy can access the information if necessary but reviewed at corporate level since pharmacy does not independently order.
47.08	Does the pharmacy have a process to handle suspect and illegitimate product investigations? *If yes, describe the process.*	Yes	Quarantine and report to corporate inventory team. Will await direction from corporate team on disposition.

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47.09	Has the pharmacy conducted any suspect or illegitimate product investigations? *If yes, describe the details, including the drug, circumstances, outcome, and identification of agencies to whom reported.*	No	
47.10	Does the pharmacy ensure transaction data (transaction history, transaction information, transaction statement, also known as 3T data) is received at the same time or before the product is received? *Examine recent purchases to determine if the pharmacy is receiving and maintaining 3T data for a minimum of 6 years.*	No	Corporate process. Pharmacy can access the information if necessary but reviewed at corporate level since pharmacy does not independently order.
47.11	Does the pharmacy have a procedure to verify product (suspect or illegitimate) including quarantine of product and reporting?	Yes	Corporate inventory team will spearhead.
48.00	Does the pharmacy utilize paper DEA-222 forms to procure Schedule II substances? *If yes, how are they secured? Who has the authority (Power of Attorney) to sign the DEA-222 forms?*	No	Pharmacy does not currently stock controlled substances and does not have any paper 222 forms on hand and no individuals on site have been granted POA.
49.00	Does the pharmacy utilize CSOS (electronic Schedule II ordering) to procure Schedule II substances? *If yes, who can place orders in CSOS?*	No	
50.00	Is the receipt of Schedule II orders documented appropriately? *DEA-222 has the quantity and date on each line of product received, the CSOS record (electronic or paper printout) indicates verification of receipt and staff performing verification.*	N/A	Pharmacy does not dispense controlled substances
51.00	Are invoices for controlled substances (Schedules I-V) that are received filed separately and are the invoices signed/initialed and dated upon receipt and every item checked in?	N/A	Pharmacy does not dispense controlled substances
52.00	Are all orders received when the pharmacy is open? *Verify the orders are brought directly to the pharmacy still sealed and not delivered before the pharmacy is open.*	Yes	
53.00	Does the pharmacy purchase any compounded products from other entities for dispensing to patients? *If so, describe which products and from where they are purchase (collect name and license of other entity).*	No	

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54.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Pharmacy inventory team performs cycle counts to track inventory. Corporate orders based upon inventory levels.
54.01	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Have not had diversion but would report to BOP.
55.00	Does the pharmacy keep a perpetual inventory log of all Schedule II controlled substances (including APIs, if applicable)?	N/A	Pharmacy does not dispense controlled substances
56.00	Is the Schedule II perpetual inventory log reconciled regularly? *Indicate how often the Schedule II controlled substances are counted. View the perpetual log and verify that reconciliation is taking place.*	N/A	Pharmacy does not dispense controlled substances
57.00	Is the most recent complete controlled substances inventory available for review? *Indicate the date of the last inventory and frequency taken (minimum every two years).*	Yes	Zero inventory count performed 5/1/2023. Pharmacy performs inventory every 2 years.
57.01	Does the pharmacy maintain other required inventories (such as change in PIC, theft/loss, etc)?	Yes	
58.00	Does the pharmacy stock and sell OTC pseudoephedrine (and/or ephedrine) products? If yes, indicate if the sale is recorded electronically or manually in a logbook.	No	
58.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	
59.00	Does the pharmacy stock and sell other OTC restricted products for which ID is required and a log kept of the sale? *If yes, indicate product types.*	No	
59.01	Are these products mailed, sent, or delivered into other states? *View logs. If yes, list the other states.*	N/A	

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60.00	Are outdated, damaged, or recalled products segregated? *If yes, how often does the pharmacy check for out-of-date products? Does it include OTC products?*	Yes	Monthly check including OTC section. Will pull most items within 6 months of expiration.
60.01	Are all drugs within active-stock within expiration date? *Examine shelves, refrigerator and freezer.*	Yes	
60.02	How often is active-stock examined for drugs past the expiration date?	[redacted]	Monthly
61.00	Does the pharmacy **prepackage** bulk containers of prescription medications into smaller containers for ease of use? *What BUD is used on the prepackaged container?*	No	
62.00	Does the pharmacy **prepack** multiple drugs into a single container for compliance packaging? *What BUD is used on the prepacked containers?*	No	
63.00	Does the pharmacy return to stock prescription drugs that were filled but never picked up?	Yes	
63.01	If yes, are they maintained in the appropriate container, with PHI removed and BUD adjusted?	Yes	

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Prescription Processing	**If any part of a question is no, enter "No" and explain the observation.**		
64.00	**Patient Profile:** Is patient profile data organized and readily accessible to facilitate consultation with the prescriber, patient, or caregiver? *Indicate who enters patient profile data into the computer system and how often it is updated?*	Yes	Information pulled automatically from client platforms. Patients or animal owner completes survey before ordering to update allergy, health conditions and other medications.
64.01	If the pharmacy dispenses veterinary prescriptions, does the information gathered and recorded include the species, and name of the animal/owner as required by resident state law? *Describe how it is indicated in the computer system that the patient is an animal? And how is it indicated in the system the prescription is a veterinary prescription?*	Yes	Information pulled automatically from Vetcove platform based on how the owner inputs information on survey. Only dispensing to companion animals.
65.00	**Prescription:** Are adequate processes in place to assure the integrity, legitimacy, and authenticity of prescription orders? *Staff is familiar with detecting fraud in hard copy, faxed, verbal, and electronic prescriptions.*	Yes	All prescriptions tied to client platforms and no outside prescriptions dispensed.
65.01	Is there a procedure to follow when a prescription is suspected of (or actually is) fraudulent? *Describe the steps and reporting process.*	Yes	Report to licensing board.
65.02	Are adequate processes in place for assuring that prescription medications are not prescribed or dispensed based on online medical consultations without there being a pre-existing prescriber-patient/client relationship? *Describe. Do the processes include comparing the physical addresses of the patient and prescriber?*	Yes	Staff trained to look for self prescribing and for veterinary prescriptions to be entered under owner's name and not animal. Prescriptions from Eli Lilly, Twenty Eight Health and Wisp are limited to certain drugs/disease states. Any discrepancies or concerns that cannot be easily resolved are reported to the corporate compliance team.
65.03	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	Have system to allow veterinary prescriptions to be received electronically through Vetcove.
65.04	If the pharmacy accepts electronic prescriptions for controlled substances, are they in compliance with federal regulations?	N/A	
66.00	**Accuracy:** Is the accuracy of the information entered into the computer system verified (patient information and prescription information)? *Indicate how and by whom.*	Yes	Pharmacy performs PV1 step prior to label being printed for fulfillment.

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67.00	**DUR:** Does staff conduct prospective DUR prior to the dispensing of a medication or product? *Describe at what point in the process does the DUR take place?*	Yes	DUR performed as part of PV1 step prior to label being printed.
67.01	Does the DUR include: • drug-drug interaction (Prescription and OTC), • drug-allergy interaction, • therapeutic duplication, • under- or over-utilization (including clinical abuse/misuse), • disease state or condition contraindication, • Incorrect dosage or duration of therapy, and • gender or age related contraindications. *Indicate if there are other parameters routinely included in the DUR.*	Yes	
67.02	In addition to the pharmacy DUR software, does the pharmacy staff obtain other information to use in the DUR process? *Describe.*	Yes	Clinical information provided during patient survey visible during PV1 step even if software does not flag the prescription. Every gabapentin prescription flagged with dispensing note of where prescription is a controlled substance so that the pharmacy does not dispense into that state.
67.03	Does the pharmacy have adequate resources/references related to the type of pharmacy practice it operates?	Yes	
67.04	Does the pharmacy report required data to the state PMP (in this state and the other states in which the pharmacy is licensed)? *Describe.*	Yes	Automatic zero reporting to those states requiring reporting.
67.05	Does the pharmacy access state PMP/PDMP data for specific patients? *Verify there is a policy regarding access and follow-up or reporting and that pharmacist can access the PMP data.*	Yes	Up to pharmacist discretion, may access for states in which gabapentin is reported but not a controlled substance.
67.06	Are DUR overrides/bypasses documented? *Indicate how the override is documented and who has override capability.*	Yes	RPH electronically override with notes required based on severity of interaction.

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67.07	Is the DUR process performed electronically by the computer system? ***Identify integrated drug database used.***	Yes	Medispan
67.08	If the DUR is manual, is there a system to document: • How manual DUR is performed • Specific issues that were identified • Pharmacist that considered the identified issues and gave the okay to proceed	N/A	
67.09	If the pharmacy dispenses veterinary prescriptions, does it have a veterinary drug database integrated into the computer system for electronic DUR? *List veterinary product electronic database used. If not, list compendia used for performing manual DUR.*	N/A	Veterinary database not integrated but some limited DUR alerts such as early refill. Plumbs available online for references.
68.00	Are filled prescriptions verified for accuracy prior to dispensing? *Indicate process, by whom, and how documented.*	Yes	PV2 process of RPH verifying labeled product prior to shipment.
69.00	Are filled prescriptions appropriately labeled? *Describe.*	Yes	
70.00	**Confidentiality:** Does the system have adequate safeguards to prevent a user from performing functions under a different user account or beyond what they are authorized to perform? *Password protected, access limited by job type, access revoked as appropriate such as upon termination. Record name/brand of pharmacy computer system used.*	Yes	Proprietary Truepill OS
70.01	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
71.00	**Mail/Delivery:** If applicable, are packing materials designed to maintain the physical integrity, stability, and purity of prescription medications and compounded preparations in transport?	Yes	Ambient packages tested for up to 5 days shipping. Use USPS primarily.
72.00	**Off-Site Processes:** Are any portions of the prescription processing (in the questions below) performed at a different location? ***Note: Please ask each question below to verify.***	No	Pharmacy will perform patient care services such as counseling and follow up for specialty medications dispensed from CA Truepill pharmacy.

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The information and comments obtained in the Nonsterile Compounding, Sterile Compounding inspections, and Hazardous Drug Compounding are based on USP Chapters <795>, <797>, and <800>.

An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

Facility Name: Truepill NY LLC dba Truepill

e-Profile ID: 1489518

Inspection Date: 9/5/2024

		Observation	Notes
72.01	If yes, is the other location under common ownership? *If not commonly owned, explain if there is a central fill/shared services or other agreement in place. Record the name and license number for the other location.*	N/A	
72.02	If yes, is that location in a different state than this facility? *If so, explain.*	N/A	
72.03	If yes, are there policies and procedures for identifying who is responsible for each step of prescription processing?	N/A	
73.00	**Off-Site Inventory:** Does the pharmacy maintain any emergency kits in nursing homes, long-term care facilities, or other entities (such as hospice, EMTs, ambulances)? *Note name(s) of facilities or entities.*	No	
73.01	Do the emergency kits contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
74.00	**Off-Site Inventory:** Does the pharmacy maintain any automated prescription dispensing devices outside the pharmacy such as Pyxis in a nursing home, or a secure mailbox device that patients access after hours, etc? *Note types and locations.*	No	
74.01	If yes, are the automated devices appropriately licensed, registered, or approved by the board of pharmacy? *Provide details.*	N/A	
74.02	Do the automated dispensing devices contain any compounded products? *If so, indicate whether sterile and/or nonsterile and are these stored, non-patient specific?*	N/A	
	Patient Counseling and Communication **If any part of a question is no, enter "No" and explain the observation.**		
75.00	Does the pharmacist provide counseling for all <u>new</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	
75.01	Is an "offer" to counsel made for all <u>new</u> prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Offer made by RPH, rarely do patients pick up prescriptions at the pharmacy.
76.00	Does the pharmacist provide counseling for all <u>refilled</u> prescriptions picked up at the pharmacy (proactively, no "offer")?	No	

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National Association of Boards of Pharmacy®
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Facility Name: Truepill NY LLC dba Truepill

e-Profile ID: 1489518

Inspection Date: 9/5/2024

		Observation	Notes
76.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy? *Indicate who makes the "offer".*	Yes	Offer made by RPH, rarely do patients pick up prescriptions at the pharmacy.
77.00	Does the pharmacist provide counseling for refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist (proactively, no "offer")?	No	
77.01	Is an "offer" to counsel made for all refilled prescriptions picked up at the pharmacy when there is a change in therapy or other issue determined by the pharmacist? *Indicate who makes the "offer".*	Yes	Offer made by RPH, rarely do patients pick up prescriptions at the pharmacy.
78.00	Is patient counseling provided for delivered prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	N/A	
79.00	Is patient counseling provided for mailed prescriptions? *Printed information sent to patient, toll-free number for patients to call, pharmacist calls patients directly, etc? Describe how.*	Yes	Printed information packet sent with each prescription.
80.00	Are patient package inserts (PPIs) provided with every fill and refill of medications for which they are required (such as hormone products, inhalers, etc)? *Describe how.*	Yes	Automatically prints with medications label.
81.00	Are MedGuides provided with every fill and refill of medications for which they are required (such as NSAIDS, antidepressants, etc)? *Describe how.*	Yes	Automatically prints with medications label.

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Facility Name: Truepill NY LLC dba Truepill
e-Profile ID: 1489518
Inspection Date: 9/5/2024

		Observation	Notes
82.00	Are REMS (Risk Evaluation Mitigation Strategy) implementation programs performed? Confirm that procedures are in place. *List programs (such as iPledge for isotretinoin, or Tikosyn).*	N/A	
83.00	Is patient counseling, the offer to counsel, or the refusal of patient counseling documented? *Describe how.*	Yes	Document patient interaction in patient profile in Truepill OS. Counseling and patient follow up for specialty medications dispensed from CA location saved to patient profile.
84.00	Do patients have 24-hour access to a pharmacist? *Note: may not be required by the resident state. Describe how (such as posted contact information and hours of operation).*	Yes	CA Truepill pharmacy provides RPH access after hours.
85.00	Are processes in place to handle a drug recall?	Yes	
86.00	Does the pharmacy accept prescription drugs back for destruction as part of a drug take-back program?	No	
86.01	Does the take-back program include controlled substances?	N/A	
86.02	Does the pharmacy have a modified DEA registration for controlled substance take-back? *If yes, list.*	N/A	

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Facility Name: Truepill NY LLC dba Truepill
e-Profile ID: 1489518
Inspection Date: 9/5/2024

		Observation	Notes
Quality Assurance/Quality Improvement Program	**If any part of a question is no, enter "No" and explain the observation.**		
87.00	Is there a documented continuous quality improvement (CQI) Program for the purpose of detecting, documenting, assessing, and preventing quality related events (QREs)? *If yes, list who oversees the program.*	Yes	Corporate compliance team with PIC
87.01	Policies and procedures for the program are maintained in the pharmacy in an immediately retrievable form. *Indicate if hard copy, electronic, or both.*	Yes	Electronic
87.02	"Quality-Related Event" (QRE) is defined to mean any departure from the appropriate dispensing of a prescribed medication that is or is not corrected prior to the delivery and/or administration of the medication including (but not limited to): 1. a variation from the prescriber's prescription drug order such as incorrect drug, strength, form, or patient; or inadequate or incorrect packaging, labeling, or directions; 2. a failure to identify and manage over-utilization or under-utilization; therapeutic duplication; drug-disease contraindications; drug-drug interactions incorrect drug dosage or duration of drug treatment; drug-allergy interactions; or clinical abuse/misuse. 3. packaging or warnings that fail to meet recognized standards, the delivery of a medication to the wrong patient, or the failure to detect and appropriately manage a significant actual or potential problem with a patient's drug therapy.	Yes	
87.03	There is documentation of initial/ongoing (at least yearly) review and training of all pharmacy employees on the CQI program and processes. *For example, may be formal training or reviewed at a yearly meeting.*	Yes	
88.00	**Documentation of QREs** starts as soon as possible, but no more than three days, after determining their occurrence. *Indicate if documentation/forms are hard copy or electronic.*	Yes	Electronic

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Facility Name: Truepill NY LLC dba Truepill

e-Profile ID: 1489518

Inspection Date: 9/5/2024

		Observation	Notes
88.01	Documentation includes all the pertinent data about the prescription involved including personnel involved at each step.	Yes	
88.02	Documentation includes documenting the type of QRE details and how/who discovered the QRE.	Yes	
88.03	Documentation incudes possible contributing factors such as day and time the QRE occurred, number of pharmacists and technicians on duty, prescription volume that day, equipment failure, or other factors affecting work-flow at the time.	Yes	
88.04	Documentation includes steps taken to remediate including communications with the patient and the provider, and if the medication was ingested, disposition of the patient.	Yes	
89.00	**QRE data** collected is analyzed to assess causes and any contributing factors (root cause). *Indicate who performs the analysis and frequency (with each event, weekly, monthly, quarterly, etc).*	Yes	At time of event and quarterly
89.01	The pharmacy uses the findings of the analysis to formulate an appropriate response and develop pharmacy systems and workflow processes designed to prevent QREs and increase good outcomes for patients.	Yes	
89.02	For pharmacies utilizing a drug formulary, a periodic review of such formulary is undertaken to ensure that appropriate medications are being offered/selected in the best interest of patients.	N/A	
90.00	**Quality meetings** are held at least annually by staff members of the pharmacy to consider the effects on quality of the pharmacy system due to staffing levels, workflow, and technological support.	Yes	
90.01	The meeting reviews data showing evidence of the quality of care for patients and develops plans for improvements to increase good outcomes for patients.	Yes	

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Facility Name: Truepill NY LLC dba Truepill
e-Profile ID: 1489518
Inspection Date: 9/5/2024

		Observation	Notes
90.02	Improvements or changes made are evaluated for performance to measure the effectiveness of the CQI program.	Yes	
91.00	**Reporting:** Incidents of QREs are reported to a nationally recognized error reporting program, an outside peer review committee, or a patient safety organization. *Indicate which organizations are reported including if the pharmacy reports QREs to the board of pharmacy.*	Yes	Would report to BOP in states requiring reporting.
91.01	Adverse events are reported to the appropriate entities such as the board of pharmacy, MedWatch, FDA, VAERS, etc?	Yes	Will report to FDA any reported side effects not listed
91.02	Incidents involving malfunctioning or defective medical equipment or devices (blood glucose meters, DME, injection devices, etc) are documented and reported to the manufacturer or distributor.	N/A	
92.00	**Quality Self-Audits** are performed by the pharmacy at least quarterly (and upon change in PIC) to determine whether the occurrence of QREs has decreased and whether there has been compliance with preventative procedures, and to develop a plan for improved adherence with the CQI program in the future.	Yes	
93.00	**Consumer Surveys** are conducted at least yearly of patients who receive pharmaceutical products and servicas at the pharmacy. A statistically valid sampling technique may be used in lieu of surveying every patient. Each pharmacy should use the results of its consumer survey to evaluate its own performance at a particular time and over a period of time.	Yes	
94.00	**Patient Complaints** are documented, tracked, and investigated as appropriate and the information is used as part of the CQI program.	Yes	

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Truepill NY LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NY NRP2793

Physical Address: 850 3rd Ave STE 404

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 518-692-3362 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Aaron Middle: Michael Last: Wurst

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✓	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (if "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Harvard Business School		08/13 - 05/15	
Address	City	State	Zip
Harvard Business School	Boston	MA	02163
Diploma/Degree obtained, if any			
MBA			

School Name		From - To (MM/YY – MM/YY)	
Cornell University		09/05 - 05/07	
Address	City	State	Zip
Cornell University	Ithaca	NY	14850
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
United States Military Academy		06/03 - 06/05	
Address	City	State	Zip
606 Thayer Rd	West Point	NY	10996
Diploma/Degree obtained, if any			
no degree			

School Name		From - To (MM/YY – MM/YY)	
University of Toledo		08/02 - 05/03	
Address	City	State	Zip
2801 Bancroft St	Toledo	OH	43606
Diploma/Degree obtained, if any			
no degree			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/16 - current	[redacted]			
08/15 - 08/16				
06/13 - 07/15				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Postmeds Inc D/B/A Truepill			11/23 - current	
Business Address	**City**		**State**	**Zip**
3121 Diablo Ave	Hayward		CA	94545
Phone	**Title**			
650-353-5495	President			
Description of Duties				
Oversee P&L and the development and execution of our business strategy, and commercial growth.				

Business Name			From - To (MM/YY – MM/YY)	
The Carlyle Group			01/21 - 11/23	
Business Address	**City**		**State**	**Zip**
1001 Pennsylvania Ave NW	Washington		DC	20004
Phone	**Title**			
	Principal			
Description of Duties				
Lead the Healthcare team for Carlyle' s Global Portfolio Solutions (GPS) group				

Business Name			From - To (MM/YY – MM/YY)	
CVS Health			08/11 - 01/23	
Business Address	**City**		**State**	**Zip**
1 CVS Drive	Woonsocket		RI	02895
Phone	**Title**			
	Vice President			
Description of Duties				
Managed and sat on the Retail Leadership Team				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Aaron Wurst

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

6 March 2025

Date

Please have this section completed in the presence of a Notary Public.

State of Rhode Island, ss. County of Providence

I, Katarina Chapman, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/6/2025

Date

Subscribed and Sworn to before me this 6th day of March 2025

Notary Public Signature

Katarina Chapman
Notary Public, State of Rhode Island
My Commission Expires October 17, 2028
Notary # 772653

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Truepill NY LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): NRP2793

Physical Address: 850 3rd Ave STE 404

City: Brooklyn State: NY Zip: 11232

Mailing Address (if different from physical address): same

City: State: Zip:

Telephone: 518-692-3362 Website: n/a

Licensing Company Email: compliance@truepill.com

Section 2: Personal Information

First: Paul Middle: James Last: Greenall

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bayes Business School, University of London			10/98 - 07/02	
Address		City	State	Zip
106 Bunhill Row		London	UK	EC1Y 8TZ
Diploma/Degree obtained, if any				
BSC Business Management				
School Name			From - To (MM/YY – MM/YY)	
Abbotsfield School			09/91-07/98	
Address		City	State	Zip
Clifton Gardens		Hillingdon	UK	UB10 0EX
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
07/20-Date	[redacted]			
From - To (MM/YY – MM/YY)				
09/11 - 07/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name	From - To (MM/YY – MM/YY)
Postmeds Inc D/B/A Truepill	07/22 - Date

Business Address	City	State	Zip
3121 Diablo Ave	Hayward	CA	94545

Phone	Title
855-910-8606	CEO

Description of Duties

Managing the overall resources and operations of company, making major corporate decisions, and acting as the main point of contact between the board of directors, employees, and the public.

Business Name	From - To (MM/YY – MM/YY)
Prophet Brand Strategy LLC	04/19 - 06/22

Business Address	City	State	Zip
150 Spear St Ste 1300	San Francisco	CA	94105

Phone	Title
(415) 518-5692	Senior Partner, Chief Strategy Officer

Description of Duties

Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name	From - To (MM/YY – MM/YY)
McKesson Corporation	07/09-12/18

Business Address	City	State	Zip
1 Post Street	San Francisco	CA	94104

Phone	Title
415-983-8300	Sr Vice President, Enterprise Strategy

Description of Duties

Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Business Name	From - To (MM/YY – MM/YY)

Business Address	City	State	Zip

Phone	Title

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/01/2007	06/01/2007	MN	Metropolitan Airport	Hennepin

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
225001	Metropolitan Airport

Reason/Charge
Petty Misdemeanor - Airport Ordinance Violation

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Self	N/A

Name of Business/Industry/Entity
N/A

Provide explanation below:

Petty Misdemeanor Airport Ordinance Violation with $300 fine, expunged 9/27/2021 by State Statute. Original documentation unavailable due to fire loss.

MN Statute 609.2 - "Petty misdemeanor" a petty offense which is prohibited by ordinance or statute, which does not constitute a crime and for which a sentence of a fine of not more than $300 may be imposed.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/5/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PAUL GREENAW

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/5/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

_____ _____

Original Signature **Date**

Subscribed and Sworn to before me this _____ day of _____.

_____

Notary Public Signature

CALIFORNIA
JURAT
ATTACHED

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 5 day of March, 2025, by Paul Greenall,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

M. DEMERS
COMM. # 2378608
SAN JOAQUIN COUNTY
NOTARY PUBLIC-CALIFORNIA
MY COMMISSION EXPIRES
OCTOBER 15, 2025

(Seal) Signature M. Demers

4622

THE UNIVERSITY OF THE STATE OF NEW YORK
EDUCATION DEPARTMENT

NEW YORK STATE BOARD OF PHARMACY

2022-25

SUPERVISING PHARMACIST
MICHELLE MEYER

THIS IS TO CERTIFY

TRUEPILL NY LLC
850 THIRD AVE.
STE 404
BROOKLYN, NY 11232

is duly recorded as a

REGISTERED PHARMACY

in conformity with the provisions of section 6808 of the Education Law

THIS CERTIFICATE IS EFFECTIVE ON THE FIRST DAY OF AUGUST, 2022.
THIS CERTIFICATE EXPIRES ON THE THIRTY-FIRST DAY OF JULY, 2025.

This certificate must be displayed conspicuously in the registered premises at all times. Authorization to operate a registered establishment is limited to the person and the premises indicated on the certificate. The regulations require the registrant to notify the Board of Pharmacy of any contemplated change in ownership, address or supervisor.

REGISTRATION NUMBER
037429

Dina Lynn
EXECUTIVE SECRETARY
STATE BOARD OF PHARMACY

TRUEPILL NY LLC

GENERAL INFO

ENFORCEMENT ACTIONS

Type	Pharmacy
Legal Name	TRUEPILL NY LLC
Trade Name	---
Street Address	850 THIRD AVE. STE 404 BROOKLYN NY 11232
Registration No	037429
Date First Registered	August 02, 2019
Registration Begins	August 01, 2022
Registered Through	July 31, 2025
Supervisor	060799 - MEYER MICHELLE LYNNE
Establishment Status	Active
Successor	NONE

April 3, 2025 01:48 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=037429&professionCode=020

TRUEPILL NY LLC

GENERAL INFO

ENFORCEMENT ACTIONS

Registration No: 037429

No Enforcement Actions Found

April 3, 2025 01:48 PM (ET)

https://eservices.nysed.gov/professions/verification-search?pharmacyRegistrationNumber=037429&professionCode=020

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-16-2022

TRUEPILL NY LLC
850 3RD AVE STE 404
BROOKLYN, NY 112321523

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	10-16-2022

TRUEPILL NY LLC
850 3RD AVE STE 404
BROOKLYN, NY 112321523

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THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

4CCCC

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

4

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a **$50.00 fee** with the application.) * Current license #: PH PH03813	☒ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☐ Nuclear ☐ Other:	☒ Retail/Community ☒ Dangerous drugs ☒ Controlled substances DEA #: [redacted] ☐ Non-sterile Compounding ☐ Sterile Compounding ☒ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Postmeds Inc. dba Truepill

Physical Address: 3121 Diablo Ave.

City: Hayward State: CA Zip: 94545

Mailing Address (if different from physical address): Same as above

City: _____ State: _____ Zip: _____

Telephone: 650-353-5495 Toll Free # (NAC 639.708, NRS 639.23286): 833·860·1057

Fax: _____ Contact Email: compliance@truepill.com

Website: https://www.truepill.com/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Lau

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 21371

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Lau	NV Pharmacist Registration #: 21371
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: DE

Parent Company (if any): Truepill, Inc.

Corporation/Organization Name: Postmeds, Inc.

Mailing Address: 3121 Diablo Ave.

City: Hayward State: CA Zip: 94545

Telephone: 650-353-5495 Email: compliance@truepill.com

Contact Person Name: Artiom Solovei

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO/President/Secretary (title) for Postmeds Inc. dba Truepill (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacist engaged in providing pharmacy services into Nevada is licensed by the Nevada State Board of Pharmacy (NRS 639.100).

Paul Greenall

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/5/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, Paul Greenall hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO/President/Secretary (title) for Postmeds Inc. dba Truepill (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

_____
Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this _____ day of _____, 20_____

_____
Notary Public

CALIFORNIA JURAT ATTACHED

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 5 day of March, 2025, by Paul Greenall,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

M. DEMERS
COMM. # 2372608
SAN JOAQUIN COUNTY
NOTARY PUBLIC-CALIFORNIA
MY COMMISSION EXPIRES
OCTOBER 15, 2025

(Seal) Signature

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Paul Greenall

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

3/5/25

Date

Board Use Only	Date Received: 3/12/25	Amount: [redacted]

POSTMEDS, INC. DBA TRUEPILL DISCIPLINARY SUMMARY

California resident license PHY 60061

California old resident license numbers: PHY 58585, PHY 56100

Illinois Board of Pharmacy

The Illinois Board issued the pharmacy (non-resident license #054.022249) a Consent Order of Discipline effective **August 8, 2024** resolving alleged violations of the Illinois Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Illinois State Board of Pharmacy.

Alaska Board of Pharmacy

The Alaska Board issued the pharmacy (non resident license #166601) a Consent Order of Discipline effective **February 15, 2024** resolving alleged violations of the Alaska Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $5,000 administrative fine to the Alaska State Board of Pharmacy.

Pennsylvania Board of Pharmacy

The Pennsylvania Board issued the pharmacy (non resident license #NP000931) a Consent Order of Discipline effective **November 7, 2023** resolving alleged violations of the Pennsylvania Pharmacy Practice Act stemming from disciplinary actions by proper licensing authority of another state. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,500 administrative fine to the Pennsylvania State Board of Pharmacy.

Alabama Board of Pharmacy

The Alabama Board issued the pharmacy (non resident license #114861) a Consent Order of Discipline dated **June 6, 2023**. The Pharmacy has resolved alleged violations of the Alabama Pharmacy Practice Act through entry of a Consent Order with the Alabama State Board of Pharmacy on June 8, 2023. As per the terms of the Consent Order, Pharmacy has agreed to pay a $3,000 administrative fine to the Alabama State Board of Pharmacy.

Kansas Board of Pharmacy

The Kansas Board of Pharmacy issued the pharmacy (non resident license #22-117859) an amended Summary Order effective **February 8, 2023**. The pharmacy did not report the change of ownership in a timely manner, and paid a fine. The Kansas Board of Pharmacy approved the change of ownership application, and issued license 22-117859 on May 20, 2022.

Louisiana Board of Pharmacy

The Louisiana Board of Pharmacy issued the pharmacy (non resident license #PHY.007761-NR) a Consent Order of Discipline dated **May 11, 2022**. The pharmacy did not report the change of ownership in a timely manner. The Louisiana Board of Pharmacy approved the change of ownership application with a new permit number PHY.008479-NR as a successor to permit number PHY.007761-NR.

North Carolina Board of Pharmacy

The North Carolina Board of Pharmacy issued the pharmacy a Consent Order of Discipline dated **March 8, 2022.** The pharmacy made inaccurate statements about its ownership and officers on its initial application in November 2017 and did not correct this until November 2021. The North Carolina Board of Pharmacy approved the change of ownership application with a new permit number 14900 as a successor to permit number 13413.

Maine Board of Pharmacy

The Maine Board of Pharmacy notified the pharmacy on **March 30, 2022** that its non-resident license (#MO40002429) was terminated effective November 6, 2019 for reporting deficiencies related to its ownership. The pharmacy submitted a change of ownership application for licensure, and has been issued a new pharmacy license (#MO40003167) on November 2, 2022.

California Board of Pharmacy

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a letter of admonishment CI 2019 84877 dated **January 23, 2020,** concluding an investigation that found the pharmacy shipped a prescription to the wrong patient and shipped two prescriptions with the wrong return address.

The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a modified citation and fine CI 2019 78633 dated **June 16, 2020,** with the fine amount of $0.00. In 2018, certain prescriptions were issued to the pharmacy by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician.

Also, The California Board of Pharmacy issued the pharmacy (former license #PHY 56100) a citation and fine order of abatement CI 2020 89223 dated **August 25, 2021,** with the fine amount of $5,000. The pharmacy was in violation when dangerous drugs were stored in temperatures exceeding the recommended storage temperatures Truepill did not consider the manufacturer's stability data for drugs which may have been adulterated by heat.

PENDING MATTERS

The following Actions are currently pending or threatened against the Company. The below Actions are currently subject to ongoing discussions, negotiations, and developments.

California Board of Pharmacy

California CI 2024 105307: On August 9, 2024, the California State Board of Pharmacy sent notice of a pending citation along with information on contesting or appealing. Truepill is in process of requesting an informal hearing to contest the citation.

South Carolina Board of Pharmacy

South Carolina 2022-49: On May 3, 2023, Postmeds agreed in principle to a proposed consent order with the South Carolina Board of Pharmacy to resolve inaccuracies in prior ownership information provided to the Board. The agreement would be categorized as a public reprimand but would not be a public document and would not be reported to the National Practitioner Data Bank. The negotiated fine was $30,000. The South Carolina Board of Pharmacy has not finalized this consent order or initiated formal disciplinary proceedings.

STATE OF ILLINOIS
DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
DIVISION OF PROFESSIONAL REGULATION

IN RE: The Application of		)	
POSTMEDS INC DBA TRUEPILL,		)	Case No. 2023-00783
054-app-4237687	APPLICANT.	)	

CONSENT ORDER

The Division of Professional Regulation of the Illinois Department of Financial and Professional Regulation ("Department"), by its attorney Nicholas V. Gallo, and Applicant POSTMEDS INC ("Applicant"), by its attorney Marc N. Wagner, hereby agree to the following:

STIPULATIONS

On or about August 22, 2022, Applicant submitted to the Department a change of ownership application (the "application") for Illinois licensed pharmacy license no. 054.022350.

On or about June 16, 2020, the California State Board of Pharmacy issued Applicant a disciplinary modified citation and fine ("California Citation and Fine") under case no. 2017-78633 for Applicant filling prescriptions issued to Applicant by prescribers that were either not yet licensed to prescribe in California or who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. The California Citation and Fine constitutes grounds for disciplinary action against Applicant on the authority of the Illinois Pharmacy Practice Act ("Act") at 225 ILCS 85/30(a)(8) as the grounds for action in the California Citation and Fine are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/4(g).

On or about August 25, 2021, the California State Board of Pharmacy issued Applicant a disciplinary citation and fine order of abatement ("California Citation and Fine Order of Abatement") under case no. 2020-89223 for, including but not limited to, Applicant storing dangerous drugs in temperatures exceeding the recommended storage temperatures. The California Citation and Fine Order of Abatement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8)

as the grounds for action in the California Citation and Fine Order of Abatement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 225 ILCS 85/3(d)(12).

On or about March 8, 2022, Applicant and the North Carolina Board of Pharmacy entered into a Consent Order of Discipline for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The North Carolina Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the North Carolina Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via the Act's Administrative Rules ("Rules") at 68 IAC 1330.780(a)(1).

On or about May 11, 2022, Applicant and the Louisiana Board of Pharmacy entered into a disciplinary Consent Agreement ("Louisiana Agreement") under case no. 21-0456 for, including but not limited to, Applicant failing to report change of ownership in a timely manner. The Louisiana Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Louisiana Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.780(a)(1).

On or about February 15, 2024, Applicant and the Board of Pharmacy for the State of Alaska entered into a disciplinary Consent Agreement ("Alaska Agreement") under case no. 2022-000434 for, including but not limited to, Applicant failing to disclose prior disciplines from another state within the required timeframe. The Alaska Agreement constitutes grounds for disciplinary action against Applicant on the authority of the Act at 225 ILCS 85/30(a)(8) as the grounds for action in the Alaska Agreement are the same or substantially equivalent to, including but not limited to 225 ILCS 85/30(a)(2) via 68 IAC 1330.40(c).

Pursuant to 68 IAC 1130.300(a) the following factor is considered in aggravation: (a) the presence of multiple adverse actions taken by other states against Applicant.

Pursuant to 68 IAC 1130.300(b) the following factors are considered in mitigation: (a) Applicant has cooperated with the Department in its investigation; and (b) Applicant has no prior disciplinary history with the Department.

At all times material to the matter set forth in this Consent Order, the Department had jurisdiction over the subject matter and the parties herein. Applicant has been advised of the right to have any allegation(s) reduced to written charges, to a hearing where the Department bears the burden to prove its allegations by clear and convincing evidence, to contest any charges brought and present mitigating evidence, and to administrative review of any order resulting from a hearing. Applicant knowingly waives each of these rights, as well as any right to administrative review of this Consent Order. Such waiver ceases if this Consent Order is rejected by the Secretary or the Secretary's designee or the Board. Applicant acknowledges that it has entered into this Consent Order freely and of Applicant's own will without threat or coercion by the Department or any person, and has not relied upon any representation made by or on behalf of the Department other than those specifically included herein. Applicant acknowledges that the Department attorney may be requested to communicate with the Board or the Secretary or the Secretary's designee in furtherance of the approval of this Consent Order. Applicant acknowledges that this Consent Order will be presented to the Secretary or the Secretary's designee. If this Consent Order is not approved, Applicant waives any right to raise any prejudice resulting from the Secretary or the Secretary's designee's consideration of this Consent Order. Applicant understands that this Consent Order is not effective unless and until it is adopted by the Secretary or the Secretary's designee. A copy of any original signature(s) affixed to this Consent Order shall be given the full force and effect of an original signature(s) affixed to this Consent Order.

Applicant and the Department agree, in order to resolve this case, that the Applicant be permitted to enter into a Consent Order with the Department providing for the terms and conditions contained herein which are fair and equitable in the circumstances and which are consistent with the best interests of the people of the State of Illinois.

CONDITIONS

Wherefore, the Department, by its attorney Nicholas V. Gallo, and Applicant, by its attorney Marc N. Wagner, agree:

A. Applicant's Illinois licensed pharmacy license no. 054.022350 shall be issued with a Reprimand.

B. Applicant shall pay a five-thousand-dollar ($5,000.00 USD) disciplinary fine within sixty (60) days of the effective date of this Consent Order.

C. All fines issued pursuant to this Consent Order are to be paid by personal check, company check, cashier's check, or personal money order. Said monetary instrument(s) shall be made payable to "Illinois Department of Financial and Professional Regulation," clearly indicate on the face of the monetary instrument the case number of 2023-00783 as well as license no. 054.022350, and be mailed to the following address:

Illinois Department of Financial and Professional Regulation
SSC – Accounts Receivable Section - Fines
P.O. Box 7086
Springfield, IL 62791-7086

D. Prior to the satisfaction of subsections B and C, above, Applicant shall not violate any state or federal law, rule, or regulation concerning controlled substances or the practice of wholesale drug distribution.

E. Applicant agrees that any violation of this Consent Order permits the Secretary or Secretary's designee to issue an Order forthwith mandating the automatic, indefinite, and immediate suspension of Applicant's license for a minimum period of twelve (12) months. This suspension shall not preclude the Department from taking any other disciplinary or other action it deems appropriate. In the event that Applicant(s) contest(s) in writing (by the filing with the Department within thirty (30) days the effective date of the suspension, a Petition complying with the Department's Rules of Practice in Administrative Hearings) the factual basis underlying said suspension, then Applicant(s) shall be afforded a hearing on the merits in accordance with the Department's Rules of Practice in Administrative Hearings, 68 Ill. Admin. Code 1110/et seq.

F. Applicant acknowledges that this Consent Order is a public disciplinary action and will be made available to the public. It will be reported to all applicable reporting databases.

G. This Consent Order is a final administrative order. This Consent Order shall become effective upon the signature of the Secretary or the Secretary's designee below unless otherwise stated herein.

Signatures on the following page

July 12, 2024
Date

Department Attorney – Nicholas V. Gallo

7/11/2024 | 1:39 PM PDT
Date

DocuSigned by:
Laura Peterson
Applicant – POSTMEDS INC
By: General Counsel, Truepill Inc. - Laura Peterson

7/11/2024 | 5:00 PM CDT
Date

DocuSigned by:
Lee Rosebush
Applicant's Attorney – Lee H. Rosebush

7/12/24
Date

Illinois State Board of Pharmacy Member

The foregoing Consent Order is approved in full.

DATED THIS 8th day of August, 2024.

ILLINOIS DEPARTMENT OF FINANCIAL AND PROFESSIONAL REGULATION
SECRETARY MARIO TRETO, JR.

Mario Treto, Jr. Secretary
Illinois Department of Financial and Professional Regulation

Case No. 2023-00783
Application No.: 054-app-4237687

STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. doing business as (Dba) TRUEPILL)
Respondent)
Case No. 2022-000434

CONSENT AGREEMENT

IT IS HEREBY AGREED by the Department of Commerce, Community and Economic Development, Division of Corporations, Business and Professional Licensing (Division) and TRUEPILL (Respondent) as follows:

1) **Licensure.** Respondent is currently registered as an Out-of-State Pharmacy in the State of Alaska and holds License number #166601. This license was first issued on 08/27/2020 and will lapse unless renewed by 06/30/2024.

2) **Admission/Jurisdiction**. Respondent admits and agrees that the Board of Pharmacy has jurisdiction over the subject matter of their license in Alaska and over this Consent Agreement.

3) **Admission/Facts.** Respondent admits to the following facts:

a) On September 25, 2017, Staff Pharmacist working for TRUEPILL, Curtis Ancar, received a disciplinary order from the California Board of Pharmacy for failure to exercise corresponding responsibility and excessive furnishing of controlled substances.

b) On January 24, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for failure to provide documentation substantiating completion of continuing education and knowingly making or signing a document with false information.

c) On December 16, 2019, the California Board of Pharmacy cited former Pharmacist-in-Charge and former owner of TRUEPILL, Mohammad Umar Afridi, for furnishing and dispensing dangerous drugs without a prescription and dispensing on order of nurse practitioner (or person of similar status).

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

d) On January 23, 2020, the California Board of Pharmacy issued a letter of admonishment to Respondent for shipping a prescription to the wrong address and shipping two prescriptions with the wrong return address.

e) On June 16, 2020, the California Board of Pharmacy issued a modified citation and fine CI 2019 78633 with the fine amount of $0.00 for receiving prescriptions by prescribers that were not licensed or have not entered into procedures with supervising physicians.

f) On April 08, 2022, Respondent submitted an Out-of-State Pharmacy Registration Ownership Change Application from license no. 166601 to license no. 193858 (now withdrawn) to the Division. Professional Fitness Question #1 was marked "Yes" indicating disciplinary actions had been issued against their license as listed above in sections a) through e).

g) Subsequent background investigation revealed Respondent failed to disclose the abovementioned 2017, 2019, and 2020 licensing actions from the California Board of Pharmacy on previous State of Alaska applications for TRUEPILL (formerly DBA Postmeds, Inc.) for licenses 137655 and 166601 dated June 08, 2018, August 06, 2020, and August 27, 2020.

h) Respondent admits that as a result of the above facts, grounds exist for possible suspension, revocation, or other disciplinary sanctions of their license pursuant to AS 08.01.075, AS 08.80.261(a)(1), AS 08.80.261(a)(6), AS 08.80.261(a)(9), AS 08.80.261(a)(11)(12)(14), 12 AAC 52.920(a)(13), and 52.920(a)(14)(c).

4) **Formal Hearing Process.** It is the intent of the parties to this Consent Agreement to provide for the compromise and settlement of all issues addressed in Paragraph 3 (above) that could be raised by an Accusation to revoke, suspend, or impose disciplinary sanctions against Respondent's license through a formal hearing process.

5) **Waiver of Rights.** Respondent understands they have the right to consult with an attorney of their own choosing and has a right to an administrative hearing on the facts in this case. Respondent understands and agrees that by signing this Consent Agreement, Respondent is waiving their rights to counsel and to a hearing. Further, Respondent understands and agrees that they are relieving the Division of any burden it has of proving the facts admitted above. Respondent further understands and agrees that by signing this Consent Agreement they are voluntarily and knowingly giving up their right to present oral and documentary evidence, to present rebuttal evidence, to cross-examine witnesses against Respondent, and to appeal the Board's decision to Superior Court.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

6) **Effect of Non-Acceptance of Consent Agreement.** Respondent and the Division agree that this Consent Agreement is subject to the approval of the Board. They agree that, if the Board rejects this Consent Agreement, it will be void, and an Accusation may be filed. If this Consent Agreement is rejected by the Board, it will not constitute a waiver of Respondent's right to a hearing on the matters alleged in an Accusation and the admissions contained herein will have no effect. Respondent agrees that, if the Board rejects this Consent Agreement, the Board may decide the matter after a hearing, and its consideration of this Consent Agreement shall not alone be grounds for claiming that the Board is biased against Respondent, that it cannot fairly decide the case, or that it has received ex parte communication.

7) **Consent Agreement, Decision, and Order.** Respondent agrees that the Board has the authority to enter into this Consent Agreement and to issue the following Decision and Order.

PROPOSED DECISION AND ORDER

IT IS HEREBY ORDERED that any license issued to Respondent by the Board shall be subject to the following terms and conditions:

A. Violation of Agreement

If Respondent fails to comply with any term or condition of this Consent Agreement, the Division may enforce this agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of this agreement. In addition, any suspended portion of the civil fine will be immediately due.

If Respondent's license is suspended under this paragraph, as provided above, they will be entitled to a hearing, on an expedited basis, regarding the issue of the suspension. If Respondent's license is suspended, they will continue to be responsible for all license requirements pursuant to AS 08.80.

Respondent shall maintain an active license for the entire duration of this Consent Agreement. If the Respondent lets their license lapse, and after receiving adequate notice from the Board fails to correct the problem, the failure to maintain active licensure will be considered a violation of this Consent Agreement.

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

B. Respondent Address

It is the responsibility of the Respondent to keep the Board's agent advised, in writing, at all times of their current mailing address, physical address, telephone number, current employment and any change in employment.

Failure to provide notice of any changes within 10 calendar days will constitute grounds for suspension of his or her license in accordance with paragraph 'B' above.

C. Compliance with Laws

Respondent shall obey all federal, state and local laws governing their license.

D. Authorization

Within 10 calendar days of a request by the Board agent, Respondent will sign all authorizations necessary for the release of information required by this Consent Agreement.

E. Good Faith

All parties agree to act in good faith in carrying out the stated intentions of this Consent Agreement.

F. Address of the Board

All required reports or other communication concerning compliance with this Consent Agreement shall be addressed to:

Attn: Holly Handley, Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
(907) 269-8124 Fax (907) 269-8195

G. Civil Fine

Respondent shall pay a fine of five thousand dollars ($5,000.00). This civil fine is due within 180 days of the adoption of this agreement and is payable to the "State of Alaska" in cash, certified check, or money order or via credit card.

All payments required by this Consent Agreement shall be addressed to:

Erika Prieksat, Chief Investigator
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567

//

//

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

IT IS HEREBY FURTHER ORDERED that this Decision and Order shall take effect immediately upon its adoption by the Board of Pharmacy and is a public record of the Board of Pharmacy and the State of Alaska. The State may provide a copy of it to any person or entity, professional licensing board, federal, state, or local government, or other entity making a relevant inquiry.

The action taken by the Board of Pharmacy in this Consent Agreement will be reported to the National Association of Boards of Pharmacy (NABP) and the National Practitioner Data Bank (NPDB) other entities as required by law.

DATED this 5 day of October 2023, at Anchorage, Alaska.

JULIE SANDE, COMMISSIONER

DocuSigned by:
By: Erika Prieksat
34F88CE5F1DF40C...

Erika Prieksat, Chief Investigator for
Sylvan Robb, Director
Division of Corporations, Business and
Professional Licensing

I, TRUEPILL, have read the Consent Agreement, understand it, and agree to be bound by its terms and conditions.

Joseph Alexander Cipriani

DATED: 20th November 2023

SUBSCRIBED AND SWORN TO before me this 20th day of November, 2023, at Newport News, Virginia, Virginia.

(city) (state)

SEAL
Winston Ndow
REGISTRATION NUMBER
8040550
COMMISSION EXPIRES
February 28, 2027

Winston Ndow

Notary Public in and for Virginia.
(state)

Winston Ndow
Notary Printed Name

Notarized online using audio-video communication

My commission expires: 02/28/2027

State of Alaska
Department of Commerce, Community and Economic Development
Division of Corporations, Business and Professional Licensing
550 West 7th Avenue, Suite 1500
Anchorage, Alaska 99501-3567
Telephone 907-269-8160 Fax 907-269-8195

State of Alaska
Department of Commerce, Community and Economic Development
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STATE OF ALASKA
DEPARTMENT OF COMMERCE, COMMUNITY AND ECONOMIC DEVELOPMENT
DIVISION OF CORPORATIONS, BUSINESS AND PROFESSIONAL LICENSING
BEFORE THE BOARD OF PHARMACY

In the Matter of:)
)
Postmeds, Inc. dba TRUEPILL)
)
Respondent)
Case No. 2022-000434

ORDER

The Board of Pharmacy for the State of Alaska, having examined the Consent Agreement and Proposed Decision and Order, Case No. 2022-000434, Respondent, license number #166601, adopts the Consent Agreement and Decision and Order in this matter.

This Consent Agreement takes effect immediately upon signature of this Order in accordance with the approval of the Board of Pharmacy.

The Division may enforce the Consent Agreement by immediately suspending Respondent's license, without an additional order from the Board or without a prior hearing, for a violation of the Consent Agreement.

DATED this 15th day of February, 2024, at Anchorage, Alaska.

Board of Pharmacy

By: Ashley Schaber
Chairperson

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**	
vs.	**Case Nos.** **21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**	

NOTICE

Formal disciplinary action has been filed against you. You may lose your license, certificate, registration or permit to practice your profession or occupation. You may be subject to civil penalties of up to $10,000 for each violation, and the imposition of costs of investigation.

If you wish to defend against the charges in the attached order to show cause or to present evidence to mitigate any penalty that may be imposed, the procedures for doing so are explained in the Order to Show Cause.

You have the right to retain an attorney. Although you may represent yourself without an attorney, you are advised to seek the help of an attorney. You also have the right to have an interpreter provided should you request one.

All proceedings are conducted under the Administrative Agency Law and the General Rules of Administrative Practice and Procedures.

You are directed to respond to the charges by filing a written answer within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. IF YOU DO NOT FILE AN ANSWER, DISCIPLINARY ACTION MAY BE TAKEN AGAINST YOU WITHOUT A HEARING. Any answer submitted in this matter must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

You must also send or email a separate copy of your answer and any other pleadings or documents related to this case to the prosecuting attorney named in the Order to Show Cause.

Prothonotary Filed On:
May 10 2023 02:10 PM
Department of State

COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

ORDER TO SHOW CAUSE

AND NOW, this 10th day of May 2023, **PostMeds Inc** ("Respondent") is hereby ORDERED TO SHOW CAUSE why the Pennsylvania State Board of Pharmacy ("Pennsylvania Board"), upon consideration of the Factual Allegations and the applicable law, should not suspend, revoke or otherwise restrict Respondent's registration, impose a civil penalty, or impose the costs of investigation. This action is brought pursuant to the Pharmacy Act, act of September 27, 1961, P.L. 1700, ("Act"), *as amended*, 63 P.S. §§ 390-1 to 390-13; and 63 Pa.C.S. Chapter 31 ("Chapter 31"); and will be conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704, Chapter 31, and the General Rules of Administrative Practice and Procedure ("GRAPP"), 1 Pa. Code §§ 31.1-35.251.

IT IS FURTHER ORDERED that Respondent file an Answer to this Order to Show Cause in writing within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, in accordance with Rule 35.37 of GRAPP, 1 Pa. Code § 35.37, *as amended.*

FACTUAL ALLEGATIONS

1. Respondent holds the following registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania: registration no. NP000931.

DOS Prothonotary.
May 10 2023

2. Respondent's registration was originally issued on July 3, 2017, and it is currently set to expire on August 31, 2023.

3. Absent further action by the Pennsylvania Board, the Respondent's registration may be renewed or reactivated upon the filing of the appropriate documentation and payment of the necessary fees.

4. At all times pertinent to the Factual Allegations, Respondent held a registration to practice as a nonresident pharmacy in the Commonwealth of Pennsylvania.

5. Respondent's last known address on file with the Board is: 3131 Diablo Ave, Hayward, CA 94545.

COUNT ONE

6. Paragraphs 1 through 5 are incorporated by reference.

7. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of North Carolina.

8. On or about March 8, 2022, the State of North Carlina Board of Pharmacy ("North Carolina Board"), by way of Consent Order of Discipline, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of North Carolina because Respondent failed to report a restructuring of ownership to the North Carolina Board.

9. In the March 8, 2022 Consent Order of Discipline, the North Carolina Board voided Respondent's permit from the time it was issued until the time the restructuring began and approved Respondent's change of ownership application as a successor permit.

10. A true and correct copy of the North Carolina Board's March 8, 2022 Consent Order of Discipline is attached as **EXHIBIT A** and is incorporated by reference.

DOS Prothonotary
May 10 2023

11. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Louisiana.

12. On or about May 11, 2022, the State of Louisiana Board of Pharmacy ("Louisiana Board"), by way of Consent Agreement at Louisiana Board Case Number 21-0456, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Louisiana because Respondent failed to report a restructuring of ownership to the Louisiana Board.

13. In the May 11, 2022 Consent Agreement, the Louisiana Board imposed a ten thousand dollar ($10,000.00) fine, two hundred fifty dollars ($250.00) in administrative costs, and three hundred twenty-four dollars and forty-eight cents ($324.48) in investigative costs.

14. A true and correct copy of the Louisiana Board's May 11, 2022 Consent Agreement, Louisiana Board Case Number 21-0456, is attached as **EXHIBIT B** and is incorporated by reference.

15. At all relevant and material times, Respondent was authorized to practice as a nonresident pharmacy in the State of Kansas.

16. On or about January 20, 2023, the State of Kansas Board of Pharmacy ("Kansas Board"), by way of Amended Summary Order at Kansas Board Case Number 22-183, found Respondent to be in violation of the laws, rules, code and/or regulations of the State of Kansas because Respondent failed to report a restructuring of ownership to the Kansas Board and failed to report disciplinary actions from North Carolina, Alabama, and California which also pertained to a failure to report a restructuring of ownership to each respective Board.

17. In the January 20, 2023 Amended Summary Order, the Kansas Board imposed a three thousand five hundred dollar ($3,500.00) fine.

DDS Prothonotary
May 10 2023

18. A true and correct copy of the Kansas Board's January 20, 2023 Amended Summary Order, Kansas Board Case Number 22-183, is attached as **EXHIBIT C** and is incorporated by reference.

19. Based upon the foregoing Factual Allegations, the Pennsylvania Board is authorized to suspend or revoke, or otherwise restrict Respondent's nonresident pharmacy registration under section 4.1(e) of the Act, 63 P.S. §§ 390-4.1(e); or impose a civil penalty under section 63 Pa.C.S. § 3108(b)(4), and/or impose the costs of investigation under 63 Pa.C.S. § 3108(b)(5), because Respondent violated the Act at section 4.1(g), 63 P.S. § 390-4.1(g), in that Respondent had a permit to conduct a pharmacy suspended or revoked or the nonresident pharmacy was otherwise disciplined by the proper licensing authority of another state.

PENALTIES

If the Pennsylvania Board finds that the Factual Allegations are true and correct, and determines that it has the authority to suspend or revoke the Respondent's registration, the Pennsylvania Board may, in its discretion, impose one or more of the following penalties:

- The revocation, suspension or other restriction of any licenses, certifications, registrations, permits or other authorizations to practice a profession held by Respondent in the Commonwealth of Pennsylvania, or the imposition of any other disciplinary or corrective action that the Act authorizes the Board to impose.
- The imposition of a civil penalty of up to ten thousand dollars ($10,000.00) for each and every violation of the Act. Where criminal proceedings are a basis for a violation of the Act, each count for which the Respondent was convicted may be considered a separate violation of the Act.

DOS Prothonotary.
May 10 2023

PROCEDURES

All proceedings are conducted in accordance with the Administrative Agency Law, 2 Pa. C.S. §§ 501-508, 701-704; Chapter 31; and the General Rules of Administrative Practice and Procedure, 1 Pa. Code §§ 31.1-35.251. **RESPONDENT IS HEREBY ORDERED TO FILE A WRITTEN ANSWER TO THIS ORDER TO SHOW CAUSE WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE.** The Answer shall specifically admit or deny each of the Factual Allegations made herein, and shall set forth the facts and state concisely the matter of law upon which Respondent relies. If Respondent fails to file an Answer within the time allowed herein, the Factual Allegations may be deemed admitted, and the Pennsylvania Board will issue an Order which may impose penalties as set forth above.

If Respondent desires a formal administrative hearing, at which Respondent may defend against the allegations in the Order to Show Cause or to present evidence in mitigation of any penalty which may be imposed upon Respondent or any of Respondent's licenses, certifications, registrations, permits or other authorizations to practice a profession, a written request for hearing must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause. **IF RESPONDENT FAILS TO FILE A WRITTEN REQUEST FOR HEARING WITHIN THIRTY (30) DAYS OF THE DATE ON THE MOST RECENT CERTIFICATE OF SERVICE ASSOCIATED WITH THIS ORDER TO SHOW CAUSE, RESPONDENT WILL BE DEEMED TO HAVE WAIVED HIS OR HER RIGHT TO A HEARING AND FINAL JUDGMENT MAY BE ENTERED WITHOUT A HEARING.**

If a hearing is scheduled, Respondent will be notified of the specific time and place of the hearing. The hearing will be held before the Board or its duly designated Presiding Officer, in

DOS Prothonotary
May 10 2023

accordance with Section 35.185 of GRAPP, 1 Pa. Code § 35.185. Respondent may appear, with or without counsel, offer testimony or other evidence on his or her behalf, and confront and cross-examine the Commonwealth's witnesses.

Answers, requests for hearings, preliminary motions, protests, petitions to intervene, or any other pleading must be filed with the Prothonotary for the Department of State via one of the following methods:

By Mail:
Prothonotary
Department of State
2601 N Third St
PO Box 2649
Harrisburg, PA 17105-2649

By Facsimile:
(717)772-1892

By E-mail:
ra-prothonotary@pa.gov

Also, you must send or e-mail a separate copy of any documents submitted in this matter to the prosecuting attorney named below at:

By Mail:
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521

By E-mail:
gmasser@pa.gov

DOS Prothonotary
May 10 2023

Notices and petitions to intervene must be filed within thirty (30) days of the date on the most recent Certificate of Service associated with this Order to Show Cause, unless in extraordinary circumstances for good cause shown, a later filing is authorized by the agency.

BY ORDER:
DEPARTMENT OF STATE

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P.O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DATE: 05.10.2023

DOS Prothonotary
May 10 2023

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

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Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

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PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

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2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

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transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

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Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

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STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date:_____

_____
Notary Public

_____

My commission expires:_____

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LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

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La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

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Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.**, understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

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SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

Harry J. Philips Jr.

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

Carlos Finalet

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R McKay

Marty R. McKay
Hearing Officer for the Board

DOS Prothonotary:
May 10 2023

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

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Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

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7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

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that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

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registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

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May 10 2023

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS. 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

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CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave.
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

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COMMONWEALTH OF PENNSYLVANIA
DEPARTMENT OF STATE
BEFORE THE STATE BOARD OF PHARMACY

Commonwealth of Pennsylvania **Bureau of Professional and** **Occupational Affairs**		
vs.	**Case Nos.**	**21-54-004050** **22-54-008273**
PostMeds Inc **Respondent**		

CERTIFICATE OF SERVICE

I, Glenn P. Masser, hereby certify that I have this 11th day of May 2023 caused a true and correct copy of the foregoing Notice and Order to Show Cause to be served upon all parties of record in this proceeding in accordance with the requirements of Rule 33.31 of the General Rules of Administrative Practice and Procedure, 1 Pa. Code § 33.31 (relating to service by the agency).

CERTIFIED MAIL, ELECTRONIC RETURN RECEIPT REQUESTED AND FIRST-CLASS MAIL, POSTAGE PREPAID:

PostMeds Inc
3121 Diablo Ave
Hayward, CA 94545
9171.9690.0935.0253.8568.95

/s/ Glenn P. Masser
Glenn P. Masser
Prosecuting Attorney
Commonwealth of Pennsylvania
Department of State
P. O. Box 69521
Harrisburg, PA 17106-9521
(717) 783-7200

DOS Prothonotary
May 10 2023

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IN THE MATTER OF:	)	
	)	**BEFORE THE ALABAMA STATE BOARD OF PHARMACY**
POSTMEDS INC. dba TRUEPILL and/or TRUEPILL f/k/a POSTMEDS INC.	)	
	)	
Non-Resident Pharmacy Permit Number: 114861	)	**CASE NO: 22-L-0114**

CONSENT ORDER

THIS MATTER comes before the Alabama State Board of Pharmacy (hereinafter referred to as the "Board") on a complaint against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** which resulted in the filing of a Statement of Charges and Notice of Hearing ("Statement") alleging violations of the Alabama Pharmacy Practice Act as are more particularly set out in the Statement which is attached hereto as **Exhibit "A."**

Prior to a hearing in this cause, and pursuant to Code of Alabama (1975), § 41-22-12(f), the matters at issue were resolved informally by the parties and the parties negotiated a Consent Order, the terms of which are as follows:

1. The Board finds that **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** has violated the provisions of law set out in the Statement.

2. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** shall pay an administrative fine in the amount of Three Thousand Dollars ($3,000.00) within thirty (30) days of the effective date of this consent order that being the day the same is signed on behalf of the Board. This payment shall not be subject to discharge in bankruptcy nor shall **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** attempt to discharge the same. Payments shall be made payable to Alabama State Board of Pharmacy and mailed to 111 Village Street, Birmingham, Alabama 35242.

3. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** expressly waives its rights pursuant to the Alabama Pharmacy Practice Act, the Alabama

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Administrative Procedure Act and the Alabama Uniform Controlled Substances Act, including but not limited to the Code of Alabama (1975), §34-23-34 and §34-23-92(12), Code of Alabama (1975), §41-22-12 and §40-22-20 and Code of Alabama (1975), §20-2-50 et seq., and including but not limited to the opportunity for a hearing before the Board in connection with any charges against it and any judicial review. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** further waives any objection to the attorney for the Board preparing, drafting, or making this Order, including the waiver of any objection or right pursuant to Code of Alabama (1975), §41-22-18.

4. By execution of this Consent Order, **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** hereby releases the Board, its members, agents, representatives, servants, and employees from any and all liability, claims, damages, fees, or expenses arising out of or made in connection with the matters relating to this Consent Order and Statement.

5. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that any future violation of the Alabama Pharmacy Practice Act, the laws that regulate the sale and/or dispensing of prescription or legend drugs and/or narcotics or any Rules and regulations of the Alabama State Board of Pharmacy or the pharmacy law or rules of the Board of Pharmacy of another state or any other applicable laws may, upon proof and hearing thereof, result in further disciplinary sanctions against **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.'s** permit, including, but not limited to revocation.

6. **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.** acknowledges and agrees that it has read this Consent Order and that it fully understands the terms, conditions, and contents of the same. **PostMeds Inc. dba Truepill and/or**

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Truepill f/k/a PostMeds Inc. acknowledges and agrees that it voluntarily and of its own free will accepts the terms and conditions set out in this Consent Order and agrees that it had the right to seek advice of counsel before executing this Consent Order.

DONE this the 6th of June, 2023.

PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.

BY: Donny Simkin
Donny Simkin

ITS: General Counsel, Truepill, Inc.

James Hoover
Counsel for **PostMeds Inc. dba Truepill and/or Truepill f/k/a PostMeds Inc.**

DONE this the 8th of JUNE, 2023.

ALABAMA STATE BOARD OF PHARMACY

By:
Robert M. Colburn, Jr., R. Ph., President

Jennifer Muro Neumann,
Attorney for the Alabama State Board of Pharmacy

OF COUNSEL:
Jennifer Muro Neumann, PC
Post Office Box 381082
Birmingham, AL 35238
(205) 451-3092

BEFORE THE KANSAS BOARD OF PHARMACY

In the Matter of	)	
	)	Case No. 22-183
PostMeds, Inc dba Truepill	)	
	)	
Registration No. 22-117859	)	

AMENDED SUMMARY ORDER

NOW on this 20th day of January, 2023, comes before the Kansas Board of Pharmacy (the "Board"), through its Executive Director, the matter of PostMeds, Inc dba Truepill ("Respondent").

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board's Executive Secretary enters this Amended Summary Order in the above-captioned matter. After reviewing the investigation materials and being otherwise duly advised in the premises, makes the following findings, conclusions and order:

FINDINGS OF FACT

1. The Board has previously issued Respondent Registration No. 22-104228 which entitled Respondent to operate as a non-resident pharmacy in the State of Kansas.

2. On November 6, 2019, the ownership of Respondent's non-resident pharmacy changed.

3. On May 22, 2020, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 3, 2020 with an expiration date of June 30, 2021. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?"

Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

4. On June 1, 2021, the Board received a renewal application for Respondent's Registration No. 22-104228, which was approved on June 21, 2021 with an expiration date of June 30, 2022. Respondent answered "No" to the question: "Has any license or registration, currently or previously held by the applicant or the PIC been surrendered to, denied, disciplined, censured, suspended, limited, placed on probation, or revoked by any state of federal government?" Respondent certified the information submitted was true, correct, and complete to the best of Respondent's knowledge.

5. Due to staffing challenges, personnel turnover and administrative oversight resulting from its early, rapid growth and restructuring and the corresponding COVID-19 pandemic, Respondent mistakenly failed to report the 2019 ownership change and related disclosures to the Board in its May 22, 2020 and June 1, 2021 renewal applications.

6. On April 18, 2022, the Board received notification from Respondent of an ownership change and several past disciplinary actions not previously reported to the Board including: North Carolina Board of Pharmacy Consent Order of Discipline dated March 8, 2022; California State Board of Pharmacy Letter of Admonishment dated January 23, 2020; California State Board of Pharmacy Citation and Fine dated June 16, 2020; California State Board of Pharmacy Citation and Fine Order of Abatement dated August 25, 2021; Alabama State Board of Pharmacy Final Order dated October 25, 2021; California State Board of Pharmacy Citation and Fine dated January 24, 2019; and California State Board of Pharmacy Citation dated December 16, 2019.

7. On April 28, 2022, the Board received from Respondent a Form BA-22 Non-Resident Pharmacy Registration Application ("Respondent's Application"), notifying of the change in ownership effective November 6, 2019, and applying for a new non-resident pharmacy registration under the new ownership.

8. On May 20, 2022, the Board approved Respondent's Application and issued Respondent the new Non-Resident Pharmacy Registration No. of 22-117859 ("Respondent's Registration") under their new ownership.

9. Prior to receiving the ownership change application, registrant provided a letter notifying of the late ownership change, as well as unreported discipline. Ownership change application completed indicating discipline had occurred and providing details of discipline (5 occurrences).

10. In mitigation, Respondent states that it has invested in additional staff, engaged internal and external legal counsel and implemented training efforts to prevent any such reporting oversights in the future.

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed $5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against a registration on any ground that would authorize the board to take action against the registration of a pharmacy under K.S.A. 65-1627, and amendments thereto.

3. Pursuant to K.S.A. 65-1627(e)(1), the Board may take action against the registration of a pharmacy upon a finding that such pharmacy has been operated in such manner

that violations of the provisions of the pharmacy act of the state of Kansas or of the rules and regulations of the board have occurred in connection therewith.

4. Pursuant to K.S.A. 65-1627(e)(4), the Board may take action against the registration of a pharmacy upon a finding that the registrant has had a registration revoked, suspended or limited, has been censured or has had other disciplinary action taken, or an application for registration denied, by the proper registering authority of another state, territory, District of Columbia or other country.

5. Pursuant to K.S.A. 65-1657, no nonresident pharmacy shall ship, mail, or deliver, in any manner, prescription drugs to a patient in this state unless registered with the Board as a nonresident pharmacy.

6. Pursuant to K.S.A. 65-1645(f), registrations shall not be transferable.

7. Pursuant to K.A.R. 68-2-9, each registrant shall notify the executive secretary of the Board in writing of any change in majority ownership of the operation for which the registration was issued within five days after the date the change in ownership becomes effective.

8. Pursuant to K.A.R. 68-2-23, each pharmacy owner shall notify the board in writing within 30 days of any denial, limitation, suspension, revocation, voluntary surrender, or other disciplinary action taken by the state of Kansas or another jurisdiction against the pharmacy or the pharmacy owner or any application, license, registration, or permit held by the pharmacy owner.

9. Respondent's registered facility changed ownership on November 6, 2019 but Respondent did not provide notification or file a new application with the Board until April 18 and 28, 2022, respectively.

10. Respondent's failure to submit the complete change of ownership to the Board until April 2022 is a violation pursuant to K.A.R. 68-2-9 and an unlawful transfer of the previous

registration to the new ownership. Respondent's actions are a violation pursuant to K.S.A. 65-1657 and K.S.A. 65-1627(e)(1), and a basis to take action against Respondent's Registration.

11. Respondent failed to notify the Board of the six disciplinary actions by North Carolina, California, and Alabama until April 18, 2022, nearly one to two years after they were effective, is a violation of K.A.R. 68-2-23 and a basis to take action against Respondent's Registration pursuant to K.S.A. 65-1627(e)(1) and (e)(4).

ORDER

Taking into account the mitigating and corrective actions of Respondent, the Board finds and concludes that Respondent's conduct, as described above, violates the Act and such conduct warrants the imposition of a fine pursuant to K.S.A. 65-1658, in the amount of $3,500.00. Respondent has 30 days from the date of this order to pay the fine.

NOTICES

The Respondent is hereby notified as follows:

1. The Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231 within fifteen (15) days after service of this order.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within fifteen (15) days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to said statute. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

1/20/2023
Date

Alex Blasi
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 24th day of January, 2023, deposit in business mail a copy of the foregoing Amended Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

PostMeds, Inc dba Truepill
3121 Diablo Ave
Hayward, CA 94545

and via email to:

Christopher C. Tillery
Seigfreid Bingham, P.C.
ctillery@sb-kc.com
Attorney for Respondent

Brenda L. Head
Disciplinary Counsel for the Kansas Board of Pharmacy

LOUISIANA BOARD OF PHARMACY

BATON ROUGE, LOUISIANA

IN THE MATTER OF: **CONSENT ORDER**

POSTMEDS, INC.

LOUISIANA PHARMACY PERMIT NO. 7761 **Case No. 21-0456**

****

CONSENT AGREEMENT

WHEREAS, an informal conference was conducted by the Violations Committee of the Louisiana Board of Pharmacy (hereinafter referred to as the "Board") on March 16, 2022 at the Board office, 3388 Brentwood Drive, Baton Rouge, LA 70809, in the matter of POSTMEDS, INC. (hereinafter referred to as "Respondent"), holding Louisiana Pharmacy Permit No. 7761, 3121 Diablo Ave., Hayward, CA 94545-2701, with attorney Skip Philips and Postmeds Corporate Counsel Donnie Simkin appearing on behalf of Respondent.

WHEREAS, WHEREAS, on August 27, 2018, the Louisiana Board of Pharmacy issued a non-resident pharmacy permit, PHY.007761-NR, to Postmeds Inc. At that time, Postmeds Inc. was 31.5% owned by Mohammad Umar Afridi, 31.5% owned by Siddharth Viswanathan, 16.5% owned by Initialized III L.P., and 20.5% owned by others with no individual owner holding more than 4%. On December 17, 2021 the Board received an "Application for New Louisiana Pharmacy Permit for Nonresident Pharmacy" from Postmeds, Inc. d/b/a Truepill. Accompanying correspondence and organization chart detailed a 100% change in the ownership structure of Postmeds Inc., effective November 6, 2019. Postmeds Inc. went from being owned 31.5% by Mohammad Umar Afridi, 31.5% by Siddharth Viswanathan, 16.5% by Initialized III L.P., and 20.5% by others with no individual owner holding more than 4%, to being owned 100% by Truepill, Inc.

WHEREAS, the Board alleges that such actions constitute violations of the following:

La. R.S. 37:1241 (A)(1): Practiced or assisted in the practice of pharmacy, or knowingly permitted or has permitted anyone in his employ or under his supervision to practice or assist in the practice of pharmacy, in violation of the provisions of this Chapter and any rules and regulations promulgated thereto in accordance with the Administrative Procedure Act.

La. R.S. 37:1221(B). No out-of-state pharmacy providing pharmacy services to residents of this state shall open, establish, operate, or maintain a pharmacy, located out-of-state, unless the pharmacy is issued a permit by the board.

La. R.S. 37:1222(A). A person applying for a permit to open, establish, operate, or maintain a pharmacy, within or outside of this state, shall complete an application in such form and contain such data as the board may require, and complete such other requirements as deemed necessary by the board, including but not limited to designation and identification of a pharmacist-in-charge.

La. R.S. 37:1222(E). A permit to operate a pharmacy shall not be transferable.

La. R.S. 37:1232(A). A pharmacy located outside this state which does business in this state within the meaning of this Chapter, shall hold a current pharmacy permit as provided in this Chapter. The pharmacy shall be designated a "nonresident pharmacy" and the permit shall be designated a "nonresident pharmacy permit."

LAC, Title 46: LIII §1101(A). Individuals, partnerships, corporations, limited liability companies, or associations desiring to operate a pharmacy in Louisiana, or outside the state where prescriptions drugs/devices are dispensed and delivered to Louisiana residents, shall execute an application for a pharmacy permit for their particular classification of pharmacy.

LAC, Title 46: LIII §1135(A)(1)(e). The holder of a pharmacy permit shall notify the board, in writing, prior to the transfer of ownership, in order for the board to complete an inspection of the pharmacy premises. A change of ownership of a pharmacy is evident under the following conditions: a 50 percent, or more, change in ownership of a corporation, limited liability company, or association since the issuance of the original permit or the last renewal application.

LAC, Title 46: LIII §1135(A)(2). The new owner(s) of the pharmacy shall submit a properly completed pharmacy permit application, with appropriate fee, to the board.

LAC, Title 46: LIII §1135(A)(4). Pharmacy permits are not transferable from the original holder(s) of the permit to the new owner(s).

LAC, Title 46: LIII §2305(A). The out-of-state pharmacy shall apply for a permit and annual permit renewals on forms provided by the board.

LAC, Title 46: LIII §2307(C). Authority and Accountability. The designated pharmacist-in-charge of the pharmacy and the pharmacy owner(s), or partners, or corporate officer(s) of the permit holder, where applicable, shall be responsible for the complete supervision, management, and compliance with all federal and state pharmacy laws and regulations pertaining to the practice of pharmacy of the entire prescription department. This responsibility necessarily includes accountability for any violation involving federal or state laws or regulations occurring within the prescription department supervised by a pharmacist-in-charge.

To facilitate the submission of this Consent Agreement, Respondent does not contest the allegations and agrees that there is sufficient evidence upon which to predicate a finding of those violations.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

Respondent further understands that this Consent Agreement shall constitute a Public Record, pursuant to La. R.S. 44:1 et seq., and is considered disciplinary action by the Board.

In order to avoid further administrative and judicial proceedings, Respondent hereby consents to accept and abide by the following order of the Board:

POSTMEDS, INC., holder of Louisiana Pharmacy Permit No. 7761, is ordered to pay a fine of $10,000.00 and to reimburse the Board $250.00 for administrative costs, and $324.48 for investigative costs with total payment due the Board of $10,574.80, due by *certified check or money order* to be paid simultaneously with the execution of this Consent Agreement by Respondent.

By signing this Consent Agreement, Respondent agrees that the Board has jurisdiction in this matter, waives all rights to informal conference, to Notice of Hearing, to a formal Administrative Hearing and to judicial review of this Consent Agreement. Moreover, at no time shall Respondent request the expungement, rescission or removal of this Consent Agreement.

By signing this Consent Agreement, Respondent agrees that any failure to comply with the terms of this Agreement is a basis for discipline by the Board.

Both Respondent and the Board stipulate that this Consent Order shall not become effective and shall not become binding on the Board unless and until approved by the Board at formal meeting. However, Respondent agrees that this Consent Order shall be effective and binding upon Respondent without recourse upon its authorized representative signing said Order.

Respondent agrees to authorize the Board to report this action to the National Practitioner Data Bank – Healthcare Integrity and Protection Data Bank (NPDB-HIPDB) as required by law.

I, Matt Davis-Ratner, authorized to act on behalf of and acting on behalf of **POSTMEDS, INC.,** understand that this Consent Agreement is effective as a Board Order upon affirmative vote by the Board at formal hearing. It is also understood that, should the Board not approve this Consent Agreement, the agreement therein does not preclude the Louisiana Board of Pharmacy from requiring a formal hearing of this case.

It is further understood that, should this Consent Agreement not be accepted by the Board, the presentation to and consideration by the Board of this Agreement, including presented documentary evidence and information, shall not unfairly or illegally prejudice or preclude the Board or any of its members from further participation in hearings or resolution of these proceedings.

[Remainder of page intentionally left blank; signature page to follow.]

SIGNED, AGREED TO AND ENTERED ON THIS 6th DAY OF April, 2022.

POSTMEDS, INC.
Louisiana Pharmacy Permit No. 7761

Matt Davis-Ratner

BY: Matt Davis-Ratner
Authorized Representative

HARRY J. "SKIP" PHILIPS
Taylor Porter
450 Laurel St, 8th Floor
Baton Rouge, LA 70801
Attorney for Respondent

APPROVED FOR SUBMISSION TO THE LOUISIANA BOARD OF PHARMACY:

CARLOS M. FINALET, III
General Counsel, Louisiana Board of Pharmacy

ACCEPTANCE OF THE CONSENT AGREEMENT BY THE LOUISIANA BOARD OF PHARMACY:

By a majority vote of the Board members voting in favor of the foregoing Consent Agreement at the Board meeting on May 11, **2022**, the Board hereby adopts said Agreement as a Final Order of the Board.

FOR THE BOARD:

Marty R. McKay
Hearing Officer for the Board

STATE OF NORTH CAROLINA
NORTH CAROLINA BOARD OF PHARMACY

IN THE MATTER OF	)	
	)	
POSTMEDS, INC. d/b/a Truepill,	)	**CONSENT ORDER**
	)	**OF DISCIPLINE**
Permit No. 13413 and Its Successor Permit(s).	)	

THIS MATTER came to be considered before a member of the North Carolina Board of Pharmacy (hereinafter, the "Board") pursuant to 21 N.C.A.C. 46 .2008. The Conference was scheduled for Thursday, February 24, 2022, and, after appropriate notice, was heard on that day by Board member Wallace E. Nelson. Respondent PostMeds, Inc. was informed of its right to be present at the pre-hearing conference and declined. The Board's General Counsel, Clinton R. Pinyan, represented the Board.

Respondent has agreed to waive a formal hearing in the above-referenced matter. It stipulates and agrees to the findings of fact and conclusions of law recited herein and to the order of discipline imposed. By its consent, Respondent also stipulates that it waives its right to appeal this Consent Order or challenge in any way the sufficiency of the findings of this Order as a basis for the action taken. Based upon the consent of the parties, the Board hereby enters the following:

FINDINGS OF FACT

1. On November 20, 2017, the Board issued Permit No. 13413 to Respondent PostMeds, Inc. d/b/a Truepill (Permit No. 13413) ("PostMeds").

2. On PostMeds' initial permit application, its then-pharmacist manager, Mohammad Umar Afridi, submitted an inaccurate statement that he was the sole owner and officer of PostMeds. In fact, PostMeds now acknowledges that Afridi and Siddharth

Viswanathan each owned 47 percent of PostMeds on November 20, 2017, with others owning six percent, and that Viswanathan was also an officer of PostMeds.

3. Viswanathan and the minority owners' interests would not have raised questions about the permit application in this particular case. If PostMeds had disclosed the true ownership and officers of PostMeds, the Board still would have granted PostMeds a permit. However, it was an inaccurate statement that Afridi, as the person who submitted the application, knew was inaccurate. That statement prevented the Board from vetting Viswanathan as the owner of the pharmacy. Because of the inaccuracy of the representations, the initial permit was void ab initio.

4. In November 2019, PostMeds went through a corporate restructuring. During that restructuring, Truepill, Inc. was created as a holding company for PostMeds. At that time, Truepill, Inc. became the sole owner of PostMeds. Afridi, Viswanathan and the other former direct owners of PostMeds became indirect owners with the same ownership interests in the holding company, Truepill, Inc., that they had before the transfer of ownership.

5. This restructuring required PostMeds to submit a transfer of ownership application and have that application granted before the restructuring closed. PostMeds failed to do this. Therefore, even if the initial permit had been valid (which it was not), it would have become invalid upon the corporate restructuring.

6. Insertion of a new holding company between the ultimate owners and PostMeds would not have raised questions about the permit application in this particular case. The ownership interests of the ultimate owners did not change. If PostMeds had disclosed the new holding company, the Board still would have granted the transfer of ownership. However,

PostMeds failed to submit the transfer of ownership application or otherwise disclose the interests of Truepill, Inc.

7. In each of its subsequent renewals, PostMeds failed to correct the ownership information that it had inaccurately submitted on its initial application or to list Truepill, Inc., as the direct owner of the pharmacy.

8. On November 4, 2021, counsel for PostMeds informed the Board that its "current ownership information on file with the North Carolina Board of Pharmacy is out of date." Upon follow-up questioning, the next day, PostMeds disclosed that it should have submitted a transfer of ownership application in November 2019. It further was apparent from the ownership information that PostMeds provided that Afridi made inaccurate representations about ownership and officers on PostMed's initial application that had never been corrected.

9. PostMeds agreed to stop shipping any drugs, devices or medical equipment into the State of North Carolina until the matter was resolved. It further agreed to stop shipping or dispensing any drugs, devices or medical equipment from six other pharmacies under its ownership until the matter was resolved (even though those pharmacies did not receive permits until after the transfer of ownership had occurred, and so did not suffer from the same problem).

10. PostMeds submitted a transfer of ownership application promptly.

11. Although PostMed's disclosure of its inaccuracies was tardy, its remedial actions are a mitigating factor in this matter.

CONCLUSIONS OF LAW

1. Reporting of correct and complete ownership information on an initial pharmacy permit application or a renewal application is material, indeed essential, to the Board's ability to ensure that a pharmacy will provide services safely and competently to the public.

2. PostMeds made inaccurate statements about its ownership and officers on its initial application, which it failed to correct at any point through its 2022 renewal. That initial permit was therefore void ab initio and violated G.S. § 90-85.38(b).

3. The creation of Truepill, Inc. as a holding company further triggered a requirement to report the ownership change and obtain a successor permit, and to do so before the closing of the transaction that created Truepill, Inc. The transaction "result[ed] in a different person . . . owning more than 50 percent interest in the permit holder . . . ." 21 NCAC 46.1603. Failure to apply for and obtain a successor permit prior to the transaction, and a continuing failure to disclose the ownership interest of Truepill, Inc., violated G.S. § 90-85.38(b).

IT IS THEREFORE ORDERED:

PostMeds was in violation of G.S. § 90-85.38(b) in North Carolina from November 20, 2017 until at least November 4, 2021. Respondent PostMed's Permit No. 13413 was **VOID** from the time that it was granted on November 20, 2017. G.S. § 90-85.38(c).

Respondent PostMed's change of ownership application is **APPROVED** as a successor permits to Permit No. 13413 (the "Successor Permit") with the following **CONDITIONS:**

1. PostMeds shall provide timely advance notice of any contemplated change in ownership to the current pharmacist-manager and any future pharmacist-manager(s) of the Successor Permit. PostMeds shall consult with the Successor Permit's pharmacist-manager(s) to determine whether any contemplated transaction triggers the need to obtain new permits. PostMeds shall authorize the Successor Permit's pharmacist-manager(s) to take any necessary action to update that ownership information with the Board or to apply for new permits. If a contemplated transaction triggers the need for new permits, PostMeds shall not complete that

transaction unless and until either the Board issues new permits or PostMeds ceases all practice of pharmacy at the permitted location.

2. The Successor Permit shall violate no laws governing the practice of pharmacy or the distribution of drugs.

3. The Successor Permit shall violate no rules or regulations of the Board.

4. If the Successor Permit fail to comply with any term or condition of this Order, it may be subject to additional disciplinary action by the Board.

This is the 8th day of March, 2022

NORTH CAROLINA BOARD OF PHARMACY

By: /s/ William A. Mixon
William A. Mixon
President

Respondent PostMeds, Inc. has full knowledge that it has the right to a formal hearing, at which it would have the right to be represented at its expense by counsel, in this matter. Respondent freely, knowingly and voluntarily waives its right to such a hearing by entering into this Consent Order.

Respondent understands and agrees that by entering into this Consent Order, it certifies that it has read the foregoing Consent Order and that it voluntarily consents to the terms and conditions set forth therein and relinquishes any right to judicial review of Board actions that may be taken concerning this matter.

Respondent further understands that should it violate the terms and conditions of this Consent Order, the Board may take additional action.

Respondent understands and agrees that this Consent Order will not become effective unless and until approved by the Board.

Respondent understands that it has the right to have counsel of its choice review and advise them with respect to their rights and this Consent Order, and represents that it enters this Consent Order after consultation with counsel or after knowingly and voluntarily choosing not to consult with counsel. Respondent further agrees that the person who is executing this Consent Order has been duly authorized by any required corporation action to execute on behalf of Respondent.

CONSENTED TO BY:

M-1 D [signature] Date 3/7/22

Printed Name: Matt Davis-Ratner

Title: General Counsel

STATE OF _____

_____ COUNTY

I, the undersigned Notary Public of the County and State aforesaid, do hereby certify that the above-named representative of PostMeds, Inc. personally appeared before me this day, and acknowledged the due execution of the foregoing document.

Date: _____

_____
Notary Public

_____

My commission expires: _____

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

August 25, 2021

TRUEPILL
ATTN: FRANCESCO CONSOLE, PIC
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2020 89223
TRUEPILL
PHY 56100

The attached Citation CI 2020 89223, has been issued to TRUEPILL, PHY 56100. A copy has been sent to the pharmacy, and a copy is being sent to the pharmacist-in-charge for informational purposes only. As pharmacist in charge it is your responsibility to insure the pharmacy's compliance with the term(s) and condition(s) of the citation by the date(s) ordered, and to ensure the pharmacy's compliance with all pharmacy laws.

The Citation references the specific statutes and regulations violated, and defines each violation charged. The Citation details the conduct that resulted in the issuance of the citation. In addition the citation may also include information regarding fine(s) assessed. If fine(s) have been assessed, the citation specifies the amount and the specific violation for which the fine was levied.

If you have any questions please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Sincerely

Joshua Monforte
Citation and Fine Analyst

Attachments

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE
ORDER OF ABATEMENT

COPY

Citation Number	Name, License No
CI 2020 89223	TRUEPILL, PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
CCR, Title 16, § 1714 subd. (b)	Operational Standards and Security; pharmacy responsible for pharmacy security	$5,000.00
Bus. & Prof. Code § 4169 subd. (a)(2)/Health & Safety Code § 111295	Prohibited Acts; Purchase, trade, sell, or transfer dangerous drugs to that the person knew or reasonably should have known were adulterated.../It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is adulterated	Citation without a fine

CONDUCT:

California Code of Regulations 1714, section b states, (b) Each pharmacy licensed by the board shall maintain its facilities, space, fixtures, and equipment so that drugs are safely and properly prepared, maintained, secured and distributed. The pharmacy shall be of sufficient size and unobstructed area to accommodate the safe practice of pharmacy. Specifically, Truepill Pharmacy, PHY56100, located at 3121 Diablo Ave, Hayward, CA 94545 was in violation when they failed to keep dangerous drugs stored according to policy and procedure 2001.4, Oversight of Pharmacy Safety, which states: "The Pharmacy will make all attempts at maintaining a room temperature below 85F and ideally between 68-77F". Between 7/1/2020 and 9/14/2020, on numerous occasions, dangerous drug storage temperatures, summarized in Table 2, exceeded the recommended storage temperatures. The most egregious of these temperature spikes were:

a)On 8/13/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 161 hours over 77 F and 47 hours over 85F.
b)On 9/6/2020, in the cage area of the warehouse, dangerous drugs were stored approximately 59 hours over 77 F and 17 hours above 85F.
c)On 8/13/2020, in the Parata Automated dispensing machine located in the warehouse, dangerous drugs were stored for approximately 163 hours above 77 F and 44 hours above 85 F.

Business and Professions Code 4169 section (a), subdivision (2) states, A person or entity shall not do any of the following: (2) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were adulterated, as set forth in Article 2 (commencing with Section 111250) of Chapter 6 of Part 5 of Division 104 of the Health and Safety Code as it relates to Health and Safety Code 111295 which states, It is unlawful for any person to manufacture, sell, deliver, hold or offer for sale any drug or device that is adulterated. Specifically, Truepill Pharmacy, PHY56100, located at3121 Diablo Ave, Hayward, CA 94545 was in violation when they used the MKT calculation alone instead of in conjunction with manufactures stability data as stated in USP <1079>, which provides guidance for assessing possible adulteration to dangerous drugs stored at the pharmacy due to excessive heat. In particular, USP<1079> states, "Knowing the MKT for an excursion is useful for evaluating the potential impact on product quality. However, it is also essential to know the upper and lower temperature limits of any excursion. If these extreme temperatures are outside available stability data, it may not be possible to predict the quality impact of the excursion with any confidence regardless of the MKT. At higher temperatures the kinetics of degradation may change or new degradation reactions may occur. Truepill Pharmacy did not consider the manufacture's stability data for at least 72 dangerous drugs stored in the cage area of the warehouse which were held and offered for sale when determining if a dangerous drug was adulterated by the extreme heat, summarized in Table 3. For each one of the 72 dangerous drugs, the maximum temperature for storage was listed by the manufacturer as 77F or storage information was not listed. As there was no stability temperature for at least the 72 drugs in question and per USP<1079>, the MKT cannot be without the stability data, these drugs which were held and offered for sale were adulterated.

ORDER OF ABATEMENT

By the Abatement date/payment date submit to the Board the following:

- Either (1) full payment of the assessed fine(s) in the amount of $5,000.00; or payment in the amount of $1,000.00 and (2) provide proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within ninety (90) days.

COPY

If you choose option (2), within 90 days of this citation, you shall submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations. Any failure to do so shall be deemed a failure to meet the abatement requirements of this citation.

If you timely submit proof of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, this citation shall be reduced to $1,000.00 and proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations shall be considered satisfactory abatement of the citation.

If you fail to submit proof of compliance of new temperature control systems in addition to central HVAC systems installed throughout the pharmacy and 30 days of temperature log from the various drug storage locations within 90 days from the date the citation was issued, the stay shall be lifted and the fine(s) in the amount of $5,000.00 shall be due and owing from you within thirty (30) days of any such failure.

CITATION ISSUED ON: August 25, 2021	TOTAL AMOUNT OF FINE(S): $5,000.00

PROOF OF ABATEMENT AND PAYMENT OF FINE(S) DUE BY: September 24, 2021

COPY

California State Board of Pharmacy
1625 North Market Boulevard, Suite N219, Sacramento, CA 95834
Phone (916) 574-7900
Fax (916) 574-8618
www.pharmacy.ca.gov

BUSINESS, CONSUMER SERVICES AND HOUSING AGENCY
DEPARTMENT OF CONSUMER AFFAIRS
GOVERNOR EDMUND G. BROWN JR.

January 23, 2020

VIA CERTIFIED MAIL

LETTER OF ADMONISHMENT

TRUEPILL
ATTN: MOHAMMAD UMAR AFRIDI, CEO
3121 DIABLO AVE
HAYWARD, CA 94545

RE: CI 2019 84877
TRUEPILL
PHY 56100

This LETTER OF ADMONISHMENT is being issued pursuant to Business and Professions Code section 4315 for failure to comply with the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the board's website at www.pharmacy.ca.gov, under Forms and Publications.)

The Board of Pharmacy has completed its investigation in the above referenced matter. All documentation and/or statements relating to the investigation have been accepted and included in an Investigation Report on file in this office. Facts contained in this report lead to the conclusion that the following violations of pharmacy laws or regulations have occurred:

JURISDICTION: Bus. & Prof. Code § 4315; 1764/56.10(a) - Unauthorized disclosure of prescription and medical information

Unauthorized disclosure of prescriptions: California Code of Regulations section 1764 states in pertinent part that no pharmacist shall exhibit, discuss, or reveal the contents of any prescription or any medical information furnished by the prescriber with any person other than the patient or his or her authorized representative and Civil Code section 56.10 subdivision (a) states, in pertinent part, no provider of health care shall disclose medical information regarding a patient of the provider of health care without first obtaining an authorization. Truepill Pharmacy was not in compliance with these regulations. Specifically, on 4/17/2019, Truepill Pharmacy (PHY56100) located at 3121 Diablo Avenue in Hayward, CA shipped prescription RX#1186395 to the wrong person. The prescription was intended for AR but was shipped to the address of MS in error. Also, Truepill Pharmacy shipped prescriptions to patients with a shipping label showing the return address of NuRx located at 6838 Ellicott Drive in East Syracuse, NY and from Apostrophe located at 330 2nd Street in Oakland, CA. NuRx and Apostrophe are not licensed pharmacies and prescription packages returned as undeliverable to these locations would cause the disclosure of medical information without authorization.

Shipping prescriptions to an unauthorized person violates California Code of Regulations section 1764 and Civil Code 56.10.

If you wish to contest this Letter of Admonishment, you may do so by submitting, within 30 days of the date of service of this Letter of Admonishment, namely February 22, 2020, the attached "Request for an Office Conference" form. If an office conference is not requested, compliance with the Letter of Admonishment shall not constitute an admission of the violations described in the Letter of Admonishment.

Unless it is dismissed following an office conference or you receive other instructions from the Board in writing, Pharmacy Law requires that you maintain and have readily available for inspection a copy of this Letter of Admonishment and any written corrective action plan, if any, for at least three years from the date of issuance at the top of this letter. The Letter of Admonishment will be considered a public record for purposes of disclosure for three years from issuance. The issuance of this Letter of Admonishment does not limit the board's ability to pursue other disciplinary or administrative action under Business and Professions Code section 4315, subdivision (f).

If you have any questions regarding this Letter of Admonishment, please contact Barbera Schleicher, Public Inquiry Analyst at (916) 518-3081.

Sincerely

Virginia Herold
Executive Officer
Board of Pharmacy

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

MODIFIED CITATION AND FINE

Citation Number	Name, License No
CI 2017 78633	TRUEPILL (FORMERLY POSTMEDS INC.), PHY 56100

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4059 subd. (a)/Bus. & Prof. Code § 4067 subd. (a)	Furnishing dangerous drugs without a prescription/Internet; Dispensing Dangerous Drugs or Devices without Prescription; No person shall dispense or furnish, or cause to be furnished dangerous drugs...on the internet...without a prescription issued pursuant to a good faith examination	Citation without a fine
Bus. & Prof. Code § 4174	Dispensing on order of nurse practitioner or person of similar status.	Citation without a fine

CONDUCT:

Furnishing Dangerous Drugs or Devices Prohibited Without Prescription: Business and Professions Code 4059 (a) states in pertinent part a person may not furnish any dangerous drug, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. A person may not furnish any dangerous device, except upon the prescription of a physician, dentist, podiatrist, optometrist, veterinarian, or naturopathic doctor pursuant to Section 3640.7. In conjunction with Business and Professions Code 4067 (a) which states no person or entity shall dispense or furnish, or cause to be dispensed or furnished, dangerous drugs or dangerous devices, as defined in Section 4022, on the Internet for delivery to any person in this state without a prescription issued pursuant to a good faith prior examination of a human or animal for whom the prescription is meant if the person or entity either knew or reasonably should have known that the prescription was not issued pursuant to a good faith prior examination of a human or animal, or if the person or entity did not act in accordance with Section 1761 of Title 16 of the California Code of Regulations and (f) for the purposes of this section, "good faith prior examination" includes the requirements for a physician and surgeon in Section 2242. In conjunction with Business and Professions Code 2290.5 (a) For purposes of this division, the following definitions shall apply: (3) "Health care provider" means either of the following: (A) a person who is licensed under this division. Between 4/1/2018 to 10/31/2018, Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by prescribers who were not licensed in California. Specifically, 2 prescriptions were issued by Nurse Practitioner Jenny Ingle; 9 prescriptions were issued by Dr. Brook Randal; 6 prescriptions were issued by Dr. Jessica Rubino and 4 prescriptions were issued by Dr. Sudhi Trye. These prescribers were not licensed in California at the time the prescriptions were initiated and shipped to a California resident. Postmeds pharmacy dispensed the prescriptions issued by unlicensed prescribers to

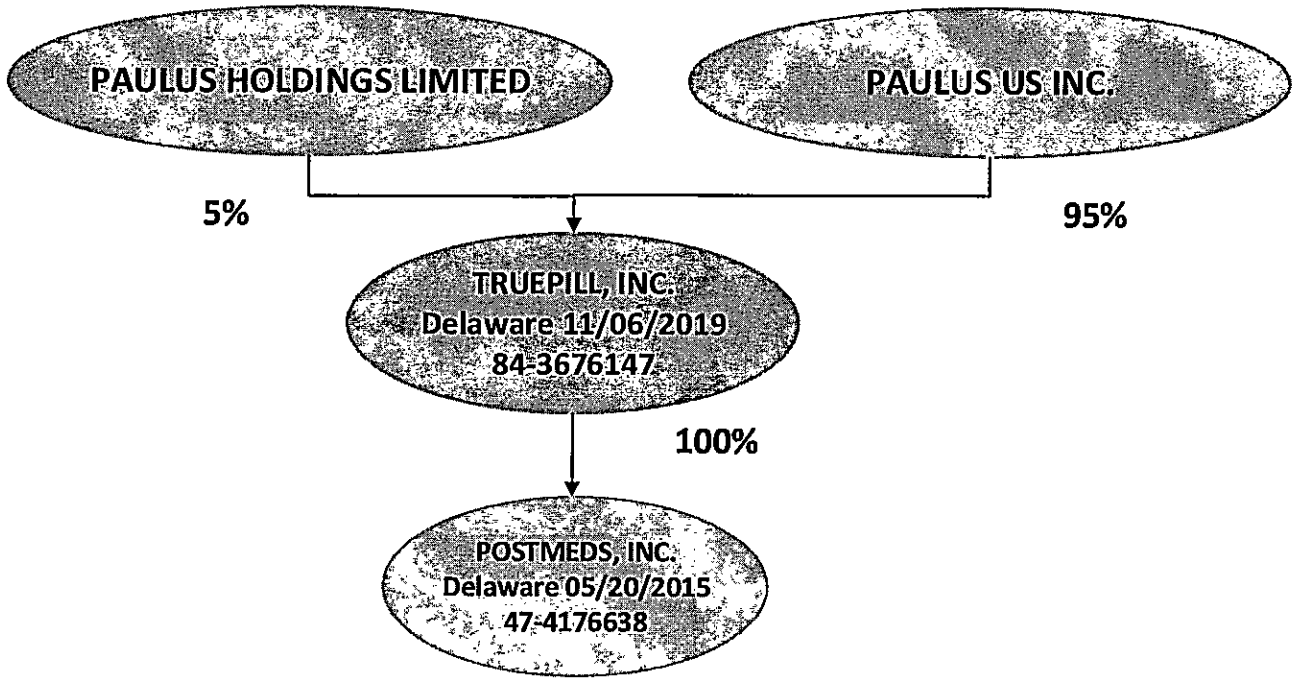
California residents in violation of Business and Professions Code 4059 (a) and Business and Professions Code 4067 (a).

Dispensing by Pharmacist Upon Order of Nurse Practitioner: Business and Professions Code 4174 states in pertinent part notwithstanding any other law, a pharmacist may dispense drugs or devices upon the drug order of a nurse practitioner functioning pursuant to Section 2836.1 or a certified nurse-midwife functioning pursuant to Section 2746.51, a drug order of a physician assistant functioning pursuant to Section 3502.1 or a naturopathic doctor functioning pursuant to Section 3640.5, or the order of a pharmacist acting under Section 4052.1, 4052.2, 4052.3, or 4052.6. Postmeds Inc. (PHY56100) located at 3121 Diablo Ave. Hayward, CA dispensed prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into an established standardized procedure or protocol developed by a supervising physician. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds without an established protocol in place: Physician's Assistant Leanne Mays issued 8 prescriptions and Physician's Assistant Susan Owen issued 6 prescriptions. Between 4/1/2018 and 10/31/2018, the following prescribers issued prescriptions to Postmeds entering into a protocol after the prescriptions were issued: Nurse Practitioner Joni Gunzburger issued 4,782 prescriptions; Nurse Practitioner Cristin Hackel issued 10,819 prescriptions and Nurse Practitioner Jessica Horwitz issued 4,711 prescriptions. Postmeds Pharmacy dispensed the prescriptions issued by Nurse Practitioners and Physicians Assistants who had not yet entered into standardized procedures or protocols as required by Business and Professions Code 4174.

CITATION ISSUED ON: June 16, 2020	TOTAL AMOUNT OF FINE(S): $0.00
PAYMENT OF FINE(S) DUE BY: July 16, 2020	

03/28/2025

POSTMEDS, INC. POST-RESTRUCTURE ORGANIZATIONAL CHART



This organizational chart was prepared by Truepill, Inc.'s Legal Team and may not be distributed to third parties without prior approval. For futher information, please reach out to entities@truepill.com

Postmeds, Inc.
3121 Diablo Ave.
Hayward, CA 94545

Delaware

The First State

I, CHARUNI PATIBANDA-SANCHEZ, SECRETARY OF STATE OF THE STATE OF DELAWARE, DO HEREBY CERTIFY "POSTMEDS, INC." IS DULY INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE AND IS IN GOOD STANDING AND HAS A LEGAL CORPORATE EXISTENCE SO FAR AS THE RECORDS OF THIS OFFICE SHOW, AS OF THE TWENTY-FOURTH DAY OF FEBRUARY, A.D. 2025.

AND I DO HEREBY FURTHER CERTIFY THAT THE ANNUAL REPORTS HAVE BEEN FILED TO DATE.

AND I DO HEREBY FURTHER CERTIFY THAT THE SAID "POSTMEDS, INC." WAS INCORPORATED ON THE TWENTIETH DAY OF MAY, A.D. 2015.

AND I DO HEREBY FURTHER CERTIFY THAT THE FRANCHISE TAXES HAVE BEEN PAID TO DATE.

C. B. Sanchez

Charuni Patibanda-Sanchez, Secretary of State

5751427 8300

SR# 20250688302

Authentication: 203003912

Date: 02-24-25

You may verify this certificate online at corp.delaware.gov/authver.shtml

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler Truepill

Pharmacy/Wholesaler License # (if applicable) PH03813

Physical Address 3121 Diablo Ave

City Hayward State CA Zip 94545

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 650-353-5495 Website https://truepill.com

Licensing Company Email compliance@truepill.com

Section 2: Personal Information

First CHRISTOPHER Middle SHUNSUN Last LAU

Alias(es, nicknames, name changes, etc.) CHRIS LAU

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
PACIFIC UNIVERSITY OREGON SCHOOL OF PHARMACY		08/11-05/14	
Address	**City**	**State**	**Zip**
222 SE 8th Ave	Hillsboro	OR	97123
Diploma/Degree obtained, if any			
DOCTOR OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF CALIFORNIA SAN DIEGO		09/02-06/06	
Address	**City**	**State**	**Zip**
9500 Gilman Dr	LAJOLLA	CA	92093
Diploma/Degree obtained, if any			
BA - ECONOMICS			

School Name		From - To (MM/YY – MM/YY)	
WILCOX HIGH SCHOOL		08/98-06/02	
Address	**City**	**State**	**Zip**
3250 Monroe St.	SANTA CLARA	CA	95051
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/19-09/24	[redacted]			
11/17-09/19				
11/13-11/17				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
POSTMEDS INC.			12/17-09/24	
Business Address		**City**	**State**	**Zip**
3121 DIABLO AVE.		HAYWARD	CA	94545
Phone	**Title**		**Number of Employed Hours**	
650-353-5495	PHARMACIST		13,700	
Description of Duties				
LICENSED DISPENSING PHARMACIST DUTIES, PATIENT CARE, PHARMACY TRAINING, ADMINISTRATIVE DUTIES				

Business Name			From - To (MM/YY – MM/YY)	
PROVIDENCE HEALTH & SERVICES ST. VINCENT MOB PHARMACY			07/15-11/17	
Business Address		**City**	**State**	**Zip**
9205 SW Barnes Rd		PORTLAND	OR	97225
Phone	**Title**		**Number of Employed Hours**	
(503) 216-1234	PHARMACIST		4,700	
Description of Duties				
LICENSED DISPENSING PHARMACIST DUTIES, CLINICAL PATIENT CARE				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title		Number of Employed Hours	
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, CHRISTOPHER S. LAU, **certify that as the designated representative for**

POSTMEDS INC.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CSL I am at least 21 years of age;
3. CSL I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CSL I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CSL I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CSL I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CSL I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

CHRISTOPHER LAU

Print Name (First, Last)

[redacted] 3/4/2025

Original Signature (electronic, copies or stamps not accepted) Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

CHRISTOPHER LAU

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/4/2025

Date

Please have this section completed in the presence of a Notary Public.

State of California, ss. County of Alameda

I, Christopher S. Lau, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

3/4/2025

Date

Subscribed and Sworn to before me this 4th day of MARCH 2025

Kayupta

Notary Public Signature

(Seal)

see attached jurat

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of alameda

Subscribed and sworn to (or affirmed) before me on this 4th day of MARCH, 2025, by CHRISTOPHER SHUN-SUN LAU,
proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

JAS1 KANAN GUPTA
COMM. # 2431361
NOTARY PUBLIC • CALIFORNIA
ALAMEDA COUNTY
MY COMMISSION EXPIRES
JAN. 14, 2027 JAS1

(Seal)

Signature K Gupta

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Postmeds Inc

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) PH03813

Physical Address 3121 Diablo Ave

City Hayward State CA Zip 94545

Mailing Address (if different from physical address) same

City _____ State _____ Zip _____

Telephone 650-353-5495 Website n/a

Licensing Company Email compliance@truepill.com

Section 2: Personal Information

First Paul Middle James Last Greenall

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City [redacted] State [redacted] Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Bayes Business School, University of London			10/98 - 07/02	
Address		City	State	Zip
106 Bunhill Row		London	UK	EC1Y 8TZ
Diploma/Degree obtained, if any				
BSC Business Management				
School Name			From - To (MM/YY – MM/YY)	
Abbotsfield School			09/91-07/98	
Address		City	State	Zip
Clifton Gardens		Hillingdon	UK	UB10 0EX
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/20-Date	[redacted]			
09/11 - 07/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Postmeds Inc D/B/A Truepill			07/22 - Date
Business Address	**City**	**State**	**Zip**
3121 Diablo Ave	Hayward	CA	94545
Phone	**Title**		
855-910-8606	CEO		

Description of Duties
Managing the overall resources and operations of company, making major corporate decisions, and acting as the main point of contact between the board of directors, employees, and the public.

Business Name			From - To (MM/YY – MM/YY)
Prophet Brand Strategy LLC			04/19 - 06/22
Business Address	**City**	**State**	**Zip**
150 Spear St Ste 1300	San Francisco	CA	94105
Phone	**Title**		
(415) 518-5692	Senior Partner, Chief Strategy Officer		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
McKesson Corporation			07/09-12/18
Business Address	**City**	**State**	**Zip**
1 Post Street	San Francisco	CA	94104
Phone	**Title**		
415-983-8300	Sr Vice President, Enterprise Strategy		

Description of Duties
Primary responsibility for strategy formulation and management, including developing the corporate vision and strategy, overseeing strategic planning, and leading strategic initiatives, including M&A, transformation, partnerships, and costs

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✓	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✓	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 & 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
06/01/2007	06/01/2007	MN	Metropolitan Airport	Hennepin
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
225001		Metropolitan Airport		
Reason/Charge				
Petty Misdemeanor - Airport Ordinance Violation				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Self			N/A	
Name of Business/Industry/Entity				
N/A				

Provide explanation below:

Petty Misdemeanor Airport Ordinance Violation with $300 fine, expunged 9/27/2021 by State Statute. Original documentation unavailable due to fire loss.

MN Statute 609.2 - "Petty misdemeanor" a petty offense which is prohibited by ordinance or statute, which does not constitute a crime and for which a sentence of a fine of not more than $300 may be imposed.

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/8/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

PAUL GREENALL

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

3/5/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

Date

Subscribed and Sworn to before me this _____ day of _____.

Notary Public Signature

CALIFORNIA JURAT ATTACHED

(Seal)

A notary public or other officer completing this certificate verifies only the identity of the individual who signed the document to which this certificate is attached, and not the truthfulness, accuracy, or validity of that document.

State of California
County of Sonoma

Subscribed and sworn to (or affirmed) before me on this 5 day of March, 2025, by Paul Greenall,

proved to me on the basis of satisfactory evidence to be the person(s) who appeared before me.

M. DEMERS
COMM. # 2378608
SAN JOAQUIN COUNTY
NOTARY PUBLIC-CALIFORNIA
MY COMMISSION EXPIRES
OCTOBER 15, 2025

(Seal) Signature

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Pharmacy X Hospital Pharmacy ___ Clinic ___ Exempt Hospital ___ Wholesaler ___ Hypodermic ___

Date: 5/2/2024 Inspector: Kavita Nankani

Firm: TRUEPILL Phone: (650) 353-5495

Address: 3121 DIABLO AVE City: HAYWARD Zip: 94545

Ownership: CORPORATION

Permit #: PHY58585 Permit Exp: 3/1/2025 DEA#: FP6189725 DEA Exp: 11/30/2025

Date of Self Assessment Form: 5/3/2023 Other Permit #: N/A Date of DEA Inventory: 3/31/2024

Hours M-F: 24Hr Hours Saturday: 24Hr Hours Sunday: 24Hr

PIC RICHARD J HAGAN MYERS RPH62320 Administrator ___

RPH Consultant ___

Staff RPH Name:	License #:
HOWARD KO	RPH58900
ARTHUR LUKAS Y KWONG	RPH83850
ANGELINE H LE	RPH86994
KAYLA PHUONG U TRAN	RPH71488
HA N TRINH	RPH72002
DANA L CHAU	RPH56397
ALEXUS JERARD V HERMOGI	RPH79237
RAJI RAJAN	RPH64706
KRISTIN R XIE	RPH68135
DIANA M LUONG	RPH71888
RUBY NGOC DAO	RPH79724
MAGGIE S GONG	RPH57624
TZE-YU LO	RPH65139
ARIELLE A MADISON	RPH77431
YI L YAO	RPH83724
KARUNDRA BEN ABRAHAM	RPH74044
JOHN J HWANG	RPH56696
KIEU T HO	RPH80597
HYO E KIM	RPH77257
CHRISTOPHER S LAU	RPH73514
EMILY PHAN	RPH77553
FLORA Y WONG	RPH44357
ARTI K MULCHANDANI	RPH77631
DAVID TRUONG	RPH74245
KHALED A ELSAIAD	RPH74423
TIFFANY N LE	RPH85307

Staff Name:	License #:
ALEXIS Y ALEJANDRO	TCH171199
ALICIA YOUNG	TCH110224
ANDREW J WIRJADISASTRA	TCH168996
ARESHNA A DEVI	TCH150606
BHAVANIBEN G PATEL	TCH158562
CARINA L ORTEGA-ROMERO	TCH179809
CHAD G SWAN	TCH168362
CHEYENNE B DOMINGUEZ	TCH151816
DEBRA MAE D SANCHEZ	TCH156582
DONLY E LAMBETH	TCH163701
FRANCHESKA C HUMARANG	TCH174164
FRANK O WUSTNER	TCH132600
JAMIKA L ACEVES	TCH134278
JENIFER S PASCUA	TCH152429
JONATHAN H NGUYEN	TCH164623
JOSEPH K BANISCH	TCH175943
KISHA A JONES-PETERSON	TCH134944
KY H NGUYEN	TCH133825
MARTA WONG	TCH154922
MEI YAN ZENG	TCH167473
MINETTE T MATEO	TCH24146
MOHYMAN A AWWAD	TCH167840
MOLLIE J JORDAN	TCH92038
RICARDO V PELAYO	TCH119174

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INSPECTION REPORT

VIDA PEJMAN	RPH49739	RODERICK M LEWIS	TCH159131
CURTIS D ANCAR	RPH57345	TERIESA N DASS	TCH185842
TRAVIS J PAU	RPH70260	TIFFANI K HAWKINS	TCH65856
DANA M NG	RPH78086	TIFFANY S ROQUE	TCH162790
VU L TRAN	RPH52752	VINCENT MATHEW C MUNIZ	TCH165168
JESSICA NGO	RPH81042		
ZHIHUA SHI	RPH73964		
JULIE V TRAN	RPH85217		
APRIL N ADAMS	RPH49949		
SHRUTHY ALEX	RPH77746		
NHATANH D NGO	RPH51783		
DAVID WILLIAM C KNIGHT	RPH78846		
PAULINA T NGUYEN	RPH48806		
LIEN T TRUONG	RPH74962		
DONNY Q NGUYEN	RPH85712		

Inspector Remarks:

ROUTINE PHARMACY INSPECTION

Retail pharmacy - majority mail order, very rare pickup of medications from customers
RX Volume approx. ~2000-2,500 prescriptions/day
Licensed in and mails Rxs to all 50 states
No compounding
No immunizations
No controlled substance dispensing since ~10/2022
24 hours pharmacy - closed from 7pm to 8:45pm
Partners with >20 companies. Major partners: Blink, Lilly, Phil, Wisp, Found, Duration, etc.
Mail carriers used: mostly USPS, FedEx for refrigerated medications, and UPS
Other TruePill locations in NY, OH, and FL
Assisted by RPH Elsaiad - pharmacy operations manager, Mr. Cathric Yaga - director of pharmacy operations, RPH Trinh - regulatory pharmacy operations supervisor.

Wholesaler: Afaxys, Agile, Anda, Aurobindo, Bausch & Lomb, Camber, Cardinal, Dr. Reddy, Evofem, Hikma, HRA, IBSA, IPC, Keysource, Lexicon, Lupin, Mayne, McKesson, Parmed, Phathom, Prasco, Primus, Sun, TopRx, WWS
Reverse Distributor: Inmar

REVIEWED:

**Consultation: written notification of consultation provided to every patient
NTC poster, Point to Your Language Sign posted
DEA registration, BOP original license/renewal posted
Community pharmacy self-assessment, DEA biennial controlled substance inventory, POA
Pharmacy security, badge access for pharmacist/technician, alarm access with select pharmacists
Pharmacy records storage in pharmacy
HIPAA disposal bins in pharmacy, locked and secured, keys in lockbox
Three drug rooms + overstock drug room + second overstock drug room dedicated to one vendor (i.e. Mark Cuban) - badge access by Rph/Tch, for overstock room - there is only key access at this time, key in the lockbox, lockbox key with supervisor
CS locked safe - currently empty with one expired medication quarantined for destruction, safe access with PIC and RPH Trinh

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INSPECTION REPORT

BOP emails, CURES access
sample invoices
All prescriptions are received electronically and maintained electronically
Schedule 2 Reconciliation Inventory Report, last 03/31/2024 - no CS in stock at this time
name badges for staff, tech ratio discussed with RPH Trinh
Rph receives and signs for order from wholesaler
No 340b drugs
No bubble packs or unit dose packaging
Does not dispense to physicians' offices for office use
No delivery services
Refrigerated items are packaged in insulated package with multiple ice packs and shipped via FedEx
Pharmacy performs cold chain testing 2x/year
Pharmacy has no automatic refill program; dispense medications pursuant to new prescription or refill request through contracted companies
SmartSense continuous digital monitoring system for ambient, refrigerator, and freezer; out of range alerts are sent via email to managers and leads
manual temperature logs also maintained and logged twice a day
sink with hot and cold running water
Prescription process - current inventory; filling/verification process observed by Rph/Tch; shipping area
Automated Dispensing Devices: 5 Parata Max and 4 Parata Mini - all of the automated dispensing devices have been decommissioned as of 2023/2024 and labeled as such, with the exception of 1 Parata Mini
Reviewed Parata Mini cells - labeled with drug name, strength, lot number, NDC, expiration dates
Kirby Lester counting machine
Recall process, quarantined from active inventory, documentation maintained on Google drive
Expired medications process, quarantined from active inventory
sample prescription labels - patient centered, description of tabs/caps, requirement for patient-centered label "generic for ___"
Reviewed QA reporting system on TruePill error/quality tracker on Google sheets, last QA reported on 04/23/2024, viewed sample report from 01/29/2024
Computer system: mostly use TruePill operating system, sometimes use Pioneer for specific vendor

Policy/Procedures: maintained in a binder and available online. Reviewed:

- Automatic prescription refill/renewal program; licensed employee, Theft or impairment; Inventory Reconciliation Report of CS; Language Line Solutions for access to an interpreter; Reporting of Errors, Issues, & Complaints of Clinical Significance

EDUCATION/DISCUSSION:

1. CCR 1714(c) - in that pharmacy sink drain was dirty. Ensure pharmacy kept in a clean and orderly condition, including sink.
2. At the time of inspection, found a large container with expired medications from a previous vendor, that was quarantined in the cage. Please ensure expired medications are returned to the reverse distributor.

EDUCATIONAL TOPIC FOR DISCUSSION

1. BPC 4052.04 – Pharmacist may furnish COVID-19 oral therapeutics following a positive test.
   - "COVID-19 oral therapeutics" means drugs that are approved or authorized by the FDA for the treatment of COVID-19 and administered orally.
   - Prior to furnishing COVID-19 oral therapeutics, a pharmacist shall utilize relevant and appropriate evidence-based clinical guidelines published by FDA in providing these patient care services.
   - A pharmacist who furnishes COVID-19 oral therapeutics shall notify patient's PCP or enter appropriate information into patient record system shared with PCP, as permitted by that PCP. If the patient does not have a PCP, the pharmacist shall provide the patient with a written record of the drugs furnished and advise the patient to consult a physician of the patient's choice.

INSPECTION REPORT

- Document the kind and amounts of COVID-19 oral therapeutics furnished, as well as any information regarding testing services provided, in the patient's record in the record system maintained by the pharmacy.
- Retain records for 3 years.

2. BPC 4113 – PIC authority to make staffing decisions
   - PIC may make staffing decisions to ensure sufficient personnel are present in the pharmacy to prevent fatigue, distraction, or other conditions that may interfere with a pharmacist's ability to practice competently and safely.
   - If PIC is not available, a pharmacist on duty may adjust staffing according to workload if needed.
   - PIC or pharmacist on duty shall immediately notify the store management of any conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff. If the conditions are not resolved within 24 hours, the PIC or RPH on duty shall ensure the BOP is timely notified. Conditions that present an immediate risk of death, illness, or irreparable harm to patients, personnel, or pharmacy staff include, but are not limited to:
     - Workplace safety and health hazards that present an immediate risk of death, illness or irreparable harm to patients, personnel, or pharmacy staff.
     - Sustained temperatures that could impact ambient temperature drug stability according to manufacturer data on acceptable drug storage conditions.
     - Vermin infestation that poses a risk to the safety or efficacy of medicine.
3. BPC 4113.1 – Reporting medication errors within 14 days from discovery.
   - Applies to "community pharmacies" – *i.e.,* any pharmacy that dispenses medication to an outpatient (but not including facilities of CDCR).
   - Per the BOP's AB 1286 Implementation Statement, the reporting of medication errors under BPC 4113.1 will not be required until the BOP approves an entity to receive the reports.
4. BPC 4113.6 – Chain community pharmacy subject to BPC 4113.5 must be staffed at all times with at least one clerk or pharmacy technician fully dedicated to performing pharmacy-related services. The BOP will not take action against a pharmacy for violation of this staffing requirement if any of the following conditions apply:
   - RPH on duty waives the requirement in writing during specified hours based on workload need.
   - The pharmacy is open beyond normal business hours (*i.e.,* before 8am, after 7pm). During the hours before 8am and after 7pm, the staffing requirement shall not apply.
   - The pharmacy's prescription volume per day on average is less than 75 prescriptions per day based on the average daily prescription volume for the past calendar year. However, if the pharmacist is also expected to provide additional pharmacy services (such as immunizations or CLIA-waived tests) this exception does not apply.

   When staffing of pharmacist hours within a chain community pharmacy does not overlap sufficiently, scheduled closures for lunch time for all pharmacy staff shall be established and publicly posted, and included on the outgoing telephone message.
5. BPC 4115 – Pharmacy technician may, under the direct supervision and control of a pharmacy, prepare and administer influenza and COVID-19 vaccines via injection or intranasally, prepare and administer epinephrine, perform specimen collection for tests that are CLIA waived, receive prescription transfers, and accept clarification on prescriptions under certain specified conditions.
6. BPC 4231 – CE required for pharmacists to renew their pharmacist license must now include at least one hour of participation in a cultural competency course which meets specified requirements.
7. The Board has posted on its website the FAQ's to address the changes in pharmacy law related to AB1286, dated 12/21/2023. Here's the link: https://pharmacy.ca.gov/publications/ab1286_faqs.pdf

DISCLAIMER:
Any issues referenced/discussed in this report are not intended to be an all-inclusive list of issues that may exist at your facility. Your facility is responsible for investigating and determining the causes of any issues and items to be corrected and for preventing their recurrence. Further review of items provided at inspection, may result in further communication after this report.

Kavita Narikani, Board Inspector

California State Board of Pharmacy
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Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8618
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Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

INSPECTION REPORT

Phone 408-515-7416
Fax 510-683-0103
Email: kavita.nankani@dca.ca.gov

Licensee Remarks:

have reviewed, discussed,understand and received a copy of this form .

Pharmacist (sign) Khaled Elsaiad

Pharmacist (print) Khaled Elsaiad

Inspector (sign) Kavita Nankani

Inspector (print) Kavita Nankani

Owner(sign) _____

Owner(print) _____

Additional information (for example - corrective plan of action, Quality Assurance outcomes, factors in mitigation, etc.) you want to submit for consideration may be sent on the attached form to my attention at the above address no later than 14 calendar days from the date above. Please include a copy of this form with any information that you submit.

Within 14 calendar days from the above date, please submit to me at the above address the following:

BOARD OF PHARMACY

LICENSING DETAILS FOR: PHY 60061

NAME: TRUEPILL

LICENSE TYPE: PHARMACY (COMMUNITY)

LICENSE STATUS: CLEAR

ADDRESS

3121 DIABLO AVE
HAYWARD CA 94545
ALAMEDA COUNTY

ISSUANCE DATE

OCTOBER 1, 2024

EXPIRATION DATE

OCTOBER 1, 2025

CURRENT DATE / TIME

APRIL 3, 2025
10:59:33 AM

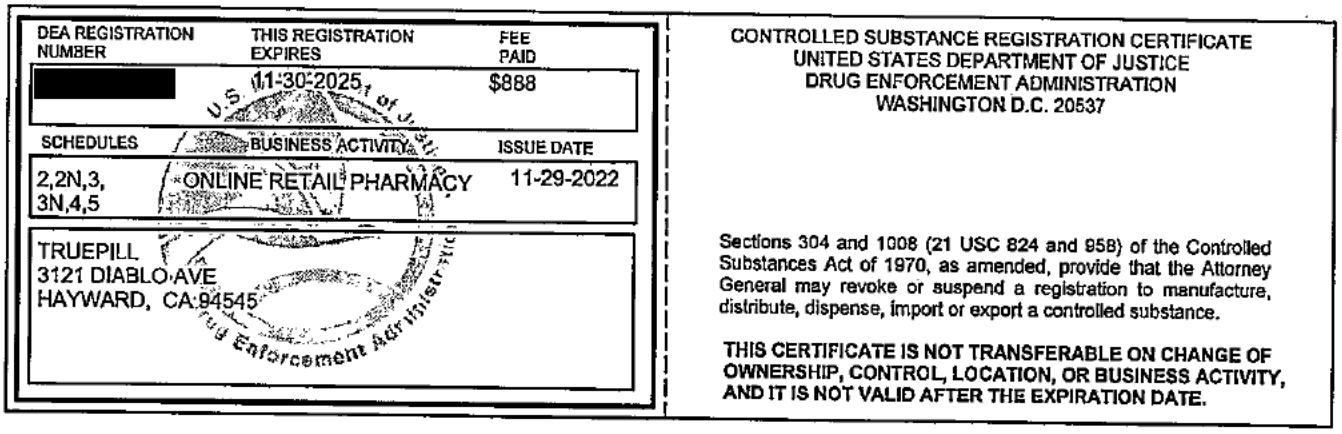
LICENSE RELATIONSHIPS

NAME: HAGAN MYERS, RICHARD JAMES

ADDRESS NOT DISCLOSED

LICENSE/REGISTRATION TYPE: REGISTERED PHARMACIST

LICENSE NUMBER: 62320 **PRIMARY STATUS:** CLEAR



DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2025	$888

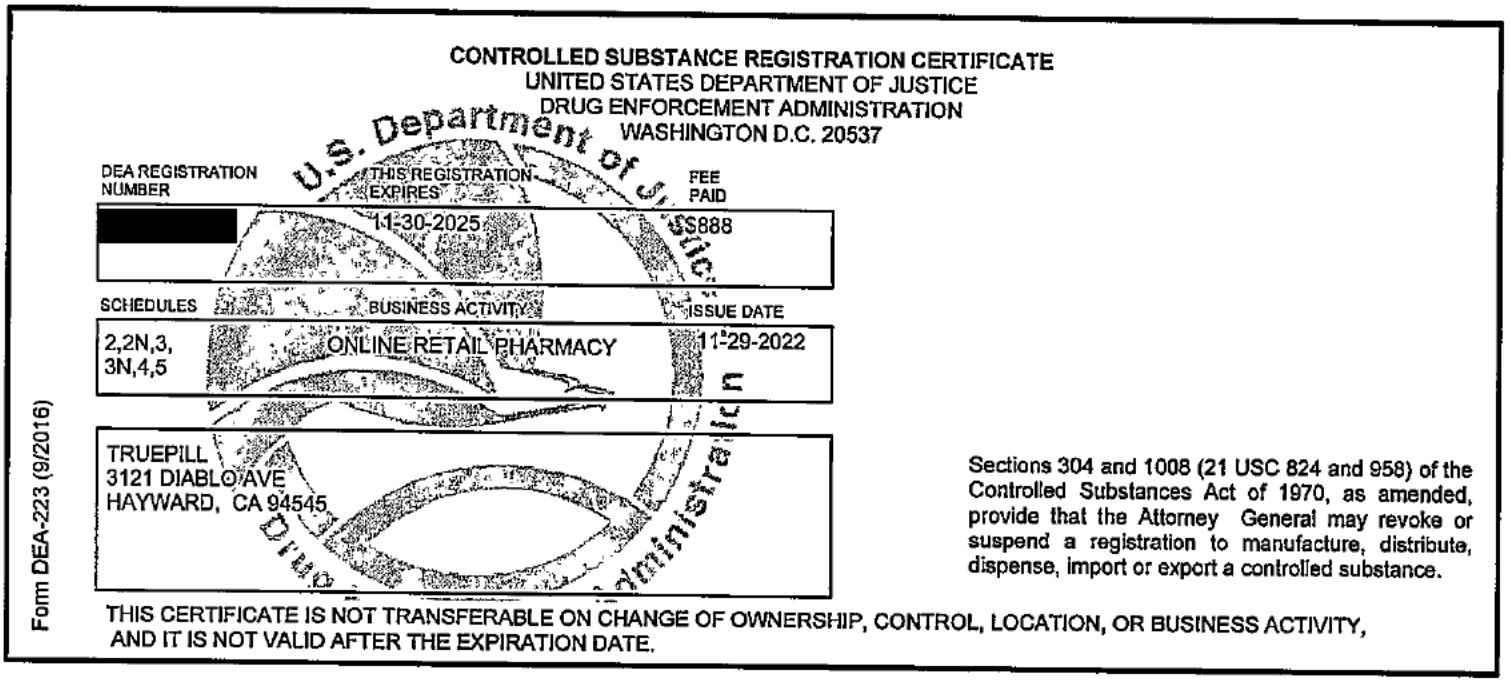
SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ONLINE RETAIL PHARMACY	11-29-2022

TRUEPILL
3121 DIABLO AVE
HAYWARD, CA 94545

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.



CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	11-30-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	ONLINE RETAIL PHARMACY	11-29-2022

TRUEPILL
3121 DIABLO AVE
HAYWARD, CA 94545

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Form DEA-223 (9/2016)

4DDDD

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☑ New OUTSOURCING FACILITY
☐ Ownership Change (Provide current license number if making changes:) OUT_____
☐ 503a OR ☐ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☐ Non Publicly Traded Corporation – Pages 1-3 & 5
☑ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: Mark Cuban Cost Plus Manufacturing and Compounding LLC

Physical Address: 3015 Taylor Street

City: Dallas State: TX Zip Code: 75226

Telephone: (682) 350-9487 Fax: (682) 428-8081

Toll Free Number: _____ (Required per NAC 639.708)

E-mail: licensing@costplusdrugs.com Website: www.markcubancostplusdrugcompany.com

Supervising Pharmacist: Raymond Iannone Nevada License #: 24080

SERVICES PROVIDED

Yes/No

☐ ☑ Parenteral
☑ ☐ Sterile Compounding
☑ ☐ Non Sterile Compounding
☐ ☑ Mail Service Sterile Compounding
☐ ☑ Other Services: _____

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 10/8/24 Amount: [redacted]

FEI Number (From FDA application): 92-1836290

Please provide the name of the facility as registered with the FDA and the registration number:
Mark Cuban Cost Plus Manufacturing and Compounding LLC FDA FEI No.: 3024611767

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
NA

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Raymond Iannone Nevada License Number: 24080

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: NA

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☑

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☑

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☐ No ☑

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☑

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☑

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☑

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Alexander Oshmyansky
Print Name of Authorized Person

10/2/2024
Date

OWNERSHIP IS A PARTNERSHIP General _____ Limited LLC

Partnership Name: Mark Cuban Cost Plus Manufacturing and Compounding LLC

Mailing Address: 3015 Taylor St

City: Dallas State: TX Zip Code: 75226

Telephone Number: (682) 350-9487 Fax Number: _____

Contact Person: Emily Hildebrand

List each partner and identify whether (G)eneral or (L)imited partner and percentage of ownership
Use separate sheet if necessary

Name	G or L	Percentage
Alexander Oshmyansky	LLC Owner	5%
Radical Investments III, LP	LLC Owner	95%

List names of 4 largest partners and percentage of ownership:

Name: NA %: _____

Name: _____ %: _____

Name: _____ %: _____

Name: _____ %: _____

List any physician shareholders and percentage of ownership.

Name: NA %: _____

Name: _____ %: _____

Name: _____ %: _____

Registered Outsourcing Facilities

Facilities Registered as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 10/21/2024

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Search: Mark

Show 10 entries

Export Excel

Facility	Contact	Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]	Intends to Compound Sterile Drugs From Bulk Substances [6]
Mark Cuban Cost Plus Manufacturing and Compounding, LLC, Dallas, TX	Alexander Oshmyansky [redacted]	11/2/2022	1/31/2024	Not yet Inspected	N/A	N/A	N/A	Yes

Showing 1 to 1 of 1 entries (filtered from 82 total entries)

Previous 1 Next

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and the establishment fee was paid in full).

   Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. A facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

   Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect according to a risk-based schedule. FDA plans to inspect outsourcing facilities within a reasonable period of time following initial registration, once it is confirmed that the facility has initiated drug production and distribution. However, the exact timing of the inspections can be affected by a number of variables, including the number of outsourcing facility registrants, other inspection priorities, and the operational status of the newly registered outsourcing facility.

   Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and other Actions (/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

Inspections may take place over several days, weeks or longer. The date of the inspection is the date a Form FDA 483 listing the investigators' observations was issued. If no FDA Form 483 was issued, the date is the last day of the inspection.

3. A Form FDA 483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.
4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.
5. "Closed" means the inspection has been closed without further action. "Open" means FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letter, seizure or injunction.
6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A" indicates the registered outsourcing facility has not provided this information.
7. This outsourcing facility was the subject of at least one previous inspection relating to compounding that resulted in a Form FDA 483, warning letter or other action. For information about such inspections and resulting actions, visit Compounding: Inspections, Recalls, and other Actions (/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions).
8. A remote regulatory assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted remotely, to evaluate compliance with applicable FDA requirements. These assessments assist in protecting human and animal health, inform regulatory decisions and verify certain information submitted to the agency.
9. Based on inspectional findings, the inspection revealed significant issues. As a result, the outsourcing facility may have either initiated a recall on their own following conversation(s) with the FDA investigator or FDA recommended a recall at the conclusion of the inspection or both. Additionally, the outsourcing facility may have conducted multiple recalls or recalled multiple drugs.

DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/26/2024-9/6/2024* FEI NUMBER 3024611767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED
Alexander Oshmyansky, Founder/CEO

FIRM NAME	STREET ADDRESS
Mark Cuban Cost Plus Manufacturing and Compounding LLC	3015 Taylor St
CITY, STATE, ZIP CODE, COUNTRY	TYPE ESTABLISHMENT INSPECTED
Dallas, TX 75226-1911	Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established.

Specifically,

A. Your firm's sterile filling technicians was observed entering and leaving different ISO 7 classified areas (storage closet, hallway, Sampling/Weighing/Dispensing Room, Formulation, and Filling Rooms which contain the ISO 5 VanRx Filling along with C4 isolators performing tasks without adequately disinfecting their sterile gloves adequate frequency to prevent potential contamination as written in your firm's procedure, Aseptic Sterile Drug Processing (Aseptic Technique), DAL-SOP-0227, Rev. 1.0, section Glove Management, sub-sections 8.14 - 8.19.

B. Your firm sterile filling technician was observed utilizing poor technique putting on sterile gloves overtop the isolator gloves within ISO 5 C4 Isolator prior to the preparation of the RCA environmental monitoring strip into the holder during the production of Epinephrine Injection, USP 5mg/5mL (1mg/1mL), Lot # 10000081, Actual Qty. 1726 vials.

C. Your firm's procedure, DAL-SOP-0237, Cleaning and Disinfection of Cleanroom Areas, failed to ensure sporicidal agent, DeconSpore, which require 15 minute contact time is achieved during the cleaning and deactivation method of production equipment used for weighing of drug components within ISO 7 Formulation Room (RM 033).

D. Your firm sterile drug product technician failed to adequately disinfect sterile 70% IPA spray bottle prior to transfer from ISO 7 Filling Room into ISO 5 C4 Isolator for use in setup of RCA stripe into the rotary centrifugal air sampler (RCS) unit for air sampling inside the VanRx

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator Rodney L Tinzie, Investigator	Cameron E Moore Investigator Signed By: Cameron E. Moore Date Signed: 09-06-2024 18:02:29 X	9/6/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/26/2024-9/6/2024* FEI NUMBER 3024611767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Alexander Oshmyansky, Founder/CEO	
FIRM NAME Mark Cuban Cost Plus Manufacturing and Compounding LLC	STREET ADDRESS 3015 Taylor St
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75226-1911	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Automated Filling System while in operation.

OBSERVATION 2

Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations.

Specifically, your firm's ISO 7 Filling Room (RM 034) containing your ISO 5 VanRx Automated Fill Isolator is designed with exposed sprinkler heads within the room ceiling preventing adequate cleaning and can be a source of contamination.

OBSERVATION 3

Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product.

Specifically, your firm fail to clean and disinfect laptop computers and desktop computer keyboards used in the production of sterile drug products within your firm's ISO 7 classified cleanroom areas (Sampling/Weighing/Dispensing Room (RM 039); Formulation Room (RM 033); and Filling Room (RM 034)) to prevent possible contamination of drug products.

OBSERVATION 4

The responsibilities and procedures applicable to the quality control unit are not fully followed.

Specifically, your firm's quality unit fail to adequately implement your firm's procedure, DAL-SOP-0032, Deviation Procedure. For example, on 8/26/2024, after becoming aware of a power failure within your facility, your firm failed to initiate a deviation to document the event and conduct an impact assessment of facility equipment and finished drug products along with components: For example, during a review of the firm's BMS system data that control and monitors temperature, relate humidity, and differential pressure, we found differential pressures within the ISO 7 cleanrooms (Sampling/

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Camerson E Moore, Investigator Rodney L Tinzie, Investigator	Camerson E Moore Investigator Signed By: Camerson E. Moore Date Signed: 09-06-2024 X	DATE ISSUED 9/6/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/26/2024-9/6/2024* FEI NUMBER 3024611767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Alexander Oshmyansky, Founder/CEO	
FIRM NAME Mark Cuban Cost Plus Manufacturing and Compounding LLC	STREET ADDRESS 3015 Taylor St
CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75226-1911	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

Weighing/ Dispensing Room, Formulation, and Filling Room) were impacted on the 8/26/2024 date between 7:58 am - 8:11 am. The differential pressure was below the minimum of 0.02 wc for greater than 10 minutes. Your firm management reported an action limit specification of 10 minutes sustained below the documented specification. Your firm was unaware of this impact prior to this inspection.

OBSERVATION 5

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm's environmental monitoring program fail to include viable air and surface monitoring sampling in areas of operations most prone to contamination within the ISO 7 Filling Room (RM 0034) that contain the ISO 5 VanRx Isolator. For example, firm fail to monitor ISO 5 C4 Isolator handles, table surface used to hold components for VanRx System, and 2 stainless-steel racks used to hold logbooks and VanRx/C4 Isolator components.

OBSERVATION 6

Labeling

1. The container of your outsourcing facility's miglustat suspension drug product did not include information required by section 503B(a)(10)(B). Specifically, your container did not include the following information:

    a. Information to facilitate adverse event reporting: ---www.fda.gov/medwatch and 1800FDA1088 <http://www.fda.gov/medwatch%20and%201800FDA1088>;

    b. Directions for use, including, as appropriate, dosage and administration.

2. The label of your outsourcing facility's miglustat suspension drug product does not include

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator Rodney L Tinzie, Investigator	Camerson E Moore Investigator Signed By: Camerson E. Moore - S Date Signed: 09-06-2024 15:42:33 X	9/6/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
1201 Main Street, Suite 7200 Dallas, TX 75202 (214)253-5200 Fax:(214)253-5314 ORAPHARM2_RESPONSES@fda.hhs.gov	8/26/2024-9/6/2024* FEI NUMBER 3024611767

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Alexander Oshmyansky, Founder/CEO	
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CITY, STATE, ZIP CODE, COUNTRY Dallas, TX 75226-1911	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

information required by section 503B(a)(10)(A). Specifically, the following information is not found on your miglustat suspension bottle label:

a. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Specifically, the Miglustat 100 mg/mL suspension bottle label is missing the "quantity or proportion" of the following ingredients: glyceryl distearate, polyglyceryl-3 oleate, medium-chain triglycerides.

OBSERVATION 7

PRODUCT REPORTING

1. Your outsourcing facility did not submit a report to FDA at the time of initial registration on November 2, 2022, as required for an outsourcing facility that registers with FDA under section 503B.

***DATES OF INSPECTION**

8/26/2024(Mon), 8/27/2024(Tue), 8/28/2024(Wed), 8/29/2024(Thu), 8/30/2024(Fri), 9/03/2024(Tue), 9/04/2024(Wed), 9/05/2024(Thu), 9/06/2024(Fri)

X Rodney L Tinzie
Investigator
Signed By: Rodney Tinzie Jr -S
Date Signed: 09-06-2024 16:02:53

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Camerson E Moore, Investigator Rodney L Tinzie, Investigator	Cameron E Moore Investigator Signed By: Cameron E Moore -S Date Signed: 09-06-2024 16:02:20 X	9/6/2024

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

To:
Emily Hildebrand
Director of Licensing
Mak Cuban Cost Plus Drugs, PBC

From:
Matt Callesen
Site Quality Head
Mark Cuban Cost Plus Drugs Manufacturing and Compounding, LLC
3015 Taylor St. Dallas TX, 75226
[redacted]

Date:
September 27th, 2024

Regarding:
The recently completed U.S. Food and Drug Administration on-site inspection:

Firm Name	Mark Cuban Cost Plus Manufacturing & Compounding, LLC	**Address**	3015 Taylor St. Dallas, TX 75226
Establishment Type	Outsourcing Facility	**FEI Number**	3024611767
Dates of Inspection	8/26/2024-9/6/2024	**Inspectors**	Camerson E. Moore Rodney L. Tinzie

MCCPMC received FDA Form 483 Inspectional Observations on 09/06/2024. Patient Safety and Regulatory Compliance are of the utmost importance to MCCPMC and have already acted on all items identified during the audit. Attached is a copy of the responses to the Form 483 Inspectional Observations that was submitted to the FDA on September 26th, 2024

Let me know if you have any questions or require any clarifications.

Regards,

Matt Callesen

Observation 1: Description and Response

Description/Notes
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established. Specifically, A. Your firm's sterile filling technicians was observed entering and leaving different ISO 7 classified areas (storage closet, hallway, Sampling/Weighing/Dispensing Room, Formulation, and Filling Rooms which contain the ISO 5 VanRx Filling along with C4 isolators performing tasks without adequately disinfecting their sterile gloves adequate frequency to prevent potential contamination as written in your firm's procedure, Aseptic Sterile Drug Processing (Aseptic Technique), DAL-SOP-0227, Rev. 1.0, section Glove Management, sub-sections 8.14 - 8.19. B. Your firm sterile filling technician was observed utilizing poor technique putting on sterile gloves overtop the isolator gloves within ISO 5 C4 Isolator prior to the preparation of the RCA environmental monitoring strip into the holder during the production of Epinephrine Injection, USP 5mg/5mL (1mg/1mL), Lot # 10000081, Actual Qty. 1726 vials. C. Your firm's procedure, DAL-SOP-0237, Cleaning and Disinfection of Cleanroom Areas, failed to ensure sporicidal agent, DeconSpore, which require 15-minute contact time is achieved during the cleaning and deactivation method of production equipment used for weighing of drug components within ISO 7 Formulation Room (RM 033). D. Your firm sterile drug product technician failed to adequately disinfect sterile 70% IPA spray bottle prior to transfer from ISO 7 Filling Room into ISO 5 C4 Isolator for use in setup of RCA stripe into the rotary centrifugal air sampler (RCS) unit for air sampling inside the VanRx.
MCCPMC Response

Commitment: MCCPMC recognizes the importance of ensuring effective procedures are in place to prevent microbiological contamination of drug products to ensure patient safety. MCCPMC appreciates the auditor feedback and intends to implement the corrective actions listed below to further mitigate the risk of viable particulate presence in ISO 5 and ISO 7 areas.
 	
Note A Commentary:
Background and Root Cause: MCCPMC invested in a fully enclosed robotic Isolator that utilizes VHP decontamination and robust engineering controls. MCCPMC also utilizes sterile gowning in all Grade C rooms to ensure particulate presence adjacent to critical areas is minimized. Based on the engineering and gowning precautions taken, the frequency of glove disinfection specified was less than what is normally prescribed in 503b facilities with lower engineering controls in place. The Environmental Monitoring Performance Qualification, and initial Aseptic Processing Simulations (media), demonstrated the environment was in a state of control prior to the start of commercial manufacturing.
 	
Corrective (and Preventive) Actions taken:
DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) was updated with additional glove disinfection best practices, for not only the processes observed but all MCCPMC processes that require sterile gloves:
• An operator must re-sanitize gloves with 70% IPA DIRECTLY BEFORE:
  • Making Grade C product pathway connections.
  • Handling components.
  • Placing gloves into the isolator sleeves.

Observation 1 Continued:

- Any operator using an electronic device shall, at minimum, re-sanitize gloves with 70% IPA before returning to processing operations.
- Entering from Grade C to Grade A environment.

- An operator must re-sanitize gloves with 70% IPA DIRECTLY AFTER:
  - Entering a Grade C room where manufacturing activities will occur unless sterile gloves are donned as part of the normal garbing process. Note: IPA addition is not required when exiting the room.
  - Completing documentation.
  - Work on Grade C work surfaces.

Reference Attachment 1-1: DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) extract.

Note B (and D) Commentary:
Background and Root Cause: MCCPMC purchased a dedicated ISO 5 Isolator to prepare the VanRx Isolator filler environmental monitoring assembly (RCS). Utilization of the isolator reduces the risk of accidental environmental monitoring contamination during the handling process. Due to the isolators use (not used to conduct any preparation processing steps) the applicable procedures did not initially require the same frequency/technique of glove sanitization as an aseptic filling environment in a 503b Facility. It also did not require the operator to perform an exterior disinfection step with a sporicidal agent on the 70% IPA bottle prior to introduction.

Corrective (and Preventive) Action Taken:
While the Isolator is not used for aseptic processing MCCPMC recognizes using an exterior disinfection of the IPA bottle with a sporicidal agent, including a 15-minute dwell time, prior to transfer will enhance our compliance posture and further mitigate the risk of contamination of the environmental monitoring media or any downstream process. ***Reference Attachment 1-2: DAL-SOP-0297: Operation SOP for C4 Isolator extract.***

Furthermore, the enhanced glove management procedure steps listed in Note A will also apply to utilization of the C4, and any Isolator installed in the future, for consistency and to further mitigate any potential risk.

Note C Commentary:
Background and Root Cause: MCCPMC developed a robust cleaning and disinfectant program per DAL-SOP-0237 *Cleaning* and Disinfection *of Cleanroom Areas*. It utilizes proven cleaning agents, DeconSpore and DeconQuat, with a 15-minute dwell time. A disinfectant efficacy study was performed to ensure the cleaning agents selected were effective for the cleanroom materials of construction. The cleaning start and end times are included on the weekly and monthly cleaning logs for both DeconSpore and DeconQuat 200C. The cleaning and disinfectant program efficacy was confirmed in The Environmental Monitoring Performance Qualification, and initial Aseptic Processing Simulations (media).
Reference Attachment 1-3: DAL-FRM-0090: Daily/Weekly Non-HD Classified Area Cleaning Log extract.
and ***Attachment 1-4. DAL-FRM-0112: Monthly Cleanroom Area Cleaning Log extract***.

Observation 1 Continued:

While a location to document the start and end times was included in the Daily, and Monthly cleaning logs, DAL-SOP-0237 *Cleaning* and Disinfection *of Cleanroom Areas* did not mandate inclusion of the start and end times for all cleanroom activities as the 15 minutes requirement was included in the SOP and associates were trained on the requirement. The document reviewed in the audit was specific to a weighing process, and the start and times were not included in the document to minimize documentation handling while performing weighing operations.

Corrective Action Taken:

- The documents which did not include the start and end time documentation location, DAL-MMR-0004: Epinephrine Injection, USP 5 mg/5 mL (1 mg/1 mL) was updated to include the requirement. ***Reference Attachment 1-5: DAL-MMR-0004: Epinephrine Injection, USP 5 mg/5 mL (1 mg/1) extract.*** *And* ***Attachment 1-6: DAL-MMR-0003: Norepinephrine Bitartrate Injection, USP 8 mg/8 mL (1 mg/mL) 8 mL extract.***

Preventive Action Taken:

- DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas was updated to require inclusion of the start and end time for any cleaning process which requires a dwell time. ***Reference Attachment 1-7: DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas extract.***

Effectiveness Plan:

The routine environmental monitoring program will continue to evaluate environmental monitoring trends and propose CAPAs if required.

Impact Assessment:

MCCPMC is confident that the observations noted did not pose any significant risk to manufacturer product for the following reasons:

- Utilization of a fully enclosed isolator with VHP decontamination.
- Completed Environmental Monitoring Performance Qualification and Aseptic Processing Simulations which met acceptance criteria
- Routine environmental testing which demonstrated the cleanrooms were in a state of control.
- finished product testing results which met release criteria, including sterility testing.

MCCPMC Overall Conclusion:

The procedural changes will prevent recurrence of the audit observations. Furthermore, the actions taken are applicable to all controlled environments, thus they will prevent future occurrences as well.

Observation 2: Description and Response

Description/Notes
Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations. Specifically, your firm's ISO 7 Filling Room (RM 034) containing your ISO 5 VanRx Automated Fill Isolator is designed with exposed sprinkler heads within the room ceiling preventing adequate cleaning and can be a source of contamination.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of selecting appropriate equipment and installing it in a manner to ensure patient safety. MCCPMC will implement the corrective action indicated below to ensure the VanRx filler resides in an environment that is not in close proximity to a water source. **Background and Root Cause:** MCCPMC invested in a fully enclosed robotic Isolator located in a greenfield site designed specifically for pharmaceutical manufacturing. While all facilities must include a fire protection system per local building codes, a different fire sprinkler head solution was not selected due to the purchasing of the fully enclosed isolator as opposed to an open processing environment. **Immediate Correction:** • A pre-filling check of the fire sprinkler head above the VanRx was added to ensure that no signs of water leaks are present. This check was added to the Batch Records as well. ***Reference Attachment 2-1: DAL-SOP-0132: Operation of the VanRx SA25 Cytiva Sterile Fill-Finish Workcell extract and Attachments 1-5 and 1-6: Epinephrine and Norepinephrine Batch Record extracts with the in-process check noted on the 2nd page of the attachments.*** **Corrective Action Completed:** • Purchase order #15221 was issued on 08/28/2024 to GFS Texas Fire Protection Contractors to modify and change out all exposed fire sprinkler heads with new recessed head fire sprinklers (approved cleanroom seals & covers) in the VanRx Fill suite. Furthermore, the purchase **also includes replacing any other exposed sprinkler head in the cleanroom environment, regardless of location.** Change Control DAL-CC-0016: Exposed fire sprinkler head replacement, will track the implementation. Due to the scope of work the replacement is scheduled to be completed during a planned shutdown period in early November with full turnover by 22NOV2024. **Preventive Action Completed:** • DAL-SOP-0081: General Facility Design and Construction was updated to require that sources of water must be designed and installed in a manner to prevent contamination of the aseptic processing environment. This includes utilizing cleanroom appropriate fire systems where required in areas where aseptic processing steps are conducted. ***Reference Attachment 2-2: DAL-SOP-0081: General Facility Design and Construction extract.***

Observation 2 Continued:

Effectiveness Plan:
Installation will be tracked via DAL-CC-0016 to ensure the risk of a leak is eliminated. No additional effectiveness check is required as the existing sprinkler heads will be removed.

Impact Assessment:
To date no fire sprinkler leaks have been observed at any cleanroom location and MCCPMC already completed the first pre-filling inspection for leaks during Epinephrine Batch 1000081 with no leaks present. Furthermore, the isolator is fully enclosed and compatible with a clean in place cycle (fully sealed in operation). Based on these factors this observation does not pose a product risk, however remediation will prevent future risks as the critical utility systems age.

MCCPMC Pending Actions and Conclusion:
MCCPMC will ensure the fire sprinkler head replacement corrective action is completed. In the interim the additional pre-startup check will ensure any leak, should one occur, is detected prior to filler use and filling will not proceed if presence of a leak is detected.

Observation 3: Description and Response

Description/Notes
Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product. Specifically, your firm fail to clean and disinfect laptop computers and desktop computer keyboards used in the production of sterile drug products within your firm's ISO 7 classified cleanroom areas (Sampling/Weighing/Dispensing Room (RM 039); Formulation Room (RM 033); and Filling Room (RM 034)) to prevent possible contamination of drug products.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of ensuring controlled environments are appropriately cleaned and disinfected, including all equipment, utensils and supporting electronics. MCCPMC will implement the corrective actions indicated below to ensure aseptic environments remain fit for use and any items which reside in ISO 7 areas are appropriate for the environment. **Background and Root Cause:** MCCPMC invested in a fully enclosed robotic Isolator that utilizes VHP decontamination and robust engineering controls. MCCPMC also utilizes sterile gowning in all Grade C rooms to ensure particulate presence adjacent to critical areas is minimized. Based on the engineering and gowning precautions taken the cleaning and disinfectant process only required an exterior disinfection of electronic devices with 70% IPA if they could not reside inside an enclosed bag. **Correction Completed:** • Work Orders GWO-000077-2024-DE and GWO-000077-2024-DE were completed to remove the computers from the clean room environment. **Corrective (and Preventive) Action Completed:** DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) was updated with specific guidance for the use of electronic devices per the following: • When electronic devices are required for batch manufacturing, they must be easy to clean, or placed in an easy to clean sealed pouch, and cleaned appropriately per the Grade and transition. • Electronic devices with fans, open keyboards, difficult to clean area, etc. are not allowed in and Grade A or C environment. ***Reference Attachment 3-1: DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) extract.*** These requirements eliminate recurrence of the observation noted but also remove the potential occurrence in future scenarios as well. **Effectiveness Plan:** The routine environmental monitoring program will continue to evaluate environmental monitoring trends and propose CAPAs if required.

Observation 3 Continued:

Impact Assessment:

MCCPMC is confident that the observations noted did not pose any significant risk to manufacturer product for the following reasons:

- Utilization of a fully enclosed isolator with VHP decontamination.
- Utilization of non-particulate generating sterile garb in all ISO 7 environments.
- Completed Environmental Monitoring Performance Qualification and Aseptic Processing Simulations which met acceptance criteria
- Routine environmental testing which demonstrated the cleanrooms were in a state of control.
- Finished product testing results which met release criteria, including sterility testing.

MCCPMC Conclusion:

The corrective actions completed have removed the potential risk of electronic devices introducing contamination in the MCCPMC ISO 7 environments. The actions will also ensure easy to clean electronic devices are used moving forward, regardless of the filling technology utilized.

Observation 4: Description and Response

Description/Notes
The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, your firm's quality unit fail to adequately implement your firm's procedure, DAL-SOP-0032, Deviation Procedure. For example, on 8/26/2024, after becoming aware of a power failure within your facility, your firm failed to initiate a deviation to document the event and conduct an impact assessment of facility equipment and finished drug products along with components. For example, during a review of the firm's BMS system data that control and monitors temperature, relate humidity, and differential pressure, we found differential pressures within the ISO 7 cleanrooms (Sampling/ Weighing/ Dispensing Room, Formulation, and Filling Room) were impacted on the 8/26/2024 date between 7:58 am - 8:11 am. The differential pressure was below the minimum of 0.02 wc for greater than 10 minutes. Your firm management reported an action limit specification of 10 minutes sustained below the documented specification. Your firm was unaware of this impact prior to this inspection.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of responding to unplanned events to ensure appropriate action is taken, even if no manufacturing activities are in progress. MCCPMC has implemented procedural updates to its Facility deviation handling process to ensure a holistic review is completed, including raising a deviation if required. **Background and Root Cause:** The MCCPMC 503b Outsourcing Facility utilizes both a Building Monitoring System (BMS) and Environmental Monitoring System (EMS) to ensure timely detection, and notification, of departures from the expected conditions in the facility. MCCPMC also utilizes DAL-SOP-0032: *Deviation Procedure* to ensure unplanned events which had a product/process impact are investigated with appropriate corrective action taken. MCCPMC began commercial manufacturing in March of 2024. In 2024 facility activities were primarily commissioning and qualification activities with minimal commercial operations. In 2024 during each BMS and EMS event the management team was notified. Upon notification each event was discussed with Engineering, Operations and Quality Assurance to assess if a deviation was required per DAL-SOP-0032. However, the scope of DAL-SOP-0032 did not include facility disruptions when no manufacturing activities were in progress, and there was no impact to the controlled environments. Regarding the power outage on 26AUG2024 a power outage due to inclement weather was detected by the Facilities Engineering team via the BMS system. Operations and Quality Management were notified immediately to assess the impact on the facility and determine if there was any product/process impact. The assessment determined there was no product impact as no commercial operations were in progress. However a deviation was not immediately raised to document the assessment. **Correction Competed:** Deviation DAL-DEV-0008 was raised on 27AUG2024 to document the inclement weather power outage assessment.

Observation 4 Continued:

Corrective (and Preventive) Action Completed:
DAL-SOP-0032: *Deviation Procedure* scope was updated to include following: *"Unplanned facility/infrastructure events, **regardless of if manufacturing is occurring during the outage**, as the events may affect the critical utilities, classified environments and controlled storage areas."*

- *Reference DAL-SOP-0088, Utilities Service Emergency Plan, for additional information regarding unplanned events that may warrant a deviation per this procedure.*
- *Reference DAL-SOP-0271, BPCS Alarm Management Standard Operating Procedure, for additional information regarding notifications through the Building Management System that may require a deviation per this procedure.*
- *Reference DAL-SOP-0315, Disaster Recovery Standard Operating Procedure, for additional information regarding disasters which may require a deviation per this procedure."*

Reference Attachment 4-1: **DAL-SOP-0032: *Deviation Procedure extract.***

These requirements eliminate recurrence of the observation noted specific to a power outage and eliminate potential future occurrences in other facility disruption scenarios as well.

Impact Assessment:
MCCPMC is confident that the observation noted did not pose any significant risk to manufacturer product for the following reasons:

- No commercial activities were in progress at the time of the event.
- A review of controlled environments and critical utilities by Facilities Engineering determined there was no impact to other controlled environments and critical utilities.
- MCCPMC has a dedicated generator to provide backup power which activated as expected.
- A holistic review of power outage event which occurred in 2024 was performed during the audit which demonstrated there was no product impact from previous events as well.

Effectiveness Plan:
By utilizing the BMS and EMS systems in place, and responding per the revised procedure, MCCPMC will prevent recurrence.

Conclusion:
While the power outage event did not have any product impact, the procedural update will ensure that the assessment after an unplanned facility event is documented, even when no commercial activities are in progress.

Observation 5: Description and Response

Description/Notes
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, your firm's environmental monitoring program fail to include viable air and surface monitoring sampling in areas of operations most prone to contamination within the ISO 7 Filling Room (RM 0034) that contain the ISO 5 VanRx Isolator. For example, firm fail to monitor ISO 5 C4 Isolator handles, table surface used to hold components for VanRx System, and 2 stainless-steel racks used to hold logbooks and VanRx/C4 Isolator components.
Response
Commitment: MCCPMC recognizes the importance of ensuring controlled environments are appropriately cleaned and disinfected, and that critical sites are routinely sampled to detect departures from the validated state. MCCPMC will implement the corrective actions indicated below to ensure aseptic environments remain fit for use and departures from the validated state are detected. **Background and Root Cause:** MCCPMC executed a robust Environmental Monitoring Performance Qualification prior to the start of commercial manufacturing with a multi-factorial risk assessment to ensure critical areas were sampled. The EMPQ results, and initial Aseptic Processing Simulations (media), demonstrated the environment was in a state of control prior to the start of commercial manufacturing. After completion of the EMPQ, sampling of all EMPQ sites continued to gather additional data and characterize recovered flora. After routine environmental data reviews were completed, some surface sample sites were removed if they demonstrated consistently low growth recovery for the sample site and room classification. While the data supported the sample site revision, MCCPMC recognizes that additional sampling would provide valuable information to further reinforce the robust state of control at the facility. **Corrective Action Completed**: • The facility environmental sampling program per DAL-SOP-0047: Environmental Monitoring Program was revised to include increased sampling at high-risk locations. The locations noted in the observation were added as well as additional sites where data collection will further demonstrate the facilities state of control. **Preventive Action Completed**: • The established environmental monitoring review per DAL-SOP-0047: Environmental Monitoring Program was updated to include additional considerations for adding and removing sites to ensure it is risk-based and includes considerations for sites that pose the highest risk for product contamination. ***Reference Attachment 5-1: DAL-SOP-0047: Environmental Monitoring Program extract.*** **Effectiveness Plan:** The routine environmental monitoring program will continue to evaluate environmental monitoring trends and propose CAPAs if required.

Observation 5 Continued:

Impact Assessment:
MCCPMC is confident that rooms utilized for aseptic manufacturing were appropriate even though the locations noted in the observation were not sampled.

- Utilization of a fully enclosed isolator with VHP decontamination.
- Utilization of non-particulate generating sterile garb in all ISO 7 environments.
- Completed Environmental Monitoring Performance Qualification and Aseptic Processing Simulations which met acceptance criteria.
- Routine environmental testing which demonstrated the cleanrooms were in a state of control.
- Finished product testing results which met release criteria, including sterility testing.

Conclusion:
MCCPMC is confident that the Facility cleanroom environments will continue to operate in a manner which ensures patient safety, and that the increased environmental monitoring sites will provide additional data to demonstrate the state of control.

Observation 6: Description and Response

Description/Notes
Labeling: 1. The container of your outsourcing facility's miglustat suspension drug product did not include information required by section 503B(a)(10)(B). Specifically, your container did not include the following information: a. Information to facilitate adverse event reporting: ---www.fda.gov/medwatch and 1800FDA1088 <http://www.fda.gov/medwatch%20and%201800FDA1088>; b. Directions for use, including, as appropriate, dosage and administration. 2. The label of your outsourcing facility's miglustat suspension drug product does not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your miglustat suspension bottle label: a. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Specifically, the Miglustat 100 mg/mL suspension bottle label is missing the "quantity or proportion" of the following ingredients: glyceryl distearate, polyglyceryl-3 oleate, medium-chain triglycerides.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of including appropriate information on drug product labeling and has taken appropriate corrective action to improve the clarity and comprehensiveness of the Miglustat label. **Background and Root Cause:** The MCCPMC 503b Outsourcing Facility utilizes DAL-SOP-0012 to provide 503b labeling guidance to the Pharmacist in Charge when creating new labeling. The requirements listed align with the Text of Compounding Quality Act labeling requirements. MCCPMC was notified of a specific clinical need for a 100mg/ml Miglustat non-sterile oral suspension preparation. The product was planned for dispensation by a pharmacy who in conjunction with the physician would provide prescribing information for the patient. For the oral suspension component of the preparation an industry standard oral suspension was selected from an industry standard supplier. Along with the order the supplier provided their technical information. The supplier indicated the suspension exact concentrations was proprietary. Thus, MCCPMC utilized the technical literature provided by the oral suspension supplier to create the product label. As the frequency and quantity of dosing was at the discretion of the prescribing physician MCCPMC included the Directions for Use: "See Prescribing information". However, the label also included the product was "For Oral Use: 150mL multiple Dose Bottle" and "Miglustat Suspension 100mg/mL" to clearly indicate the strength and method of administration (Oral). Also, "To report suspected adverse events, contact MCCPMC or FDA at www.fda.gov/medwatch and 1-800-FDA-1088." was present on the label as well. ***Reference Attachment 6-1: DAL-LBL-0008 Miglustat Oral Suspension 100 mg/mL - 150 mL Original Bottle Label with adverse event contact information.*** Based on the background information noted above the label was approved for use for a single order of three units.

Observation 6 Continued:

Correction Competed:
The oral suspension manufacturer was notified that specificity regarding the ingredients was required to continue use per audit feedback. Based on the communicated need they agreed to provide additional information provided the manufacturer name was not supplied. The additional information was included in a new version of the label that also reformatted the content to provide additional clarity. ***Reference Attachment 6-2: DAL-LBL-0008 Miglustat Oral Suspension 100 mg/mL - 150 mL Bottle Label.***

Corrective (and Preventive) Actions Competed:
DAL-SOP-0012: Required Labeling of 503B Compounded Drug Preparations was updated to include If the provided technical literature from a drug component supplier lacks ingredient specificity, then appropriate follow up action must be taken to ensure labeling information is comprehensive. This action applies to not only the Miglustat label, but all future product labels. ***Reference Attachment 6-3: DAL-SOP-0012 Required Labeling of 503B Compounded Drug Preparations extract.***

Effectiveness Plan:
Each new label must meet the updated requirements of DAL-SOP-0012. Each label is reviewed and approved by the Pharmacist in Charge and the Quality Unit to ensure it meets the requirements. The procedure update, in conjunction with the required review and approval of each future label, will ensure the action taken is effective.

Impact Assessment:
As the product was prescribed by a physician for a specific patient, dispensed by a licensed pharmacy, and included contact information for adverse events, there is no impact due to the lack of inactive ingredient specificity and initial label formatting.

Conclusion:
The procedural update will ensure any future labels produced include the specificity of ingredients, even if the original information provided is insufficient. The Miglustat label was also updated per FDA and CDER feedback.

Observation 7: Description and Response

Description/Notes
PRODUCT REPORTING 1. Your outsourcing facility did not submit a report to FDA at the time of initial registration on November 2, 2022, as required for an outsourcing facility that registers with FDA under section 503b.
Response
Commitment: MCCPMC recognizes the importance of timely reporting to the FDA under section 503b and intends to fulfill its obligations for timely reporting as a 503b Outsourcing Facility. **Background and Root Cause:** The MCCPMC 503b Outsourcing Facility is a greenfield site that was undergoing commissioning in 2022. A certificate of occupancy by the City of Dallas was granted on 5/22/2023. However, as a proactive measure the Site Leadership submitted their initial 503b Registration which was approved on 11/2/2022. As the Facility was still undergoing commissioning, The Facility did not have an occupancy permit, and no batches were compounded in 2022, the associate responsible for reporting incorrectly did not submit an initial report. ***Reference Attachment 7-1: City of Dallas Certificate of Occupancy.*** MCCPMC submitted the required FDA 503b Outsourcing Facility Bi-Annual reports for both 2023 reporting periods after Facility occupancy was granted and the first 2024 reporting period. **Correction Note:** As the observation was from 2022, prior to building occupancy, there were no unreported batches to add to the MCCPMC 503b Facility compounded drug history. After commissioning was complete MCCPMC began bi-annual Reporting through the CDER portal in 2023. **Corrective (and Preventive) Action Completed**: • *The governing procedure DAL-SOP-0281: Biannual Product Reporting to the FDA* was updated to clearly state If the outsourcing facility has not compounded any drug products during the previous six-month period (including any initial report after registration), it is still required to submit a report to FDA indicating that it has not compounded any drug products during the period. ***Reference Attachment 7-2: DAL-SOP-0281: Biannual Product Reporting to the FDA extract.*** This action will apply not only to the existing MCCPMC Facility but any expansions as well. **Effectiveness Plan:** As bi-annual reports are required by the FDA and per MCCPMC procedures, and failure to complete the report will be detected, no additional effectiveness plan is required. **Impact Assessment:** As the facility was not occupied, and no drugs were compounded prior to the initial report, there is no risk of an absence of Facility history being accurately reported. Furthermore, there is no product risk as the observation was for report submittal only. **Conclusion:** The procedural update will ensure that future reports are submitted when no saleable drug products are manufactured, even if it is an Initial FDA Report at a new MCCPMC facility.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Mark Cuban Cost Plus Manufacturing and Compounding LLC

NV Pharmacy or Outsourcing facility license # (if applicable): In Progress

Physical Address: 3015 Taylor Street

City: Dallas State: TX Zip: 75226

Mailing Address (if different from physical address): 2909 Taylor St, Suite A

City: Dallas State: TX Zip: 75226

Telephone: (682) 350-9487 Toll Free # (NAC 639.708, NRS 639.23286): (888) 228-6576

Fax: (682) 428-8081 Contact Email: licensing@costplusdrugs.com

Website: www.markcubancostplusdrugs.com

Nevada Business License # (if applicable)

Supervising/Managing Pharmacist Name (NRS 639.220): Raymond Iannone

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24080

Name of Designated Person(s) as defined by revised USP-797 guidelines: Alexander Oshmyansky

Email of Designated Person(s): licensing@costplusdrugs.com

Telephone of Designated Person(s): (972) 349-1016

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☐ Category 2 ☐ Category 3 N/A

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? N/A ☐ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? N/A ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? HEPA filters were last certified 11/2024

6. What is the frequency of the recertification for the ISO classified areas? Every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? N/A

10. Will you be performing sterile hazardous drug compounding? ■ Yes No

If you marked "**Yes**", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Information as of January 28th, 2025

Norepinephrine Bitartrate Injection USP 8 mg/8 mL (1 mg/mL)
Oxytocin 30 USP Units/3 mL (10 USP Units/mL) Injection USP (Synthetic)

12. What laboratory performs your sterility or endotoxin testing?

Name: Eagle Analytical

Address: 11111 S Wilcrest Dr., S1000

City: Houston State: TX Zip: 77099

Telephone: (800) 745-8916

13. What is your procedure for visual inspection of compounded sterile products?
DAL-SOP-0222 Visual Inspection of Finished Drug Products and Preparations v5.1

7.0 PROCEDURE
GENERAL INFORMATION
7.1 Before being released for distribution, ALL CSPs must undergo 100% visual inspection for defects per this procedure per
USP and FDA requirements.
7.2 USP <1790> Visual Inspection of Injections provides guidelines for the visual inspection of sterile injectable products.

14. How often do you perform glove fingertip and medial fill testing?
DAL-SOP-0211 Gowning Qualification Initial and Quarterly Including Fingertip Sampling
DAL-SOP-0230 Aseptic Process Simulation (Media Fill) Program Initial and every 6 mo (process) 12 mo (personnel)

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:
DAL-SOP-0016: GMP Training Management Program
7.0 PROCEDURE
GENERAL INFORMATION
7.1 In order to guarantee the quality, safety, and security of drug products or preparations, employees must possess a sufficient level of education, training, and experience, or any combination thereof.
7.2 Contract employees will be trained according to the scope of their contract responsibilities.
7.3 Employees returning from a leave of absence must complete any overdue required training prior to resuming the applicable work task.
New Employee Training, Periodic Retraining, Documentation of Training, Annual Review of JD, Event Training

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:
DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas - 8.0 PROCEDURE
GENERAL INFORMATION
8.1 Qualified Cleaning Agents at the Facility are DeconQuat 200C, DeconSpore 200 Plus, IPA 70%, and WFI.
8.14 DAILY CLEANING
8.14.1 Daily Cleaning must be performed in the rooms that are utilized for that day8.15 WEEKLY CLEANING
8.15.1 WEEKLY CLEANING is performed once per week – a week is defined as starting on Monday and ending on Sunday.
8.16 MONTHLY CLEANING
8.16.1 Monthly Cleaning is performed once per calendar month.

17. Who performs the sterile compounding process at your facility?

Production Supervisors and Production Technicians

18. Who is responsible and accountable for the sterile compounding process at your facility?
Quality Department as well as the Pharmacist-in-Charge

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?
DAL-SOP-0188: Shipping and Distribution Procedure (Inspection of Outgoing Shipments)
7.13 The final packaging method is driven by the product requirements. The packaging method should be sufficient to ensure the package withstands reasonable and anticipated physical transportation conditions, including drop

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)

1. What type of primary engineering controls will you be using in your facility?

Open Restricted Access Barrier, C-8 Isolator

2. Are you complying with all USP 800 guidelines? To follow established FDA and cGMP requirements for hazardous compounding, as well as many of the USP 800 elements	■ Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	■ Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	■ Yes	No
8. Will you be utilizing a closed system transfer device?	■ Yes	No

9. If yes, list the name of the device:

Within the C8 Isolator is an inherent material transfer processes that allows material transfer in/out of the compounding isolator without compromising worker exposure to undesirable levels of airborne drug or unwittingly compromising the sterility of the compounding environment. Bulk API is maintained in its original container but also placed permanently into a separate closed container for additional safety to personnel when transferring within the building.

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

MCCPMC only manufactures copies of current compendium products that already exist in the marketplace. We adhere to the 503B Outsourcing Facility FDA Guidance on what labeling and documentation that must accompany any product that we provide to customers. We do not directly dispense any products to patients.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

DAL-SOP-0016: GMP Training Management Program
NEW EMPLOYEE ONBOARDING
7.22 Before independently performing work in their designated area(s), new employees must complete New Hire Orientation, which consists of the following:
7.22.1 GMP training on DAL-SOP-0003, General Good Manufacturing Practices followed by an assessment/examination with passing results
7.22.2 An introduction into Mark Cuban Cost Plus MCCPMC
7.22.3 A hazardous drug (if currently manufactured) and safety training session
7.22.4 A HIPPA (Health Insurance Portability and accountability) training session

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

Norepinephrine Bitartrate Injection USP 8 mg/8 mL (1 mg/mL)
Oxytocin 30 USP Units/3 mL (10 USP Units/mL) Injection USP (synthetic)

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

DAL-SOP-0211 Gowning Qualification Initial and Quarterly Including Fingertip Sampling
DAL-SOP-0230 Aseptic Process Simulation (Media Fill) Program Initial and every 6 mo (process) 12 mo (personnel)

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ■ Yes No

4. What is the frequency for completing volumetric active air sampling?

DAL-SOP-0047: Environmental Monitoring Program
Weekly
Pre and post batch viable for Class A compounding/filling areas. Continuous non-viable sampling for Class A during filling activities.

5. What is the frequency for completing surface sampling? DAL-SOP-0047: Environmental Monitoring Program Weekly Surface samples are taken weekly monthly for Class C and D rooms, and pre and post batch of Class A filling areas.		
6. What is the frequency for using sporicidal agents? DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas Monthly		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	■ Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	■ Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Raymond Iannone

Name of Person who Completed the Form

Pharmacist-in-Charge

[redacted]

Signature (copies or stamps not accepted)

2/3/25

Date

Board Use Only	Date Received: _____ Date Approved: _____ Approved By: _____

To:
Emily Hildebrand
Director of Licensing
Mak Cuban Cost Plus Drugs, PBC

From:
Matt Callesen
Site Quality Head
Mark Cuban Cost Plus Drugs Manufacturing and Compounding, LLC
3015 Taylor St. Dallas TX, 75226
[redacted]

Date:
September 27th, 2024

Regarding:
The following recently completed Texas Department of State Health Services (DSHS) on-site inspection:

Name	MARK CUBAN COST PLUS DRUG MANUFACTURING & COMPOUNDING LLC	**License Type**	Prescription Drugs
Address	3015 TAYLOR ST DALLAS TX 75226	**License Number**	1003649
Inspection Type	Periodic/Routine	**Inspection Number**	247014

MCCPMC received a Texas Department of State Health Services Notice of Inspectional Observations, on 09/06/2024. Patient Safety and Regulatory Compliance are of the utmost importance to MCCPMC and have already acted on all items identified during the audit. Attached is a copy of the responses which were submitted to the TX DSHS on September 20th, 2024

Let me know if you have any questions or require any clarifications.

Regards,

Matt Callesen

Observation 1: Description and Response

Description/Notes
The firm is not in conformance with 21 CFR, Part 205, Guidelines for State Licensing of Wholesale Prescription Drug Distributors. Notes: Specifically, the firm is in receipt of active pharmaceutical ingredients (API) from entities not licensed with the Texas Department of State Health Services as an Out-of-State Prescription Drug Wholesaler. Receiving records for API (epinephrine, norepinephrine, miglustat) were reviewed during the inspection. The receiving records show that the API was distributed by the unlicensed firm listed below: a.Gyma Laboratories of America, Inc. 210 Crossways Park Drive, Suite 100, Woodbury, NY 11797

MCCPMC Response

Commitment: MCCPMC recognizes the importance of meeting all Texas Department of State Health Services requirements and intends to comply with the requirement for API distributors to be licensed as Out-of-State Prescription Drug Wholesaler distributors in the State of Texas.

Background and Root Cause: MCCPMC has a thorough API supplier qualification program as defined in DAL-SOP-0194, Supplier Qualification Program for all APIs and Distributors of APIs for commercial manufacturing. The MCCPMC API distributor, GYMA, used to supply APIs for the launch products met the requirements for "Conditionally Approved". Specifically, they completed a supplier questionnaire, are FDA registered, provided DEA registration as a Distributor, provided products which met specifications and received a paper-based audit with an overall rating of "Satisfactory". GYMA also provided a State of New York Registered Wholesaler License. However, DAL-SOP-0194 did not specify that a specific State of Texas license as Out-of-State Prescription Drug Distributor was required when the procedure was drafted in 2023.

Corrective Actions Taken:

- DAL-SOP-0194, Supplier Qualification Program, was updated to clearly state that the API Distributors must be licensed in the state of Texas. ***Reference Attachment 1-1: DAL-SOP-0194 extract.***
- MCCPMC requested for GYMA to obtain licensure in the State of Texas, as an Out-of-State Wholesale Distributor of Prescription Drugs, in accordance with TAC Title 25, Part I, Chapter 229, Subchapter W. as of 18SEP2024 GYMA communicated the application was in process. ***Reference Attachment 1-2: GYMA Commitment.***

Interim Controls in Place:

- While the GYMA application is in process the following interim actions were taken to ensure no APIs are purchased by GYMA for commercial manufacturing:
  - GYMA was placed in a "Blocked" status in the MCCPMC ERP, SAP. ***Reference Attachment 1-3: SAP Supplier Status.***
  - GYMA status in the MCCPMC Quality Management System (ACE) was changed to "Not Approved". ***Reference Attachment 1-4: ACE QMS Supplier Status.***

MCCPMC Pending Actions and Conclusion:
Upon successfully obtaining a license in the State of Texas, as an Out-of-State Wholesale Distributor of Prescription Drugs utilization of GYMA for commercial purposes may resume. MCCPMC is confident that the actions identified will eliminate recurrence.

Observation 2: Description and Response

Description/Notes
Production personnel were not practicing good sanitation and health habits required by 21 CFR 211.28(b). Notes: Specifically, within the ISO7 fill room, personnel were observed touching various surfaces and objects but failed to re-sanitize gloves at adequate intervals. This occurred during pre-production preparation for aseptic fill operations. Personnel were also observed entering the ISO7 fill room and immediately performing tasks and touching surfaces, without first re-sanitizing their gloves.

Response

Commitment: MCCPMC recognizes the importance of practicing good sanitization and health habits to ensure patient safety. MCCPMC appreciates the auditor feedback and intends to implement the corrective actions listed below to further mitigate the risk of viable and non-viable particulate presence in ISO7 areas.

Background and Root Cause: MCCPMC invested in a fully enclosed robotic Isolator that utilizes VHP decontamination and robust engineering controls. MCCPMC also utilizes sterile gowning in all Grade C rooms to ensure particulate presence adjacent to critical areas is minimized. Based on the engineering and gowning precautions taken the frequency of glove disinfection specified was less than what is normally prescribed in 503b facilities with lower engineering controls in place. The Environmental Monitoring Performance Qualification, and initial Aseptic Processing Simulations (media), demonstrated the environment was in a state of control prior to the start of commercial manufacturing.

Corrective Actions Taken:

- DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) was updated with additional glove disinfection best practices, regardless of the equipment utilized, including but limited to:
  - An operator must re-sanitize gloves with 70% IPA DIRECTLY BEFORE:
    - Making Grade C product pathway connections.
    - Handling components.
    - Placing gloves into the isolator sleeves.
    - Any operator using an electronic device shall, at minimum, re-sanitize gloves with 70% IPA before returning to processing operations.
    - Entering from Grade C to Grade A environment.
  - An operator must re-sanitize gloves with 70% IPA DIRECTLY AFTER:
    - Entering a Grade C room where manufacturing activities will occur unless sterile gloves are donned as part of the normal garbing process. Note: IPA addition is not required when exiting the room.
    - Completing documentation.
    - Work on Grade C work surfaces.

Reference Attachment 2-1: DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) extract.

MCCPMC Pending Actions and Conclusion:
MCCPMC will continue to monitor the controlled environments after the addition of the aseptic best practices to ensure they remain appropriate for compounding preparations. MCCPMC is confident that the utilization of robust engineering controls and best practices, will continue to ensure patient

safety while compounding sterile preparations.

Observation 3: Description and Response

Description/Notes

The production or holding areas are not sufficiently separated or defined or implemented with control systems in place as necessary to prevent contamination or mix-ups as required by 21 CFR 211.42(c).

Notes:

1) Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions. Specifically, on 08/30/2024, the firm initiated aseptic fill operations within the ISO5 VanRx (Isolator) for a sterile drug product, Epinephrine (Lot #10000081). A pre-batch cleaning/wipe-down with IPA was not performed prior to starting (Step 8.4.3 of Batch Record states this should be performed).
2) Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, the firm is not adequately sampling the environment within the ISO7 fill room, where the ISO5 isolator is located and where aseptic fill operations occurs. Surface sampling is being performed but does not include areas that technicians are frequently contacting.
3) Personnel did not perform adequate sterile garbing technique within the ISO5 Isolator. 4) Introducing a non-sterile item that is difficult to clean into the ISO5 isolator (removing bag from Sterile IPA in the ISO7 then placing in the ISO5)

Response

Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of ensuring controlled environments are appropriately cleaned and disinfected, and that critical sites are routinely sampled to detect departures from the validated state. MCCPMC will implement the corrective actions indicated below to ensure aseptic environments remain fit for use and departures from the validated state are detected.

Note 1 Commentary: Due to the differential pressure deviation which occurred during batch manufacturing an additional pre-batch cleaning/wipe-down with IPA was performed. Both the first, and second, batch wipe downs were included as attachments in the Batch Production Record. ***Reference Attachment 3-1: Lot #10000081 pre-batch wipe down initial and repeat cleaning.***

Note 2 Commentary:

Background and Root Cause: MCCPMC executed a robust Environmental Monitoring Performance Qualification prior to the start of commercial manufacturing with a multi-factorial risk assessment to ensure critical areas were sampled. The EMPQ results, and initial Aseptic Processing Simulations (media), demonstrated the environment was in a state of control prior to the start of commercial manufacturing. After completion of the EMPQ, sampling of all EMPQ sites continued to gather additional data and characterize recovered flora. After routine environmental data reviews were completed, some surface sample sites were removed if they demonstrated consistently low growth recovery for the sample site and room classification. While the data supported the sample site revision, MCCPMC recognizes that additional sampling would provide valuable information to further reinforce the robust state of control at the facility.

Observation 3 Continued:

Corrective Action Taken:

- After auditor feedback a holistic review of surface sampling sites was performed by Quality and Operations personnel. The review resulted in an update to the routine surface samples site at the facility per the following:
  - Addition of worst-case location surface sample sites in the ISO5 isolator which is used for adding the environmental monitoring strip to the RCS air sampler assembly.
  - Additional surface sampling in critical ISO7 processing areas that are frequently contacted.

  Reference Attachment 3-2: DAL-SOP-0047: Environmental Monitoring Program extract.

Note 3 Commentary:
Background and Root Cause: MCCPMC purchased a dedicated ISO5 Isolator to prepare the VanRx Isolator filler environmental monitoring assembly (RCS). Utilization of the isolator reduces the risk of accidental environmental monitoring contamination during the handling process. As the isolator is not used to conduct any preparation processing steps the procedure to utilize it did not require exterior sanitization with a sporicidal agent, or a no touch transfer, of the 70% IPA disinfectant used during assembly of the RCS unit. While the Isolator is not used for aseptic processing MCCPMC recognizes using an exterior disinfection of the IPA bottle with a sporicidal agent, including a 15-minute dwell time, prior to transfer will enhance our compliance posture and further mitigate the risk of contamination of the environmental monitoring media. ***Reference Attachment 3-3: DAL-SOP-0297: Operation SOP for C4 Isolator extract.***

MCCPMC Pending Actions and Conclusion:
MCCPMC will continue to monitor the controlled environments after the revision to the sampling sites. MCCPMC is confident that the combination of best practices and robust engineering controls will continue to ensure patient safety.

Observation 4: Description and Response

Description/Notes
Equipment used in the manufacture, processing, packing or holding of drug products does not comply with the requirements in 21 CFR 211.63, Equipment design, size and location. Notes: Specifically, the firm's ISO5 isolator (VanRx), is positioned directly beneath a ceiling fire sprinkler. A water source should not be located in close proximity to an ISO5 area.

Response

Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of selecting appropriate equipment and installing it in a manner to ensure patient safety. MCCPMC will implement the corrective action indicated below to ensure the VanRx filler resides in an environment that is not in close proximity to a water source.

Background and Root Cause: MCCPMC invested in a fully enclosed robotic Isolator located in a greenfield site designed specifically for pharmaceutical manufacturing. Due to the selection of a fully enclosed, positively pressured and clean in place compatible Isolator the engineering firm specified an open sprinkler design which was subsequently installed. While all facilities must include a fire protection system per local building codes, a different solution was not selected due to the equipment selection.

Corrective Action Taken:

- Purchase order #15221 was issued on 08/28/2024 to GFS Texas Fire Protection Contractors to modify and change out all exposed fire sprinkler heads with new recessed head fire sprinklers (approved cleanroom seals & covers) in the VanRx Fill suite. Furthermore, the purchase also includes replacing any other exposed sprinkler head in the cleanroom environment, regardless of location. Change Control DAL-CC-0016: Exposed fire sprinkler head replacement, will track the implementation. Due to the scope of work the replacement is scheduled to be completed during a planned shutdown period in early November with full turnover by 22NOV2024. ***Reference Attachment 4-1: Change Control DAL-CC-0016: Exposed fire sprinkler head replacement extract.***

Interim Controls in Place:

- While the materials are procured, and prior to the completion of the fire sprinkler head replacement, a pre-filling check of the fire sprinkler head above the VanRx was added to ensure there are no signs of leaks prior to filling. ***Reference Attachment 4-2: DAL-SOP-0132: Operation of the VanRx SA25 Cytiva Sterile Fill-Finish Workcell extract for procedure update. Note:*** Attachment 5-4 and Attachment 5-5 include the applicable Batch Record page which documents confirmation of completion.

MCCPMC Pending Actions and Conclusion:
MCCPMC will ensure the fire sprinkler head replacement corrective action is completed. In the interim the additional pre-startup check will ensure any leak, should one occur, is detected prior to filler use and filling will not proceed if presence of a leak is detected. Furthermore, as the VanRx is a fully enclosed/sealed isolator in use there is no product/patient risk in the interim until the corrective action is implemented.

Observation 5: Description and Response

Description/Notes
Written procedures for equipment cleaning and maintenance are inadequate and do not conform to the requirements in 21 CFR 211.67(b). Notes: Specifically, the firm is using DeconQuat 200C as a deactivating, disinfecting, and cleaning solution, with an established dwell time of 15 minutes. Cleaning logs were reviewed during the inspection and it was noted that the firm is not documenting start and end times after applying the cleaning solution.
Response

Commitment: MCCPMC recognizes the importance of ensuring controlled environments are appropriately cleaned and disinfected. While our cleanroom procedure, DAL-SOP-0237 *Cleaning* and Disinfection *of Cleanroom Areas,* already includes the 15-minute dwell time requirement we have updated it to require documentation of start and end times when cleaning and disinfecting Cleanroom Areas.

Background and Root Cause: MCCPMC developed a robust cleaning and disinfectant program per DAL-SOP-0237 *Cleaning* and Disinfection *of Cleanroom Areas.* It utilizes proven cleaning agents, DeconSpore and DeconQuat, with a 15-minute dwell time. A disinfectant efficacy study was performed to ensure the cleaning agents selected were effective for the cleanroom materials of construction. The cleaning start and end times are included on the weekly and monthly cleaning logs for both DeconSpore and DeconQuat 200C. The cleaning and disinfectant program efficacy was confirmed in The Environmental Monitoring Performance Qualification, and initial Aseptic Processing Simulations (media).
Reference Attachment 5-1: DAL-FRM-0090: Daily/Weekly Non-HD Classified Area Cleaning Log extract.
and ***Attachment 5-2. DAL-FRM-0112: Monthly Cleanroom Area Cleaning Log extract***.

While a location to document the start and end times was included in the Daily, and Monthly cleaning logs, DAL-SOP-0237 *Cleaning* and Disinfection *of Cleanroom Areas* did not mandate inclusion of the start and end times for all cleanroom activities as the 15 minutes requirement was include in the SOP and associates were trained on the requirement. The document reviewed in the audit was specific to a weighing process, and the start and times were not included in the document to minimize documentation entries prior to entering the weighing station.

Corrective Actions Taken:

- DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas was updated to require inclusion of the start and end time for any cleaning process which requires a dwell time. ***Reference Attachment 5-3: DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas extract.***
- The documents which did not include the start and end time documentation location, DAL-MMR-0004: Epinephrine Injection, USP 5 mg/5 mL (1 mg/1 mL) was updated to include the requirement. ***Reference Attachment 5-4: DAL-MMR-0004: Epinephrine Injection, USP 5 mg/5 mL (1 mg/1) extract.*** *And* ***Attachment 5-5: DAL-MMR-0003: Norepinephrine Bitartrate Injection, USP 8 mg/8 mL (1 mg/mL) 8 mL extract.***

Conclusion:
The procedural update will ensure that future controlled area cleaning processes will include a location to document the cleaning start and end time if a dwell is required. While the existing cleaning regimen has proven effective, and the procedural requirement is in place, documenting

the times will improve visibility and our compliance posture.

Observation 6: Description and Response

Description/Notes

Records of the calibration checks and inspections of automatic, mechanical or electronic equipment, including computers or related systems are not maintained as required by 21 CFR 211.68(a). Notes: Specifically, the firm experienced a power outage early on 08/26/24, which caused the firm's laboratory incubators to incorrectly display time (by around 7 hours). There was no deviation or OOS investigation opened until after it was noted during the inspection.

Response

Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of responding to unplanned events to ensure appropriate action is taken, even if no manufacturing activities are in progress. MCCPMC has implemented procedural updates to its Facility deviation handling process to ensure a holistic review is completed, including raising a deviation if required.

Background and Root Cause: The MCCPMC 503b Outsourcing Facility utilizes both a Building Monitoring System (BMS) and Environmental Monitoring System (EMS) to ensure timely detection, and notification, of departures from the expected conditions in the facility. MCCPMC also utilizes DAL-SOP-0032: *Deviation Procedure* to ensure unplanned events which had a product/process impact are investigated with appropriate corrective action taken.

MCCPMC began commercial manufacturing in March of 2024. In 2024 facility activities were primarily commissioning and qualification activities with minimal commercial operations. In 2024 during each BMS and EMS event the management team was notified. Upon notification each event was discussed with Engineering, Operations and Quality Assurance to assess if a deviation was required per DAL-SOP-0032. However, the scope of DAL-SOP-0032 did not include facility disruptions when no manufacturing activities were in progress, and there was no impact to the controlled environments.

Note: The start time and end time (incubation duration) for media stored in the incubator was recorded using the internal Facility time system. The local display was not utilized to make any cGMP decisions.

Corrective Actions Taken:

- DAL-SOP-0032: *Deviation Procedure* scope was updated to include following: *"Unplanned facility/infrastructure events,* ***regardless of if manufacturing is occurring during the outage****, as the events may affect the critical utilities, classified environments and controlled storage areas.*
  - *Reference DAL-SOP-0088, Utilities Service Emergency Plan, for additional information regarding unplanned events that may warrant a deviation per this procedure.*
  - *Reference DAL-SOP-0271, BPCS Alarm Management Standard Operating Procedure, for additional information regarding notifications through the Building Management System that may require a deviation per this procedure.*
  - *Reference DAL-SOP-0315, Disaster Recovery Standard Operating Procedure, for additional information regarding disasters which may require a deviation per this procedure."*

Reference Attachment 6-1:* DAL-SOP-0032: *Deviation Procedure extract.

Observation 6 Continued:

- DAL-SOP-0269: *General Incubation Procedure* was updated to include a daily check to verify the date and time are correct as an enhancement to ensure the data is correct if it is needed. ***Reference Attachment 6-2:* DAL-SOP-0269: *General Incubation Procedure extract.***

Conclusion:
While the previous events did not have any product impact, the procedural update will ensure that the assessment after an unplanned facility event is documented, even when no commercial activities are in progress. By utilizing the BMS and EMS systems in place, and responding per the revised procedure, MCCPMC will prevent recurrence.

Attachment List

- Attachment 1-1: DAL-SOP-0194 extract
- Attachment 1-2: GYMA Commitment
- Attachment 1-3: SAP Supplier Status
- Attachment 1-4: ACE QMS Supplier Status
- Attachment 2-1: DAL-SOP-0227: Aseptic Sterile Drug Processing (Aseptic Technique) extract
- Attachment 3-1: Lot #10000081 Pre-batch wipe-down (initial and repeat cleaning)
- Attachment 3-2: DAL-SOP-0047: Environmental Monitoring Program
- Attachment 3-3: DAL-SOP-0297: Operation SOP for C4 Isolator extract
- Attachment 4-1: Change Control DAL-CC-0016: Exposed fire sprinkler head replacement extract
- Attachment 4-2: DAL-SOP-0132: Operation of the VanRx SA25 Cytiva Sterile Fill-Finish Workcell extract
- Attachment 5-1: DAL-FRM-0090: Daily/Weekly Non-HD Classified Area Cleaning Log extract
- Attachment 5-2: DAL-FRM-0112: Monthly Cleanroom Area Cleaning Log extract
- Attachment 5-3: DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas extract
- Attachment 5-4: DAL-MMR-0004: Epinephrine Injection, USP 5 mg/5 mL (1 mg/1) extract
- Attachment 5-5: DAL-MMR-0003: Norepinephrine Bitartrate Injection, USP 8 mg/8 mL (1 mg/mL) 8 mL extract
- Attachment 6-1: DAL-SOP-0032: Deviation Procedure extract
- Attachment 6-2: DAL-SOP-0269: General Incubation Procedure extract

To:
Emily Hildebrand
Director of Licensing
Mak Cuban Cost Plus Drugs, PBC

From:
Matt Callesen
Site Quality Head
Mark Cuban Cost Plus Drugs Manufacturing and Compounding, LLC
3015 Taylor St. Dallas TX, 75226
Email: Matthew.Callesen@costplusdrugs.com

Date:
September 27th, 2024

Regarding:
The recently completed U.S. Food and Drug Administration on-site inspection:

Firm Name	Mark Cuban Cost Plus Manufacturing & Compounding, LLC	**Address**	3015 Taylor St. Dallas, TX 75226
Establishment Type	Outsourcing Facility	**FEI Number**	3024611767
Dates of Inspection	8/26/2024-9/6/2024	**Inspectors**	Camerson E. Moore Rodney L. Tinzie

MCCPMC received FDA Form 483 Inspectional Observations on 09/06/2024. Patient Safety and Regulatory Compliance are of the utmost importance to MCCPMC and have already acted on all items identified during the audit. Attached is a copy of the responses to the Form 483 Inspectional Observations that was submitted to the FDA on September 26th, 2024

Let me know if you have any questions or require any clarifications.

Regards,

Matt Callesen

Observation 1: Description and Response

Description/Notes
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile are not established. Specifically, A. Your firm's sterile filling technicians was observed entering and leaving different ISO 7 classified areas (storage closet, hallway, Sampling/Weighing/Dispensing Room, Formulation, and Filling Rooms which contain the ISO 5 VanRx Filling along with C4 isolators performing tasks without adequately disinfecting their sterile gloves adequate frequency to prevent potential contamination as written in your firm's procedure, Aseptic Sterile Drug Processing (Aseptic Technique), DAL-SOP-0227, Rev. 1.0, section Glove Management, sub-sections 8.14 - 8.19. B. Your firm sterile filling technician was observed utilizing poor technique putting on sterile gloves overtop the isolator gloves within ISO 5 C4 Isolator prior to the preparation of the RCA environmental monitoring strip into the holder during the production of Epinephrine Injection, USP 5mg/5mL (1mg/1mL), Lot # 10000081, Actual Qty. 1726 vials. C. Your firm's procedure, DAL-SOP-0237, Cleaning and Disinfection of Cleanroom Areas, failed to ensure sporicidal agent, DeconSpore, which require 15-minute contact time is achieved during the cleaning and deactivation method of production equipment used for weighing of drug components within ISO 7 Formulation Room (RM 033). D. Your firm sterile drug product technician failed to adequately disinfect sterile 70% IPA spray bottle prior to transfer from ISO 7 Filling Room into ISO 5 C4 Isolator for use in setup of RCA stripe into the rotary centrifugal air sampler (RCS) unit for air sampling inside the VanRx.
MCCPMC Response

Commitment: MCCPMC recognizes the importance of ensuring effective procedures are in place to prevent microbiological contamination of drug products to ensure patient safety. MCCPMC appreciates the auditor feedback and intends to implement the corrective actions listed below to further mitigate the risk of viable particulate presence in ISO 5 and ISO 7 areas.
 	
Note A Commentary:
Background and Root Cause: MCCPMC invested in a fully enclosed robotic Isolator that utilizes VHP decontamination and robust engineering controls. MCCPMC also utilizes sterile gowning in all Grade C rooms to ensure particulate presence adjacent to critical areas is minimized. Based on the engineering and gowning precautions taken, the frequency of glove disinfection specified was less than what is normally prescribed in 503b facilities with lower engineering controls in place. The Environmental Monitoring Performance Qualification, and initial Aseptic Processing Simulations (media), demonstrated the environment was in a state of control prior to the start of commercial manufacturing.
 	
Corrective (and Preventive) Actions taken:
DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) was updated with additional glove disinfection best practices, for not only the processes observed but all MCCPMC processes that require sterile gloves:
• An operator must re-sanitize gloves with 70% IPA DIRECTLY BEFORE:
  • Making Grade C product pathway connections.
  • Handling components.
  • Placing gloves into the isolator sleeves.

Observation 1 Continued:

- Any operator using an electronic device shall, at minimum, re-sanitize gloves with 70% IPA before returning to processing operations.
- Entering from Grade C to Grade A environment.

- An operator must re-sanitize gloves with 70% IPA DIRECTLY AFTER:
  - Entering a Grade C room where manufacturing activities will occur unless sterile gloves are donned as part of the normal garbing process. Note: IPA addition is not required when exiting the room.
  - Completing documentation.
  - Work on Grade C work surfaces.

Reference Attachment 1-1: DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) extract.

Note B (and D) Commentary:

Background and Root Cause: MCCPMC purchased a dedicated ISO 5 Isolator to prepare the VanRx Isolator filler environmental monitoring assembly (RCS). Utilization of the isolator reduces the risk of accidental environmental monitoring contamination during the handling process. Due to the isolators use (not used to conduct any preparation processing steps) the applicable procedures did not initially require the same frequency/technique of glove sanitization as an aseptic filling environment in a 503b Facility. It also did not require the operator to perform an exterior disinfection step with a sporicidal agent on the 70% IPA bottle prior to introduction.

Corrective (and Preventive) Action Taken:

While the Isolator is not used for aseptic processing MCCPMC recognizes using an exterior disinfection of the IPA bottle with a sporicidal agent, including a 15-minute dwell time, prior to transfer will enhance our compliance posture and further mitigate the risk of contamination of the environmental monitoring media or any downstream process. ***Reference Attachment 1-2: DAL-SOP-0297: Operation SOP for C4 Isolator extract.***

Furthermore, the enhanced glove management procedure steps listed in Note A will also apply to utilization of the C4, and any Isolator installed in the future, for consistency and to further mitigate any potential risk.

Note C Commentary:

Background and Root Cause: MCCPMC developed a robust cleaning and disinfectant program per DAL-SOP-0237 *Cleaning* and Disinfection *of Cleanroom Areas*. It utilizes proven cleaning agents, DeconSpore and DeconQuat, with a 15-minute dwell time. A disinfectant efficacy study was performed to ensure the cleaning agents selected were effective for the cleanroom materials of construction. The cleaning start and end times are included on the weekly and monthly cleaning logs for both DeconSpore and DeconQuat 200C. The cleaning and disinfectant program efficacy was confirmed in The Environmental Monitoring Performance Qualification, and initial Aseptic Processing Simulations (media).

Reference Attachment 1-3: DAL-FRM-0090: Daily/Weekly Non-HD Classified Area Cleaning Log extract.
and ***Attachment 1-4. DAL-FRM-0112: Monthly Cleanroom Area Cleaning Log extract.***

Observation 1 Continued:

While a location to document the start and end times was included in the Daily, and Monthly cleaning logs, DAL-SOP-0237 *Cleaning* and Disinfection *of Cleanroom Areas* did not mandate inclusion of the start and end times for all cleanroom activities as the 15 minutes requirement was included in the SOP and associates were trained on the requirement. The document reviewed in the audit was specific to a weighing process, and the start and times were not included in the document to minimize documentation handling while performing weighing operations.

Corrective Action Taken:

- The documents which did not include the start and end time documentation location, DAL-MMR-0004: Epinephrine Injection, USP 5 mg/5 mL (1 mg/1 mL) was updated to include the requirement. ***Reference Attachment 1-5: DAL-MMR-0004: Epinephrine Injection, USP 5 mg/5 mL (1 mg/1) extract.*** *And* ***Attachment 1-6: DAL-MMR-0003: Norepinephrine Bitartrate Injection, USP 8 mg/8 mL (1 mg/mL) 8 mL extract.***

Preventive Action Taken:

- DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas was updated to require inclusion of the start and end time for any cleaning process which requires a dwell time. ***Reference Attachment 1-7: DAL-SOP-0237: Cleaning and Disinfection of Cleanroom Areas extract.***

Effectiveness Plan:

The routine environmental monitoring program will continue to evaluate environmental monitoring trends and propose CAPAs if required.

Impact Assessment:

MCCPMC is confident that the observations noted did not pose any significant risk to manufacturer product for the following reasons:

- Utilization of a fully enclosed isolator with VHP decontamination.
- Completed Environmental Monitoring Performance Qualification and Aseptic Processing Simulations which met acceptance criteria
- Routine environmental testing which demonstrated the cleanrooms were in a state of control.
- finished product testing results which met release criteria, including sterility testing.

MCCPMC Overall Conclusion:

The procedural changes will prevent recurrence of the audit observations. Furthermore, the actions taken are applicable to all controlled environments, thus they will prevent future occurrences as well.

Observation 2: Description and Response

Description/Notes
Buildings used in the manufacture, processing, packing, or holding of a drug product do not have the suitable construction to facilitate cleaning, maintenance, and proper operations. Specifically, your firm's ISO 7 Filling Room (RM 034) containing your ISO 5 VanRx Automated Fill Isolator is designed with exposed sprinkler heads within the room ceiling preventing adequate cleaning and can be a source of contamination.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of selecting appropriate equipment and installing it in a manner to ensure patient safety. MCCPMC will implement the corrective action indicated below to ensure the VanRx filler resides in an environment that is not in close proximity to a water source. **Background and Root Cause:** MCCPMC invested in a fully enclosed robotic Isolator located in a greenfield site designed specifically for pharmaceutical manufacturing. While all facilities must include a fire protection system per local building codes, a different fire sprinkler head solution was not selected due to the purchasing of the fully enclosed isolator as opposed to an open processing environment. Immediate Correction: • A pre-filling check of the fire sprinkler head above the VanRx was added to ensure that no signs of water leaks are present. This check was added to the Batch Records as well. ***Reference Attachment 2-1: DAL-SOP-0132: Operation of the VanRx SA25 Cytiva Sterile Fill-Finish Workcell extract and Attachments 1-5 and 1-6: Epinephrine and Norepinephrine Batch Record extracts with the in-process check noted on the 2nd page of the attachments.*** Corrective Action Completed: • Purchase order #15221 was issued on 08/28/2024 to GFS Texas Fire Protection Contractors to modify and change out all exposed fire sprinkler heads with new recessed head fire sprinklers (approved cleanroom seals & covers) in the VanRx Fill suite. Furthermore, the purchase **also includes replacing any other exposed sprinkler head in the cleanroom environment, regardless of location.** Change Control DAL-CC-0016: Exposed fire sprinkler head replacement, will track the implementation. Due to the scope of work the replacement is scheduled to be completed during a planned shutdown period in early November with full turnover by 22NOV2024. Preventive Action Completed: • DAL-SOP-0081: General Facility Design and Construction was updated to require that sources of water must be designed and installed in a manner to prevent contamination of the aseptic processing environment. This includes utilizing cleanroom appropriate fire systems where required in areas where aseptic processing steps are conducted. ***Reference Attachment 2-2: DAL-SOP-0081: General Facility Design and Construction extract.***

Observation 2 Continued:

Effectiveness Plan:
Installation will be tracked via DAL-CC-0016 to ensure the risk of a leak is eliminated. No additional effectiveness check is required as the existing sprinkler heads will be removed.

Impact Assessment:
To date no fire sprinkler leaks have been observed at any cleanroom location and MCCPMC already completed the first pre-filling inspection for leaks during Epinephrine Batch 1000081 with no leaks present. Furthermore, the isolator is fully enclosed and compatible with a clean in place cycle (fully sealed in operation). Based on these factors this observation does not pose a product risk, however remediation will prevent future risks as the critical utility systems age.

MCCPMC Pending Actions and Conclusion:
MCCPMC will ensure the fire sprinkler head replacement corrective action is completed. In the interim the additional pre-startup check will ensure any leak, should one occur, is detected prior to filler use and filling will not proceed if presence of a leak is detected.

Observation 3: Description and Response

Description/Notes
Equipment and utensils are not cleaned and sanitized at appropriate intervals to prevent contamination that would alter the safety, identity, strength, quality or purity of the drug product. Specifically, your firm fail to clean and disinfect laptop computers and desktop computer keyboards used in the production of sterile drug products within your firm's ISO 7 classified cleanroom areas (Sampling/Weighing/Dispensing Room (RM 039); Formulation Room (RM 033); and Filling Room (RM 034)) to prevent possible contamination of drug products.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of ensuring controlled environments are appropriately cleaned and disinfected, including all equipment, utensils and supporting electronics. MCCPMC will implement the corrective actions indicated below to ensure aseptic environments remain fit for use and any items which reside in ISO 7 areas are appropriate for the environment. **Background and Root Cause:** MCCPMC invested in a fully enclosed robotic Isolator that utilizes VHP decontamination and robust engineering controls. MCCPMC also utilizes sterile gowning in all Grade C rooms to ensure particulate presence adjacent to critical areas is minimized. Based on the engineering and gowning precautions taken the cleaning and disinfectant process only required an exterior disinfection of electronic devices with 70% IPA if they could not reside inside an enclosed bag. **Correction Completed:** • Work Orders GWO-000077-2024-DE and GWO-000077-2024-DE were completed to remove the computers from the clean room environment. **Corrective (and Preventive) Action Completed:** DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) was updated with specific guidance for the use of electronic devices per the following: • When electronic devices are required for batch manufacturing, they must be easy to clean, or placed in an easy to clean sealed pouch, and cleaned appropriately per the Grade and transition. • Electronic devices with fans, open keyboards, difficult to clean area, etc. are not allowed in and Grade A or C environment. ***Reference Attachment 3-1: DAL-SOP-0227, Aseptic Sterile Drug Processing (Aseptic Technique) extract.*** These requirements eliminate recurrence of the observation noted but also remove the potential occurrence in future scenarios as well. **Effectiveness Plan:** The routine environmental monitoring program will continue to evaluate environmental monitoring trends and propose CAPAs if required.

Observation 3 Continued:

Impact Assessment:
MCCPMC is confident that the observations noted did not pose any significant risk to manufacturer product for the following reasons:

- Utilization of a fully enclosed isolator with VHP decontamination.
- Utilization of non-particulate generating sterile garb in all ISO 7 environments.
- Completed Environmental Monitoring Performance Qualification and Aseptic Processing Simulations which met acceptance criteria
- Routine environmental testing which demonstrated the cleanrooms were in a state of control.
- Finished product testing results which met release criteria, including sterility testing.

MCCPMC Conclusion:
The corrective actions completed have removed the potential risk of electronic devices introducing contamination in the MCCPMC ISO 7 environments. The actions will also ensure easy to clean electronic devices are used moving forward, regardless of the filling technology utilized.

Observation 4: Description and Response

Description/Notes
The responsibilities and procedures applicable to the quality control unit are not fully followed. Specifically, your firm's quality unit fail to adequately implement your firm's procedure, DAL-SOP-0032, Deviation Procedure. For example, on 8/26/2024, after becoming aware of a power failure within your facility, your firm failed to initiate a deviation to document the event and conduct an impact assessment of facility equipment and finished drug products along with components. For example, during a review of the firm's BMS system data that control and monitors temperature, relate humidity, and differential pressure, we found differential pressures within the ISO 7 cleanrooms (Sampling/ Weighing/ Dispensing Room, Formulation, and Filling Room) were impacted on the 8/26/2024 date between 7:58 am - 8:11 am. The differential pressure was below the minimum of 0.02 wc for greater than 10 minutes. Your firm management reported an action limit specification of 10 minutes sustained below the documented specification. Your firm was unaware of this impact prior to this inspection.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of responding to unplanned events to ensure appropriate action is taken, even if no manufacturing activities are in progress. MCCPMC has implemented procedural updates to its Facility deviation handling process to ensure a holistic review is completed, including raising a deviation if required. **Background and Root Cause:** The MCCPMC 503b Outsourcing Facility utilizes both a Building Monitoring System (BMS) and Environmental Monitoring System (EMS) to ensure timely detection, and notification, of departures from the expected conditions in the facility. MCCPMC also utilizes DAL-SOP-0032: *Deviation Procedure* to ensure unplanned events which had a product/process impact are investigated with appropriate corrective action taken. MCCPMC began commercial manufacturing in March of 2024. In 2024 facility activities were primarily commissioning and qualification activities with minimal commercial operations. In 2024 during each BMS and EMS event the management team was notified. Upon notification each event was discussed with Engineering, Operations and Quality Assurance to assess if a deviation was required per DAL-SOP-0032. However, the scope of DAL-SOP-0032 did not include facility disruptions when no manufacturing activities were in progress, and there was no impact to the controlled environments. Regarding the power outage on 26AUG2024 a power outage due to inclement weather was detected by the Facilities Engineering team via the BMS system. Operations and Quality Management were notified immediately to assess the impact on the facility and determine if there was any product/process impact. The assessment determined there was no product impact as no commercial operations were in progress. However a deviation was not immediately raised to document the assessment. **Correction Competed:** Deviation DAL-DEV-0008 was raised on 27AUG2024 to document the inclement weather power outage assessment.

Observation 4 Continued:

Corrective (and Preventive) Action Completed:
DAL-SOP-0032: *Deviation Procedure* scope was updated to include following: *"Unplanned facility/infrastructure events, **regardless of if manufacturing is occurring during the outage**, as the events may affect the critical utilities, classified environments and controlled storage areas."*

- *Reference DAL-SOP-0088, Utilities Service Emergency Plan, for additional information regarding unplanned events that may warrant a deviation per this procedure.*
- *Reference DAL-SOP-0271, BPCS Alarm Management Standard Operating Procedure, for additional information regarding notifications through the Building Management System that may require a deviation per this procedure.*
- *Reference DAL-SOP-0315, Disaster Recovery Standard Operating Procedure, for additional information regarding disasters which may require a deviation per this procedure."*

Reference Attachment 4-1: DAL-SOP-0032: ***Deviation Procedure extract.***

These requirements eliminate recurrence of the observation noted specific to a power outage and eliminate potential future occurrences in other facility disruption scenarios as well.

Impact Assessment:
MCCPMC is confident that the observation noted did not pose any significant risk to manufacturer product for the following reasons:

- No commercial activities were in progress at the time of the event.
- A review of controlled environments and critical utilities by Facilities Engineering determined there was no impact to other controlled environments and critical utilities.
- MCCPMC has a dedicated generator to provide backup power which activated as expected.
- A holistic review of power outage event which occurred in 2024 was performed during the audit which demonstrated there was no product impact from previous events as well.

Effectiveness Plan:
By utilizing the BMS and EMS systems in place, and responding per the revised procedure, MCCPMC will prevent recurrence.

Conclusion:
While the power outage event did not have any product impact, the procedural update will ensure that the assessment after an unplanned facility event is documented, even when no commercial activities are in progress.

Observation 5: Description and Response

Description/Notes
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions. Specifically, your firm's environmental monitoring program fail to include viable air and surface monitoring sampling in areas of operations most prone to contamination within the ISO 7 Filling Room (RM 0034) that contain the ISO 5 VanRx Isolator. For example, firm fail to monitor ISO 5 C4 Isolator handles, table surface used to hold components for VanRx System, and 2 stainless-steel racks used to hold logbooks and VanRx/C4 Isolator components.
Response
Commitment: MCCPMC recognizes the importance of ensuring controlled environments are appropriately cleaned and disinfected, and that critical sites are routinely sampled to detect departures from the validated state. MCCPMC will implement the corrective actions indicated below to ensure aseptic environments remain fit for use and departures from the validated state are detected. **Background and Root Cause:** MCCPMC executed a robust Environmental Monitoring Performance Qualification prior to the start of commercial manufacturing with a multi-factorial risk assessment to ensure critical areas were sampled. The EMPQ results, and initial Aseptic Processing Simulations (media), demonstrated the environment was in a state of control prior to the start of commercial manufacturing. After completion of the EMPQ, sampling of all EMPQ sites continued to gather additional data and characterize recovered flora. After routine environmental data reviews were completed, some surface sample sites were removed if they demonstrated consistently low growth recovery for the sample site and room classification. While the data supported the sample site revision, MCCPMC recognizes that additional sampling would provide valuable information to further reinforce the robust state of control at the facility. **Corrective Action Completed**: • The facility environmental sampling program per DAL-SOP-0047: Environmental Monitoring Program was revised to include increased sampling at high-risk locations. The locations noted in the observation were added as well as additional sites where data collection will further demonstrate the facilities state of control. **Preventive Action Completed**: • The established environmental monitoring review per DAL-SOP-0047: Environmental Monitoring Program was updated to include additional considerations for adding and removing sites to ensure it is risk-based and includes considerations for sites that pose the highest risk for product contamination. ***Reference Attachment 5-1: DAL-SOP-0047: Environmental Monitoring Program extract.*** **Effectiveness Plan:** The routine environmental monitoring program will continue to evaluate environmental monitoring trends and propose CAPAs if required.

Observation 5 Continued:

Impact Assessment:
MCCPMC is confident that rooms utilized for aseptic manufacturing were appropriate even though the locations noted in the observation were not sampled.

- Utilization of a fully enclosed isolator with VHP decontamination.
- Utilization of non-particulate generating sterile garb in all ISO 7 environments.
- Completed Environmental Monitoring Performance Qualification and Aseptic Processing Simulations which met acceptance criteria.
- Routine environmental testing which demonstrated the cleanrooms were in a state of control.
- Finished product testing results which met release criteria, including sterility testing.

Conclusion:
MCCPMC is confident that the Facility cleanroom environments will continue to operate in a manner which ensures patient safety, and that the increased environmental monitoring sites will provide additional data to demonstrate the state of control.

Observation 6: Description and Response

Description/Notes
Labeling: 1. The container of your outsourcing facility's miglustat suspension drug product did not include information required by section 503B(a)(10)(B). Specifically, your container did not include the following information: a. Information to facilitate adverse event reporting: ---www.fda.gov/medwatch and 1800FDA1088 <http://www.fda.gov/medwatch%20and%201800FDA1088>; b. Directions for use, including, as appropriate, dosage and administration. 2. The label of your outsourcing facility's miglustat suspension drug product does not include information required by section 503B(a)(10)(A). Specifically, the following information is not found on your miglustat suspension bottle label: a. A list of active and inactive ingredients, identified by established name and the quantity or proportion of each ingredient. Specifically, the Miglustat 100 mg/mL suspension bottle label is missing the "quantity or proportion" of the following ingredients: glyceryl distearate, polyglyceryl-3 oleate, medium-chain triglycerides.
Response
Commitment: Mark Cuban Cost Plus Manufacturing and Compounding recognizes the importance of including appropriate information on drug product labeling and has taken appropriate corrective action to improve the clarity and comprehensiveness of the Miglustat label. **Background and Root Cause:** The MCCPMC 503b Outsourcing Facility utilizes DAL-SOP-0012 to provide 503b labeling guidance to the Pharmacist in Charge when creating new labeling. The requirements listed align with the Text of Compounding Quality Act labeling requirements. MCCPMC was notified of a specific clinical need for a 100mg/ml Miglustat non-sterile oral suspension preparation. The product was planned for dispensation by a pharmacy who in conjunction with the physician would provide prescribing information for the patient. For the oral suspension component of the preparation an industry standard oral suspension was selected from an industry standard supplier. Along with the order the supplier provided their technical information. The supplier indicated the suspension exact concentrations was proprietary. Thus, MCCPMC utilized the technical literature provided by the oral suspension supplier to create the product label. As the frequency and quantity of dosing was at the discretion of the prescribing physician MCCPMC included the Directions for Use: "See Prescribing information". However, the label also included the product was "For Oral Use: 150mL multiple Dose Bottle" and "Miglustat Suspension 100mg/mL" to clearly indicate the strength and method of administration (Oral). Also, "To report suspected adverse events, contact MCCPMC or FDA at www.fda.gov/medwatch and 1-800-FDA-1088." was present on the label as well. ***Reference Attachment 6-1: DAL-LBL-0008 Miglustat Oral Suspension 100 mg/mL - 150 mL Original Bottle Label with adverse event contact information.*** Based on the background information noted above the label was approved for use for a single order of three units.

Observation 6 Continued:

Correction Competed:
The oral suspension manufacturer was notified that specificity regarding the ingredients was required to continue use per audit feedback. Based on the communicated need they agreed to provide additional information provided the manufacturer name was not supplied. The additional information was included in a new version of the label that also reformatted the content to provide additional clarity. ***Reference Attachment 6-2: DAL-LBL-0008 Miglustat Oral Suspension 100 mg/mL - 150 mL Bottle Label.***

Corrective (and Preventive) Actions Competed:
DAL-SOP-0012: Required Labeling of 503B Compounded Drug Preparations was updated to include If the provided technical literature from a drug component supplier lacks ingredient specificity, then appropriate follow up action must be taken to ensure labeling information is comprehensive. This action applies to not only the Miglustat label, but all future product labels. ***Reference Attachment 6-3: DAL-SOP-0012 Required Labeling of 503B Compounded Drug Preparations extract.***

Effectiveness Plan:
Each new label must meet the updated requirements of DAL-SOP-0012. Each label is reviewed and approved by the Pharmacist in Charge and the Quality Unit to ensure it meets the requirements. The procedure update, in conjunction with the required review and approval of each future label, will ensure the action taken is effective.

Impact Assessment:
As the product was prescribed by a physician for a specific patient, dispensed by a licensed pharmacy, and included contact information for adverse events, there is no impact due to the lack of inactive ingredient specificity and initial label formatting.

Conclusion:
The procedural update will ensure any future labels produced include the specificity of ingredients, even if the original information provided is insufficient. The Miglustat label was also updated per FDA and CDER feedback.

Observation 7: Description and Response

Description/Notes
PRODUCT REPORTING 1. Your outsourcing facility did not submit a report to FDA at the time of initial registration on November 2, 2022, as required for an outsourcing facility that registers with FDA under section 503b.
Response
Commitment: MCCPMC recognizes the importance of timely reporting to the FDA under section 503b and intends to fulfill its obligations for timely reporting as a 503b Outsourcing Facility. **Background and Root Cause:** The MCCPMC 503b Outsourcing Facility is a greenfield site that was undergoing commissioning in 2022. A certificate of occupancy by the City of Dallas was granted on 5/22/2023. However, as a proactive measure the Site Leadership submitted their initial 503b Registration which was approved on 11/2/2022. As the Facility was still undergoing commissioning, The Facility did not have an occupancy permit, and no batches were compounded in 2022, the associate responsible for reporting incorrectly did not submit an initial report. ***Reference Attachment 7-1: City of Dallas Certificate of Occupancy.*** MCCPMC submitted the required FDA 503b Outsourcing Facility Bi-Annual reports for both 2023 reporting periods after Facility occupancy was granted and the first 2024 reporting period. **Correction Note:** As the observation was from 2022, prior to building occupancy, there were no unreported batches to add to the MCCPMC 503b Facility compounded drug history. After commissioning was complete MCCPMC began bi-annual Reporting through the CDER portal in 2023. **Corrective (and Preventive) Action Completed**: • *The governing procedure DAL-SOP-0281: Biannual Product Reporting to the FDA* was updated to clearly state If the outsourcing facility has not compounded any drug products during the previous six-month period (including any initial report after registration), it is still required to submit a report to FDA indicating that it has not compounded any drug products during the period. ***Reference Attachment 7-2: DAL-SOP-0281: Biannual Product Reporting to the FDA extract.*** This action will apply not only to the existing MCCPMC Facility but any expansions as well. **Effectiveness Plan:** As bi-annual reports are required by the FDA and per MCCPMC procedures, and failure to complete the report will be detected, no additional effectiveness plan is required. **Impact Assessment:** As the facility was not occupied, and no drugs were compounded prior to the initial report, there is no risk of an absence of Facility history being accurately reported. Furthermore, there is no product risk as the observation was for report submittal only. **Conclusion:** The procedural update will ensure that future reports are submitted when no saleable drug products are manufactured, even if it is an Initial FDA Report at a new MCCPMC facility.

Corporations Section
P.O.Box 13697
Austin, Texas 78711-3697

Jane Nelson
Secretary of State

Office of the Secretary of State

Certificate of Fact

The undersigned, as Secretary of State of Texas, does hereby certify that the document, Application for Registration for Mark Cuban Cost Plus Manufacturing and Compounding LLC (file number 804898676), a DELAWARE, USA, Foreign Limited Liability Company (LLC), was filed in this office on January 26, 2023.

It is further certified that the entity status in Texas is in existence.

In testimony whereof, I have hereunto signed my name officially and caused to be impressed hereon the Seal of State at my office in Austin, Texas on August 21, 2024.

Jane Nelson
Secretary of State

TEXAS
Health and Human Services

Texas Department of State Health Services

Jennifer A. Shuford, M.D., M.P.H.
Commissioner

June 27, 2024

Emily Hildebrand
Mark Cuban Cost Drug Company
Emily.Hildebrand@costplusdrugs.com

CFN: 2111413
Lic.: 1003649
Type: 2501
File: 6807

Re: License Verification

Dear Emily Hildebrand:

This letter shall serve as a verification of licensure for the following firm:
MARK CUBAN COST PLUS DRUG MANUFACTURING & COMPOUNDING LLC
3015 TAYLOR ST
DALLAS, TX 75226

License No.	1003649
Type of license:	Prescription Drug Manufacturer, Outsourcing Facility
Status of license:	Current
Date license issued:	06/27/2023
Date license expires:	02/05/2025
Disciplinary action:	None

The firm is in good standing as of the date of this letter.

If you have questions or need additional information, please contact me at 512-834-4503, via fax at (512) 834-6759, or email me at Justin.Arnold@dshs.texas.gov.

Sincerely,

Justin Arnold, MBA, RS
Medical Research Specialist
Drugs and Medical Devices Unit
Consumer Protection Division

Mailing address:
Justin Arnold
Drugs and Medical Devices Unit, MC 1987
PO Box 149347
Austin, TX 78714-9347

4EEEE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Pkwy, Suite 206 – Reno, NV 89521 – (775) 850-1440

APPLICATION FOR OUT-OF-STATE OUTSOURCING FACILITY LICENSE

$500.00 Fee made payable to: Nevada State Board of Pharmacy

(**non-refundable** and **not transferable money order or cashier's check only**)

Application must be printed legibly or typed

Any misrepresentation in the answer to any question on this application is grounds for refusal or denial of the application or subsequent revocation of the license issued and is a violation of the laws of the State of Nevada.

☐ New OUTSOURCING FACILITY
☒ Ownership Change (Provide current license number if making changes:) OUT 00025
☐ 503a OR ☒ 503b Apply as retail pharmacy only.

Check box below for type of ownership and complete all required forms for type of ownership that you have selected. If LLC use Non Public Corporation or Partnership

☐ Publicly Traded Corporation – Pages 1-3 & 4
☒ Non Publicly Traded Corporation – Pages 1-3 & 5
☐ Partnership - Pages 1-3 & 6
☐ Sole Owner – Pages 1-3 & 7

GENERAL INFORMATION to be completed by all types of ownership

Facility Name: OPS International Incorporated dba Olympia Pharmaceuticals

Physical Address: 6700 Conroy Road, Ste 155

City: Orlando State: FL Zip Code: 32835

Telephone: 407-673-2222 Fax: N/A

Toll Free Number: 800-991-9079 (Required per NAC 639.708)

E-mail: Licensing@olympiapharmacy.com Website: www.olympiapharmacy.com

Supervising Pharmacist: Michael Bogard Nevada License #: 23202

SERVICES PROVIDED

Yes/No

☐ ☑ Parenteral
☑ ☐ Sterile Compounding
☐ ☑ Non Sterile Compounding
☑ ☐ Mail Service Sterile Compounding
☐ ☐ Other Services:

All boxes must be checked for the application to be complete

An appearance will be required at a board meeting before the license will be issued.

Board Use Only Date Processed: 11/21/24 Amount: [redacted]

FEI Number (From FDA application): 3009724085

Please provide the name of the facility as registered with the FDA and the registration number:
Olympia Compounding Pharmacy and 3009724085

Please provide a list of all DBA's used by outsourcing facility. A separate sheet is acceptable.
Olympia Pharmaceuticals

Please provide the name and Nevada license number of the supervising pharmacist:
Name: Michael Bogard Nevada License Number: 23202

A Nevada business license is not required, however if the OUTSOURCING FACILITY has a Nevada business license please provide the number: N/A

This page must be submitted for all types of ownership.

Within the last five (5) years:

1) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)? Yes ☐ No ☒

2) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration? Yes ☐ No ☒

3) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry? Yes ☒ No ☐

4) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances? Yes ☐ No ☒

5) Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)? Yes ☐ No ☒

If the answer to question 1 through 5 is "yes", a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement, or other disposition may be required.

APPLICATION FOR OUT-OF STATE OUTSOURCING FACILITY - Page 3

I hereby certify that the answers given in this application and attached documentation are true and correct. I understand that any infraction of the laws of the State of Nevada regulating the operation of an authorized OUTSOURCING FACILITY may be grounds for the revocation of this permit.

I have read all questions, answers and statements and know the contents thereof. I hereby certify, under penalty of perjury, that the information furnished on this application are true, accurate and correct. I hereby authorize the Nevada State Board of Pharmacy, its agents, servants and employees, to conduct any investigation(s) of the business, professional, social and moral background, qualification and reputation, as it may deem necessary, proper or desirable. The facility must be registered with the FDA as an outsourcing facility (503B) to obtain an outsourcing facility from the Board of Pharmacy.

Federal and State law require a licensed pharmacist to supervise the compounding taking place in a registered outsourcing facility. This supervising pharmacist must be licensed by the Nevada Board of Pharmacy.

Does your outsourcing facility wholesale compounded medication for resale? Yes ☐ No ☒

The Law prohibits the resale of compounded medication. By signing this application you are attesting that your medications will be labeled with the statement "Not for Resale" and that the outsourcing facilities products will not be resold.



Original Signature of Person Authorized to Submit Application, no copies or stamps

Taylor Stone

Print Name of Authorized Person

11/13/24

Date

OWNERSHIP IS A NON PUBLICY TRADED CORPORATION

State of Incorporation: Florida

Parent Company if any: John Paul Holdings LLC

Address: 5551 Vanguard Street

City: Orlando State: FL Zip: 32819

Telephone: 407-673-2222 Fax: N/A

Contact Person: Taylor Stone

For any corporation non publicly traded, disclose the following:

1) List top 4 persons to whom the shares were issued by the corporation?

a) N/A - Applicant entity is wholly owned by parent company, John Paul Holdings LLC
Name Address

b) _____
Name Address

c) _____
Name Address

d) _____
Name Address

2) Provide the number of shares issued by the corporation. The answers to questions 2-5 will be supplemented upon closing of the transaction.

3) What was the price paid per share? _____

4) What date did the corporation actually receive the cash assets? _____

5) Provide a copy of the corporation's stock register evidencing the above information

Include with the application for a non publicly traded corporation

Certificate of Corporate Status (also referred to as Certificate of Good Standing). The Certificate is obtained from the Secretary of State's office in the State where incorporated. The Certificate of Corporate status must be dated within the last 6 months.

List of officers and directors

OPS International Inc. dba Olympia Pharmaceuticals

Nevada Disclosure

3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been the subject of an administrative action, board citation, cite fine or proceeding relating to the pharmaceutical industry?

On March 23, 2024, the California State Board of Pharmacy adopted a Stipulated Settlement and Disciplinary Order ("Stipulated Settlement Agreement") that resolved an administration matter pending against this facility. Even though this facility is an FDA-registered 503B outsourcing facility, this facility was previously licensed and regulated as a non-resident pharmacy in California resulting in allegations that this facility failed to comply with California's unique sterile compounding requirements. The Stipulated Settlement Agreement imposed a reprimand on this facility and allowed this facility to cancel its non-resident pharmacy and non-resident sterile compounding permits to provide a pathway for licensure as an outsourcing facility in the future. Since the Stipulated Settlement Agreement was adopted, this facility has not applied for licensure in California.

Taylor Stone
Chief Operating Officer and Sole Director
OPS International Inc.

Registered Outsourcing Facilities

Facilities Registered as Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act)

Updated as of 3/4/2025

- Information Concerning Outsourcing Facility Registration (/drugs/compounding/questions-and-answers-outsourcing-facility-registration)
- Outsourcing Facility Product Reporting Information (/drugs/compounding/information-outsourcing-facilities#reporting)

This table lists the outsourcing facilities that have submitted registration information that has been determined to be complete by the data lock date for the latest weekly update of the table.

Search: Olympia pharmaceuticals

Show 10 entries

Export Excel

Facility	Contact	Initial Registration Date [1]	Most Recent Registration Date [1]	Last Inspection [2]	Form 483 Issued? [3]	Recall Conducted? [9]	Action Based on Last Inspection [4,5]	Intends to Compour Drugs Fr Bulk Sub
Olympia Pharmaceuticels, Orlando, FL	Mark Mikhael 1-407-673-2222	3/10/2014	10/18/2024	5/29/2024	Yes (/media/180579/download?attachment)	No	Open[7]	Yes

Showing 1 to 1 of 1 entries (filtered from 83 total entries)

Previous 1 Next

Notes

1. The "initial date of registration as an outsourcing facility" is the date the facility was first registered (i.e., the date FDA determined that the initial registration information submitted for the facility was complete, and the establishment fee was paid in full).

   Under section 503B(b) of the FD&C Act, after the initial registration, a facility that elects to continue to be registered with FDA as an outsourcing facility must re-register annually. A facility that elects to register (or re-register) with FDA as an outsourcing facility must pay an annual establishment fee. The "date of most recent registration as an outsourcing facility" reflects the date FDA determined the most recently submitted registration information was complete and the annual establishment fee for that fiscal year paid in full.

   Unless a previously registered outsourcing facility re-registers and pays the annual establishment fee in full during the registration period (between October 1 and December 31 of each calendar year), the facility will be removed from the list of registered outsourcing facilities on January 1 of the next calendar year.

2. Once an outsourcing facility is registered, the facility will be added to the list of facilities FDA intends to inspect according to a risk-based schedule. FDA plans to inspect outsourcing facilities within a reasonable period of time following initial registration, once it is confirmed that the facility has initiated drug production and distribution. However, the exact timing of the inspections can be affected by a number of variables, including the number of outsourcing facility registrants, other inspection priorities, and the operational status of the newly registered outsourcing facility.

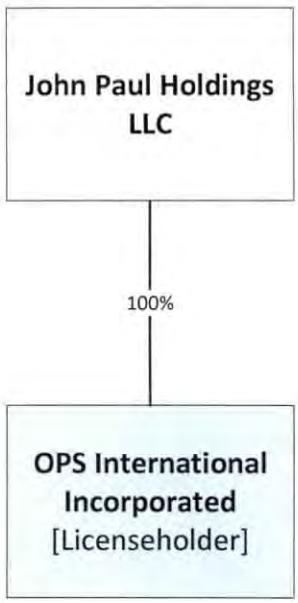
   Inspections identified in this table are associated with the facility at the listed address. A company may own or operate more than one registered outsourcing facility. FDA's web page Compounding: Inspections, Recalls, and other Actions (/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions) may contain information about compounding facilities under the same ownership as the listed registered outsourcing facility.

   Inspections may take place over several days, weeks or longer. The date of the inspection is the date a Form FDA 483 listing the investigators' observations was issued. If no FDA Form 483 was issued, the date is the last day of the inspection.

3. A Form FDA 483 is issued when investigators observe any significant objectionable conditions. It does not constitute a final agency determination of whether any condition is in violation of the FD&C Act or any relevant regulations.

4. This table does not include State Board of Pharmacy actions, if any. To determine whether a registered outsourcing facility has been the subject of a state enforcement action, check with the State Board of Pharmacy for the state in which the facility is located. Some states post disciplinary or other actions on their web sites.
5. "Closed" means the inspection has been closed without further action. "Open" means FDA has not determined whether further action will be taken. If an action has been taken, it will be listed. Possible FDA actions include warning letter, seizure or injunction.
6. The information in this column was provided by the registered outsourcing facility at the time of registration and has not been verified by FDA. "N/A" indicates the registered outsourcing facility has not provided this information.
7. This outsourcing facility was the subject of at least one previous inspection relating to compounding that resulted in a Form FDA 483, warning letter or other action. For information about such inspections and resulting actions, visit Compounding: Inspections, Recalls, and other Actions (/drugs/human-drug-compounding/compounding-inspections-recalls-and-other-actions).
8. A remote regulatory assessment (RRA) is an examination of an FDA-regulated establishment and/or its records, conducted remotely, to evaluate compliance with applicable FDA requirements. These assessments assist in protecting human and animal health, inform regulatory decisions and verify certain information submitted to the agency.
9. Based on inspectional findings, the inspection revealed significant issues. As a result, the outsourcing facility may have either initiated a recall on their own following conversation(s) with the FDA investigator or FDA recommended a recall at the conclusion of the inspection or both. Additionally, the outsourcing facility may have conducted multiple recalls or recalled multiple drugs.

Post-Closing Structure Chart



OPS International Inc. operates two facilities in Orlando, Florida: (1) a compounding pharmacy; and (2) an FDA-registered outsourcing facility

State of Florida
Department of State

I certify from the records of this office that OPS INTERNATIONAL INCORPORATED is a corporation organized under the laws of the State of Florida, filed on October 3, 2013, effective October 2, 2013.

The document number of this corporation is P13000081512.

I further certify that said corporation has paid all fees due this office through December 31, 2024, that its most recent annual report/uniform business report was filed on February 6, 2024, and that its status is active.

I further certify that said corporation has not filed Articles of Dissolution.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Eighth day of October, 2024

Secretary of State

Tracking Number: 4486135631CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

STATE OF FLORIDA
DEPARTMENT OF HEALTH
INVESTIGATIVE SERVICES
INV359 - Community Requirements

File # 20618
Insp # 178338

NAME	PERMIT NUMBER	DATE OF INSPECTION
OPS INTERNATIONAL INCORPORATED	27363	06/06/2023
DOING BUSINESS AS		
OLYMPIA PHARMACY		
STREET ADDRESS	**TELEPHONE #**	**EXT**
6700 CONROY ROAD STE 155	407-267-6468	
CITY	**COUNTY**	**STATE/ZIP**
ORLANDO	ORANGE	FL/32835

Additional Information

Business Operation Hours

M-T-W-TH-F Y	Weekly Hours 9 AM to 6 PM
Monday N	Monday Hours
Tuesday N	Tuesday Hours
Wednesday N	Wednesday Hours
Thursday N	Thursday Hours
Friday N	Friday Hours
Saturday N	Saturday Hours closed
Sunday N	Sunday Hours closed

Registered Pharmacist / Intern / Tech

License # PS 28085	Licensee Name Myriam Concepcion
License Type Registered Pharmacists	
License # PS31891	Licensee Name Naomi Loomis
License Type Registered Pharmacists	
License # PS15695	Licensee Name Robert Loomis
License Type Registered Pharmacists	
License # 35695	Licensee Name Jenny Loleit
License Type Pharmacy Tech	

ACS Manager

Optional Information

Basic License Data - PSD

DEA Reg # F04589505	

License Relations

Pharmacy Affiliate

LOLEIT, MARCO	License #

RX DPT MGR/COR/POR

CONCEPCION, MYRIAM M	License # 28085

Special Sterile Compounding

OPS INTERNATIONAL INCORPORATED	License # 27414

INV 359 - Community Requirements

Signage Requirements Section

Signage stating the hours the pharmacy department is open. [64B16-28.1081 (2) F.A.C.]	Yes
A sign with bold letters not less than 2 inches in width and height is displayed in a prominent place where it is easily read by patrons stating, "Prescription Department Closed". [64B16-28.109 F.A.C.]	N/A
Patient Consultation Area sign is posted. [64B16-30.003, F.A.C]	Yes

Community Requirements General Section

Expired medications removed from the shelves. [64B16-28.110 F.A.C.]; [64B16-28.1191 F.A.C.]	Yes
Rx Department is open for a minimum of 20 hours per week. [64B16-28.1081 (1) F.A.C.]	Yes
All controlled substance prescriptions (electronic, faxed, verbal and written) contain required information. [893.04(a)(b)(c) F.S.]; [21CFR1306.05] *No CS*	N/A
Certified daily log or signed printout maintained. [21CFR1306.22(f)(3)]; [64B16-28.140(3)(d) & F.A.C]	Yes
Prescription department has current copy of laws and rules, references and equipment necessary to the professional practice of pharmacy. [64B16-28.102 F.A.C.]	Yes
Pharmacy technicians and interns properly identified and supervised [64B16-27.100 (2) F.A.C.]; [64B16-27.4001 F.A.C.]; [64B16-27.410 F.A.C.]; [64B16-27.420 F.A.C.].	Yes
Legend drugs properly stored. [64B16-28.118 F.A.C.]; [64B16-28.120 F.A.C.]	Yes
Documentation of destruction of controlled substances. [64B16-28.303, F.A.C.] *RX return services but no CS*	Yes
Generic equivalent sign is posted. [465.025(7), F.S]	Yes

Additional Community Requirements

Prescription department is clean and safe, has a sink with running water convenient to the prescription department. [64B16-28.102 F.A.C.]	Yes
Pharmacist on duty when Rx department open. [64B16-28.109, F.A.C.]	Yes
When a pharmacist is not on duty, the prescription department is securely locked, and no other personnel remain in the department. [64B16-28.109 F.A.C.]	Yes
Written policy and procedure manual regarding the number of technician positions and their utilization. [64B16-27.410(2) (a), F.A.C.]	Yes
Documentation signed by Pharmacy technician acknowledging review of the Policy and Procedure manual within 90 days of hire. [64B16-27.410(2) (b), F.A.C.]	Yes
Documentation that Pharmacy technician has been trained in the established job description. [64B16-27.410(2)(c), F.A.C.]	Yes
Pharmacy licenses are current. [465.015(1)(a) F.S.]	Yes
Private consultation area available [6416-28.1035 F.A.C.]	Yes
Upon receipt of a new or refill prescription, a verbal and printed offer to counsel is made to the patient or the patient's agent. [64B16-27.820(1), F.A.C.]	Yes
Medication properly labeled. [499 F.S.]; [64B16-28.108 F.A.C.]; [893.04(1)(e) F.S.] [21CFR1306.24]; [21CFR1306.14]	Yes
Continuous Quality Improvement Program described in the Pharmacy policy and procedure manual and summarization of Quality -Related Events which have been reviewed by the CQI committee quarterly are available for inspection. [64B16-27.300 F.A.C.]; [766.101(1)(a)(l) F.S.]	Yes
Policy and Procedure available and implemented to prevent the fraudulent dispensing of controlled substances. [465.022(4), F.S.]	N/A
Pharmacy maintains patient profile records. [64B16-27.800, F.A.C.]	Yes
Written prescriptions for controlled substances are on counterfeit-proof pads from Department-approved vendors. [893.065 F.S.]; [456.42(2) F.S.]	N/A
Controlled substance inventory taken on a biennial basis and available for inspection. [893.07(1)(a) F.S.]; [21CFR1304.11] *April 3, 2023 start of business*	Yes
DEA 222 forms properly completed or records of CSOS orders electronically completed, linked to the original order, archived and retrievable. [893.07(2) F.S.]; 21CFR 1305.13(e)]; [21CFR1305.22(g)] *No CS onsite. Current DEA license active.*	N/A
Controlled substance records and Rx information in computer system are retrievable. [21CFR1304.04]; [465.022(12) (a) F.S.]; [21CFR1306.22]; [64B16-28.140 F.A.C.]	Yes
Controlled substance records are maintained for 4 years [465.022(12) (b) F.S.] [64B16-28.140 F.A.C.]	Yes
Pharmacy is reporting to law enforcement any instance of fraudulent prescriptions within 24 hours or close of business on next business day of learning of instance. Reports include all required information. [465.015(3), F.S.]	N/A
Record of theft or significant loss of all controlled substances is being maintained and reported to the sheriff and board within 24 hours of discovery. [893.07(5)(b) F.S.]; [465.022(11) (b) F.A.C.]	N/A
Pharmacy is reporting to the PDMP within 24 hours of dispensing controlled substance. [893.055(4) (3)(a), F.S.] *zero reported automatically*	Yes
Compounding records properly maintained. [64B16-28.140(4), F.A.C.] *Part of 503b pharmacy. No compounding in community pharmacy area only in 503b area.*	N/A
The pharmacy maintains an audit trail for all drugs from receipt or acquisition to sale or disposition [499.005 F.S.] [61N-1.012 F.A.C.]	Yes
Invoices for medications purchased from a Florida licensed wholesaler/distributor are retrievable for inspection. [499.005 (14) F.S.] *abc*	Yes
Administration begins not later than 1 hour following start of immediate use CSPs preparation. [64B16-27.797 F.A.C.]	N/A
Facility engaged in non-sterile office use compounding for human use is registered with FDA as an outsourcing facility [F.A.C 64B16-27.700(3)(g)]	Yes
Signage indicating that any patient receiving testing, screening, or treatment services is advised to seek followup care from his or her primary care physician. [465.1895 (9) F.S.]	N/A
Pharmacist has a written collaborative practice agreement. [465.1865, F.S.]	N/A

Human Trafficking signage is posted in a conspicuous place accessible to employees that is at least 11 inches by 15 inches in size, printed in a clearly legible font and in at least a 32-point type which gives instructions in English and Spanish on how to report to the National Human Trafficking Resource Center. [456.0341, F.S] *in break room*	Yes

Pharmacy Ships Medicinal Drugs to Patients [64B16-28.10801, F.A.C]

Pharmacy has policies and procedures in place to ensure that medicinal drugs are not adulterated at the time of receipt by the patient or their agent. *cold chain studies*	Yes
Pharmacy has policies and procedures in place to provide instructions to the patient on reporting concerns with delivery and storage of medicinal drugs. *information cards provide*	Yes

Pharmacy engages in Centralized Prescription Filling? [64B16-28.450, F.A.C.]

Pharmacies have the same owner or have a written contract specifying the services to be provided by each pharmacy.	
Current P&P Manual available for inspection designating at minimum: types of medications that may be filled, procedures for communicating orders, procedures for securely transporting the filled prescriptions.	
The originating pharmacy is identified with pharmacy name and address on the prescription container label.	
The central fill pharmacy is identified by name and address or a by a code available at the originating pharmacy.	
If a controlled substance, the word "central fill" appears on the face of the original prescription.	
The originating pharmacy keeps a record of receipt of the filled prescription, including the date of receipt, method of delivery and the name of the originating pharmacy's employee accepting delivery.	

Automated Pharmacy System [465.0235, F.S.]

Pharmacy maintains a record of the medicinal drugs dispensed, including the identity of the pharmacist responsible for verifying the accuracy of the dosage and directions and providing patient counseling.	
Pharmacy maintains written policies and procedures to ensure the proper, safe, and secure functioning of the automated pharmacy system for a minimum of 4 years.	

Internet Pharmacy

A toll-free telephone number is provided to facilitate communication between patients in this state and a pharmacist at the pharmacy who has access to the patient's records. [465.0197 (3)(e), F.S.]	
Toll free number is disclosed on the label affixed to each container of dispensed medicinal drugs. [465.0197 (3)(e), F.S.]	
Documentation of a valid, unexpired pharmacy license, permit or registration in the state in which the dispensing facility is located and from which the medicinal drugs shall be dispensed. [465.0197(3)(a) F.S]	

Remarks:

I have read and have had this inspection report and the laws and regulations concerned herein explained, and do affirm that the information given herein is true and correct to the best of my knowledge.

Inspector Signature

GRUBB, SWANIEE

Date:6/6/2023

Representative:

Nicole Snow

Date:6/6/2023

4801

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
[redacted]	12-31-2025	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	11-07-2022

OPS INTERNATIONAL INCORPORATED
OLYMPIA PHARMACY
6700 CONROY RD STE 155
ORLANDO, FL 328353515

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

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OLYMPIA PHARMACY
6700 CONROY RD STE 155
ORLANDO, FL 328353515

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Form DEA-223 (9/2016)

OPS International, Inc.

Owners and Officer List

Name	Title	Address	License
John Paul Holdings LLC	Parent Company	[redacted]	N/A
Taylor Stone, PharmD.	Chief Operating Officer and Sole Director		PS65902, Exp. 9/30/2025 (Florida)
Mark Mikhael, PharmD.	Chief Executive Officer		PS34124, Exp. 9/30/2025 (Florida)
Evan Stone, PharmD.	Chief Production Officer		PS67551, Exp. 9/30/2025 (Florida)
Josh Fritzler	Chief Financial Officer		N/A

Department of Health

OPS INTERNATIONAL INCORPORATED

OLYMPIA PHARMACY

License Number: PH32627

Data As Of 4/3/2025

Profession	Pharmacy
License	PH32627
License Status	CLEAR/
Qualifications	Community Pharmacy Schedule II & III
License Expiration Date	2/28/2027
License Original Issue Date	03/03/2020
Address of Record	4600 LB MCLEOD ROAD ORLANDO, FL 32811
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

No Emergency Actions Found

Discipline Cases

No Discipline Found

Public Complaints

No Public Complaint Found

If a link does not appear for the case number, we do not have a scanned copy of the final order available in our database. To obtain a paper copy, please contact Public Records by clicking the link below:

Discipline Public Records Request

You may also contact Public Records by telephone at (850) 245-4252, option 4 or by written correspondence at:
Division of Medical Quality Assurance
Public Records
4052 Bald Cypress Way, Bin C01
Tallahassee, FL 32399-3251

Please include the following:
1. Full name and license number of the practitioner;
2. Name and address where documents are to be sent; and
3. If you require certification of the documents, a $25 fee will be charged, in addition to the duplicating charges. Certification of the requested records will not be done unless specifically requested. An invoice will be sent to you and payment will be expected within thirty days. Upon receipt of payment, material will be sent to you.

Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
CHURCH, MICHAEL JOEL	RX DPT MGR/COR/POR	PHARMACIST	56988	01/05/2024
LOLEIT, MARCO	PHARMACY AFFILIATE	PHARMACY AFFILIATE		02/04/2020
OPS INTERNATIONAL INC.	PHARMACY	PHARMACY	32707	04/08/2020

Click on the License Number to view License Details for that Practitioner

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Florida HEALTH Department of Health

OPS INTERNATIONAL INC.

OLYMPIA PHARMACY

License Number: PH32707

Data As Of 4/3/2025

Profession	Pharmacy
License	PH32707
License Status	CLEAR/
Qualifications	Special Sterile Compounding
License Expiration Date	2/28/2027
License Original Issue Date	04/23/2020
Address of Record	4600 L B MCLEOD ROAD ORLANDO, FL 32811
Discipline on File	No
Public Complaint	No

Secondary Locations

No secondary locations found.

Discipline/Admin Action

Emergency Actions

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Discipline Cases

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Public Complaints

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Supervising Practitioners

Name	Relationship	Profession	License	Effective Date
CAMPBELL, KATE MICHELLE	RX DPT MGR/COR/POR	PHARMACIST	65892	10/01/2024
LOLEIT, MARCO	PHARMACY AFFILIATE	PHARMACY AFFILIATE		03/04/2020

Click on the License Number to view License Details for that Practitioner

Subordinate Practitioners

Name	Relationship	Profession	License	Effective Date
OPS INTERNATIONAL INCORPORATED	STERILE COMPOUNDING	PHARMACY	32627	4/8/2020

Click on the License Number to view License Details for that Practitioner

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DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	5/14/2024-5/29/2024* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark W. Mikhael, PharmD, CEO	
FIRM NAME Olympia Compounding Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Drug products failing to meet established specifications are not rejected.

Specifically, your firm released and distributed drug product MICC (methionine 25mg, inositol 50mg, choline 50mg, cyanocobalamin 330 mcg) Lot#B66D07-23, BUD: 08 JUL 23 that failed finished product testing for low cyanocobalamin assay at 87.4%. On 03/24/2023 Lot#B66D07-23 was rejected and dispositioned to be destroyed by your quality unit but your firm already began distributing this lot 10 days prior on 03/14/2023. A total of 369 vials of lot#B66D07-23 were distributed from 03/14/2023 through 05/08/2023.

*****This is a repeated observation from the previous FDA Inspection dated 2/14-2/23/22.**

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

1. Your firm failed to conduct a Performance Qualification (PQ) where your firm establishes all filling parameters including but not limited to cap placement involving circular vibrator speed and the cap crimping station involving crimp time and adequate in-process sampling for all your drug products produced on the Flexicon Auto Filling Machines.

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE		DATE ISSUED
	Kayla V Sprague, Investigator Jessica P Mcalister, Investigator Libia M Lugo, Investigator Logan T Williams, Investigator	X	5/29/2024

DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
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CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

A. On 5/14/24, Flexicon Auto Filling Machine (AF2) faulted during the production of Vitamin D3 50,000 IU/mL lot #E13A03-24, BUD 09 NOV 24 due to issues with the crimping station. Deviation # D-2024-017 was opened and the investigation is on-going.

B. On 5/15/24, during the filling operation for Lysine lot #E16A05-24, BUD: 31 AUG 24 on the Flexicon Auto Filling Machine (AF3) the line was stopped numerous times for defective crimping. According to your firm you produced 452 vials in total prior to stopping production. Two hundred twenty-four (224) vials were discarded. Deviation # D-2024-022 was opened and the investigation is on-going.

C. On 5/15/24, I observed vials of Semaglutide 5mg/mL (3mL) lot # E06A02-24, CPD 06 May 24, BUD 03 SEP 24 that were visually inspected by your firm with fill weight discrepancies. Your firms in-process sampling (every 15-min.) for fill weight is inadequate as it fails to include measuring the volume with a calibrated instrument and instead you only conduct a visual check for the volume filled allowing for variability between operators.

2. Your firm failed to establish a procedure for the assembly/disassembly of the Flexicon Auto Filling Machines following cleaning operations. In addition, your firm's preventative maintenance conducted on an annual basis is inadequate as it fails to incorporate the inspection and potential replacement of the manual-seals, slide bearings and timing belts which are outlined in the Flexicon Auto Filling Machine manual.

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

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CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

1. Your firm failed to validate your manual sterilization process which incorporates the use of SteraMist iHP (ionized Hydrogen Peroxide) utilizing biological indicators within the lyophilizer.

2. On 5/14/24 in preparation for lyophilizing a drug product the next day per SOP #P-806, Operation and Maintenance of the Lyophilizer, Section 8.6.5 your firm conducted a manual cleaning and sterilization of the interior chamber from 17:10pm until 17:30pm with Vest-Syde SQ128 RTU and SteraMist spraying the internal surfaces.

   On 5/15/24 at 11:31am (approximately 19 hours later with no established hold time) during visual inspection of the interior chamber of your lyophilizer I observed residual liquid on multiple product shelves. Your firm was unable to provide evidence on what the residual liquid was and that it does not introduce contamination to your lyophilization cycle.

3. Your firm failed to include the stopper chute (product contact surface) within your cleaning validation/sterilization of the Flexicon Auto filling machine therefore there is no documentation ensuring the residual detergent (Steris CIP 100 Alkaline, part number 1D1008) from your cleaning operation is adequately removed.

   *****This is a repeated observation from the previous FDA Inspection dated 2/14-2/23/22.**

4. On 5/15/24, during the production of Lysine, lot #E16A05-24, BUD: 31 AUG 24 within Cleanroom CR3 (ISO 7) we observed the wheel of a stainless-steel cart and the stainless-steel external base of your lyophilizer to contain an amber colored residue. Your firm opened Deviation # D-2024-019. In addition, within Cleanroom CR2 (ISO 7) where bulk sterilization occurs chipped/peeling caulking or paint was observed on the ceiling.

OBSERVATION 4

Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

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Specifically, your firm failed to use a broth containing disinfectant neutralizers for your viable surface swab samples. Your firm conducts viable surface swab samples on the stopper bowl (product contact surface), filling needle (product contact surface) and tube transport port.

OBSERVATION 5

Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, your firm does not assure that worst-case processing conditions for line speed are met as outlined in "Verification Protocol for Process 1 by Aseptic Process Simulation". Per protocol, the 30mL size vial should be filled at the slowest speed of 14 vials per minute (vpm) and the 10mL size vial should be filled at the fastest speed of 21.8 vials per minute. Vials per minute is an output of all parameters set up on the auto filler. No vial per minute monitoring is performed during execution of aseptic processing simulations. In addition, on 5/14/2024, during observation of sterile filling for 30mL L-Lysine lot E16A05-24, the vials per minute was observed to be 13.3 vpm which is slower than the worst-case scenario outlined in the aseptic process simulation protocol.

OBSERVATION 6

Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, your firm failed to investigate complaints received by your complaint intake team, including complaints related to apparent adverse drug events. Currently, your firm has identified 167 received complaints from 3/13/2024 - 5/22/2024, and is working backwards by date to retrospectively capture all missed complaints.

In addition, these complaints were restored from a "Deleted Items" folder within the complaint intake

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kayla V Sprague, Investigator Jessica P Mcalister, Investigator Libia M Lugo, Investigator Logan T Williams, Investigator	X	DATE ISSUED 5/29/2024

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team's email folders. Additionally, your firm did not document all complaints as required by complaint procedure "Complaint Handling, Drug Safety, and Surveillance". Complaints not investigated include but are not limited to:

a. Glutathione 200mg/mL lot B13E01-24, BUD 5/13/2024 – this complainant stated that they had an adverse reaction and thought they were going into cardiac arrest.

b. B12 Methylcobalamin 5mg/mL lot B12D05-24, BUD 5/12/2024 – this complainant stated a patient came into the clinic and received an injection of B12 and had to be rushed to the hospital.

c. Sodium Bicarbonate 8.4% lot H23A03-23, BUD 2/19/2024 – this complainant stated that the sodium bicarbonate precipitated out when it was mixed with Lidocaine. They stated they have performed this many times with no issues.

d. Tri-Immune unknown lot number and unknown BUD – this complainant stated that the vial was warm when it was received. This product requires storage from 2-8 degrees C. Your firm responded from an Olympia Pharmacist email stating that the product was okay to use.

e. Semaglutide unknown lot and unknown BUD – complainant stated they've had a multitude of patients and staff members expressing dissatisfaction in the effectiveness of the firm's semaglutide.

f. Tirzepatide Injectable unknown lot and unknown BUD – complainant stated that the product was not controlling blood glucose effectively.

OBSERVATION 7

Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, drug products were compounded and not identified on your reports dated June 2023 and December 2023, including, but not limited to:

- PGE1 (alprostadil) 40 mcg/mL injection
- PGE3 (alprostadil) 150 mcg/mL injection
- Sodium tetradecyl sulfate 0.1% injection

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DISTRICT ADDRESS AND PHONE NUMBER	DATE(S) OF INSPECTION
555 Winderley Place, Suite 200 Maitland, FL 32751 (407)475-4700 Fax:(407)475-4768 ORAPHARM2_RESPONSES@fda.hhs.gov	5/14/2024-5/29/2024* FEI NUMBER 3009724085

NAME AND TITLE OF INDIVIDUAL TO WHOM REPORT ISSUED	
Mark W. Mikhael, PharmD, CEO	
FIRM NAME Olympia Compounding Pharmacy	STREET ADDRESS 6700 Conroy Rd Ste 155
CITY, STATE, ZIP CODE, COUNTRY Orlando, FL 32835-3515	TYPE ESTABLISHMENT INSPECTED Outsourcing Facility

☐Sodium tetradecyl sulfate 0.3% injection
☐Zinc sulfate 10 mg/mL injection

*****This is a repeated observation from the previous FDA Inspection dated 2/14-2/23/22.**

***DATES OF INSPECTION**

5/14/2024(Tue), 5/15/2024(Wed), 5/16/2024(Thu), 5/17/2024(Fri), 5/20/2024(Mon), 5/21/2024(Tue), 5/22/2024(Wed), 5/23/2024(Thu), 5/29/2024(Wed)

SEE REVERSE OF THIS PAGE	EMPLOYEE(S) SIGNATURE Kayla V Sprague, Investigator Jessica P Mcalister, Investigator Libia M Lugo, Investigator Logan T Williams, Investigator	X	DATE ISSUED 5/29/2024

The observations of objectionable conditions and practices listed on the front of this form are reported:

1. Pursuant to Section 704(b) of the Federal Food, Drug and Cosmetic Act, or
2. To assist firms inspected in complying with the Acts and regulations enforced by the Food and Drug Administration.

Section 704(b) of the Federal Food, Drug, and Cosmetic Act (21 USC 374(b)) provides:

"Upon completion of any such inspection of a factory, warehouse, consulting laboratory, or other establishment, and prior to leaving the premises, the officer or employee making the inspection shall give to the owner, operator, or agent in charge a report in writing setting forth any conditions or practices observed by him which, in his judgment, indicate that any food, drug, device, or cosmetic in such establishment (1) consists in whole or in part of any filthy, putrid, or decomposed substance, or (2) has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. A copy of such report shall be sent promptly to the Secretary."

OLYMPIA
Pharmaceuticals

6700 Conroy Road, Ste 155
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July 10, 2024

Via Electronic Mail
Jessica P. McAlister, Investigator
Kayla V. Sprague, Investigator
Libia M. Lugo, Investigator
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Food & Drug Administration
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Re: Olympia Compounding Pharmacy d/b/a Olympia Pharmacy (FEI 3009724085)

Dear Investigators McAlister, Sprague, Lugo, and Williams:

Olympia Compounding Pharmacy d/b/a Olympia Pharmacy ("*Olympia*") writes in response to the FDA Form 483 issued on May 29, 2024.[1] Form 483, attached as **Exhibit A**. Olympia trusts that the significant resources it invested and the comprehensive initiatives it undertook over the past two years were evident to FDA during this recent inspection. Olympia is confident that the improvements made to its control and evaluation of raw materials, facility design and equipment, expansion of its quality assurance department, standardization of personnel training, and implementation of team-based cross-department controls provide the necessary oversight to ensure the production of quality drug products.

While Olympia has dedicated significant time, effort, and resources over the past two years to establish a foundation for consistently producing high-quality preparations, Olympia remains committed to continual improvement. Toward that end, Olympia is constantly assessing and improving its operations to ensure it remains abreast of industry best practices and operates in accordance with current Good Manufacturing Practices ("*cGMP*"). Given Olympia's commitment to continuous quality improvement, Olympia appreciates the constructive discussion with FDA during its recent inspection. Olympia welcomes the opportunity to finetune, where necessary, the already extensive quality systems and compounding processes that Olympia has in place, as set forth below.

[1] Please note that FDA may not post the contents of this letter or the corresponding attachments to FDA's website without Olympia's express permission.

OBSERVATION 1
Drug products failing to meet established specifications are not rejected.

Specifically, your firm released and distributed drug product MICC (methionine 25 mg, inositol 50 mg, choline 50 mg, cyanocobalamin 330 mcg) Lot # B66D07-23, BUD: 08 JUL 23 that failed finished product testing for low cyanocobalamin assay at 87.4%. On 3/24/2023, Lot # B66D07-23 was rejected and dispositioned to be destroyed by your quality unit but your firm distributed this lot days prior on 3/14/2023. A total of 369 vials of lot # B66D07-23 were distributed from 03/14/2023 through 05/08/2023.

Response to Observation 1:

Olympia understands the importance of ensuring all released drug products are within the acceptable potency range. Toward that end, as FDA is aware, Olympia previously overhauled its batch review and finished product release procedures by increasing quality oversight and implementing team-based controls. As a result of these controls, contrary to the suggestion made in Observation 1, Olympia *did not* release any vials from Lot # B66D07-23 (the *"Lot"*). Rather, Olympia's extensive investigation determined that Lot # B66D07-23 was listed on the distribution report in error. Olympia has rectified the root cause of this error, as explained below.

(a) Olympia Promptly Identified the OOS, Investigated the Root Cause, and Destroyed the Lot

By way of background, Olympia compounded the Lot on February 7, 2023. There were 3,849 total vials in the Lot. Olympia sent 62 vials for end-product release testing. While third-party release testing was pending, the Lot was placed in a locked quarantine cage. P-214.8-SOP-011 Batch Release for Sterile Drug Products, attached as **Exhibit B**. Access to the quarantine cage was limited to a Quality Assurance (*"QA"*) Manager. On February 24, 2023, the third-party lab, ARL, released the certificates of analysis (*"COA"*). The QA Manager, with the key to the locked quarantine cage, reviewed the COAs. Because the ARL testing determined that the Lot was potentially OOS, the QA Manager immediately placed a sign in the locked quarantine cage indicating "do not use—under investigation."

Olympia promptly initiated a deviation investigation to determine whether the OOS was valid and to evaluate the root cause for the OOS if the ARL results were valid. Deviation D-2023-007, attached as **Exhibit C**. During the investigation, the QA Manager updated the quarantine cage sign to "Investigation D-2023-007" and the Lot remained in the locked quarantine cage to prevent distribution. Olympia's investigation was comprehensive and included interviewing personnel, analyzing component COAs to ensure all Active Pharmaceutical Ingredients (*"API"*) were within specifications, assessing API storage conditions, and reviewing prior compounded MICC lots to assess for trends. Ex. C, p. 3. The investigation confirmed that there was no lab error, and that the OOS lab result was valid. Ex. C, pp. 3-4. Ultimately, Olympia determined the root cause was an error in component mixing. Namely, a small quantity of Cyanocobalamin API spilled resulting in an insufficient quantity of Cyanocobalamin added thereby causing the sub-potent batch. Ex. C, p. 4. No other errors were found, and Olympia conducted technician training to address the identified root cause of the OOS. *Id.*

As the investigation determined that the OOS result was valid, QA dispositioned the Lot for destruction but retained six vials for sampling. Olympia's destruction log affirms that the *entire* Lot was destroyed on March 31, 2023. F-500.a-B66A07-23 Destruction Log, attached as **Exhibit D**. As demonstrated by the destruction log, 3,781 vials were destroyed—the complete number of vials that remained in the Lot after accounting for the 62 vials sent for testing and 6 vials retained for sampling.

$$3849\ vials\ produced - 62\ vials\ sent\ for\ testing\ - 3781\ vials\ destroyed - 6\ vials\ retained = 0\ vials\ remaining.$$

The Lot's destruction is further supported by the batch record. Specifically, the Lot's batch record demonstrates that the Lot *was never* labeled. MICC Batch Record Labeling Section, attached as **Exhibit E**. Only six labels were generated for this Lot—all were to label the six retained vials: two labels for B66B07-23, two labels for B66C07, and two labels for B66D07-23. MICC Sample Retention Log, attached as **Exhibit F**. Further, confirming that this Lot was not distributed.

Based on the above, Olympia is confident that all vials from the Lot were appropriately destroyed, that Olympia's production processes for MICC are appropriate, and that Olympia's comprehensive batch release controls work effectively. Nevertheless, in accordance with FDA's recommendations, Olympia modified its quarantine cage procedures and revised its SOP to reflect these changes. Ex. B. In addition to the washable quarantine placards identifying the status of lots, Olympia has also implemented a color-coded system. For example, QA will tag lots that are under investigation or OOS with a bright orange sign and QA will tag lots that it has authorized for release with a white sign. Ex. B, Section 7.3. A sample of the QA Quarantine Sign is attached as **Exhibit G**. Further, Olympia personnel were trained on this revised procedure. SOP 214.8 Training Logs, attached as **Exhibit H.**

While Olympia is confident that the Lot was not distributed, Olympia's investigation did identify an error on its distribution report that has been fully rectified as described below.

(b) There Was a Discrepancy on Olympia's Distribution Report and Olympia Implemented Remediations to Prevent Recurrence

While Olympia is confident that no vials from the Lot were released, Olympia's deviation investigation revealed an error on Olympia's distribution report. D-2024-020, attached as **Exhibit I**. Below Olympia provides context for how the error occurred and information demonstrating that the discrepancy cannot reoccur.

By way of background, Olympia's production team and dispensing team coordinate consistently to ensure that the dispensing team is aware of products being compounded to allow for appropriate order management. In this case, the production team notified the dispensing team that the Lot had been compounded. At that time, 10 mL MICC vials were running low in inventory. Therefore, a dispensing team pharmacist proactively created Lot # B66D07-23 in Olympia's software system, intending to use this Lot to fill pending orders after the Lot passed release testing. Once the Lot number was created in the dispensing system, the Lot number became active and selectable. Ex. I. Olympia's distribution report

is a function of this software system. Meaning that, the Lot number selected in Olympia's system is the Lot number listed in the distribution report.

Because the Lot was ultimately destroyed and not released (Ex. D), Olympia's inventory of 10 mL MICC vials was insufficient to fill pending orders. Therefore, as Olympia has done in the past, Olympia's dispensing pharmacist determined that customers with pending orders for 10 mL MICC vials would receive 30 mL MICC vials from existing inventory. In this case, as determined by Olympia's deviation investigation, 30 mL MICC vials from Lot # A24C09-23 were used to fill orders for 10 mL MICC vials. Ex. I.

The data confirms that Lot # A24C09-23 was the lot that was distributed. Specifically, Lot # A24C09-23 included 1,293 30 mL vials and 460 10 mL vials. Olympia's distribution log demonstrates that all 460 10 mL vials were distributed. However, the distribution log indicates that only 884 vials of the 30 mL vials were distributed, leaving 409 unaccounted vials. Olympia's investigation determined that 40 vials were destroyed when a dispensing basket was dropped. The remaining 369 vials are the vials that were inaccurately identified on the distribution report as being from Lot # B66D07-23. Because Lot #B66D07-23 was proactively created in the system, this Lot was available for selection and subsequently erroneously selected by the dispensing pharmacists when filling orders even though that Lot had been destroyed. Ex. I.

To prevent this error from reoccurring, Olympia implemented several new controls. First, dispensing pharmacists will no longer be allowed to create lot numbers in the system. Rather, QA will have sole control over the creation of lot numbers in the system. P-603.4-SOP-041 Verification of Prescriptions and Products for Dispensing, Section 7.6.5.2, attached as **Exhibit J**; *see also* Ex. B, Section 7.3.2. QA will only create lot numbers after the lot has been approved for release. By doing so, lots that are ultimately rejected and destroyed will not exist in the dispensing software and therefore, said lots cannot inadvertently be selected in the system. Further, Olympia trained its dispensing team on this revised process and retrained its dispensing team on verifying that the lot number on the label matches the lot number listed in the dispensing software. P-603-Training Logs, attached as **Exhibit K**. Finally, Olympia conducted an inventory reconciliation of 30 batches compounded in 2024. Olympia assessed quantities produced and amounts dispensed as reflected in Olympia's distribution report against current inventory, and confirmed that all numbers match. Moving forward, Olympia will include an inventory reconciliation in its monthly Management Review Team meetings to ensure Olympia's distribution log aligns with its inventory.

In conclusion, Olympia is confident that its distribution log is accurate but, as a result of this occurrence, Olympia recognized areas for improvement and implemented additional controls to prevent recurrence.

OBSERVATION 2

Your firm failed to establish written procedures for production and process controls designed to assure that the drug products have the identity, strength, purity, and quality that they are purported or represented to possess.

Specifically,

1. Your firm failed to conduct a Performance Qualification (PQ) where your firm establishes all filling parameters including but not limited to cap placement involving circular vibrator speed and the cap crimping station involving crimp time and adequate in-process sampling for all your drug products produced on the Flexicon Auto Filling Machines.

A. On 5/14/24, Flexicon Auto Filling Machine (AF2) faulted during the production of Vitamin D3 50,000 IU/mL lot #E13A03-24, BUD 09 NOV 24 due to issues with the crimping station. Deviation # D-2024-017 was opened and the investigation is on-going.

B. On 5/15/24, during the filling operation for Lysine lot #E16A05-24, BUD: 31 AUG 24 on the Flexicon Auto Filling Machine (AF3) the line was stopped numerous times for defective crimping. According to your firm you produced 452 vials in total prior to stopping production. Two hundred twenty-four (224) vials were discarded. Deviation # D-2024-022 was opened and the investigation is on-going.

C. On 5/15/24, I observed vials of Semaglutide 5mg/mL (3mL) lot # E06A02-24, CPD 06 May 24, BUD 03 SEP 24 that were visually inspected by your firm with fill weight discrepancies. Your firms in-process sampling (every 15-min.) for fill weight is inadequate as it fails to include measuring the volume with a calibrated instrument and instead you only conduct a visual check for the volume filled allowing for variability between operators.

2. Your firm failed to establish a procedure for the assembly/disassembly of the Flexicon Auto Filling Machines following cleaning operations. In addition, your firm's preventative maintenance conducted on an annual basis is inadequate as it fails to incorporate the inspection and potential replacement of the manual-seals, slide bearings and timing belts which are outlined in the Flexicon Auto Filling Machine manual.

Response to Observation 2:

Olympia is confident that the production and quality processes and controls that it has in place provide for the production of drug products with uniform identity, strength, purity, and quality.

2.1. As a threshold matter, in response to FDA's comments, Olympia conducted a comprehensive assessment of the last 100 batches produced using the Flexicon Auto Filling Machines. Batch Review Data, attached as **Exhibit L.** Olympia analyzed the batch record data for key indicators that would demonstrate an issue with the auto fillers' performance. Specifically, Olympia assessed for production yield discrepancies, truncated or extended filling times, and any operator notes indicating filling errors. The assessment confirmed that the prior filling sessions were uniform in run time and met assigned thresholds. Further, Olympia's batch yield is consistently in the 90th percentile, demonstrating uniformity and consistency in the production of Olympia's batches. As such, FDA's observations are not indicative of the auto fillers' prior performance. Regardless, Olympia understands the importance in conducting

Performance Qualifications (*"PQ"*) and has begun executing PQs for the filling lines and the lyophilizer. FPC50 PQ (VP-OCP-FLEX-PQ-01), attached as **Exhibit M**; FP50 PQ (VP-OCP-AF1-PQ-01), attached as **Exhibit N**.

2.1(a) & (b). Olympia reiterates that the past batch data demonstrates that the crimping station errors were a new occurrence. Regardless, Olympia conducted two deviation investigations to assess for root cause. D-2024-017, attached as **Exhibit O**; D-2024-022, attached as **Exhibit P**. Olympia's investigations were thorough and included flying Flexicon engineers from Denmark to Olympia's outsourcing facility in Florida, so that the Flexicon engineers could perform in-person evaluations of *all* Olympia's auto fillers—not just the two auto fillers at issue in this observation.

Ultimately, the Flexicon engineers, alongside Olympia's engineering staff, determined that the error was caused by the misalignment of the guide track resulting in vials being improperly positioned under the cap crimping station. The guide track's misalignment was caused by a loosening of the guide track screws due to continued use. The Flexicon engineers explained that the machine's vibrations can cause this occurrence over time and that this occurrence is not described in the Flexicon manual.

To address this root cause, Olympia implemented a more robust preventative maintenance plan for the Flexicon Auto Fillers. P-809.3-SOP-056 Operation of the Flexicon Auto Filler, attached as **Exhibit Q**; F-809.d.3 Maintenance Log Flexicon Auto Filler, attached as **Exhibit R**. The revised preventative maintenance plan is based on the Flexicon manual and the Flexicon engineers' recommendations. Now, in addition to the annual maintenance previously performed, Olympia will perform quarterly maintenance checks of the auto filler which will include a review of the guide track, screw connections, timing belt, and rotation bearings. Olympia trusts that these new measures will ensure the auto fillers remain in good working condition.

2.1(c). Olympia acknowledges FDA's comments relative to fill weight and has therefore implemented a process to accompany its in-process visual volume checks. Moving forward, Olympia will rely upon calibrated scales to assess the weight of filled vials to provide better consistency in fill volumes. Olympia has further created an appendix setting forth the acceptable fill volume ranges for each product. A-809.a- Fill Check Acceptance Ranges, attached as **Exhibit S**. Olympia's staff were trained on this new procedure including equipment calibration. A-809.a.1-Training Logs, attached as **Exhibit T**.

2.2. While Olympia is confident that its prior SOP and Flexicon Setup Form provided for consistent use, Olympia acknowledges that these materials could include more granularity. Toward that end, Olympia has rewritten its SOP and its Flexicon Setup Form. Ex. Q; F-809.a.4-Flexicon Setup, attached as **Exhibit U**. Olympia's revised SOP and the accompanying materials were rewritten with input from the Flexicon manual and the Flexicon engineers. As a result of Olympia's efforts, the revised SOP now includes a more thorough discussion of the auto filler set

up including a step-by-step discussion regarding how to attach the beam arm to the beam controller, install and adjust the capper bowl, and determine crimper height. Ex. Q, Sections 8.6, 8.7, 8.8, and 8.10. The SOP further discusses disassembly and cleaning, and preventative maintenance. Ex. Q, Sections 10 and 11. As discussed above in response to Observation 2.1(a) and (b), Olympia comprehensively rewrote the preventative maintenance plan. Not only does Olympia's preventative maintenance plan now fully align with the Flexicon manual but the plan goes above and beyond these processes as a result of the additional insights provided by the Flexicon engineers. Finally, Olympia created a competency assessment for the Flexicons to ensure technicians thoroughly understand how to set-up, clean, and run the auto fillers. F-809.g.1 Competency Assessment Flexicon Gen 3_4, attached as **Exhibit V.** Olympia's staff underwent training on the revised SOP. P-809.3-Training Logs, attached as **Exhibit W.**

OBSERVATION 3

Aseptic processing areas are deficient regarding the system for cleaning and disinfecting the room and equipment to produce aseptic conditions.

Specifically,

1. Your firm failed to validate your manual sterilization process which incorporates the use of SteraMist iHP (ionized Hydrogen Peroxide) utilizing biological indicators within the lyophilizer.

2. On 5/14/24 in preparation for lyophilizing a drug product the next day per SOP #P-806, Operation and Maintenance of the Lyophilizer, Section 8.6.5 your firm conducted a manual cleaning and sterilization of the interior chamber from 17:10 pm until 17:30 pm with Vest-Syde SQ128 RTU and SteraMist spraying the internal surfaces.

On 5/15/24 at 11:31 am (approximately 19 hours later with no established hold time) during visual inspection of the interior chamber of your lyophilizer I observed residual liquid on multiple product shelves. Your firm was unable to provide evidence on what the residual liquid was and that it does not introduce contamination to your lyophilization cycle.

3. Your firm failed to include the stopper chute (product contact surface) within your cleaning validation/sterilization of the Flexicon Auto filling machine therefore there is no documentation ensuring the residual detergent (Steris CIP 100 Alkaline, part number 1D1008) from your cleaning operation is adequately removed.

4. *On 5/15/24, during the production of Lysine, lot #E16A05-24, BUD: 31 AUG 24 within Cleanroom CR3 (ISO 7) we observed the wheel of a stainless-steel cart and the stainless-steel external base of your lyophilizer to contain an amber colored residue. Your firm opened Deviation # D-2024-019. In addition, within Cleanroom CR2 (ISO 7), where bulk sterilization occurs chipped/peeling caulking or paint was observed on the ceiling.*

Response to Observation 3:

Olympia is confident in the systems and processes it has in place relative to the cleaning and disinfecting of its room and equipment. Nevertheless, Olympia has implemented the additional measures described below to fmetune its processes.

3.1. With regard to Observation 3.1., Olympia conducted a two-step validation of its cleaning practices for the lyophilizer. First, Olympia simulated three runs of the lyophilizer to mimic normal use. After each use, Olympia conducted its normal cleaning procedures using the established hold times. Following each clean, Olympia obtained surface samples from the lyophilizer. Olympia then incubated all samples for 7 days. No growth occurred, confirming that Olympia's cleaning practices are appropriate. Cleaning Validation Protocol for Lyophilizer LYO-003, attached as **Exhibit X**. Further, Olympia placed inoculated spore strips in the lyophilizer and then TOMI conducted a sterilization using the SteraMist iHP (ionized Hydrogen Peroxide). Sterilization Validation Protocol for Lyophilizer LYO-003, attached as **Exhibit Y**. The Certificates of Analysis demonstrate that the SteraMist sufficiently removed the microbials present on the inoculated strips, confirming that Olympia's sterilization procedure is appropriate. Lyo Sterilization Validation COAs, attached as **Exhibit Z**. Olympia will supplement the full validation report upon completion.

3.2. Olympia is confident that the residual liquid observed on the lyophilizer product shelves did not—and would not—have introduced contamination into the lyophilizer. Olympia's procedures for using the lyophilizer confirm this fact. P-806.9 Operation and Maintenance of the Lyophilizer, attached as **Exhibit AA**. As set forth in Olympia's SOP, before the lyophilizer is used, the technician must conduct a fulsome assessment of the exterior and interior of the machine. Ex. AA, Section 8.6. Notably, this inspection includes an assessment for any spills, residual compounding components, or residual liquid. *Id.* Further, only certain technicians at Olympia are authorized to use the lyophilizer. These technicians are thoroughly trained on the manner in which to set up the lyophilizer, how to clean the lyophilizer, and how to inspect the lyophilizer before and after use. 2024 Lyophilizer Training Logs, attached as **Exhibit BB**. Based on Olympia's SOP and extensive technician training, Olympia is confident that this residual liquid would have been identified, and the liquid would have been cleaned using Olympia's validated lyophilizer cleaning procedures. Therefore, there has never been a risk of contamination to Olympia's drug products.

With regard to the etiology of the residual liquid, Olympia comprehensively assessed the entirety of the lyophilizer while FDA was onsite and confirmed that the residual liquid was not the result of any lyophilizer defect. The lyophilizer was operating appropriately. All parts were assessed and found to be in good working order. Notably, the interior chamber where the liquid was observed is not connected to any pump or line that could introduce liquid into the chamber. As such, Olympia is confident that the source of the residual liquid was the sterilization performed the prior day.

Namely, as FDA is aware, Olympia conducted a cleaning of the lyophilizer on the evening of May 14, 2024. When doing so, Olympia wets a sterile low-lint wipe with sterile Vesta-Syde SQ 128 RTU and wipes the internal surfaces. Olympia follows this process by spraying the interior of the machine with SteraMist and then the door to the lyophilizer is closed resulting in an air-tight, closed-system environment. The SteraMist is not wiped but rather evaporates over time. Importantly, the SteraMist should only be sprayed on each product shelf for 2 seconds to avoid saturation. Ex. AA, Section 8.6.5.9. If saturation occurs, given the air-tight environment, the SteraMist does not evaporate. In this case, based on Olympia's review of the evidence, Olympia is confident that the technician over-sprayed the SteraMist resulting in cleaning product saturation. Because the cleaning product became saturated, the cleaning product was unable to evaporate in the airtight environment resulting in the residual liquid observed by FDA.

Olympia developed an investigation protocol to confirm the source of the residual liquid was the SteraMist. Residual Liquid Protocol, attached as **Exhibit CC**. Specifically, Olympia will conduct a simulation using the SteraMist consistent with Olympia's procedure and another simulation in which the product is over-sprayed resulting in saturation. Olympia will assess the lyophilizer under controlled conditions to determine whether residual liquid remains when SteraMist becomes saturated inside the chamber. Olympia is confident that this process will confirm that the residual liquid resulted from the technician's technique. Toward that end, to prevent recurrence of this issue, Olympia conducted technician retraining to ensure technicians only apply SteraMist for 2 seconds. Ex. BB. Olympia reiterates, however, that its technicians would have identified the residual liquid prior to using the lyophilizer and performed the necessary cleaning. Therefore, Olympia is confident that the processes that it has in place ensure that the lyophilizer operates under aseptic conditions.

3.3. Olympia understands the importance of validating its cleaning procedures to ensure the adequate removal of residual detergents. As FDA is aware, Olympia completed a cleaning validation for the auto filler in May 2023. While Olympia acknowledges that its cleaning validation inadvertently did not include the stopper chute, Olympia is confident that the cleaning validation data demonstrates no product impact occurred.

Specifically, when Olympia conducted the cleaning validation, Olympia tested the stopper bowl and the filling needle. The stopper chute is the intermediary between these two parts, meaning stoppers are placed in the bowl and travel through the chute to reach the vial after the filling needle. Importantly, the same cleaning and disinfecting procedures are used to clean the stopper bowl and the stopper chute, with the filling needle remaining single-use. As such, the cleaning validation data from the stopper bowl supports the fact that Olympia's cleaning procedures adequately remove residual detergent. Regardless, Olympia has executed a new cleaning validation that includes the stopper chute as a test point. PRO-617-001.2 Autofiller Cleaning Validation Protocol JUN24, attached as **Exhibit DD**.

3.4. Olympia takes cleaning and disinfecting of the cleanroom very seriously. We wish to note that contrary to the suggestion made in Observation 3.4, Olympia *did not* compound Lysine lot #E16A05-24 for release. Rather, at FDA's behest, Olympia agreed to conduct a compounding

simulation to demonstrate aseptic technique. Prior to performing the simulation, Olympia informed FDA that any lot compounded would have to be destroyed due to there being unqualified personnel (the FDA inspectors) in the cleanroom.

With regard to FDA's observation related to the cartwheel and the lyophilizer, as Olympia explained prior to entering the cleanroom, Cleanroom CR3 was set up earlier that day for an aseptic process simulation (*"APS"*) or media fill. When FDA requested a simulation, Olympia offered the scheduled media fill, but FDA requested that Olympia simulate production of a drug product. Therefore, out of deference to FDA, Olympia's technicians removed the media fill vials that had been set up in the cleanroom. However, in the process of disposing of the vials in a red bin positioned near the lyophilizer, one of the technicians dropped a vial. While the technician conducted a spot clean of the area, she did not conduct a comprehensive clean nor was a comprehensive clean performed on the cleanroom prior to FDA entering because Lysine was *only* being compounded for simulation.

Regardless, following receipt of FDA's observation, Olympia conducted a thorough investigation. The investigation confirmed that the amber colored liquid was caused by the vial that the technician had dropped earlier that day. D-2024-019, attached as **Exhibit EE** Specifically, the soybean casein digest growth medium used for the media fill is an amber colored liquid—the same color as the substance FDA observed on the cartwheel and the base of the lyophilizer. Olympia stresses that under normal production processes, the cleanroom would have undergone either a post-simulation clean following the completed media fill or a comprehensive daily clean before the cleanroom was authorized to be used for actual production. P-304.16-Cleaning of the Compounding Facility, attached as **Exhibit FF**, Section 9.1. Olympia is confident the amber liquid would have been identified on the cart leg and the base of the lyophilizer because those areas are assessed and disinfected during each of those cleaning procedures. Ex. FF, Section 9.1.

Finally, with regard to FDA's observation related to Cleanroom CR2 (ISO 7), Olympia's investigation determined that the "chipped caulk" was aesthetic, was surface-level, and did not impact the aseptic environment. Ex. EE. Regardless, Olympia recaulked the entire area. Caulk Repair Photograph, attached as **Exhibit GG**. Olympia assures FDA that it is committed to assessing its facility to ensure appropriate operating conditions. Toward that end, Olympia had in place a cleanroom inspection procedure requiring production staff to assess all aspects of the cleanroom for discoloration, chipping or peeling paint, as well as the general integrity of the materials in the cleanroom. F-304.f Facility Inspection Form, attached as **Exhibit HH**. However, moving forward, this assessment will be performed by QA. Olympia believes that involving QA in the process will introduce a fresh set of eyes in the area and ensure that areas requiring improvement are timely identified and corrected. *See* Ex. EE, CAPA Summary, p.7.

OBSERVATION 4
Aseptic processing areas are deficient regarding the system for monitoring environmental conditions.

Specifically, your firm failed to use a broth containing disinfectant neutralizers for your viable surface swab samples. Your firm conducts viable surface swab samples on the stopper bowl (product contact surface), filling needle (product contact surface) and tube transport port.

Response to Observation 4:

Olympia respectfully disagrees that its processes for monitoring environmental conditions were deficient. Over the course of the past few years, Olympia's QA personnel have, in conjunction with a consulting microbiologist, developed a comprehensive system to assess environmental and personnel monitoring conditions, and Olympia is confident in the processes that it has in place. Olympia understands that disinfectant neutralizers should be used for viable surface swab samples to provide for an accurate assessment of the presence of potential microbials. Olympia's prior practice aligned with this requirement.

Previously, Olympia used BBL CultureSwabs. While the BBL CultureSwab's Broth did not themselves contain disinfectant neutralizer, the swabs were always transferred to contact plates that utilized neutralizers. In other words, disinfectant neutralizers were always introduced into the sampling process; however, Olympia did so through an additional step in the sampling process. Olympia's prior sampling method was validated. The data demonstrates that, if microbials were present, recovery was shown in the sampling results. CultureSwab Trend Report-2023-2024, attached as **Exhibit II**; EM Swab Statement GB 24 JUN 2024, attached as **Exhibit JJ**. Therefore, Olympia's prior sampling method was appropriate.

Nevertheless, in light of the productive conversation with FDA, Olympia has streamlined its practices. Namely, Olympia implemented a change control and moving forward, Olympia will use Millipore ICR-Swabs. CRM-2024-019, attached as **Exhibit KK**. The Millipore ICR-Swabs utilize Tryptic Soy Broth with disinfectant neutralizers to ensure that Olympia's viable surface samples accurately detect the presence or absence of microbials. Through this change control, Olympia has eliminated an additional step in its sampling process and aligned its process with FDA's preference. Olympia staff have been trained on the use of these new swabs. EM Swab Training Logs, attached as **Exhibit LL.**

In sum, while Olympia is confident that its prior method appropriately recorded the presence or absence of microbials, Olympia appreciates the feedback from FDA resulting in the streamlining of Olympia's processes.

OBSERVATION 5
Procedures designed to prevent microbiological contamination of drug products purporting to be sterile did not include adequate validation of the aseptic process.

Specifically, your firm does not assure that worst-case processing conditions for line speed are met as outlined in "Verification Protocol for Process 1 by Aseptic Process Simulation". Per protocol, the 30mL size vial should be filled at the slowest speed of 14 vials per minute (vpm) and the 10mL size vial should be filled at the fastest speed of 21.8 vials per minute. Vials per minute is an output of all parameters set up on the auto filler. No vial per minute monitoring is performed during execution of aseptic processing simulations. In addition, on 5/14/2024, during observation of sterile filling for 30mL L-Lysine lot E16A05-24, the vials per minute was observed to be 13.3 vpm which is slower than the worst-case scenario outlined in the aseptic process simulation protocol.

Response to Observation 5:

Olympia respectfully disagrees that vials per minute monitoring provides an accurate determination of actual vial output. Specifically, the total run time divided by the total vials filled does not equal vials filled per minute because vials are not being filled the entire time that the machine is running. Rather, Olympia believes that the pump and line speed are better indicators of worst-case processing conditions.

Toward that end, Olympia conducted a comprehensive assessment of historical data to determine the average fill and beam speed for the 10 mL size vial for the Gen 3 Auto Filler and the Gen 4 Auto Filler. Similarly, Olympia conducted the same assessment to determine the average fill and beam speed for the 30 mL size vial for the Gen 3 Auto Filler and the Gen 4 Auto Filler. In turn, Olympia updated its Aseptic Process Simulation Policy and its Verification Protocol for Process 1 APS to align with the historical data demonstrating worst-case processing conditions. P-700.4-SOP-048 Aseptic Process Simulation Policy, attached as **Exhibit MM**; VP-APS-P1.14-Verification Protocol for Process 1 by Aseptic Process Simulation, attached as **Exhibit NN.**

Olympia is confident that the fill and beam speed provide a better assessment of worst-case processing conditions. Regardless, as Olympia is performing its PQ for the auto filler, Olympia will revisit this analysis following the PQ's completion. Further, Olympia will use the Human Machine Interface (*"HMI"*) printouts from the auto filler to verify line speed and pump speed, and this data will be incorporated into every APS batch to confirm that Olympia's APS aligns with worst-case operating conditions.

OBSERVATION 6
Procedures describing the handling of all written and oral complaints regarding a drug product are not followed.

Specifically, your firm failed to investigate complaints received by your complaint intake team, including complaints related to apparent adverse drug events. Currently, your firm has identified 167

received complaints from 3/13/2024 - 5/22/2024, and is working backwards by date to retrospectively capture all missed complaints.

In addition, these complaints were restored from a "Deleted Items" folder within the complaint intake team's email folders. Additionally, your firm did not document all complaints as required by complaint Procedure "Complaint Handling, Drug Safety, and Surveillance". Complaints not investigated include but are not limited to:

a. Glutathione 200mg/mL lot B13E01-24, BUD 5/13/2024 – this complainant stated that they had an adverse reaction and thought they were going into cardiac arrest.

b. B12 Methylcobalamin 5mg/mL lot B12D05-24, BUD 5/12/2024 – this complainant stated a patient came into the clinic and received an injection of B12 and had to be rushed to the hospital.

c. Sodium Bicarbonate 8.4% lot H23A03-23, BUD 2/19/2024 – this complainant stated that the sodium bicarbonate precipitated out when it was mixed with Lidocaine. They stated they have performed this many times with no issues.

d. Tri-Immune unknown lot number and unknown BUD – this complainant stated that the vial was warm when it was received. This product requires storage from 2-8 degrees C. Your firm responded from an Olympia Pharmacist email stating that the product was okay to use.

e. Semaglutide unknown lot and unknown BUD – complainant stated they've had a multitude of patients and staff members expressing dissatisfaction in the effectiveness of the firm's semaglutide.

f. Tirzepatide Injectable unknown lot and unknown BUD -- complainant stated that the product was not controlling blood glucose effectively.

Response to Observation 6.

Olympia acknowledges the need to involve QA in all aspects of the investigation and evaluation of complaints to allow for a proper trend analysis. Toward that end, on May 13, 2024, prior to FDA's arrival onsite, Olympia transitioned a QA representative, Maritza Reyes, to a new role: QA complaints. Olympia did so because it identified the need to include QA at the complaint intake stage to ensure that complaints are assessed in accordance with Olympia's SOP. Complaint Flow Chart, attached as **Exhibit OO**. As a result of this reconfiguration, QA will be involved in complaint intake and will follow complaints through all the stages set forth in the Complaint Flow Chart. Therefore, QA will be aware of all complaints coming in, will be aware of the conduct at issue in all complaints, will be aware of the resolution of all complaints, and will be able to assess for potential adverse trends or adverse events. Olympia trusts that its reconfiguration of the complaint intake process addresses FDA's concerns and ensures that moving forward QA is thoroughly involved in the investigation of all complaints.

With the above in mind, Olympia also initiated two deviation investigations to address Observation 6. D-2024-023 assessed the root cause for the complaint handling oversight and performed a fulsome retrospective assessment of all complaints received in 2022, 2023, and 2024. D-2024-023, attached as **Exhibit PP**. By way of background, customer inquiries and complaints are submitted via email to customerservice@olympiapharmacy.com, a Microsoft Outlook account. Prior to May 13, 2024, Olympia's customer services team performed the initial step in the intake process. The customer service team reviewed the customer correspondence, identified the complaints, and then routed the complaints to the QA and the pharmacist team. However, the deviation investigation determined, that in certain circumstances, the customer service team only forwarded the complaints to the pharmacist team. In these instances, the customer service team believed that the pharmacist team was notifying QA. Please note, however, that the pharmacist team did properly investigate these complaints. The pharmacist team communicated with the patient or clinic, evaluated the root cause of the patients' or clinics' complaint, and resolved the complaints through the exercise of their professional judgment. While these complaints were investigated, evaluated, and resolved in accordance with the pharmacist teams' professional judgment, Olympia recognizes that a breakdown in communication occurred that caused QA to be excluded from certain complaint investigations. Thus, by incorporating QA directly into the intake process, as Olympia did prior to FDA's arrival, this oversight cannot reoccur.

Further, Olympia's investigation also assessed FDA's observations related to the "Deleted Items" folder. Specifically, as discussed above, customer inquiries and complaints are submitted via email to customerservice@olympiapharmacy.com. This email account is shared by the entire customer service team, has only 50GB of storage space, and receives a high volume of emails—meaning, that the shared account can quickly run out of memory if the inbox is not appropriately managed. Toward that end, the customer service team set up a number of "rules" to automatically transfer emails from the inbox to folders including the "Archive folder" and the "Deleted folder." To address this storage space issue, Olympia purchased a software system, HubSpot Customer Service, that will be used for complaint intake moving forward. HubSpot Purchase Order, attached as **Exhibit QQ**. HubSpot provides greater storage capacity and allows for more streamlined management of customer complaints. Notably, HubSpot includes an audit trail feature to track and trace all customer complaints, so that complaints cannot be deleted. Further, HubSpot has system controls to ensure all customer complaints are addressed. Specifically, if a customer inquiry is not responded to or opened within a certain amount of time, HubSpot automatically moves the complaint to the top of the queue, ensuring that all complaints are reviewed and investigated. Olympia anticipates HubSpot will be fully implemented within the next 45 days, as the system is currently undergoing testing.

In addition, Olympia has created a process to conduct cross-department complaint reviews on a monthly basis. P-231.1 Management Review, attached as **Exhibit RR**. Specifically, QA will meet with the pharmacist-in-charge, the production manager, and the customer service manager to review a summary of the monthly complaints received. The review will include a discussion regarding the types of complaints received that month and a discussion of the processes, controls, or trainings that could be implemented or performed to address any trends. Via this process, Olympia will ensure greater transparency across departments regarding complaint trends and will allow for greater collaboration regarding the implementation of corrective actions, when indicated.

Finally, D-2023-023 also included a fulsome evaluation by QA of all complaints received in 2022, 2023, and 2024. QA assessed all the complaints received during this time frame and categorized the complaints by type *i.e.*, a service-related or product-related complaint. Of the complaints that QA identified as product-related complaints that were within expiry, QA performed a comprehensive evaluation of each complaint to assess for adverse trends or adverse events. A thorough discussion of QA's evaluation of each of these complaints is set forth in D-2024-023. Ex. PP.

In addition, D-2024-021 addressed the complaints set forth in Observation 6 subparagraphs (a) through (f), as discussed below:

a. Glutathione 200mg/mL lot B13E01-24, BUD 5/13/2024. Olympia comprehensively assessed the batch record data associated with this complaint and also interacted with the patient to obtain more information. D-2024-021, attached as **Exhibit SS.** Lot B13E01-24 passed all end-product release testing and was within the acceptable potency range. Olympia received no other complaints related to this lot. As to Olympia's interactions with the patient, the patient indicated that he was seen by a practitioner at a clinic in Florida, where he was dispensed a vial of Olympia's Glutathione 200 mg/mL. The patient then returned to California and administered the medication consistent with his prior practices. However, the patient did not realize that Olympia's Glutathione is more potent than other products he has used in the past which were Glutathione 50 mg/mL. Therefore, when the patient administered his normal dose, he administered more Glutathione at once than was recommended by his practitioner. During Olympia's discussions with the patient, the patient indicated that he realized his error after the fact and further, that his symptoms resolved without medical intervention. Based on QA's investigation, Olympia determined that this was not a product-related complaint or an adverse event. Rather, the complaint arose from a dosing error.

b. B12 Methylcobalamin 5mg/mL lot B12D05-24, BUD 5/12/2024. Olympia comprehensively assessed the batch record data associated with this complaint and also interacted with the clinic to obtain more information. Ex. SS. Lot B12D05-24 passed all end-product release testing and was within the acceptable potency range. Olympia received no other complaints related to this lot. As to Olympia's interactions with the clinic, the clinic provided limited additional information. However, the clinic indicated that the patient received the injection after fasting and then proceeded to work out. The clinic is unaware whether the patient was taking other medications or supplements, and the patient would not provide this information. As such, Olympia is unable to determine whether the B12 injection was the cause of the patient's reaction. Regardless, out of an abundance of caution, Olympia will report this as an adverse event to FDA's portal.

c. Sodium Bicarbonate 8.4% lot H23A03-23, BUD 2/19/2024. Olympia comprehensively assessed the batch record data associated with this complaint and also interacted with the clinic to obtain more information. Ex. SS. Lot H23A03-23 passed all end-product release testing and was within the acceptable potency range. Olympia received no other complaints related to this lot. As to Olympia's interactions with the clinic, the clinic indicated that they were mixing the Sodium Bicarbonate with Lidocaine. When doing so, the solution precipitated out and had a

cloudy appearance. The clinic indicated that it was using the same needle to draw up both medications. Olympia determined that this process resulted in a cross contamination causing a reaction between the combination of Sodium Bicarbonate and the Lidocaine. Further, QA advised the clinic against combining the two products, as there is no data to support the combination's stability. Based on QA's investigation, Olympia determined that this was not a product-related complaint.

d. Tri-Immune lot B07C02-24, BUD 08/05/2024. Olympia comprehensively assessed the batch record data associated with this complaint and also interacted with the clinic to obtain more information. Ex. SS. Lot B07C02-24 passed all end-product release testing and was within the acceptable potency range. Olympia received no other complaints related to this lot. Olympia conducted a supplemental investigation of this complaint which included assessing associated shipping records and engaging in additional discussions with the clinic. Olympia's records confirmed that this product was packed in accordance with Olympia's validated shipping procedures. Further, the shipping records confirmed that the refrigerated product was shipped overnight and delivered to the clinic within the requisite timeframe. Because the product had been delivered in accordance with Olympia's validated shipping methods, the pharmacist assured the client that no product impact had occurred. Nevertheless, moving forward, when a complaint is received that a product feels warm, Olympia will instruct the customer not to use the product. Based on Olympia's investigation, Olympia determined that this was not a product-related complaint.

e. Semaglutide lot B15A01-24, BUD 06/13/2024. Olympia comprehensively assessed the batch record data associated with this complaint and also interacted with the clinic to obtain more information. Ex. SS. Lot B15A01-24 passed all end-product release testing and was within the acceptable potency range. Olympia received no other complaints related to this lot. QA conducted a thorough review of this complaint which included additional interaction with the clinic. The investigation determined that the clinic ordered Semaglutide 5mg/ml 3ml and Semaglutide 5mg/ml 3ml was entered into the dispensing system. However, Olympia did not have 5 mg/ml 3 ml in inventory and therefore, the clinic was notified that Olympia would send 2.5 mg/ml vials. The clinic agreed but did not adjust patients' dosing which caused the efficacy complaints. As such, Olympia's investigation determined that this was not a product-related complaint. Rather, the complaint was due to dosing miscalculations.

f. Tirzepatide Injectable lot D15A01-24, BUD 06/14/2024. Olympia comprehensively assessed the batch record data associated with this complaint and also interacted with the clinic to obtain more information. Ex. SS. Lot D15A01-24 passed all end-product release testing and was within the acceptable potency range. Olympia received no other complaints related to this lot. QA conducted a comprehensive assessment of this complaint through additional interactions with the clinic. Ultimately, based on the information provided by the clinic which included a copy of the patient's prescription, QA determined that the patient was not administering the correct amount of drug product prescribed by his practitioner. Specifically, the patient was prescribed a 7.5 mg/ml dose and the patient was only injecting a 5 mg/ml dose. Because the patient was taking less than the prescribed dose, the patient was experiencing the complained of symptoms

regarding the drug product allegedly being ineffective. Based on QA's comprehensive review, Olympia determined that this patient complaint was not due to Olympia's drug product. Rather, the complaint was due to dosing miscalculations.

OBSERVATION 7
Your outsourcing facility has not submitted a report to FDA identifying a product compounded during the previous six months as required by section 503B(b)(2)(A) of the Federal Food, Drug, and Cosmetic Act (FD&C Act).

Specifically, drug products were compounded and not identified on your reports dated June 2023 and December 2023, including, but not limited to:

PGE1 (alprostadil) 40 mcg/mL injection
PGE3 (alprostadil) 150 mcg/mL injection
Sodium tetradecyl sulfate 0.1% injection
Sodium tetradecyl sulfate 0.3% injection
Zinc sulfate 10 mg/mL injection

Response to Observation 7:

Through its constructive conversations with FDA, Olympia recognized room for improvement in the manner in which Olympia was verifying the accuracy of the six-month product report. Namely, Olympia determined that the process could benefit from a team-based approach relying on input from both pharmacists and QA to confirm all necessary product information is reported.

Olympia updated SOP-026 Electronic Drug Product Reporting to include team review of the six-month product report prior to submission. Electronic Drug Product Reporting - SOP-026, attached as **Exhibit TT**. Now, before a six-month product report is electronically submitted, QA and a team of pharmacists will review the electronic report to ensure all of the information including dosage forms, ingredients, strength, and quantities of compounded drugs is accurate. Ex. TT, Section 8.4. Prior to submitting the report, the review team will complete Form F-232.a, as an additional verification check. Electronic Drug Product Reporting Form-F-232.a.1, attached as **Exhibit UU**.

In addition, Olympia resubmitted its six-month product report from June 2023 through December 2023 to address the products listed in Observation 7. Reporting for Jun-Dec 2023 (Resubmission) SPL 2023-2 06-24-24, attached as **Exhibit VV**. Finally, Olympia submitted its most recent six-month report in June 2024. 6mo Reporting for Dec - Jun 2024, attached as **Exhibit WW.**

Conclusion

In closing, Olympia appreciated the opportunity to demonstrate the significant improvements that Olympia has made over the past few years. As a result of these efforts, Olympia is confident in its ability to provide consistent sterility assurance, reliable process performance, and excellent product

quality. Olympia trusts that the above actions have fully addressed FDA's observations, but Olympia welcomes a constructive dialogue with FDA should FDA have any additional questions.

Thank you for the opportunity to respond to this Form 483. If you have any questions or would like to discuss our responses to these observations, please feel free to reach out to us.

Very truly yours,



Mark Mikhael, PharmD, CEO
Olympia Pharmacy

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: OPS International Incorporated dba Olympia Pharmaceuticals

NV Pharmacy or Outsourcing facility license # (if applicable): OU00025 (Pending CHOW)

Physical Address: 6700 Conroy Road, Ste 155

City: Orlando, State: FL Zip: 32835

Mailing Address (if different from physical address): Same as Physical Address

City: State: Zip:

Telephone: 407-673-2222 Toll Free # (NAC 639.708, NRS 639.23286): 800-991-9079

Fax: N/A Contact Email: Licensing@olympiapharmacy.com

Website: www.olympiapharmacy.com

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Michael Bogard

Supervising/Managing Pharmacist NV Pharmacist Registration #: 23202

Name of Designated Person(s) as defined by revised USP-797 guidelines: Michael Bogard

Email of Designated Person(s): [redacted]

Telephone of Designated Person(s): [redacted]

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ☐ Category 2 ☒ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? N/A ☐ Yes ☐ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? N/A ☐ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ☒ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 1st flr: 28SEP24 2nd: 21DEC24

6. What is the frequency of the recertification for the ISO classified areas? 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ☒ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☒ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? N/A

10. Will you be performing sterile hazardous drug compounding? Yes ☒ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

see attatched - Drug list

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL BIOPharma

Address: 840 Research pkwy #546

City: Oklahoma city State: OK Zip: 73104

Telephone: 405-271-1144

13. What is your procedure for visual inspection of compounded sterile products?

see attatched – P-203

14. How often do you perform glove fingertip and medial fill testing?

every 6 months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

See attatched – P-110 P-213

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached – P-304

17. Who performs the sterile compounding process at your facility?

pharmacist & pharm techs

18. Who is responsible and accountable for the sterile compounding process at your facility?

Michael Rosen – PIC
Max Everett – Quality Director
Mike Farragalla – Sterile manager

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

see attatched – P-502

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)			
1. What type of primary engineering controls will you be using in your facility? N/A			
2. Are you complying with all USP 800 guidelines?	N/A	Yes	No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	N/A	Yes	No
4. Is your BSC or CACI vented 100% to the outside?	N/A	Yes	No
5. Do you have a negative pressure buffer room at your facility?	N/A	Yes	No
6. Will you be compounding with antineoplastic HDs or HD API?	N/A	Yes	No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	N/A	Yes	No
8. Will you be utilizing a closed system transfer device?	N/A	Yes	No
9. If yes, list the name of the device: N/A			

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

see attached – drug list

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

6 months

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? X Yes No

4. What is the frequency for completing volumetric active air sampling?

see attatched – P-212

5. What is the frequency for completing surface sampling? see attatched – P2i2		
6. What is the frequency for using sporicidal agents? see attatched – P2i2		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	X Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	X Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Bogard

Name of Person who Completed the Form

Pharmacist In Charge

[redacted]

Signature (copies or stamps not accepted)

2/18/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

1. Approvals and Version History

1.1 Approvals

Role	Name and Title	Signature	Date
Author	Christian Doell Quality Engineer Supervisor	[redacted]	15OCT24
Department Representative	Michael Gonzalez Supply Chain Manager		15OCT2024
Quality Unit Representative	Max Everett Director of Quality		15OCT2024

1.2 Version History

Version No.	Effective Date	Changes
1	02MAR15	Initial Release
2	30NOV21	• Updated quality representative name. • Updated section 5.4 delivery standards.
3	04JAN2023	• Updated delivery standards, now section 7.4 • Added materials and equipment list, section 6 • Added abbreviations and definitions section, section 5 • Updated procedure, now section 7 • Added Table 8-1: Overview of Appropriate Packing Structure per Vial Quantity of Product
4	26MAY2023	• Added PCM gel packs to materials list. • Added thermal foil lining to materials list. • Designation of appropriate cold packs to use for cold products, section 7.2
5	16OCT2024	• Updated document number from P-502 to SOP-034 to align with MasterControl. • Edited and updated for clarity • Added References , section 5 • Establish proper procedure for the storage and rotation of cold pack boxes within shipping department freezers, section 8.2.4. • Reformatted Table 9-1

2. Purpose

The purpose of this procedure is to provide the general technical requirements and operations guidelines for the proper packing and shipping of compounded preparations, in a manner such that product integrity, quality, safety, and efficacy are not compromised.

3. Scope

This procedure applies to all shipping personnel and the Quality Unit at Olympia Pharmaceuticals.

4. Abbreviations and Definitions

Table 4-1: Abbreviations

Abbreviation	Description
UPS	United Parcel Service – Shipping service used by Olympia Pharmacy.

Abbreviation	Description
Medi	Abbreviated name for a medicine box, consisting of a 5-7/8"x 5-7/8"x 2-7/16" box with a folding lid and foam insert with sleeves.
Small Medi	Abbreviated name for a medicine box, consisting of a 7"x 6-1/2"x 2-1/2" box with a folding lid and carboard insert with sleeves.

Table 4-2: Definitions

Term	Definition
Ambient	Controlled room temperature. These products require 20-to-25-degree Celsius storage with allowable excursions from 15 to 30 °C.
Cold Product	Product that has either a refrigerated or frozen storage specification temperature. Refrigeration specification requires 2-to-8-degree Celsius storage and frozen specification requires -10 to -25 degrees Celsius.
Saturday Next Day	UPS practice of delivering packages on a Saturday.
Next Day Air Early	UPS shipping method in which packages arrive early the next business day.
Next Day Air	UPS shipping method in which packages are shipped and arrive within 1 business day.
2nd Day Air	UPS shipping method in which packages are shipped and arrive within 2 business days.

5. References

Table 5-1: Internal References

Document Number	Document Title
P-219/SOP-016	Complaint Handling, Drug Safety, and Surveillance
P-225/SOP-020	Continuous Monitoring Systems

Table 5-2: External References

Document Number	Document Title	Author
21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	FDA

6. Responsibilities

6.1 Pharmacy Front-End Staff

6.1.1 Provide all necessary and corresponding devices for each product that is to be shipped out to the patient's home, facility, or laboratory for testing.

6.2 Shipping Personnel

6.2.1 The shipping department shall ensure that the compounded preparation is delivered properly to the patient or health care facility without compromising the product's integrity, quality, safety, and efficacy.

6.2.2 Resolve any shipping errors, and questions regarding the shipment of products.

6.2.3 Work with the different pharmacy departments to ensure fastidious and efficient service for all products leaving the building.

6.3 Quality

6.3.1 Review shipping documentation and packaging practices as needed to ensure compliance with this SOP, and to ensure shipping labeling corresponds to the patient and product being shipped.

7. Materials and Equipment

Table 7-1: Shipping Materials

Materials	
• Clear Bubble Wrap Envelope	• Cardboard Insert
• UPS Express Pak Envelope	• Cellophane Packing Tape
• FillPak Stock Material (packing paper)	• UPS Mini Box (8 x 6 x 3)
• Thermal Foil Liners	• Small Security Corrugated Box (9 x 7 x 3)
• PCM Gel Packs	• Large Security Corrugated (12.5 x 10 x 3)
• Ice Packs	• Corrugated Box (8 x 6.5 x 6)
• Storage Instruction Pamphlet	• Corrugated Box (10 x 8 x 6)
• "Please Handle with Care - Glass" Sticker	• Corrugated Box (10 x 10 x 6)
• "Refrigerate Upon Arrival" Sticker	• Corrugated Box (10 x 10 x 10)
• Large "Refrigerate Upon Arrival" Sticker	• Corrugated Box (12 x 10 x 8)
• Large "Fragile – Glass Handle with Care" Sticker	• Corrugated Box (12 x 10 x 10)
• Small Foam Cooler (6 x 5 x 4)	• Corrugated Box (14 x 10 x 10)
• Medium Foam Cooler (10 x 8 x 6)	• Corrugated Box (16 x 10 x 10)
• Large Cooler (12 x 8 x 7)	• Corrugated Box (18 x 10 x 10)
• Medi Box (5-7/8 x 5-7/8 x 2-7/16)	• Corrugated Box (18 x 14 x 10)
• Small Medi Box (7 x 6-1/2 x 2-1/2)	• Corrugated Box (18 x 18 x 12)
• Foam Insert	• Corrugated Box (18 x 18 x 18)

8. Procedure

8.1 General Shipping Requirements

8.1.1 All compounded preparations shall be shipped in appropriate containers that will protect products from wide variations in temperatures, structural damage, or unapproved light sources.

8.1.1.1 Logistics Technician in the shipping department should refer to **Table 9-1** in the Appendix for guidance on determining appropriate packing structure.

8.1.1.2 Technicians are encouraged to use their best judgment when assembling packing structures not listed within **Table 9-1**; packing structures that offer the best protection or restrict product movement are more appropriate.

8.1.2 Front end pharmacy technicians shall provide necessary devices or equipment that is to be included and corresponds with each product.

8.1.3 The location of the delivery shall be recorded in the patient profile.

8.1.4 If any issues, such as leakage or damage are reported by the recipient, they are documented and investigated according to *P-219/SOP-016 Complaint Handling, Drug Safety and Surveillance.*

8.1.5 Storage instructions shall be provided to the patient or caregiver to ensure that the product is stored appropriately at the patient's home or at the health care facility.

8.1.6 Guidance shall be provided to the patient or caregiver on how to contact the pharmacy for patient counseling or any questions regarding products received.

8.1.7 An electronic log of shipments that leaves the pharmacy will be maintained online for at least one year for records.

8.2 Packing Temperature Sensitive Compounded Preparations and Samples

8.2.1 Temperature sensitive compound preparations must be maintained at temperatures of 2°C to 8°C for refrigerated products, and -10 °C to -25°C for frozen products, during the entire duration of transit.

8.2.2 If shipping refrigerated products, the standard ice packs must be used.

- The standard ice packs are stored in dedicated shipping department freezers and are only to be used for products requiring refrigerated storage conditions.

8.2.3 If shipping frozen products, the PCM gel packs, meant for sub-zero storage conditions, must be used in conjunction with thermal foil liners.

- The PCM gel packs are stored in -30°C shipping deep freezers. They are only to be used for products requiring frozen storage conditions.

8.2.4 When storing boxes of cold packs in freezers, new unopened boxes are stacked no more than 3 boxes high and are not to be stacked on top of opened boxes to prevent stacks of boxes from falling over.

- Cold pack inventory is to be used for cold product shipment on a first in, first out basis. The oldest cold packs are to be used for shipments first with newer cold pack boxes to be opened once all older inventory has been used.

8.2.5 Cold preparations are to be placed in an appropriately sized cooler, based on the quantity and vial size of the product; the preparation cooler must be large enough to comfortably house the product and an appropriate number of cold packs. Cold packs are to be positioned along the base of the cooler and on either the sides or top of the drug product, depending on the size and positioning of product within the cooler.

8.2.5.1 If the number of cold products is less than nine 30 ml vials and less than eleven 10 ml vials, the small Cooler (6 x 5 x 4) and the small box (8 x 6.5 x 6) are the appropriate choices.

8.2.5.1.1 For 30 ml refrigerated vials, two ice packs and two bubble wrapped layers containing up to 4 vials per layer is sufficient to fit inside the small cooler.

8.2.5.1.2 For 10 ml refrigerated vials, two ice packs and a bubble wrapped layer of 10 vials is sufficient to fit inside the small cooler.

8.2.5.1.3 For 10 ml frozen vials, two PCM packs and a bubble wrapped layer containing up to 10 vials, are to be enclosed within a thermal foil liner pouch before placement inside the small cooler.

8.2.5.2 If the number of cold products ranges from 9-32 for 30 ml vials and 11-60 for 10 ml vials, the medium cooler (10 x 8 x 6) and a medium box (10 x 10 x 6) are the appropriate choices.

8.2.5.2.1 For 30 ml refrigerated vials, six ice packs and four layers of bubble wrap containing up to 8 vials per layer (32 vials total) is sufficient to fit inside the medium cooler.

8.2.5.2.2 For 10 ml refrigerated vials, six ice packs and three layers of bubble wrap containing up to 20 vials per layer (60 vials total) is sufficient to fit inside the medium cooler.

8.2.5.2.3 For 10 ml frozen vials, six PCM packs and three layers of bubble wrap containing up to 20 vials per layer (60 vials total) is sufficient to fit inside a medium cooler with an inserted thermal foil lining.

8.2.5.3 For large cold product orders containing 33-60 30 ml vials and 61-100 10 ml vials, a large cooler (12 x 8 x 7) and a large box (14 x 10 x 10) must be used to accommodate the larger quantities.

8.2.5.3.1 For 30 ml refrigerated vials, eight ice packs and six layers of bubble wrapped vials containing up to 10 vials per layer (60 vials total), is sufficient to fit inside the large cooler.

8.2.5.3.2 For 10 ml refrigerated vials, eight ice packs and five layers of bubble wrapped vials containing up to 20 vials per layer (100 vials total), is sufficient to fit inside a large cooler.

8.2.5.3.3 For 10 ml frozen vials, eight PCM packs and five layers of bubble wrapped vials containing up to 20 vials per layer (100 vials total), is sufficient to fit inside a large cooler with an inserted thermal foil lining.

8.2.5.4 **NOTE**: If the shipment contains samples for testing, the samples must be in laboratory-specified containers. Ensure the appropriate documentation that is provided by the Quality Manager is in the box prior to shipping.

8.2.6 Seal the cooler by applying a double layer of packing tape along the seam of the cooler's lid and place in an appropriately sized shipping box. Use brown packing paper and bubble wrap as needed to ensure the cooler is secure and stationary within the box.

8.2.7 Seal the box shut with packing tape and place two of each shipping sticker on the outside of the box: "Refrigerate Upon Arrival" and "Please Handle with Care - Glass". One of each sticker should be placed on the top of the box, with the additional pair of stickers being placed on opposite sides of the box.

8.2.7.1 For boxes larger than the 14 x 10 x 10 box size, use the large "Refrigerate Upon Arrival" sticker and large "Fragile – Glass Handle with Care" stickers.

8.2.8 Put a UPS label on top of the box and make sure there are no tears or creases near the barcode. Creases near the barcode may affect transit times as the barcode may not be easily scanned.

8.2.8.1 UPS labels are generated and printed from the 'World Ship Application Software' as sticker labels that are adhered to the appropriately sized UPS box/envelope or brown shipping box.

8.3 Packing Non-Temperature Sensitive Preparations

8.3.1 If the preparation is stored in a glass container or vial, it must be bubble wrapped first before it is placed into a box dependent on the number of vials.

8.3.1.1 If the number of ambient 30 ml vials is less than 9 or if the number of 10 ml vials is less than 11, the small self-sealing UPS Mini Express box (8 x 6 x 3) is suitable for use.

8.3.1.2 If the number of 30 ml ambient vials exceeds 8, they are placed within a Medi box. If the number of 10 ml ambient vials exceeds 10, they are placed within a Small Medi box. Each Medi box is placed in a UPS Express Pak Envelope; they're shipped by using a Medium Security box for a single Medi box and a Small Security for a single Small Medi box.

8.3.1.2.1 At least 4 Medi boxes can be placed in a (12 x 10 x 10) box for shipping.

8.3.1.2.2 At least 6 Medi boxes can be placed in a (18 x 10 x 10) box for shipping.

8.3.1.2.3 Counts of Medis beyond 6 will require either multiple shipping boxes or use of a larger box; however, with use of larger boxes additional packing paper and bubble wrap are required for added protection.

8.3.1.2.4 Two Small Medi boxes can be placed within a (8 x 6.5 x 6) box, while Small Medi counts greater than 2 require use of a (12 x 10 x 8) box with additional packing paper.

8.3.1.3 **NOTE**: If the shipment contains samples for testing, the samples must be in laboratory-specified containers. Ensure the appropriate documentation that is provided by the Quality Manager is in the box prior to shipping.

8.3.2 Place compounded preparation in the appropriate shipping box using bubble wrap and brown packing paper as needed to immobilize the prepared product within the shipping box.

8.3.3 Seal the box shut with tape.

8.3.4 Place two "Please Handle with Care Glass" stickers on the outside of the box, one on top and one on the side if preparations are in glass containers.

8.3.5 Put UPS label on top of the box and make sure there are no tears or creases near the barcode. Creases near the barcode may affect transit times as the barcode may not be easily scanned.

8.3.5.1 UPS labels are generated and printed from the 'World Ship Application Software' as sticker labels that are adhered on the appropriately sized UPS box/envelope or brown shipping box.

8.4 Delivery Standards

8.4.1 Timely delivery: Olympia Pharmaceuticals' standard is for all deliveries to be made within the parameters shipping option chosen by the provider or patient.

8.4.1.1 If the prescription is a refill requested by the patient, the pharmacy will suggest the best type of shipping so the prescription will arrive a day before the initial dose or the next dosing schedule.

8.4.1.1.1 Ambient products have the option of being shipped: Saturday Next Day, Next Day Air Early, Next Day Air, and 2nd Day Air.

8.4.1.1.2 All cold products are shipped using UPS next day services: Saturday Next Day, Next Day Air Early, and Next Day Air.

8.4.2 Failure of delivery contingencies:

8.4.2.1 If delivery fails (i.e., lost, stolen) or is delayed and the patient, patient's agent or provider does not take possession of the package, the pharmacy will do their best to track the package and make the decision to resend the packaged product.

8.4.2.2 If the failure is due to actions of the pharmacy, the prescriptions will be reshipped at the cost of the pharmacy.

8.4.2.3 If failure is due to circumstances (i.e., weather events) outside of normal control of the pharmacy, the pharmacy will contact the courier (UPS or USPS) to verify the timeline on when the package will be delivered.

8.4.3 Upon receipt of a prescription for an acute illness, the pharmacy shall:

8.4.3.1 Contact the patient and give the patient an option for Next Day Early morning shipment, Next Day, or Saturday Next Day shipment if the prescription was received on a Friday.

8.4.3.2 If Olympia Pharmaceuticals does not carry the medication, the pharmacy will contact the provider or the patient to inform them of the situation and to provide the option to transfer the prescription to a local pharmacy that carries the medication written for the patient.

8.4.4 In the event the pharmacy is advised that the patient's medication has not been received within the normal delivery time and that the patient is out of medication and requires interim dosage until mailed prescription drugs become available, the pharmacy shall:

8.4.4.1 Contact the patient to inform them of the option to have the prescription transferred to their local pharmacy.

8.4.4.2 Contact the provider to inform them of the delay and to give them an option to fill the prescription with Olympia Pharmaceuticals to be sent USP Next Day or to fill the prescription locally.

9. Appendices

Table 9-1: Overview of Appropriate Packing Structure per Vial Quantity of Product

Product Type	Vial Count	Vial Volume	Component Prep. (Max Limit)	Shipping Box (Inches)	Cooler Size	# Cold Packs
AMBIENT	0-10	10mL	2 layers of 5 vials	Mini Express	N/A	N/A
	0-8	30mL	2 layers of 4 vials			
	11-16	10mL	Small Medi Box	Small Security	N/A	N/A
	9-20	30mL	Medi Box	Large Security		
	17-32	10mL	Small Medi Box	8 x 6 x 6	N/A	N/A
	21-80	30mL	Medi Box	12 x 10 x 10		
	33+	10mL	Small Medi Box	12 x 10 x 8 or larger	N/A	N/A
	81+	30mL	Medi Box	18 x 10 x 10 or larger		
COLD	0-10	10mL	1 layer of 10 vials	8 x 6.5 x 6	Small Cooler	2
	0-8	30mL	2 layers of 4 vials			
	11-60	10mL	3 layers of 20 vials	10 x 10 x 6	Medium Cooler	6
	9-32	30mL	4 layers of 8 vials			
	61-100	10mL	5 layers of 20 vials	14 x 10 x 10	Large Cooler	8
	33-60	30mL	6 layers of 10 vials			
	101+	10mL	5+ Layers of 20 vials	Appropriate Box Size(s)	Appropriate # of Coolers	Appropriate # per Cooler Sizes Used
	61+	30mL	6+ Layers of 10 vials			

1. Approvals and Version History

1.1. Approvals

Role	Name and Title	Signature	Date
Author	Max Everett, Director of Quality	[redacted]	28SEP2023
Department Representative	Mike Faragalla Sterile Pharmacy Manager		28SEP23
Quality Unit Representative	Laura Krebaum Quality Systems Manager		28SEP2023

1.2. Version History

Version No.	Effective Date	Changes
1	16MAY13	Initial release.
9	16SEP19	Refer to version 13 for complete Change History.
10	27APR20	
11	02AUG21	
12	01APR22	
13	30JUN22	
14	15AUG2022	• Updated Format • Abridged Version History more than 3 years old • As per DCR-22-033: Revised Cleaning Forms and created new Forms. Therefore, Form references in this main SOP were updated. (Table 6-1) • Deleted Section 9 "Attachments". Forms are no longer attached to the Parent SOP and may be revised independently. • Form F-304.c "Cleaning Log for the General Pharmacy Prep Area" will be made obsolete because the Purpose & Scope of this SOP has changed so that the form is no longer applicable to this document.
15	18MAY2023	• Revised SOP to include the addition of the new cleanroom suite on the second floor. Cleanroom 300's. • Addition of cleaning forms for new second floor cleanroom suite. New cleaning logs include daily, weekly, monthly, and quarterly for the ISO 7 and ISO 8 rooms. • Section 7.1: Added descriptions for cleaning agents Vesta-Syde SQ 128 RTU and Spor-Klenz RTU. • Section 9: Added cleaning procedure for the cleanroom suite on the second floor utilizing the Vesta-Syde SQ 128 RTU and Spor-Klenz RTU cleaning agents. • Section 10: Addition of procedure to use the Vileda mopping system for the new cleanroom suite located on the second floor. Description of how to use and detail in using the mopping system was added.
16	02OCT2023	• Revised SOP to remove all references to use of 0.525% Sodium Hypochlorite (bleach). • Revised Section 5 Form names to match new ISO classifications of all facility cleanrooms. • Revised entire document for continuity of the cleaning procedure for the entire facility. • Section 8.3. revised to remove cleaning of the inside chamber and exterior condensing unit of the lyophilizer. This is now located in P-806 "Operation & Maintenance of the VirTis Ultra 35L Lyophilizer". • Addition of quarterly cleaning logs for the first-floor cleanrooms: F-304.b-15 and F-304.b-16. • Section 9.2: Addition of CNC cleaning requirements and CNC cleaning log F-304.b-17.

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Version No.	Effective Date	Changes
		• Removed references to HD and Non-HD areas, as the entire facility is now "non-HD", the HD areas were removed. Retired forms F-304.d-1, F-304.d-2, F-304.d-3. • Clarification of cleaning schedule, including frequency for ceilings. • Retired forms F-304.e-1, F-304.e-2, and F-304.e-3 because those rooms were decommissioned. • Change in terminology on the log forms: "glass panes" changed to "windows". • Removed Section 10 instructions for Vileda mops to separate Appendix: A-304.a

2. Purpose

This Standard Operating Procedure (SOP) defines the process by which the Sterile Compounding Facility is cleaned and disinfected in a manner that ensures a suitable environment for producing compounded sterile drug products (SDPs).

3. Scope

This SOP applies to all Controlled Areas, including ISO-classified cleanrooms, controlled-not-classified (CNC) rooms, laminar air flow workbenches (LAFWs), lyophilizers, and other equipment located in the controlled areas.

4. Abbreviations and Definitions

Table 4-1: Abbreviations

Abbreviation	Description
HEPA	High Efficiency Particulate Air
IPA	Isopropyl Alcohol
LAFW	Laminar Air Flow Workbench
LYO	Lyophilizer or Lyophilized
CNC	Controlled, but not Classified

Table 4-2: Definitions

Term	Definition
Cleanroom	A room in which the concentration of airborne particles is controlled, and which is constructed and used in a manner to minimize the introduction, generation, and retention of particles inside the room, and in which other relevant parameters, i.e. temperature, humidity, and pressure, are controlled as necessary.
Cleaning Agent	An agent for the removal from facility and equipment surfaces of product residues that may inactivate sanitizing agents or harbor microorganisms.
Decontamination	The removal of microorganisms by disinfection or cleaning.
Disinfectant	A chemical or physical agent that destroys or removes vegetative forms of harmful microorganisms when applied to a surface.
Sanitizing agent	An agent for reducing, on inanimate surfaces, the number of all forms of microbial life including fungi, viruses, and bacteria.
Sporicidal Agent	An agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Compounding	A process wherein bulk substance is combined with another bulk drug substance and/or one or more excipients to produce a drug product.

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5. References

Table 5-1: Internal References

Document Title	Document Number
Hand Hygiene and Garbing	P-404
Employee Training Program	P-410
Cleaning of Small Equipment and Utensils	P-617
Operation of the Auto-Filler System at Olympia Pharmacy	P-809
Operation & Maintenance of the VirTis Ultra 35L Lyophilizer	P-806
Competency Assessment: Hand Hygiene and Garbing	F-404.a
DAILY Cleaning Log - ISO 7 - 1st Floor	F-304.b-1
WEEKLY Cleaning Log - ISO 7 - 1st Floor	F-304.b-2
MONTHLY Cleaning Log - ISO 7 - 1st Floor	F-304.b-3
QUARTERLY Cleaning Log – ISO 7 – 1st Floor	F-304.b-15
DAILY Cleaning Log - ISO 8 - 1st Floor	F-304.b-4
WEEKLY Cleaning Log - ISO 8 - 1st Floor	F-304.b-5
MONTHLY Cleaning Log - ISO 8 - 1st Floor	F-304.b-6
QUARTERLY Cleaning Log – ISO 8 – 1st Floor	F-304.b-16
DAILY Cleaning Log - Controlled Non-Classified Area	F-304.b-17
DAILY Cleaning Log - ISO 7 – 2nd Floor	F-304.b-7
WEEKLY Cleaning Log - ISO 7 - 2nd Floor	F-304.b-8
MONTHLY Cleaning Log - ISO 7 - 2nd Floor	F-304.b-9
QUARTERLY Cleaning Log – ISO 7 – 2nd Floor	F-304.b-10
DAILY Cleaning Log - ISO 8 - 2nd Floor	F-304.b-11
WEEKLY Cleaning Log - ISO 8 - 2nd Floor	F-304.b-12
MONTHLY Cleaning Log - ISO 8 - 2nd Floor	F-304.b-13
QUARTERLY Cleaning Log – ISO 8 – 2nd Floor	F-304.b-14
Facility Inspection Form	F-304.f
Competency Assessment: Cleaning and Disinfecting	F-304.g
Preparation of the Vileda Mopping System	A-304.a

Table 5-2: External References

Document Title	Document Number	Source
Pharmaceutical Compounding, Sterile Preparations	Chapter 797	USP-NF
Current Good Manufacturing Practice for Finished Pharmaceuticals	21 CFR Part 211	FDA
Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing	N/A	FDA

6. Responsibilities

6.1. Quality Unit

6.1.1. Create, manage, and monitor compliance and execution of this SOP with all relevant policies and related SOPs.

6.1.2. Manage and monitor all records of cleaning and disinfecting activities.

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6.2. Operations Personnel (Technicians & Cleaning Custodians)

6.2.1. Execution of sterilizing, disinfecting, and cleaning activities.

6.2.2. Manage all equipment and supplies required for cleaning and disinfecting.

7. Safety, Materials, and Equipment

7.1. Safety

7.1.1. Since cleaning and disinfecting agents are irritants with the potential to harm the skin and eyes, appropriate personal protective equipment (i.e., safety glasses, face mask or shield, coat or gown, and gloves) must be worn.

7.1.2. Material Safety Data Sheets must be readily available for reference in the pharmacy for all cleaning and disinfecting agents used.

7.2. Disinfecting and Cleaning Agents

7.2.1. PeridoxRTU® – Ready to Use

- PeridoxRTU® is a broad-spectrum EPA-registered sporicidal, bactericide, virucide, tuberculocidal and fungicide one-step disinfectant and hard surface cleaner.
- PeridoxRTU® contains no alcohol or bleach and, unlike most other disinfectants, leaves minimal residue on surfaces.
- Effective for hazardous drug decontamination on stainless steel surfaces.
- Specific to Olympia's microbial cleaning efficacy study for the cleanroom surfaces described above, the cleanroom surfaces shall be cleaned with PeridoxRTU® weekly & monthly, for a minimum contact time of 2-minutes.

⚠ PeridoxRTU® is a transparent with light gray tinge liquid that causes severe skin burns and eye damage and is harmful if swallowed.

7.2.2. Sterile 70% Isopropyl Alcohol (IPA)

- All sterile alcohols used at Olympia Pharmacy contains 70% by volume USP-grade Isopropanol (IPA) and 30% USP-purified water.
- 70% IPA is filtered to 0.2µm and induction sealed to assure sterility, the bottles are double-bagged, and gamma irradiated. Each bottle is lot coded and has an expiration date for easy record keeping
- For use in critical environments, cleanrooms areas and equipment
- Hard Surface Disinfectant
- Gamma Irradiated
- Filtered at 0.2 microns
- Pyrogen Free

⚠ Isopropyl Alcohol 70% (IPA) is a flammable clear liquid that is irritating to eyes, is a mild skin irritant, and may cause headache / dizziness if inhaled and harmful if swallowed.

7.2.3. Spor-Klenz RTU by Steris Life Sciences

- Spor-Klenz Ready-To-Use (RTU) cold sterilant is an environmental protection agency (EPA) registered product designed to be used as a sterilant, sporicide or as a disinfectant for cleanroom environmental surfaces and equipment.
- Spor-Klenz RTU is EPA registered, pre-mixed, stable solution.
- Use on hard, non-porous surfaces.
- Contains peracetic acid and hydrogen peroxide.

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- The minimum wet contact time is 2-minutes.

7.2.4. Vesta-Syde SQ 128 RTU

- Vesta-Syde SQ Quaternary Ammonium Disinfectant Ready-To-Use is a phosphate-free one-step cleaner and disinfectant. It is a liquid concentrate consisting of quaternary ammonium active ingredient formulated with a compatible biodegradable detergent system.
- Disinfectant is intended for use as a disinfectant on washable hard, non-porous environmental surfaces such as floors, walls, counters, tools, carts, and other equipment.
- Formulated with surfactants.
- The minimum wet contact time is 2-minutes.

7.3. Equipment and Materials

7.3.1. Pharma™-Sat Plus (sterile wipes saturated with sterile 70%IPA)

7.3.2. Sterile lint-free wipes

7.3.3. Vileda Mopping System:

- Pole handles + Frames
- Mopheads
- Box (Bucket) with disposable Liner
- Graduated Cylinder(s)
- Box Lid with Sieve

7.3.4. Storage and Use Requirements:

- All cleaning equipment and supplies must be stored in a designated area to ensure segregation from compounding equipment supplies.
- If spray bottles are used, they must be of appropriate size to allow for cleaning the area without the need for re-gowning and used within their labeled use-by date.

8. Procedure

8.1. General Cleaning Standards and Principles

8.1.1. Do not perform cleaning and disinfecting of the cleanrooms while compounding is taking place. Equipment surfaces may be wiped down with sterile wipes wetted with sterile 70% IPA as required during compounding, however spray bottles are not to be used in the LAFW while in the presence of exposed containers, closures, or product.

8.1.2. Perform necessary restocking or other activities prior to cleaning and floor washing so that the cleanroom may be exited and allowed to dry until the next shift.

8.1.3. If cleaning and disinfection occurs at the start of the compounding day, adequate time (at least 30 minutes) must be given to allow all cleaned surfaces to dry prior to starting any compounding activity.

8.1.4. Properly gown and glove in accordance with SOP P-404 *Hand Hygiene and Garbing* prior to entering the cleanrooms to perform cleaning and disinfection.

8.1.5. Tasks performed must be documented onto the appropriate area cleaning forms.

8.1.6. If any equipment or device used during compounding is removed from an ISO 7 cleanroom, it must be properly cleaned and disinfected prior to being placed back into service within that environment. This consists of the same cleaning as for an ISO 5 work area or a monthly cleaning.

8.1.7. Before use, ensure all materials to be used for cleaning and disinfection are within their labeled expiration date. Once opened, containers of 70% IPA, Vesta-Syde SQ 128 RTU,

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PeridoxRTU® and Spor-Klenz RTU must be used within seven (7) days. Record the date opened and use-by date onto the container.

8.1.8. All areas being cleaned with Vesta-Syde 128, Spor-Klenz and Peridox RTU require a minimum 2-minute wet contact time. The surface being cleaned should have a sheen-like appearance once cleaned with the cleaning agent.

8.1.9. Never allow any cleaning agents to wet the HEPA filters; and be careful when cleaning the HEPA filter grilles.

8.1.10. Ensure no tools or equipment in the area show signs of corrosion or rust. If signs of corrosion or rust are observed on any room or equipment surfaces, contact the supervisor.

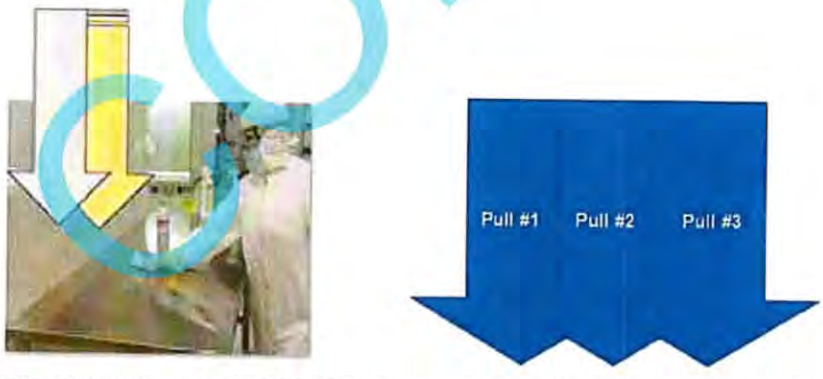
8.1.11. Cleaning of the floors and walls must begin at the farthest point from the entrance and work towards the exit. Avoid tracking over cleaned surfaces. Move any wheeled carts, shelving and chairs as cleaning is accomplished. Cleaning should always start from the highest point first.

8.1.12. Cleaning and disinfection shall be in order from the highest to lowest classified area (i.e., ISO 5, then ISO 7, then ISO 8, then non-classified area).

8.2. Using Wipes and Wipers

8.2.1. Cleaning / disinfection with wipes and wipers should be performed with overlapping strokes applied to the surface using the "Pull and Lift" technique.

Figure 1: Pull and Lift Technique



8.2.2. When using pre-saturated 70% IPA wipes, ensure the wipes are not dry. If wipes are dry, dispose of pack and open a new pack.

8.2.3. Make sure the wipes are folded in half or in quarter folds to produce multiple clean surface areas and allow better contact time. Change to a new (clean) portion of the wipe after two 2-3ft strokes. When re-wiping an area, always use a clean portion of the wipe. If disinfectant is applied to wipes with a spray bottle, wet each portion of the wipe before wiping.

8.2.4. When wiping, hold the wipe so that the folded edge is facing toward the area to be wiped and wipe in one direction with overlapping strokes.

8.2.5. Wipe from the cleanest to the least clean surfaces systematically, e.g. either from top to bottom or back to front.

8.3. Using Mops

8.3.1. Refer to **Appendix A-304.a** for how to assemble and prepare the Vileda mops for use.

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8.3.2. New mop heads are to be flipped over after cleaning 200 square feet of surface, and then discarded after the second 200 square feet.

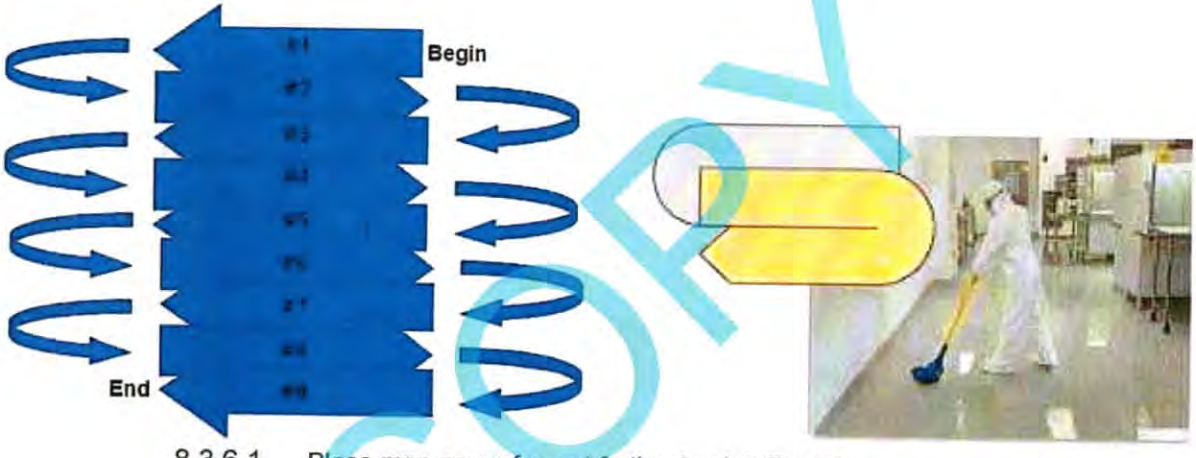
8.3.3. For walls and ceilings, the mop should be as saturated as possible without dripping. For floors, apply sufficient quantity of the cleaning / disinfecting agent directly onto the floor prior to mopping.

8.3.4. Clean from top of room to bottom of room: ceilings first, then walls, then floors last.

8.3.5. Cleaning of floors must begin at the farthest point from the entrance and work towards the exit. Avoid tracking over cleaned surfaces. Move any wheeled carts, shelving and chairs as cleaning is accomplished.

8.3.6. Use the "Overlapping S" method (Figure 2) for most areas whenever possible.

Figure 2: Overlapping S Technique



8.3.6.1. Place mop on surface at farthest point (Begin).

8.3.6.2. Keeping the mop between your body and the surface, move mop horizontally. Pivot mop in opposite direction maintaining contact with the surface. Overlap strokes by 2-4 inches. Always move the mop in one direction (see arrow).

8.3.6.3. Continue this back-and-forth "S" motion until 150-200 sq. ft. has been mopped.

8.3.6.4. Flip mop to opposite "clean" side for fresh disinfectant and continue the motion for another 150-200 sq. ft. Then remove the mop.

8.3.7. Use the "Pull and Lift" method (Figure 1) when the Overlapping S cannot be performed.

8.3.7.1. Place mop no more than 3 feet in front of the body. Place mop on surface and pull straight back towards body.

8.3.7.2. Lift the mop and replace it on the surface slightly to the side, again 3 feet in front of the body. Strokes should overlap by at least 3 inches.

8.3.7.3. Continue this motion until 150-200 sq. ft. has been mopped.

8.3.7.4. Flip mop to the opposite "clean" side for fresh disinfectant and continue the motion for another 150-200 sq. ft. Then remove the mop.

8.4. Cleaning and Disinfection of the ISO 5 LAFWs

8.4.1. Ensure that the LAFW is on and that it has been running continuously for a minimum of 30 minutes prior to cleaning and disinfection.

8.4.2. Roll the Auto-Filler out of the LAFW before cleaning the LAFW.

8.4.3. Inspect for any spills or residual compounding residue. Clean the spills with wipes prior to proceeding with the routine cleaning procedure.

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8.4.4. If Daily cleaning was performed the night before, at the start of compounding for each new workday, the surfaces within the LAFW must be wiped down with sterile 70% isopropyl alcohol (IPA) prior to startup.

8.4.5. Cleaning of the LAFW should follow the order of: Top, Back, Sides, and Center.

8.4.6. LAFW surfaces to be cleaned inside the workstation include the exposed surfaces of the filling, stoppering and capping equipment.

8.4.7. Carefully clean the HEPA grilles with wipes that are pre-wetted with the required cleaning or decontamination solution.
Note: Do not splash or spray the HEPA filter with cleaning and disinfectant solutions.

8.5. Cleaning and Disinfection of the Lyophilizer

8.5.1. When the Lyophilizer is running, the front door panel, HMI, hinges, and handle (everything on the wall of the ISO-classified room) are to be wiped down with a wiper pre-saturated with sterile 70% IPA.

8.5.2. When the Lyophilizer is between cycles, cleaning of the interior of the chamber and the condensing unit (everything outside the ISO-classified room) is to be performed according to the instructions in P-806.

8.6. Cleaning and Disinfection of the Auto Filler

8.6.1. The auto-filler is to be cleaned between batches as per P-809.

8.6.2. Roll the auto-filler out of the LAFW for cleaning of both the filler and the LAFW. After cleaning, return the cleaned auto-filler to the cleaned LAFW before continuing on to the rest of the room cleaning.

9. Cleaning Sequence and Frequency

Each area of the Compounding Facility is to be cleaned every normal business day, and the proper form filled out to document the task. (See Table 5-1.) If any individual room is not cleaned on a normal business day, the form is to be completed, with an explanation in the Comments section as to why cleaning was not done. (I.e., out-of-service for maintenance, closed due to weather emergency, etc.)

9.1. DAILY Cleaning and Disinfection of Cleanrooms

9.1.1. Remove any trash and re-stock the rooms with any necessary components, if applicable. Remove portable equipment that is not room-dedicated, such as Viable Air Samplers.

9.1.2. Roll the Auto-Fillers out of the LAFWs.

9.1.3. Using sterile wipes wetted with sterile Vesta-Syde SQ 128 RTU, clean / disinfect the following surfaces and areas in order:

- 9.1.3.1. All LAFW surfaces; first the inside and then the outside, as per Section 8.4.
- 9.1.3.2. The Auto-Fillers. Return to inside the LAFW enclosure after cleaning.
- 9.1.3.3. All other compounding equipment, including mixers, scales, HMI screens, keyboards, and pumps.
- 9.1.3.4. All counters, benches, tables, carts, stools, storage bins, and other cleanable surfaces.
- 9.1.3.5. Vent grilles where present.
- 9.1.3.6. All surfaces of the Pass-Through areas.
- 9.1.3.7. Door handles and Door Sensors.

9.1.4. Allow surfaces to completely dry.

9.1.5. Using sterile Vileda mops wetted with sterile Vesta-Syde SQ 128 RTU, clean / disinfect the cleanroom floors. Allow surfaces to completely dry.

9.1.6. At the cleaner's discretion, residues left by the cleaning agents may be removed using sterile wipes wetted with sterile 70% IPA. This step is optional.

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9.2. DAILY Cleaning of Controlled Non-Classified Lab Area

9.2.1. Remove any trash and re-stock the rooms with any necessary components, if applicable.

9.2.2. Using sterile wipes wetted with sterile 70% IPA, clean the following surfaces and areas:

- Tabletops, counters, equipment exterior cabinets, and storage shelving.
- Glass windows, windowsills, walls and doors, vent grilles, door handles and sensors.
- Hand-washing Sink. (Dish-washing sink is discussed in P-617.)

9.2.3. Using Vileda mops wetted with sterile Vesta-Syde SQ 128 RTU, clean / disinfect the CNC area floors. Allow surfaces to completely dry.

9.2.4. At the cleaner's discretion, residues left by the cleaning agents may be removed using sterile 70% IPA. This step is optional.

9.3. WEEKLY Cleaning and Disinfection of Cleanrooms

- Weekly cleaning is to be done on the last business day of the week. This is usually Friday, but may be adjusted for holidays.
- The weekly cleaning and disinfection of the cleanrooms includes all the elements of the daily procedure with the addition of Spor-Klenz RTU prior to the Vesta-Syde.

9.3.1. Using sterile wipes and mops wetted with sterile Spor-Klenz RTU, clean / disinfect the same surfaces, areas, and floors as the DAILY cleaning, in the order listed in steps 9.1.1 through 9.1.5.

9.3.2. Repeat using sterile Vesta-Syde SQ 128 RTU. Allow surfaces to completely dry.

9.3.3. At the cleaner's discretion, residues left by the cleaning agents may be removed using sterile wipes wetted with sterile 70% IPA. This step is optional.

9.4. WEEKLY Facility Inspection

9.4.1. At least once per week, perform an inspection of all classified clean rooms and controlled (not classified) Areas and document on form F-304.f.

9.4.2. If any results are "unacceptable", immediately notify the sterile pharmacy manager and the quality unit.

9.5. MONTHLY Cleaning and Disinfection of Cleanrooms

- Monthly cleaning is to be done on the last Friday of the month, or the last business day of the last FULL week of the month. This may mean more than 12 monthly cleanings per year.
- In addition to the normal schedule, monthly cleaning is to be done after shutdowns, maintenance work performed in the cleanrooms, loss of room pressurization or HEPA filter integrity, or other activity that could compromise environmental integrity.
- Monthly cleaning includes all the elements of the daily and weekly cleaning plus the walls.

9.5.1. Remove any trash and re-stock the rooms with any necessary components, if applicable. Remove portable equipment that is not room-dedicated, such as Viable Air Samplers.

9.5.2. Roll the Auto-Fillers out of the LAFWs.

9.5.3. Using sterile wipes wetted with sterile Spor-Klenz RTU, clean / disinfect the LAFWs and the Auto-Fillers, as per the DAILY cleaning steps 9.1.3.1 and 9.1.3.2.

9.5.4. Using sterile Vileda mops wetted with sterile Spor-Klenz RTU, clean / disinfect the cleanroom Walls. Mop in order: Back wall, Side walls, Front wall.

9.5.5. Using sterile wipes wetted with sterile Spor-Klenz RTU, clean / disinfect the rest of the room as per the DAILY cleaning steps 9.1.3.4 through 9.1.3.7.

9.5.6. Using sterile Vileda mops wetted with sterile Spor-Klenz RTU, clean / disinfect the cleanroom floors.

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9.5.7. Allow surfaces to completely dry; all Spor-Klenz RTU must be dry before proceeding.

9.5.8. Repeat the above steps 9.5.1 through 9.5.6 using Vesta-Syde SQ 128 RTU, in the same order: LAFWs and Auto-fillers, back wall, side walls, front wall, other equipment and surfaces, then the floor.

9.5.9. Allow surfaces to completely dry.

9.5.10. At the cleaner's discretion, residues left by the cleaning agents may be removed using sterile wipes wetted with sterile 70% IPA. This step is optional.

9.6. QUARTERLY Cleaning and Disinfection of Cleanrooms

- Quarterly cleaning will be done *instead of* a monthly cleaning every three months. This does not have to correspond to calendar quarters, but rather starting the third month after the area was brought on-line or this procedure was first implemented.
- Quarterly cleaning includes all the elements of monthly cleaning plus the ceilings and the use of Peridox RTU.

9.6.1. Remove any trash and re-stock the rooms with any necessary components, if applicable. Remove portable equipment that is not room-dedicated, such as Viable Air Samplers.

9.6.2. Roll the Auto-Fillers out of the LAFWs.

9.6.3. Using sterile wipes wetted with sterile Peridox RTU, clean / disinfect the LAFWs and the Auto-Fillers, as per the DAILY cleaning steps 9.1.3.1 and 9.1.3.2.

9.6.4. Using sterile Vileda mops wetted with sterile Peridox RTU, clean / disinfect the cleanroom Ceiling and Walls. Mop in order: Ceiling, Back wall, Side walls, Front wall.

9.6.5. Using sterile wipes wetted with sterile Peridox RTU, clean / disinfect the rest of the room as per the DAILY cleaning steps 9.1.3.4 through 9.1.3.7.

9.6.6. Using sterile Vileda mops wetted with sterile Peridox RTU, clean / disinfect the cleanroom Floors.

9.6.7. Allow surfaces to completely dry; all Peridox RTU must be dry before proceeding.

9.6.8. Repeat the above steps 9.6.2 through 9.6.6 using Spor-Klenz RTU in the same order: LAFWs and Auto-fillers, Ceiling, Back Wall, Side Walls, Front Wall, other equipment and surfaces, then the Floor.

9.6.9. Allow surfaces to completely dry; all Spor-Klenz RTU must be dry before proceeding.

9.6.10. Repeat the above steps 9.6.2 through 9.6.6 using Vesta-Syde SQ 128 RTU, in the same order: LAFWs and Auto-fillers, Ceiling, Back Wall, Side Walls, Front Wall, other equipment and surfaces, then the Floor.

9.6.11. Allow all surfaces to completely dry.

9.6.12. At the cleaner's discretion, residues left by the cleaning agents may be removed using sterile wipes wetted with sterile 70% IPA. This step is optional.

9.7. BETWEEN BATCH Cleaning and Disinfection of Cleanrooms

9.7.1. Clean / disinfect the LAFW surfaces inside the workstation using sterile wipes wetted with sterile 70% IPA.

9.7.2. Clean / disinfect the carts and associated equipment in the mixing room using sterile wipes wetted with sterile 70% IPA upon completion of mixing operations and before bringing materials into the room for the next batch.

9.7.3. All materials going into the cleanroom are to be wiped down with sterile 70% IPA before going into the pass through.

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1. Approvals and Version History

1.1. Approvals

Role	Name and Title	Signature	Date
Author	Lawrence Solomon Quality Control Manager	[redacted]	18 JUN 2024
Department Representative	Mike Faragalla Sterile Pharmacy Manager		18JUN2024
Quality Unit Representative	Max Everett Quality Director		18 JUN2024

1.2. Version History

Version No.	Effective Date	Changes
1	05MAY14	Initial release.
13	10OCT22	Refer to Version 14 for complete Change History
14	16JAN2023	
15	24APR2023	• Adding Setra 5000 Series Non-Viable Air Sampler to section 8.6 and Appendix 2. • Adding MasterControl documentation to sections 8.3 – 8.6, 8.8 and 10.
16	28JUL2023	• Updated Section 7.2.2. temperature specification of the Thermo Heratherm IGS180 and IMH750-S • Added Section 7.2.9 Setra Airborne Particle Counter • Created SOP P-815 detailing the use of the Non-viable and Viable Air samplers • All Appendices removed to separate documents rather than attachments. • Added Second-floor diagram, Environment Monitoring Appendix for location, forms for Environment Monitoring and In-process Environmental Monitoring • Removed Section 10, Environmental Monitoring forms to a separate Appendix document (A-212.f)

17	18MAR2024	• Updated SOP title from "Environmental Monitoring for the Positive Pressure Cleanrooms" to "Environmental Monitoring of the Controlled Production Areas".
		• Changes throughout the document as per CRM-2023-043:
		  ○ Replaced RCS equipment with MAS-100 Eco
		  ○ Removed references to TC-γ and YM.
		• Updated Responsibilities Section 6 to align with P-213 Personnel Monitoring.
		• Updated both equipment and method for Non-Viable Particle sampling. (Sec. 7.2 and 8.5)
		• Revised Section 8 to make current with site practices. Removed references to ISO 5 Cleanrooms and the General Sampling Procedure. Added Certification requirement and position of Runner. Replaced "Lint-free" with "Low-lint". Regrouped and re-arranged steps for better flow and understanding.
		• Updated Appendices:
		  ○ Appendices 1 and 2 merged and retitled. A-212.b now obsolete
		  ○ Appendix 3 removed as per CRM-2023-037. A-212.c is now obsolete.

Version No.	Effective Date	Changes
18	19JUN2024	• Updated document number from P-212 to SOP-009 for implementation of MasterControl System. • As per CRM 2024-019 replaced BBL™ CultureSwab™ with Millipore™ ICR-Swab,™ Section 7.1.5. • Section 8.2 Added Sterile Technicians to the Environmental Monitoring Certification. • Section 8.4.3 Removed process of using CultureSwab and updated with process for using ICR-Swab • Section 8.9.2 Added ICR-Swab™ incubation temperature and time

2. Purpose

This Standard Operating Procedure (SOP) describes the activities for carrying out Environmental Monitoring (EM) sampling and testing at Olympia Pharmacy.

3. Scope

This SOP applies to all Sterile Pharmacy Technicians, Sterile Pharmacists, Quality Unit personnel, and Sterile Compounding Controlled Areas at Olympia Pharmacy's 503B facility on Conroy Road.

4. Abbreviations and Definitions

Table 4-1: Abbreviations and Definitions

Abbreviation	Description
EM	Environmental Monitoring
CFU	Colony Forming Units
IPA	Isopropyl Alcohol
LAFW	Laminar Airflow Workbench
TSA	Tryptic Soy Agar
SDA	Sabouraud Dextrose Agar
TSB	Tryptic Soy Broth
Term	**Definition**
Action Levels	Established criteria (e.g., microbiological, or particulate levels) that when exceeded, require immediate investigation, including impact to product quality, and corrective action.
Alert Levels	A level that when exceeded indicates when a process might have drifted from normal operating conditions (e.g., microbiological, or particulate levels). An investigation may be performed, and corrective action may be implemented, but no action is required. It can be assumed that repetitive excursions above the alert level may be addressed as if it were an action level.
Aseptic Processing	Handling sterile materials in a controlled environment, in which the air supply, materials, equipment, and personnel are regulated to control microbiological and particulate contamination to specified levels.
Compounding	The process of combining active ingredients, excipients, and solvent components into a homogenous mixture.
Daily	Daily during or after compounding activities are completed, but prior to cleaning.
Environmental Monitoring Program	Defined, documented program that describes the routine particulate and microbiological monitoring of processing areas and includes a corrective action plan when action levels are exceeded.

Abbreviation	Description
Growth Promotion Test	Test performed to demonstrate that media will support microbiological growth.
In-Process	During Compounding Activities of each batch.
Runner	The technician performing material transfer into the filling room.
Sampling Frequency	Established period for collecting samples.
Sterile	Free of any detectable viable organisms. Note: In practice, no such absolute statement regarding the absence of microorganisms can be proven.
Sterilization	Validated process used to render a product free of viable organisms. Note: In a sterilization process, the nature of microbiological death or reduction is described by an exponential function. Therefore, the number of microorganisms which survive a sterilization process, can be expressed in terms of probability. While the probability may be reduced to a very low number, it can never be reduced to zero.
Sterility Test	Test performed to determine if viable microorganisms are present in a specified sample size of a compounded sterile preparation or sterile drug product.

5. References

Table 5-1: Internal References

Document No.	Document Title
P-211	Policy for the Environmental and Personnel Monitoring Program
P-220	Investigating Out-of-Specification (OOS) Test Results
P-225	Continuous Monitoring Systems
P-224	Deviation Management
P-223	Corrective Action and Preventative Action
P-815	Operation and Maintenance of Air Samplers
A-212.a	Appendix 1: First Floor Environmental Monitoring Sample Sites
A-212.d	Appendix 4: Environmental Monitoring Alert and Action Levels
A-212.e	Appendix 5: Second Floor Cleanroom Environmental Monitoring Sample Sites
A-212.f	Appendix 6: Environmental Monitoring Forms
VSR-PRO-212-002	Summary Report for the Environmental and Personnel Monitoring Media Validation

Table 5-2: External References

Document No.	Document Title	Source
21 CFR Part 211	Current Good Manufacturing Practice for Finished Pharmaceuticals	FDA
N/A	Guidance for Industry: Sterile Drug Products Produced by Aseptic Processing	FDA
N/A	Current Good Manufacturing Practice – Guidance for Human Drug Compounding Outsourcing Facilities under Section 503B of the FD&C Act	FDA
ISO 14644-1	Cleanrooms and Associated Controlled Environments – Part 1: Classification of Air Cleanliness	ISO
Chapter <1116>	Microbiological Control and Monitoring of Aseptic Processing Environments	USP-NF
Chapter <61>	Microbiological Examination of Nonsterile Products: Microbial Enumeration	USP-NF
Chapter <797>	Pharmaceutical Compounding, Sterile Preparations	USP-NF
ISO 14644-2: 2015	Cleanrooms and associated controlled environments — Part 2: Monitoring to provide evidence of cleanroom performance related to air cleanliness by particle concentration	ISO
USP-NF 1117	Microbiological Best Laboratory Practices	USP-NF

6. Responsibilities

6.1. Sterile Compounding Technicians

6.1.1. Perform and document all sampling activities as assigned in this procedure.

6.2. Quality Unit

6.2.1. Manage execution of all sampling activities.
6.2.2. Manage equipment and supplies necessary for sampling and testing.
6.2.3. If assigned to read and evaluate plates or perform any tasks in the cleanrooms, complete training program as described in Section 8.2.
6.2.4. Initiate a Deviation and determine batch disposition as per P-224, Deviation Management for any Action Level results obtained during the processing of a lot intended for distribution to patients.
6.2.5. Perform trending of EM data and generate corresponding reports.
6.2.6. Monitor compliance of this SOP with all relevant policies and related SOPs.

7. Materials and Equipment

7.1. Materials

7.1.1. Triple-wrapped, sterile 55mm Tryptic Soy Agar (TSA) *with lecithin and Tween® 80* Contact Plates (EMD Millipore 1465520200 or equivalent)
7.1.2. Triple-wrapped, sterile 55mm Sabouraud Dextrose Agar (SDA) *with lecithin, Tween® 80, histidin, and thiosulfate* Contact Plates (EMD Millipore 1465010200 or equivalent)
7.1.3. Triple-wrapped, sterile 90mm TSA Plates (EMD Millipore 1460500120 or equivalent)
7.1.4. Triple-wrapped, sterile 90mm SDA Plates (EMD Millipore 1460050120 or equivalent)
7.1.5. Sterile swabs (Millipore™ ICR-Swab™ 1465290100 or equivalent).
7.1.6. Perforated lid for MAS-100 Eco®
7.1.7. Dust-cover for MAS-100 Eco®

7.2. Equipment

7.2.1. Incubators
  7.2.1.1. Chamber incubator (reach-in or walk-in) capable of maintaining 32.5 ± 2.5°C.
  7.2.1.2. Chamber incubator (reach-in or walk-in) capable of maintaining 22.5 ± 2.5°C.
7.2.2. Portable Viable-Particle Air Sampler (MAS-100 Eco® or similar)
7.2.3. Portable Non-Viable-Particle Air Sampler (Lighthouse 3016-series, Lighthouse Apex Z50, or similar)
7.2.4. Fixed Non-Viable Airborne particle counter (Setra 5000 Series or similar.)
7.2.5. Wireless chamber-temperature monitoring system (Senso-Scientific or similar.)
7.2.6. Wireless Differential Air Pressure Sensor system (Clean Room Design or similar).

8. Procedure

8.1. Quality Control of Growth Media

Prior to utilizing media for environmental monitoring, confirm that each plate meets the quality standards as stated in P-211, Policy on the Environmental and Personnel Monitoring Program.

8.2. Environmental Monitoring Certification

All Quality Unit members and Sterile Technicians involved in the Environmental Monitoring quality system must obtain an Environmental Monitoring Certification.

8.2.1. The Quality Unit EM Certification program includes

8.2.1.1. Classroom lecture presentations and quiz on the following topics:

- Environmental Monitoring Fundamentals
- Environmental/Personnel Monitoring
- Fundamentals of Reading Environmental Monitoring Plates

8.2.1.2. An annual eye examination.

8.2.1.3. The Certification must be renewed annually; if any changes to the Environmental or Personnel monitoring procedure occur within a year, quality must update and complete the Certification.

8.2.2. The Sterile Technician EM Certification program includes

8.2.2.1. Classroom lecture presentations and quiz on the following topics:

- Environmental Monitoring SOP
- Appendix 1 (A-212.a) and Appendix 5 (A-212.e)

8.2.2.2. On-the-job training by Quality Control on The Operation and Maintenance of Air samplers (P-815) and sampling techniques.

8.2.2.3. Environmental Monitoring Competency Assessment.

8.2.2.4. An annual eye examination.

8.2.2.5. The Certification must be renewed semi-annually; if any changes to the Environmental Monitoring procedure occur within 6 months, quality must update and complete the Certification.

8.3. Viable Surface Sampling: Contact Plates

8.3.1. Flat equipment surfaces and room surfaces are sampled using sterile 55mm TSA and SDA Contact plates (triple-wrapped).

8.3.2. **Schedule:** Collect viable surface samples from the ISO Class 5 laminar airflow workbenches (LAFWs), ISO 7 and ISO 8 cleanrooms once daily at the end of all compounding / filling activities but prior to cleaning.

8.3.3. Spray the outer surface of the media plate wrapping with sterile 70% IPA.

8.3.4. Remove the plates from the wrapping and label the outside of all contact plates (plastic side containing the agar) with a sterilized permanent marker OR disinfected pre-printed plastic labels indicating: the sampling date, sample ID, and sampling location.

8.3.5. Remove the lid from each contact plate with one hand. With the other hand, hold the base with two fingers and gently press the plate with a third finger to the surface using a gentle rolling motion. Do not move the plate laterally while sampling.

8.3.6. Sample each location with a contact plate as indicated in Appendices 1 and 5. Replace the lid after sampling, being careful not to touch the agar surface while sampling.

8.3.7. Immediately after sampling, clean any agar residue from the sampled surface with a sterile low-lint wipe and sterile 70% IPA.

8.3.8. The Runner or Quality Specialist must record all viable surface sampling data, including date, media lot, media expiration, incubator ID, and calibration due date. The Sampling technician will sign and date any paper forms indicating the completion of sampling.

8.3.9. Incubate plates and record results as per section 8.9.

8.4. Viable Surface Sampling: Swabs

8.4.1. Irregular (not flat) equipment surfaces are sampled using sterile single-use Swabs.

8.4.2. **Schedule:** Collect viable surface samples from the Filling Needle at the end of every batch filling operation. Collect samples from the Stopper Bowl and Tube Transfer Port once daily at the end of all compounding / filling activities but prior to cleaning.

8.4.3. Tear open the Millipore™ ICR-Swab™ sterile pouch from the slit located on both sides of the pouch.

8.4.4. Stopper Bowl:

8.4.4.1. Twist the blue section directly under the TSB to remove the Swab from the transport tube. Take care not to touch the swab tip.

8.4.4.2. Swab the interior surfaces of the sides of the Stopper Bowl for 3 seconds while rotating the swab. Insert the Swab back into the tube.

8.4.4.3. Snap the reservoir at the top of the Swab containing the culture broth. Squeeze the reservoir until the broth has fully saturated the swab.

8.4.5. Filling Needle:

8.4.5.1. Twist the blue section directly under the TSB to remove the Swab from the transport tube. Take care not to touch the swab tip.

8.4.5.2. Swab the exterior surfaces of the bottom inch of the filling needle for 3 seconds while rotating the swab. The sides of the swab, not the tip, should contact the needle. Insert the Swab back into the tube.

8.4.5.3. Snap the reservoir at the top of the Swab containing the culture broth. Squeeze the reservoir until the broth has fully saturated the swab.

8.4.6. Tube Transfer Port:

8.4.6.1. Snap the reservoir at the top of the Swab containing the culture broth. Squeeze the reservoir until the broth has fully saturated the Swab.

8.4.6.2. Swab the interior surface of the Transfer port, about 2-4 inches from the opening of port for 3 seconds while rotating the swab.

8.4.6.3. Gently press the sides of the swab to the surface of a TSA Contact Plate. Swab the entire surface of the plate using overlapping strokes while rotating the swab. Rotate the plate approximately 90° degrees and repeat the swabbing process.

8.4.6.4. Repeat steps 8.4.6.1– 8.4.6.3 with an SDA Contact Plate.

8.4.7. The Runner or Quality Specialist must record all viable surface sampling data, including date, media lot, media expiration, incubator ID, and calibration due date. The Sampling technician will sign and date any paper forms indicating the completion of sampling.

8.4.8. Incubate plates and record results as per section 8.9.

8.5. Viable Active Air Sampling

8.5.1. Active Viable air sampling uses sterile TSA and SDA 90mm plates (triple-wrapped) and the MAS-100 Eco® sampler. Reference "Operation and Maintenance of Air Samplers", P-815, for operating instructions.

8.5.2. **Schedule:** Collect viable active air samples from each of the ISO Class 5 LAFWs during filling of each batch. If no batch is filled that day, collect a sample from each LAFW once daily. Collect viable active air samples from the ISO 7 and ISO 8 cleanrooms once daily during normal operations.

8.5.2.1. If used in more than one room during the day, the MAS unit must be used beginning with the cleanest room or area classification first and working progressively toward the less-clean room or area classifications.

8.5.2.2. MAS perforated lid and dust cover must be sterilized prior to the first use of the day.

8.5.3. Set the MAS-100 Eco® to take 1000L ($1m^3$) per sample.

8.5.4. Remove the appropriate TSA or SDA 90mm plates from the wrapping. Label all the plates (outside "bottom" half containing the agar) with the sampling date, Sample ID, time, and sampler's initials. Use either a sterilized permanent marker OR disinfected pre-printed plastic labels.

8.5.5. Wipe the outer surface of the MAS-100 Eco® Air sampling unit with a low-lint wipe saturated with sterile 70% IPA.

8.5.6. Place a TSA or SDA 90mm plate on the MAS unit dish support and remove the plate lid.

8.5.7. Remove the sterilized MAS perforated lid and dust cover from the wrapping. Place the plate lid over dust cover to prevent contamination while sampling.

8.5.8. Attach the perforated lid to the MAS unit, and close it by rotating to the right.

8.5.9. Turn on the MAS unit to collect a 1000L sample at each location as indicated in Appendices 1 and 5.

8.5.10. After the sample cycle has completed, remove the plate, and replace the plate cover. Replace the perforated lid and the dust cover on the MAS unit until it is next used.

8.5.11. The Runner or Quality Specialist must record all viable active air sampling data, including date, media lot, media expiration, incubator ID, and calibration due date. The Sampling technician will sign and date forms indicating the completion of sampling.

8.5.12. Incubate plates and record results as per section 8.9.

8.6. Viable Passive Air Sampling

8.6.1. Viable Passive air sampling uses sterile TSA and SDA 90mm plates (triple-wrapped).

8.6.2. **Schedule:** Collect a continuous viable passive air sample from the ISO 5 Filling LAFWs throughout the entire aseptic filling operation. Change the plate every 4 hours as needed to ensure passive air sampling occurs during the full duration of the filling operation. Collect viable passive air samples from the ISO 5 filtering LAFWs and ISO 7 Passthrough during normal operations: including the aseptic setup connections, filtering, and filling of each batch. Change plate(s) every 4 hours as needed.

8.6.3. Spray the outer surface of the media plate wrapping with sterile 70% IPA.

8.6.4. Remove the TSA and/or SDA 90mm plates from the wrapper. Label all the plates (outside "bottom" half containing the agar) with the sampling date, Sample ID, time, and sampler's initials. Use either a sterilized permanent marker OR disinfected pre-printed plastic labels.

8.6.5. Sample each location as indicated in Appendices 1 and 5.

8.6.5.1. **Filter LAFWs and Passthroughs:** Place both of the 90mm plates (TSA and SDA) on the surface, agar side down and remove the lid, placing the lid with the open side down alongside the exposed plate during exposure.

8.6.5.2. **Filling LAFWs:** Place the TSA 90mm plate on the surface, agar side down and remove the lid, placing the lid under the 90mm plate during exposure.

8.6.6. Remove the plate after 4 hours or when operation ends, whichever occurs first, by inverting the lid, so it is facing up, placing the exposed plate onto the lid, agar side up and recording the time the plate is closed.

8.6.7. The Runner or Quality Specialist must record all Passive viable air sampling data, including date, media lot, media expiration, incubator ID, and calibration due date. The Sampling technician will sign and date forms indicating the completion of sampling.

8.6.8. Incubate plates and record results as per section 8.9.

8.7. Non-Viable Active Air Sampling

8.7.1. Non-Viable Active air sampling uses the Setra 5000 Series Airborne Particle Counters, both fixed and portable. If a Setra unit is not available, the portable Lighthouse Handheld 3016 or Lighthouse Apex Z 50 may be used instead.

8.7.2. **Schedule:** Collect Non-Viable Active air samples continuously from the ISO 5 LAFWs during filtering and filling operations. Collect Non-Viable Active air samples daily from the ISO 7 and 8 cleanrooms during filtering and filling operations. Do not collect samples during cleaning.

8.7.3. For In-Process sampling in the ISO 5 LAFWs:

8.7.3.1. Place the sampling device in the upright position.

8.7.3.2. Set the sampling device to record counts in the cumulative mode, which represents the total number of particles that the sampling device counted for particle sizes of either 0.5 particles/m3 and greater, or 5.0 particles/m3 and greater per cycle.

8.7.3.3. Set the sample device to run 1 continuous cycle during the filtering or batching process. Set a 30-second delay to allow placement of the device. Devices are pre-set with the correct flow rate.

8.7.4. For Routine EM Sampling in the ISO 5 LAFW, ISO 7 and ISO 8 areas:

8.7.4.1. Confirm that the fixed Setra unit is operational. If it is, proceed to Step 8.6.5. If it is not, notify Quality immediately and proceed to Step 8.6.4.2.

8.7.4.2. Obtain a portable sampler unit. Place the sampler in the slanted position at sample locations located in Appendices 1 and 5.

8.7.4.3. For routine sampling, set the sample device to run 1 ten-minute cycle at each location. Set a 30-second delay to allow placement of the device. Devices are pre-set with the correct flow rate.

8.7.5. Recording Non-Viable Air Sample Data

8.7.5.1. Setra 5000 series devices: download the data to a USB drive, then display the data on a computer screen.

8.7.5.2. Lighthouse devices: Read the data directly from the screen on the device.

8.7.5.3. For electronic batch records, process-specific EM data is recorded in Section 8.2 of the MasterControl electronic production batch record.

8.7.5.4. For paper batch records, refer to Appendix 6 (A-212.f) for the list of paper forms to be used for recording process-specific EM data results.

8.7.5.5. For routine EM (non-process-specific), first check to see if a MasterControl record option has been enabled. If it has, record the data in MasterControl. If no electronic record option is available, refer to Appendix 6 (A-212.f) for the list of paper forms to be used for recording EM data results.

8.7.5.6. The Sampling technician will either make the MasterControl entries, or sign and date the forms indicating the completion of sampling.

8.7.5.7. The results recorded onto the forms are independently reviewed and verified against the results on the Lighthouse or Setra readout and approved by the Quality Unit.

8.7.5.8. A Quality Unit Specialist must also download the particle counts data from device Weekly to correspond with written documentation.

8.7.5.9. In case of any Action Level results within the laminar air flow work benches (LAFWs) and ISO 7 filling cleanrooms, stop all compounding activities and notify Quality Unit Manager or designee for instructions and investigation.

8.8. Room Condition Monitoring

8.8.1. Continuous monitoring of the Controlled Production Areas for temperature and humidity, and the ISO-classified cleanrooms for differential pressure is performed by the fixed Continuous Monitoring systems described in SOP# P-225.

8.8.2. Throughout the day, the room conditions are visually observed for any excursions from set specifications.

8.8.3. If any out-of-specification is observed during compounding activities in the mixing room, ISO 7 cleanrooms, and/or LAFWs, proceed as follows:

8.8.3.1. Notify Quality Unit personnel immediately.

8.8.3.2. Quality will make an assessment for impact to compounding and notify technicians on how to proceed.

8.8.4. For requirements for continuous monitoring system documentation and review, refer to P-225, Continuous Monitoring Systems.

8.9. Incubating Plates & Reading Test Results

8.9.1. Put plates into the incubator on their lids, with the agar-half of the plate on top, surface facing down. Organize the plate location by sampling date to minimize the time the incubator door is kept open when the plates are removed.

8.9.2. Incubate TSA media plates at 30 to 35°C for 3 to 5 days and the SDA media plates at 20 to 25°C for 5 to 7 days. Incubate Millipore™ ICR-Swab ™ at 30 to 35°C for 3 to 5 days and monitor for turbidity. In case of a Holiday that affects the incubation schedule, the media validation VSR-PRO-212-002 report states that exposed TSA media plates may be incubated for a maximum of 10 days at 30 to 35°C. If after the extended incubation, any of the TSA plates exhibit desiccation, Quality will treat those plates like an action level.

8.9.3. Read the plates on a stainless steel surface in the Controlled-Not-Classified Area. The 2nd floor is preferred, but the 1st floor is acceptable if the 2nd floor is not available.

8.9.4. Count the number of discrete colonies on each plate sampled from the LAFWs and report as CFU per plate on the appropriate Environmental Monitoring record.

8.9.4.1. For electronic batch records, process-specific EM data is recorded in Section 8.2 of the MasterControl electronic production batch record.

8.9.4.2. For paper batch records, refer to Appendix 6 (A-212.f) for the list of paper forms to be used for recording EM data results.

8.9.4.3. For routine EM (non-process-specific), first check to see if a MasterControl record option has been enabled. If it has, record the data in MasterControl. If no electronic record option is available, refer to Appendix 6 (A-212.f) for the list of paper forms to be used for recording EM data results.

8.9.5. All plates, whether positive or negative for growth, must be reviewed and verified against the results recorded onto the sampling form or in MasterControl by a member of the Quality Unit.

8.9.6. In the unlikely event that the verifying Quality Unit member is not immediately available, plates awaiting verification will be returned to the incubator on the bottom-most shelf. Plates are allowed to be held in the incubator for a maximum of 4 hours.

8.9.7. Clean Stainless-Steel surface with sterile 70% IPA and a low-lint wipe after recording the information.

8.10. Results / Excursions:

8.10.1. Evaluate each individual sampling result from the monitoring for its significance by comparison to the alert and action levels specified in Appendix 4 (A-212.d).

8.10.2. Identify samples suspected or known of contamination after initial sampling with an X across plates. The Quality Unit will then be notified by Production of contamination. A Quality Unit representative and Production Pharmacist will initial the sample before placing it in the incubator. A note on the form will document any suspected or known contamination after sampling. These samples will be sent to Analytical Research Lab (ARL) for bacterial identification at the species level.

8.10.3. Report action level excursions to the Quality Unit Manager immediately. Excursions must be recorded, investigated, and documented in a Deviation report, including a product impact assessment according to SOP P-224 Deviation Management.

8.10.4. The observance of two consecutive alert level excursions recovered from a given sample site is considered an action level.

8.10.5. Send plates with growth exceeding alert or action levels including all plates with any growth recovered from the ISO 5 LAFW for identification to species level.

8.10.6. The results of the identification must be included in the investigation with special attention paid to the repeated recovery of molds, gram-positive spore-forming and gram-negative organisms.

8.11. Environmental Monitoring Data Trending

8.11.1. Generate trend reports monthly, quarterly, and annually to assess the general state of environmental control, normally organized by room classification.

8.11.2. The environmental monitoring data may be further organized by room, sampling location, personnel, or other parameters of significance as required, e.g., when trends are detected.

8.11.3. Monthly trend reports include, but are not limited to:

- A tally of the total numbers of samples taken and the number of alert and action level excursions that occurred during the month, along with a description of the excursions that occurred.
- A summary of any investigations performed in response to action level excursions and corrective / preventive action taken as applicable.

8.11.4. Quarterly trend reports include, but are not limited to:

- All aspects of the monthly trend report
- A data comparison to the previous quarter with respect to frequencies of alert and action level excursions, recovery rates, and microbiological identification profile with conclusions made regarding the presence or absence of any differences or trends
- Control charts plotting the results with lines indicating the alert and action levels
- Contamination recovery rates for each classified area
- Microorganism identification profile for the quarter
- Identification of any potential CAPA to address adverse trends
- Root cause of any deviation mentioned in the Monthly report

8.11.5. Annual trend reports include, but are not limited to:

- All aspects of the quarterly report
- An overall evaluation and conclusions of the environmental monitoring results for the year including the frequencies of alert and action levels, the relative recovery rates, and microbiological identification profile
- Alert levels in the ISO 7 or ISO 8 areas may be adjusted down, based on the data to make these levels more sensitive for detecting developing trends

Olympia Pharmaceuticals List of Compounded Products	
Drug Name	NDC
Alpha Lipoic Acid 25mg/mL	73198-0144-30
Amino Blend	73198-0147-30
AT-6 (10ml)	73198-0040-10
AT-6 (2.5ml)	73198-0040-03
Biotin 0.5mg/ml (10ml)	73198-0087-10
Bimix-3 (10ml)	73198-0027-10
Bimix-3 (2.5ml)	73198-0027-03
Calcium Chloride 100mg/ml	73198-0064-30
Cyanocobalamin 2mg/ml (10ml)	73198-0115-10
Dexpanthenol 250mg/ml	73198-0070-30
Diluent for Reconstitution	73198-0113-10
FA (10ml)	73198-0006-10
FA (2.5ml)	73198-0006-03
Formula F-1 (10ml)	73198-0137-10
Formula F-1 (2.5ml)	73198-0137-03
Formula F-9 (10ml)	73198-0138-10
Formula F-9 (2.5ml)	73198-0138-03
Glutathione 200mg/ml (30ML)	73198-0049-30
Glutathione 200mg/ml (5ml)	73198-0049-05
Glycerin 72%	73198-0103-10
Glycerin / Lidocaine	73198-0134-10
Hydroxocobalamin B12 2mg/ml (30ml)	73198-0128-30
L-Arginine 200mg/ml	73198-0069-30
L-Carnitine 500mg/ml	73198-0155-30

Ondansetron 1mg/ml (30ml)	73198-0127-30
PGE-1 40mcg – (10ml)	73198-0139-10
PGE-1 40mcg – (2.5ml)	73198-0139-03
PGE-2 80mcg – (10ml)	73198-0140-10
PGE-2 80mcg – (2.5ml)	73198-0140-03
Phenylephrine 1mg/ml (5ml)	73198-0021-05
Preserved Acetylcysteine 200mg/ml	73198-0073-30
Preserved Ascorbic Acid 500mg/ml (30ml)	73198-0079-30
Pyridoxine HCl 100mg/ml (30ml)	73198-0066-30
QM-2 (10ml)	73198-0018-10
QM-2 (2.5ml)	73198-0018-03
QM-2 (5ml)	73198-0018-05
QM-3 (10ml)	73198-0019-10
QM-3 (2.5ml)	73198-0019-03
QM-3 (5ml)	73198-0019-05
QM-4 (10ml)	73198-0020-10
QM-4 (2.5ml)	73198-0020-03
RE1 (10ml)	73198-0015-10
RE1 (2.5ml)	73198-0015-03
RE2 (10ml)	73198-0016-10
RE2 (2.5ml)	73198-0016-03
SB4 (10ml)	73198-0023-10
SB4 (2.5ml)	73198-0023-03
SB4 (5ml)	73198-0023-05
SB5 (10ml)	73198-0024-10
SB5 (2.5ml)	73198-0024-03

Tri-Immune Boost (30ml)	73198-0104-30
Vitamin D3 (30ml)	73198-0133-30
Zinc Sulfate 10mg/ml (10ml)	73198-0132-10

1. Approvals and Version History

1.1 Approvals

Role	Name and Title	Signature	Date
Author	Maria Belgodere Quality Specialist II	[redacted]	11SEP2024
Department Representative	Mike Faragalla Sterile Pharmacy Manager		11SEP2024
Quality Unit Representative	Eileen King Assistant Director of Quality		11SEP24

1.2 Version History

Version No.	Effective Date	Changes
1	10MAR17	Initial release.
2	19MAR18	Refer to Version 6 for complete version history
3	12OCT20	
4	07SEP21	
5	12OCT21	
6	07JAN22	
7	16JAN2023	• Reformatted entire SOP. • Added detail in Section 5 Definitions. • Added detail in Section 8 describing when a second 100% visual inspection is appropriate. • Section 8.3 added to provide more detail in qualifying technicians for visual inspection. • Section 8.5 added detail for supplemental inspection of lyophilized vials. • Forms removed as attachments, are now separate documents. Also: o F-203.a reformatted to incorporate -b, -c, and -d. Those forms are now obsolete. o F-203.e reformatted for improved ease-of-use. o F-203.f split into two forms. Part A remains -f, Part B is now F-203.j. o F-203.g and -h are obsolete. o F-203.k is for AQL inspections. o F-203.m is supplemental inspection for lyophilized products only.
8	06FEB2023	• Section 8.7.2: changed rest period interval and the documentation requirement. • Forms F-203.f, F-203.k, and F-203.m revised to maintain alignment with parent SOP. • Adding F-203.p for additional inspection stations being brought on-line.
9	17MAR2023	• Revised section 8.7 to include the documentation of rest period intervals.
10	02JUN2023	• Sections 7.1 and 8.5.2: Changed equipment specification to include any model that is functionally equivalent to the listed model.

Version No.	Effective Date	Changes
11	19APR2024	• Regrouped and re-arranged sections for better flow and understanding. • Sec. 8.1: Added information on certification program • Sec. 8.4: Revised Test Kit ID's • Sec. 8.5: Edited to remove impertinent or redundant text. • Sec. 8.10: Added more detail in Visual Inspection of lyophilized vials. • Removed requirement for tracking and trending • Sec. 9 Appendices 1, 2 and 3 removed and re-named. Appendix 1, renamed to Figure 1 Section 8.11.8, Appendix 2 renamed to Figure 2 Section 8.11.9, Appendix 3 renamed Section 8.4.8 Note.
12	13SEP2024	• Updated document number from P-203 to SOP-007 for implementation of MasterControl System. • Section 9.2.7 added more detail in qualifying technicians for visual inspection. • Section 9.4.4 updated Table 9-1 cap colors: Test Kit IDS: CCS-2.5 from Red to Ochre; CLP-3 from Brown to Red and CLP-2 from Pumpkin to Brown.

2. Purpose

The purpose of this procedure is to describe the requirements for the 100% Visual Inspection process for sterile injectable products produced at Olympia Pharmaceuticals (Olympia).

3. Scope

This procedure applies to the visual inspection of all sterile injectable products produced at Olympia's 503B Outsourcing facility on Conroy Road.

4. Acronyms and Definitions

Table 4-1: Acronyms and Definitions

Acronym	Description
ANSI	American National Standard Institute
AQL	Acceptable Quality Limit
ASQ	American Society for Quality
IPA	Isopropyl Alcohol
Refer to *Policy on Document Control* (P-215) for common abbreviations and acronyms.	
Term	**Definition**
Acceptable Quality Limit (AQL)	The maximum number of defective units considered acceptable in a particular sample size.
Essentially Free of Visible Particulates	When injectable drug products are inspected as described herein, no more than the specified number of units may be observed to contain visible particulates
Acceptance Sampling and Testing	Inspection of a statistically significant sample set pulled from the acceptable units of a batch from the 100% visual inspection.
Particulate Matter	Extraneous mobile undissolved particles, other than gas bubbles, unintentionally present in the solutions.
Extrinsic Particles	Particles that are not associated with the manufacturing process, e.g. hair, insect parts, dust, or other inorganic or organic materials.
Intrinsic Particles	Particles that are associated with the process, e.g. from processing equipment, primary packaging materials, foil, steel, glass, etc.
Inherent Particles	Particles directly from the associated product but not included in the product description, e.g. precipitation.

Critical Defect	Those defects that may cause serious adverse reaction or death of the patient if the product is used.
Major Defect	Those defects that carry the risk of a temporary impairment or medically reversible reaction or involve a remote probability of a serious adverse reaction.
Minor Defect	Those defects that do not impact product performance or compliance; they are often cosmetic in nature, affecting only product appearance or pharmaceutical elegance.
Manual Visual Inspection	Method where the units to be inspected are handled by a technician without any help of a transportation or vision system other than an appropriate light source and a white and black inspection background.

5. References

Table 5-1: References

Document No.	Title	Source
Chapter <1>	Injections and Implanted Drug Products (Parenterals) – Product Quality Tests	USP-NF
Chapter <790>	Visible Particulates in Injections	USP-NF
Chapter <1790>	Visual Inspection of Injections	USP-NF
N/A	Inspection of Injectable Products for Visible Particulates, Draft FDA Guidance, Dec. 2021	FDA
N/A	ANSI/ASQ Z1.4 Sampling Procedures and Tables for Inspection by Attributes	ANSI/ASQ
P-218	Corrective Action and Preventive Action (CAPA) System	Olympia
P-224	Deviation Management	Olympia
P-230	Annual Product Review	Olympia
F-203.a	Visual Inspection Qualification Form	Olympia
F-203.e	Daily Visual Inspection Station Light Check Form – 1st Floor	Olympia
F-203.f	100% Visual Inspection Form	Olympia
F-203.j	Quality Assurance Post-Inspection Review	Olympia
F-203.k	AQL Visual Inspection Form	Olympia
F-203.m	Supplemental Visual Inspection for Lyophilized Vials	Olympia
F-203.p	Daily Visual Inspection Station Light Check Form – 2nd Floor	Olympia
F.203.q	Visual Inspection of Sterile Drug Products Quiz	Olympia
A.203.a	Answer Key for Quiz F-203.q	Olympia
P-219	Complaint Handling, Drug Safety and Surveillance	Olympia
N/A	Current Good Manufacturing Practices (cGMP) Training Presentation	Olympia

6. Responsibilities

6.1 Quality Assurance (QA)

Select members of the Quality Unit will be chosen for the Visual Inspection Team. These personnel will:

6.1.1 Provide Quality oversight over the training and qualification of the visual inspection technicians and ensure compliance with this procedure.
6.1.2 Be qualified to perform the 100% inspection (initial and annual qualification)
6.1.3 Monitor the effectiveness of each 100% visual inspection process by performing AQL acceptance sampling and inspection.
6.1.4 Pass a visual acuity exam on an annual basis to support performing the AQL inspection.
6.1.5 Investigate and document non-conforming results post review of the visual inspection of finished drug products.
6.1.6 Institute a Corrective Action and Preventive Action (CAPA) plan when necessary.

7. Inspection Technician

Inspection Technicians will generally be chosen from the pool of Sterile Pharmacy Technicians. Additionally, Front-End Pharmacy Technicians and Sterile Production Pharmacists can be trained as Visual Inspection Technicians. These personnel will:

7.1.1 Pass a visual acuity exam on an annual basis to support performing the 100% visual inspection.

7.1.2 Complete the training and qualification to perform the 100% inspection (initial and annual qualification)

7.1.3 Perform 100% Visual Inspections on products following this procedure.

8. Materials and Equipment

8.1 Visual Inspection Booth, Bosch MIH-LX Light Station or equivalent. Must have:

- Non-glare white and matte-black backgrounds
- Two non-flickering lamps above the inspection area able to provide light intensity at each inspection point in the range of 2000 to 3750 Lux.

8.2 Dedicated Inspection Workstation. Must have:

- Booth equipment described above
- Sufficient space to maintain separation between inspected, uninspected, and rejected product.
- Sufficient separation (e.g., mobile walls, separate tables) between different workstations to reduce distraction and maintain separation between different lots of products.

8.3 Light Meter with NIST-Traceable Calibration, Digi-Sense Data Logging (or equivalent)

8.4 70% IPA or 70% IPA saturated wipes

8.5 Low-lint wipes

9. Procedure

9.1 Visual Inspection Certification Program

The program includes a combination of training materials, SOPs, on-the-job training, and testing. Inspector candidates are trained in relevant cGMP requirements.

9.1.1 The Certification program includes:

- Classroom lecture presentation. Discuss any questions with the trainer
- Quiz (F-203.q) on P-203, with a passing score of 80%
- An eye exam within the previous 12 months showing 20/20 vision (with correction if needed).
- No impairment of color vision exam
- On-the-Job training with QA trainer.
  - Technician must view both clear and amber glass vials containing each type of defect relevant to Olympia products to learn how to detect and categorize them.
- Successfully inspect each visual qualification test kit three (3) times.

9.2 Technician Qualification

9.2.1 Once the trainer has confirmed initial training has been successfully completed, the technician is ready for initial qualification.

9.2.2 If corrective lenses are required to achieve 20/20 vision, they must be worn during qualification.

9.2.3 Technician records test answers on the Visual Inspection Qualification Form, F-203.a.

9.2.4 The acceptance criteria for detecting true defects is ≥ 80%.

9.2.5 The acceptance criteria for false rejects is ≤ 5%.

9.2.6 Trainer scores the tests and records the results on F-203.a.

9.2.7 Technician must be qualified on all eleven test kits prior to performing Visual Inspection for any product. All eleven test kits must be completed in one working day to simulate worse-case conditions.

9.2.8 If a technician fails any test kit (initial or re-qualification):

9.2.8.1 Trainer must examine any defect missed by the trainee to verify adequacy of the unit, i.e. ensure the defect is still present and observable.

9.2.8.2 Trainer must examine any false reject to verify that the unit has not been damaged or degraded and is now exhibiting a defect not previously present.

9.2.8.3 Retraining should be initiated to allow the technician to receive additional instruction prior to attempting to repeat the qualification.

9.2.8.4 If qualification is not achieved after 3 attempts (for any of the test kits), the technician must wait 3 months before the next attempt.

9.3 Requalification:

9.3.1 All visual inspection technicians, including those in QA, must requalify at least annually.

9.3.2 More frequent requalification may be required if determined by the supervisor or QA.

9.3.3 Personnel are considered requalified upon completing a single successful inspection of each qualification test kit using the same acceptance criteria as used for initial qualification.

9.3.4 Annual visual acuity exam.

9.4 Visual Inspection Test Kits

9.4.1 Each kit is prepared and approved by a Quality Unit visual inspector team member.

9.4.2 Visual inspection test kits are composed of common production defects that range from cosmetic abrasions to the presence of particulate matter.

9.4.3 Particulate defects in the test kits should be detectable but small enough to provide a suitable challenge during qualification.

9.4.4 There are separate test kits for each product type (e.g. aqueous, oil based, colored solution, lyophilized product), container type (e.g. clear or amber glass) and size, using the lowest and highest production fill volume for each selected container. Test kits are coded as follows:

Table 9-1: Test Kit Contents

Test Kit ID	Appearance & Contents					
	Vial Size	Fill Volume	Glass Color	Cap Color	Product Appearance	Product Form
ADS-30	30 mL	30 mL	Amber	Pumpkin	Dark	Liquid
AOS-30	30 mL	30 mL	Amber	Black	Oil	Liquid
ACS-30	30 mL	30 mL	Amber	Lilac	Clear	Liquid
ADS-10	10 mL	10 mL	Amber	Blue	Dark	Liquid
CCS-10	10 mL	10 mL	Clear	Turquoise	Clear	Liquid
ACS-10	10 mL	10 mL	Amber	Light Blue	Clear	Liquid
ACS-5	10 mL	5 mL	Amber	Black Stripe	Clear	Liquid
CCS-3	10 mL	3 mL	Clear	Green Stripe	Clear	Liquid
CCS-2.5	10 mL	2.5 mL	Clear	Ochre	Clear	Liquid
CLP-3	10 mL	3 mL	Clear	Red	Lyophilized	Powder: Cake
CLP-2	10 mL	2mL	Clear	Brown	Lyophilized	Powder: Cake

9.4.5 Each test kit has between 10% and 20% of the units containing defects, with the rest of the kit containing units that have been verified to have no defects.

9.4.6 Test kits used for training or qualification must be verified and documented on a periodic basis semi-annually to include at least the following:

- The known defects are still visible and unchanged.
- No new defects have been inadvertently introduced (e.g. container-closure defect).

9.4.7 The test kits must be updated, as required based on their verification results.

9.4.8 Each unit in the test kit should be marked with a unique code (e.g. number or alpha-numeric) that identifies if the unit has a defect of not, and defect type as applicable. Only the trainer or other designated personnel should have access to the Defect Code Key that is used to score each test.

Note: The test kit answer keys are limited-access documents and are not available for general viewing. They will be maintained and updated as needed by the Quality Department. In order to facilitate independent revision, they will be assigned document number F-203.n.

9.4.9 Each test kit must be evaluated using F-203.a, Visual Inspection Qualification Form.

9.4.10 Upon introduction of a new product to be compounded at Olympia the following is required:

- Evaluate the new product (e.g. appearance, fill volume, container-closure type and size) and determine if the product falls into an existing group.
- If the new product is considered significantly different, a new test kit representing this product will be required. All technicians must be qualified with this new kit.

9.5 Inspection Process Overview

9.5.1 Injectable products undergo a 100% Inspection for manufacturing and primary packaging defects and the presence of particulate matter. They must be inspected after the containers are sealed, but prior to labeling and secondary packaging. Refer to form F-203.f for the complete list and descriptions of defects.

9.5.2 After 100% Inspection, a statistically valid representative sample (as per ANSI / ASQ Z1.4) is taken from the acceptable vials and re-inspected by QA. This ensures that the number of any remaining defects does not exceed established Acceptable Quality Limits (AQLs).

9.5.3 For lyophilized products, supplemental destructive testing (reconstitution) and inspection will be performed on a representative sample to enable the detection of particulates.

9.5.4 If the acceptance criteria of the sampling plan are not met, a Deviation will be opened as per P-224 *Deviation Management*.

9.5.5 The investigation will include forensic characterization of the particles or other defect, as well as examinations of the entire production lifecycle including the 100% inspection process.

9.5.6 If after investigation, the inspection process is deemed capable of detecting the defect(s) in question, the batch may be reinspected.

9.5.7 After the 100% reinspection, a new AQL inspection is performed.

9.6 Preparation of Inspection Area

9.6.1 Before using each inspection station, inspect the area to ensure that all product and other materials from the previous inspection have been removed. Wipe down the inspection station with 70% IPA and document onto F-203.f Visual Inspection Form.

9.6.2 Turn on the Bosch MIH-LX or equivalent inspection hood by turning the power entry module off/on switch at the back of the hood.

9.6.3 Test the light intensity within the inspection area of the hood with the calibrated data logging light meter prior to the first inspection of the day.

9.6.3.1 The light intensity must be between 2000 and 3750 LUX.

9.6.3.2 If the light intensity does not meet the specification the booth must be tagged out of service and repaired prior to any further use.

9.6.3.3 Document the results of the light intensity test on F-203.e and F-203.p, Daily Light Check Log.

Note: It is recommended to have spare bulbs on hand to ensure continuity of operations.

9.6.4 Ensure the light intensity is verified by a second person and documented onto F-203.e.

9.7 Delivery of Product and Preparation for Inspection

9.7.1 Receive delivery of the finished product to be inspected to the inspection area. Allow only one lot of product in the inspection area at any time of use.

9.7.2 Record the following information onto F-203.f for the product type being inspected:

- Product Name
- Lot Number
- Station / Table Number

9.7.3 Attach in-process product identification labels on separate containers in the inspection area to receive inspected vials that are further identified as "Inspected – Acceptable" for those vials that passed inspection with no defects, or "Inspected – Defects", for those vials that failed inspection with defects detected. Maintain segregation of the "Acceptable" vials and "Defects" vials throughout the inspection process.

9.8 100% Visual Inspection

9.8.1 Make sure the product is at room temperature prior to the inspection so that condensation does not form on the exterior of the vials.

9.8.2 Each technician must take, at a minimum, a five to eight-minute break after each 60 minutes of inspection to avoid eye fatigue. Record the time at which an eye break is taken onto form F-203.f.

9.8.3 Examine the exterior surface of the glass vial for residue or stains. Clean with a non-shedding wipe and 70% IPA to clean out any stain or residues, as necessary.

9.8.4 Place each vial next to a designated sterile water-filled glass vial of the same size and fill volume whose volume has been verified by measurement (control vial) and compare the fill level in both vials. Compare the fill level in both vials to detect overfills and underfills.

Note: The control vial MUST have a different cap that is a different color than the vials being inspected, be appropriately labeled indicating its contents and accounted for and documented as part of the final line clearance.

9.8.5 Ensure that the "Begin Inspection" is shown on the LED display of the inspection station.

9.8.6 Place vial into the visual inspection zone as close to the light source as possible, to inspect for particles.

9.8.6.1 Location of vial for white background: Approximately 9 inches from the right side of the station and 5 inches forward from the background.

9.8.6.2 Location of vial for black background: Approximately 10 inches from the left side of the station and 5 inches forward from the background.

9.8.7 Hold the vial by the neck and invert the vial 180° two to four times to mix the contents and ensure contact with the closure. Do not shake the vial.

9.8.8 Gently swirl the vial so that the liquid inside is in motion and inspect for 5 seconds taking care not to create bubbles.

Notes:

(1) There is a photoelectric sensor mounted over both the white and black backgrounds of the machine. When the glass vial is presented to the white background, the system will confirm with an audible tone and a yellow LED indicator lamp will illuminate. Observe the vial for 5 seconds in front of white background, then repeat in front of the black background. The MIH-LX system has a timer and sensor to notify the technician if the vial is removed from the background in less than 5 seconds.

(2) During the "white background" inspection, if the technician's hand or any object triggers the "black background" sensor, the system will alarm with the message "container expected at white background". The alarm is silenced by removing the hand or object from the "black background" area and returning it to the "white background" area. When the container is presented to the white background, the inspection timer will continue.

(3) The MIH-LX is equipped with a "Timer Reset" button. Pressing the reset button at any point in the inspection sequence restarts the sequence at the "Begin Inspection" screen so the technician can restart their inspection.

9.8.9 Move the vial to the black background after the white background timer has completed and the message "move to black" appears on the LED screen. Repeat the inspection process.

Note: Once the vial is presented to the black background, the inspection hood will confirm the photoelectric sensor was activated by emitting an audible tone and the "Green" indicator lamp will illuminate.

9.8.10 Inspect vial against the black background until the station emits an audible tone to signal "end of inspection" on the LED screen.

9.8.11 During inspection, immediately report any uncommon critical characteristics, e.g. discrepancy in product appearance, wrong component, etc. to the supervisor and Quality Assurance.

9.8.12 Document the occurrence of each observed defect onto F-203.f.

Note: If a vial has multiple defects record the defect of the highest criticality onto the form.

9.8.13 Place each inspected vial with a defect(s) into containers and label each with the lot number and defect type.

9.8.14 Place the containers with the defective vials identified as defects and with the in-process label and store in the defective product cabinet.

9.8.15 Place the inspected vials that do not have defects into containers identified with the in-process label plus "Visually Inspected Product" signage.

9.8.16 At the completion of inspection, each inspector must record the following total quantities onto F-203.f

- Number of vials inspected
- Number of passing vials with no observable defects.
- Number of vials with defects
- Number of defects classified by defect type.

9.8.17 Tabulate the inspection results from each inspector for the batch onto F-203.j Quality Assurance Post-Inspection Review Form recording the following:

- Total number of vials inspected
- Total number of passing vials with no observable defects
- Total number of vials with defects
- Total numbers of defects classified by defect type
- Total numbers and reject rates (%) of vials with Critical, Major, and Minor defects

9.8.18 Compare the reject rates to the below Alert and Action levels.

- Critical Defects: Alert = N/A / Action = 1%
- Major Defects: Alert = 1% / Action = 2%
- Minor Defects: Alert = 2% / Action = 3%

9.8.19 Contact the supervisor and Quality Assurance if any of the Alert or Action levels are exceeded. If an Alert or Action level is exceeded, the "defective" vials must be re-inspected by a second, qualified inspector from Quality Assurance to verify the defects. Document the results of the defect verification onto F-203.j.

9.8.20 Document any occurrences where the re-calculated reject rates no longer exceed the Action levels based on the re-inspection of the defects by a second inspector including the justification (e.g. defects originally identified as "particles" were verified to actually be bubbles and therefore are considered acceptable).

9.8.20.1 Discuss any discrepancies with the technician who performed the initial 100% inspection and re-train and/or re-qualify if deemed necessary.

9.8.20.2 Re-calculate the reject rates, if required based on the results of the defect verification of the "defective" vials.

Note: Frequent invalidation of vials initially determined to have defects may be an indication of a problem with the inspection process and/or the technicians and may need to be investigated.

9.8.21 Open an investigation following P-224, *Deviation Management* and this procedure for any batches that still exceed Action levels after the re-inspection of the "defective" vials.

9.8.22 Based on the outcome of the investigation, a second 100% inspection may be performed following the initial 100% inspection exceeding an Action level incorporating any CAPA identified in the investigation, as applicable. The decision to perform a second 100% inspection must be approved by Quality Assurance.

9.8.23 Investigate the batch further if an Action level is exceeded after the second 100% inspection.

9.8.24 Sign and date the form once it is completed, which is also signed and dated by the reviewer.

9.8.25 Store the non-rejected "Good" vials in Quarantine status in the designated in-process storage area.

9.8.26 Complete the visual inspection form for batch that has been 100% inspected.

9.9 Physical Visual Inspection of Lyophilized Products

9.9.1 Invert vial 180 degrees so that the base of the cake is facing up for inspection of the bottom of the vial

9.9.2 Inspection entails checking for the vial integrity as well as the cake integrity.

9.9.3 Spin vial around to ensure no particles are present.

9.9.4 Ensure the product is airtight sealed with a stopper and cap

9.9.5 After physical visual inspection, refer to section 8.10 Supplemental Inspection (for lyophilized products only)

9.10 Supplemental Inspection (for lyophilized products only)

9.10.1 Upon successful completion of the 100% visual inspection, representatively sample 20 vials from the non-rejected "Good" vials.

Note: The sample size of 20 vials is based on ANSI/ASQ Z1.4 Special Inspection Level 4 and an AQL = 0.65%, which corresponds to "Accept" = 0 defects and "Reject" = 1 defect.

9.10.2 Reconstitute each of the 20 vials with 0.2µm-filtered, particle-free Water for Injection to the specified fill volume in a clean environment with appropriate particle-control measure, taking care to avoid contamination during reconstitution that can lead to false-positive results.

9.10.3 Visually inspect each reconstituted vial following the same procedure as used for the 100% inspection and record the results onto F-203.m.

9.10.4 The supplemental inspection meets requirements if no visible particles are detected.

9.10.5 Contact the supervisor and Quality Assurance if particles are detected in one (1) or more of the 20 reconstituted vials. The "defective" vial(s) must be re-inspected by a second, qualified inspector from Quality Assurance to verify the defect. Document the results of the defect verification onto F-203.m.

9.10.6 Open an investigation following P-224 and this procedure. The investigation should consider the potential of the particle being from the batch or inadvertently added during reconstitution.

9.10.7 Based on the outcome of the investigation, a second supplemental inspection may be performed incorporating any CAPA identified in the investigation, as applicable. The decision to perform a second supplemental inspection must be approved by Quality Assurance.

9.11 AQL Inspection

9.11.1 Determine the required Sample Size Code from Figure 1 by lining up the batch size with ANSI/ASQ Z1.4 General Inspection Level II. The sample size and acceptance / rejection values next determined based on the AQLs assigned to each defect category as follows:

- Critical Defect AQL = 0.10%
- Major Defect AQL = 0.65%
- Minor Defect AQL = 1.5%

9.11.2 Determine the required sample size from Figure 2 by lining up the Sample Size Code with the Critical defect AQL to find the correct row on the table. If needed, follow the down arrows in the appropriate column until reaching the first row with "Ac / Re" numbers indicated. Obtain the sample size associated with the row.

9.11.3 Sample the required number of vials randomly from the 100% inspected "Good" vials.

9.11.4 Inspect the sampled vials following the same inspection process used for the 100% inspection process and record the results onto F-203.k, AQL Inspection Form:

- Total numbers of defects classified by defect category (Critical, Major, or Minor)
- Total numbers of defects within each category subclassified by defect type.

9.11.5 Open an investigation for any batches where the number of defective vials observed exceeds the AQL inspection criteria following P-224 and this procedure.

9.11.6 Based on the outcome of the investigation, a second 100% inspection may be performed following the failed AQL inspection incorporating any CAPA identified in the investigation, as applicable. The decision to perform a second 100% inspection must be approved by Quality Assurance.

9.11.7 Repeat the AQL inspection following any second 100% inspection.

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9.11.8 *Figure 1:* ANSI/ASQ Z1.4 Sample Size Code Letters

ANSI/ASQ Z1.4- Sample Size Code Letters

Lot or Batch Size	Special Inspection Levels				General Inspection Levels		
	S-1	S-2	S-3	S-4	I	II	III
2 to 8	A	A	A	A	A	A	B
9 to 15	A	A	A	A	A	B	C
16 to 25	A	A	B	B	B	C	D
26 to 50	A	B	B	C	C	D	E
51 to 90	B	B	C	C	C	D	E
91 to 150	B	B	C	D	D	F	G
151 to 280	B	C	D	E	E	G	H
281 to 500	B	C	D	E	F	H	J
501 to 1200	C	C	E	F	G	J	K
1201 to 3200	C	D	E	G	H	K	L
3201 to 10000	C	D	F	G	J	L	M
10001 to 35000	C	D	F	H	K	M	N
35001 to 150000	D	E	G	J	L	N	P
150001 to 500000	D	E	G	J	M	P	Q
500001 and over	D	E	H	K	N	Q	R

9.11.9 *Figure 2:* ANSI/ASQ Z1.4 Table 2-A: Single Sampling Plans for Normal Inspection

Table 2-A — Single sampling plans for normal inspection (Master table)

Sample size code letter	Sample size	Acceptance quality limit, AQL, in percent nonconforming items and nonconformities per 100 items (normal inspection)																											
		0,010	0,015	0,025	0,040	0,065	0,10	0,15	0,25	0,40	0,65	1,0	1,5	2,5	4,0	6,5	10	15	25	40	65	100	150	250	400	650	1 000
		Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re	Ac Re
A	2	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇩	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31
B	3	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45
C	5	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧
D	8	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧	
E	13	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	30 31	44 45	⇧		
F	20	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧	⇧	⇧	⇧		
G	32	⇩	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧						
H	50	⇩	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧							
J	80	⇩	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧								
K	125	⇩	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧									
L	200	⇩	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧										
M	315	⇩	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧											
N	500	⇩	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧												
P	800	⇩	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧													
Q	1 250	0 1	⇧	⇩	1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧														
R	2 000	⇧		1 2	2 3	3 4	5 6	7 8	10 11	14 15	21 22	⇧															

⇩ = Use the first sampling plan below the arrow. If sample size equals, or exceeds, lot size, carry out 100 % inspection.

⇧ = Use the first sampling plan above the arrow.

Ac = Acceptance number

Re = Rejection number

9.12 Investigations and Batch Release

9.12.1 Open an investigation following P-224 if any of the following events occur:.

- A reject level during the 100% or supplemental inspection exceeds the Action level.
- The number of defective vials exceeds the AQL inspection criteria.
- Any other reasons that inspection results are considered atypical, or there are concerns about the suitability of the product.

9.12.2 Examine all potential factors that could contribute to the occurrence of exceeding the inspection action levels or a failed AQL inspection including the adequacy of the 100% inspection process and the inspection technicians.

9.12.3 Review past 100% inspection and AQL performance history for the same product, container-closure type, and/or process.

9.12.4 Identify a Corrective Action and Preventive Action (CAPA) based on the identified root cause or most probable root case, as appropriate to eliminate its occurrence or recurrence following P-218, *Corrective Action and Preventive Action (CAPA) System*. If the investigation results in a recommendation that no CAPA is warranted, the justification for no CAPA must be documented.

9.12.5 Recommend batch disposition based on the results of the investigation including the results of the 100% and AQL inspections and re-inspections.

9.12.6 All supporting documentation must be attached to the Investigation form.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacist to Engage in the Practice of Pharmacy at a Site other than a Licensed Pharmacy

Rev (04/18/2023)

This application cannot be returned by fax or email.
We must have an original signature to process.

Section 1: Select the following that applies to you.

- ☐ **I am employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 3, 5, 7)**
- ☐ **I am a pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution (If you marked this answer complete section 1, 2, 3, 5, 7)**
- ☒ **I am NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity (If you marked this as your answer complete sections 1, 2, 4, 5, 6, 7)**

Section 2: General Information

First: Shyla Ann Middle: Baloran Last: Mariano

NV Pharmacist Registration # 23929

Telephone: [redacted] Email: [redacted]

Section 3: Nevada Licensed Pharmacy as defined in NRS 639.012, or Nevada State Government Entity Information

Pharmacy/State Government Entity Name:

NV Pharmacy License # (if Pharmacy) or State Issued License # (if State Government Entity):

Address:

City: State: Zip:

Employer Contact Name:

Employer Contact Telephone: Employer Contact email:

Section 4: Employer Information

Name or Identity of Employer or Business as registered with the Nevada Secretary of State chapter 76 of NRS:

First Person Care Clinic

Address: 916 W Owens Ave

City: Las Vegas State: NV Zip: 89106

Employer Contact Name: Geneve Rodriguez

Employer Contact Telephone: (702) 617-6313 Employer Contact email: grodriguez@firstpersonclinic.org

Section 5: Place where the Pharmacist will Engage in the Practice of Pharmacy (list all sites)

Name of Site (if applicable): First Person Care Clinic
Address: 5412 Boulder Hwy
City: Las Vegas State: NV Zip: 89122
Country/Territory/Province: USA
Is this a medical, residential, or business site? ☒ Medical ☐ Residential ☐ Business
Days of the week and hours services will be provided at this site? Tuesday; 0900-1630

Name of Site (if applicable): First Person Care Clinic
Address: 1200 S 4th St Suite 111
City: Las Vegas State: NV Zip: 89104
Country/Territory/Province: USA
Is this a medical, residential, or business site? ☒ Medical ☐ Residential ☐ Business
Days of the week and hours services will be provided at this site? Wednesday; 0900-1630

Name of Site (if applicable): First Person Care Clinic
Address: 916 W Owens Ave
City: Las Vegas State: NV Zip: 89106
Country/Territory/Province: USA
Is this a medical, residential, or business site? ☒ Medical ☐ Residential ☐ Business
Days of the week and hours services will be provided at this site? Thursday and Friday; 0900-1630

Name of Site (if applicable): _____
Address: _____
City: _____ State: _____ Zip: _____
Country/Territory/Province: _____
Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business
Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____
Address: _____
City: _____ State: _____ Zip: _____
Country/Territory/Province: _____
Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business
Days of the week and hours services will be provided at this site? _____

Name of Site (if applicable): _____
Address: _____
City: _____ State: _____ Zip: _____
Country/Territory/Province: _____
Is this a medical, residential, or business site? ☐ Medical ☐ Residential ☐ Business
Days of the week and hours services will be provided at this site? _____

(Use and make copies of this page if necessary)

Section 6: NAC 639.403 A registered pharmacist who is NOT employed by or under contract with a pharmacy and who is NOT an employee of the State Government MUST complete this section.

1. Provide a description of the services that you intend to provide at the site, to include only those services listed in Section 7 (A) of this application.

Provide medication therapy management (MTM) services; review referrals from practitioner, which include a working diagnosis and any specific request for drug therapy management; teaching and precepting pharmacy students from Roseman University of Health Sciences, College of Pharmacy; access, analyze, document patients' visit notes and findings in electronic health record; select, initiate, modify, monitor, or discontinue medication therapy, devices, and supplies; perform basic physical assessments and labs for medication-related issues; order and interpret lab values for monitoring outcomes of medication therapy; participate in multidisciplinary reviews of patients' progress; verbally order or renew prescriptions for patients; enhancement of therapeutic outcomes through medication and disease state education; provide individualized or group classes on health promotion and disease prevention education

2. Provide the identification of the types of patients or other persons to whom you intend to provide services.

Patients with diabetes, hypertension, hyperlipidemia, hypothyroidism, taking anticoagulant therapy

3. Provide a description of all resources, both paper and electronic, that will be available to you in the course of providing the services.

Patient-reported medications, allergies, medical conditions, incidents and health-related habits; Clinical Pharmacology; Facts & Comparisons; Lexicomp Online; Micromedex; UpToDate; Pharmacists Letter; Natural Medicines Database; clinical guidelines and evidence-based sources as necessary for various disease states; ADA DSMES curriculum

4. Provide an explanation of the policy for users of the services when you are unavailable.

Services will be available by appointment only. All referrals submitted and appointments scheduled will be made through the respective clinics appointment system. In the event that the pharmacist is unavailable, patients will be able to speak with receptionists, medical assistants, and/or medical providers during office hours. In the case of an emergency, patients will be directed to emergency services.

5. Provide an explanation of the policy regarding the confidentiality and security of the patient data that will be gathered, made, and maintained as part of the services which are provided, including without limitation, paper and electronic records.

Records and data will be kept confidential in compliance with HIPAA regulations and best practices. Data will be stored in the patient's electronic health record and password-protected devices accessible by authorized users only.

6. Provide a description of the business plan for the services provided.

No business plan is needed. Services provided through Roseman University are covered through grant-funding and volunteer services.

Section 7: Laws pertaining to engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy. Please read Section 7 in its entirety. By signing this application, you attest you have read and understood the components in this section.

A. NAC 639 - For all registered pharmacists engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy

1. While engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy, a registered pharmacist may perform only:
    a. The functions described in paragraphs (b), (c), (d) and (g) to (j), inclusive, of subsection 1 or NRS 639.0124, except for dispensing or administering drugs;
    b. The functions described in section 4 of LCB File No. R036.21, except for dispensing a self-administered hormonal contraceptive; and
    c. The administration of immunizations pursuant to a written protocol established in accordance with NAC 639.297 to 639.2978, inclusive.
2. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall:
    a. Provide written notice of the site of practice to the Executive Secretary in accordance with NAC 639.225 on this application; (NAC 639.225 states that a Nevada pharmacist, within 10 days after changing residence or place of practice, must give written notice of the change to the Board.)
    b. Ensure that the records of the registered pharmacist are made readily accessible to members of the Board and employees, agents and designees of the Board; and
    c. Comply with all applicable federal and state laws and regulations, including, without limitation:
        i. The Health Insurance Portability and Accountability Act of 1996, Public Law 104-191, and the regulations adopted pursuant thereto, and any other applicable federal or state law concerning the privacy of information regarding health care; and
        ii. Requirements relating to the maintenance or records.
3. A registered pharmacist who engages in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not maintain an inventory of drugs at that location.
4. A registered pharmacist shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy if he or she:
    a. Serves as a managing pharmacist; or
    b. Provides pharmaceutical services at:
        i. A facility for modified medical detoxification, as defined in NRS 449.00385;
        ii. An independent center for emergency medical care, as defined in NRS 449.013;
        iii. A facility for intermediate care, as defined in NRS 449.0038;
        iv. A facility for skilled nursing, as defined in NRS 449.0039; or
        v. A surgical center for ambulatory patients, as defined in NRS 449.019.

B. NAC 639 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is employed by or under contract with a pharmacy or who is an employee of the State Government may engage in the practice of pharmacy at a location other than the site of a licensed pharmacy shall not engage in the practice of pharmacy at a location other than the site of a licensed pharmacy unless he or she is provided with the same computerized system and access to data regarding a patient for whom a prescription has been submitted that is available to a registered pharmacist in the pharmacy. Such data must include, without limitation:

a. A legible copy of the prescription that is available as an electronic copy or a scanned image in the computerized system of the pharmacy or by facsimile machine; and
b. Any information that is available in the computerized system of the pharmacy that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.

C. NAC 639.403 - For a registered pharmacist who is NOT employed by or under contract with a Nevada licensed pharmacy or a Nevada State Government entity.

For a registered pharmacist who is NOT employed by or under contract with a pharmacy or who is an employee of the State Government shall not engage in the practice of pharmacy at a site other than the site of a licensed pharmacy unless he or she obtains the approval of the Board to engage in the practice of pharmacy at a site other than the site of a licensed pharmacy. To request such approval, the registered pharmacist must submit this application. The application must be approved before a registered pharmacist may commence any practice.

D. NAC 639.4916 - For a registered pharmacist who is employed by or under contract with a Nevada licensed pharmacy located within a hospital or correctional institution.

1. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide the remote chart order processing services to the hospital or correctional institution that the pharmacy is required by NAC 639.4915 to provide must:
    a. Be trained in the policies and procedures of the hospital or correctional institution regarding all policies and procedures of the hospital or correctional institution with which the registered pharmacist must comply, including, without limitation, the provisions of pharmaceutical services, security, and confidentiality of patient records; and
    b. Be provided with the same computerized system and access to data regarding a patient for whom a chart order has been submitted that would be available to a registered pharmacist employe by the pharmacy located within the hospital or correctional institution, including, without limitation:
        i. The height, weight and age of the patient and any allergies that the patient may have;
        ii. The medical records regarding any medications prescribed to the patient;
        iii. The results of any relevant laboratory tests;
        iv. The health history and notes regarding physical examinations, to the extent that the information is available in the computerized system of the hospital or correctional institution;
        v. Any notes provided by a physician, nurse or other medical staff of the institution, to the extent that those notes are available in the computerized system of the hospital or correctional institution;
        vi. A legible copy of the chart order that is available through a scanned image in the computerized system of the hospital or correctional institution or by facsimile machine; and
        vii. Any other information that is available in the computerized system of the hospital or correctional institution that is relevant or necessary for the registered pharmacist to provide pharmaceutical services.
2. Before a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution, the registered pharmacist must review any relevant information regarding the patient for whom a chart order has been submitted. The registered pharmacist must, before approving a chart order to be filled, evaluate:
    a. The overutilization or underutilization of a medication;
    b. Therapeutic duplication;
    c. The appropriateness of the prescribed dosage and route of administration;
    d. The appropriateness of the directions for use of the medication;
    e. The appropriateness of the duration of the treatment with the prescribed medication;
    f. Any contraindication of the medication and a particular disease, ailment or allergy of the patient;
    g. Any contraindication or interactions between multiple medications prescribed for the patient; and
    h. The potential abuse or misuse of a medication.
3. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution provides remote chart order processing services to the hospital or correctional institution shall comply with the requirements of Section 7 (A) to the same extent as a registered pharmacist engaging in the practice of pharmacy at a location other than the site of a licensed pharmacy pursuant to the provisions in Section 7 (B) and Section 7 (C).
4. In an emergency, a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may render remote chart order processing services without being provided with all the information required by paragraph (b) of subsection 1 of Section 7 (D) if the registered pharmacist believes, in his or her professional judgement, that he or she has received sufficient information from the staff of the hospital or correctional institution to render the services.
5. A registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution may refuse to approve the filling of a chart order if, in the judgement of the registered pharmacist, the chart order is not safe or reasonable for the patient. A registered pharmacist who refuses to approve the filling of a chart order pursuant to this subsection must notify the hospital or correctional institution as soon as practicable that he or she has refused to approve the filling of the chart order.
6. Each time that a registered pharmacist who is employed by or under contract with a pharmacy located within a hospital or correctional institution to provide remote chart order processing services to the hospital or correctional institution

provides remote chart order processing services pursuant to this section, the registered pharmacist shall make a notation in the computerized system of the hospital or correctional institution that indicates:

a. The name or identifier of the registered pharmacist;
b. The date and time that the registered pharmacist provided the services and, if applicable, approved the filling of a chart order; and
c. The specific services provided by the registered pharmacist.

7. The managing pharmacist of a pharmacy located within a hospital or a correctional institution may limit the remote chart order processing services provided pursuant to this section (Section 7 (D)).

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

I attest to the knowledge of and compliance with the guidelines of the Centers for Disease Control and Prevention concerning the prevention of transmission of infectious agents through safe and appropriate injection practices. NRS 639.132

I understand that Nevada law requires a registered pharmacist who, in their professional or occupational capacity, knows or has reasonable cause to believe a child has been abused/neglected to report the abuse/neglect to an agency which provides child welfare services or to a local law enforcement agency, and make such a report as soon as reasonably practicable but not later than 24 hours after the person knows or has reasonable cause to believe that the child has been abused/neglected. NRS 432B.220.

Shyla Ann Mariano

Print Name

Original Signature, no copies or stamps accepted

4/7/25

Date

Board Use Only	Date Received: 4/23/25 For applicants who marked box 1 or 2 in Section 1: Executive staff to review, scanned into applicant file. For applicants who marked box 3 in Section 1: Executive staff to review, place on consent agenda.

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ANNUAL DISCIPLINE CASES Reporting Period: January 2024 – April 2025			
FINDING	**HARM**	**DISCIPLINE INDIVIDUAL**	**DISCIPLINE FACILITY**
SY was engaged to serve as medical director of a practice that allowed unlicensed persons to access, possess, furnish and administer dangerous drugs without a direct practitioner supervision, including drug products intended for distribution in foreign markets and not approved in the U.S.	No	Certificate of Registration No. CS27231, is placed on probation for a period of one year subject to the following conditions: 1) public reprimand; 2) $2,500 fine; and 3) assessed $1,000 for attorney's fees and costs.	N/A
MH was engaged to serve as medical director of a practice that allowed unlicensed persons to access, possess, furnish and administer dangerous drugs without a direct practitioner supervision, including drug products intended for distribution in foreign markets and not approved in the U.S.	No	Certificate of Registration No. CS22622 is suspended. The suspension is stayed, and Respondent is placed on probation for a period of one year subject to the following conditions: 1) public reprimand; 2) $2,500 fine; and 3) assessed $1,000 for attorney's fees and costs.	N/A
JG pled guilty pursuant to a plea agreement and was convicted on one felony count of conspiracy in United States of America v. Jeffrey Dave Gress, United States District Court for Central District of California, Case 8:18-cr-00014-JLS. Respondent subsequently surrendered his DEA Registration No. FG3245455 by executing a DEA Form 104	No	Certificate of Registration No. CS20182 is revoked; Respondent may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent fined $5,000and assessed $1,000 for attorney's fees and costs.	N/A
WP dispensed a prescription with erroneous directions for use which resulted in negative outcome to patient and failed to properly document medication counseling.	Yes	N/A	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.

WH performed data entry review and final product verification of a prescription and failed to detect erroneous directions for use which resulted in a negative outcome to the patient.	Yes	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.	N/A
HB failed to properly document medication counseling for a prescription.	Yes	Respondent fined $1,000 and assessed $500 for attorney's fees and costs.	N/A
NSP compounded and dispensed drug products for 64 patients located in Nevada without holding a Nevada Pharmacy license, and the prescriptions dispensed may not have been compounded in compliance with Nevada Law.	No	N/A	Respondent fined $25,000 for the violations.
JK surrendered his Neveda Medical License No. 15386 to practice medicine for cause and no longer qualifies as a practitioner for registration to dispense controlled substances, and he committed acts that render his registration inconsistent with the public interest.	No	Certificate of Registration No. CS24228 is revoked; Respondent may not petition for reinstatement for a period of one year from the effective date of the Order. Respondent fined $2,000 and assessed $1,880.42 for attorney's fees and costs.	N/A
JB failed to disclose arrests and/or convictions on his original Pharmaceutical Technician in Training application. The Board held a hearing to address the charges against him on January 15, 2025, where he failed to appear, and a default order was taken.	No	Certificate of Registration No. PT28790 was revoked for a period of one year and assessed $511.46 in attorney's fees and costs.	N/A

AL transported a supply of controlled substances between his home/vehicle/office and various hospital operating rooms and/or surgery centers in a location other than a registered office in violation of Nevada Law. In addition, he knowingly or intentionally acquired controlled substances and/or dangerous drugs without a prescription and failed to query the controlled substance information in the PMP in violation of Nevada Law.	No	Certificate of Registration No. CS18089 is revoked. The revocation is stayed and placed on probation for a period of five years from the effective date of the Order. Respondent Lee shall not possess controlled substances except while on the premises of a hospital, a surgery center for ambulatory patients, or another medical facility where respondent is treating or caring for a surgical patient. Respondent Lee shall participate in four quarterly inspections from the effective date of the Order to January 14, 2026. Respondent fined $10,000 for the violations; and assessed $5,000 in attorney's fees and costs.	N/A
YS failed to secure dangerous drugs in a locked cabinet thereby allowing access to dangerous drugs by unlicensed personnel and administered drug products to a patient that were not acquired in compliance with Nevada Law.	No	YS accepts the Stipulation and Order as a public reprimand; fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.	N/A
RR worked as a pharmaceutical technician in training without obtaining a certificate of registration from the Board for the work location.	No	Certificate of Registration No. PT28825 is revoked, and Respondent may not petition for reinstatement for a period of one year from the effective date of the Order; and assessed $1,222.85 in attorney's fees and costs.	N/A

JS failed to disclose disciplinary order on his 2022 biennial renewal application for his Certificate of Registration No. CS09874. Respondent Siems issued sixty-eight controlled substance prescriptions on a suspended registration and permitted his medical assistants to forge and issue prescriptions for controlled substances.	No	Respondent's Certificate of Registration No. CS09874 is revoked, and Respondent may not petition for reinstatement for a period of two years from the effective date of the Order; Respondent fined $5,000 for the violations; and assessed $2,968.64 in attorney's fees and costs.	N/A
SCS engaged in the sale and or distribution of counterfeit HIV-1 drugs and transmitted falsified transaction records.	No	N/A	Respondent's License No. WH02131 is revoked, the revocation is stayed and Respondent placed on probation for a period of three years subject to the following conditions: a) Respondent shall pay a fine of $5,000 for the violations; b) assessed $3,584.10 in attorney's fees and costs; and c) Respondent shall be subject to an inspection by Board staff at respondent's expense.
WP is responsible for the acts of its employees who made an error in a prescription and failed to maintain a written record showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business on January 31, 2024.	No	N/A	Respondent fined $2,000 for the violations; and assessed $500 in attorney's fees and costs.
JE failed to maintain a written record showing the pharmacists, pharmaceutical technicians and pharmaceutical technicians in training on duty during the hours of business on January 31, 2024.	No	Respondent fined $500 for the violations; and assessed $500 in attorney's fees and costs.	N/A

CQ fined $500 for the violations; and assessed $500 in attorney's fees and costs.	No	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.	N/A
OM billed insurers for products that were never delivered to patients, failed to maintain an adequate system to resolve complaints by these patients, and failed to notify the Board of the departure of its facility administrator within three business days.	No	N/A	Respondent is not eligible to apply for a license or engage in business as a medical products provider or medical products wholesaler for a period of two years after the effective date of this Stipulation; Respondent shall notify the Board in writing if it becomes aware that any of its current officers, directors, shareholders, partner, or members have applied in an individual or representative capacity for a license to conduct business as a medical products provide or medical products wholesaler; Respondent shall accept this Stipulation as a public reprimand; Respondent shall refund payments or deposits as described in sections 1a, 1b, 1c, 1d, and 1f of the Investigate Report by June 30, 2025; Respondent fined $5,000 for the violations; and assessed $1,000 in attorney's fees and costs.
WP is responsible for the acts of an employee who accessed protected health information for the purpose of learning personal information about a patient.	No	N/A	Respondent fined $1,000 for the violations; and assessed $500 in attorney's fees and costs.

MR accessed protected health information for the purpose of learning personal information about a patient.	No	Certificate of Registration No. PT28786 is revoked retroactively to October 31, 2024, and may not petition the Board for reinstatement for a period of one year from the effective date of the revocation; and assessed $500 in attorney's fees and costs.	N/A
EC diverted controlled substances from her place of employment at CVS Pharmacy.	No	Certificate of Registration No. PT18610 is revoked and may not petition for reinstatement for a period of one year.	N/A
LI failed to properly service the respiratory equipment furnished to a patient at least every 24 months as required by the manufacturer's product manual.	N/A	N/A	Respondent fined $1,000 for the violations; and assessed $1,000 in attorney's fees and costs.
HM failed to pay the $10,000 fine and $544.55 in attorney's fees and costs in Case No. 20-070-PR-N ordered on April 17, 2024. The Board filed an Order to Show Cause due to non-compliance with the Order, and HM petitioned the Board to vacate the disciplinary actions in the case.	No	The Board denied the request to vacate the decision and upheld the $10,000 fine and $544.55 in attorney's fees and costs.	N/A
MPS is responsible for the acts of its employees who filled and dispensed unlawful prescriptions for controlled substances and compounded semiglutide, employed one pharmaceutical technician in training (PTT) on an expired registration and another PTT without obtaining a registration to work at Meta Pharmacy.	No	N/a	Respondent fined $10,000 for the violations; $2,000 in attorney's fees and costs; and quarterly inspections for a period of one year not to exceed $500 at owner's expense.

SB Respondent filled and dispensed unlawful prescriptions for controlled substances and compounded semiglutide, employed one pharmaceutical technician in training (PTT) on an expired registration and another PTT without obtaining a registration to work at MPS.	No	Certificate of Registration No. 17303 is revoked, the revocation is stayed, and respondent is placed on probation for a period of ten years subject to the following conditions: a) a public reprimand; b) pay a $10,000 fine for the violations; c) pay $2,000 in attorney's fees and costs; d) 12 additional continuing education on pharmacy law and ethics within six months of the Order date; e) shall not be a managing pharmacist at Meta Pharmacy or any pharmacy licensed by the Board during the probation period; f) shall divest himself of any ownership interest in Meta Pharmacy within 90 days of the Order and shall not hold any ownership in any pharmacy licensed by the Board during the probation period; and g) shall not work as a pharmacist for Meta Pharmacy for a period of two years from the effective date of the Order.	N/A
MB knowingly filled and dispensed unlawful prescriptions for controlled substances.	No	Certificate of Registration No. 14966-B is suspended, the suspension is stayed, and respondent is placed on probation for a period of one year subject to the following conditions: a) a public reprimand; b) pay a $1,000 fine for the violations; c) pay $1,000 in attorney's fees and costs	N/A

CP in Case No. 23-175-RPH-S refused to transfer a prescription as requested by a patient and engaged in unprofessional conduct, and he knowingly filled and dispensed unlawful prescriptions for controlled substances in Case No. 24-125-RPH-B-S.	No	Certificate of Registration No. 16325 is suspended, the suspension is stayed, and respondent is placed on probation for a period of two years subject to the following conditions: a) a public reprimand; b) pay a $2,000 fine for the violations; c) pay $2,000 in attorney's fees and costs; and d) shall complete ten additional continuing education (CE) hours on pharmacy law and ethics within six months of the effective date of the Order.	N/A
UAK has failed to pay the fine payment of $1,300 and $749 in attorney's fees and costs ordered December 1, 2021. The Board filed an Order to Show Cause due to non-compliance with the Order, and a default hearing was heard on April 16, 2025, due to his failure to appear.	No	The Board upheld the fine payment of $1,300 and $749 in attorney's fees and costs.	N/A
EM has failed to pay the fine payment of $5,000 and $812.50 in attorney's fees and costs ordered April 21, 2021. The Board filed an Order to Show Cause due to non-compliance with the Order, and a default hearing was heard on April 16, 2025, due to his failure to appear.	No	The Board upheld the fine payment of $5,000 and $812.50 in attorney's fees and costs.	N/A
The Board filed an Order of Summary Suspension based upon the preliminary findings that AG diverted controlled substances. AG failed to appear, and a default hearing was heard on April 16, 2025.	No	The Board upheld the summary suspension for AG's Certificate of Registration No. PT20499 pending the filing of charges.	N/A

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FILED
APR 22 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8824,** **Pharmacy License No. PH00947, and** **KARLO NIKKO ARCEO, RPH,** **Certificate of Registration No. 19679,** **Respondents.**	**CASE NOS. 22-509-PH-S** **22-509-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Karlo Nikko Arceo, RPh (Arceo), Certificate of Registration No. 19679, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #8824, Pharmacy License No. PH00947, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Arceo was employed as a staff pharmacist by CVS Pharmacy #8824 at the time of the events alleged herein.

3. On or about November 27, 2022, patient K.M. requested that two existing prescriptions for cephalexin 500mg capsules and ondansetron 4mg tablets be transferred to CVS Pharmacy #8824. The pharmacy instead erroneously transferred one prescription for cephalexin 500mg capsules, designated prescription no. 2554970, and one prescription for misoprostol 200mcg tablets, designated prescription no. 2554971.

4. On or about November 27, 2022, Arceo filled and dispensed both prescription no. 2554970 and prescription no. 2554971 from CVS Pharmacy #8824; no counseling was performed for either prescription although neither prescription had previously been dispensed from CVS Pharmacy #8824.

5. Misoprostol may be prescribed off-label to induce a medical abortion. K.M. was pregnant at the time and after ingesting one misoprostol tablet orally experienced discomfort but did not require intervention or treatment.

COUNT ONE

Failure to Provide Medication Counseling to Patient/Unprofessional Conduct
(Respondent Arceo)

6. A pharmacist shall provide medication counseling to a patient when dispensing a prescription that has not been previously dispensed to the patient from that pharmacy and shall review a patient's record before dispensing a prescription to determine its therapeutic appropriateness. NRS 639.266; NAC 639.707(1) and (4).

7. Unprofessional conduct includes a registrant performing his or her duties in an "incompetent, unskillful, or negligent manner." NAC 639.945(1)(i).

8. Respondent Arceo violated NRS 639.266 and/or NAC 639.707(1) and/or (4) and/or engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when he failed to provide medication counseling to K.M. for prescription nos. 2554970 and 2554971, neither of which had previously been dispensed from CVS Pharmacy #8824, and is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility
(Respondent CVS Pharmacy #8824)

9. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business

or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

10. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #8824 is responsible for those violations, including all errors and omissions of Respondent Arceo, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 22nd day of April 2025

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241. To do so, you must complete and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8824,** **Pharmacy License No. PH00947,** **Respondent.**	**Case No. 22-509-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of April 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8824,** **Pharmacy License No. PH00947,** **Respondent.**	**Case No. 22-509-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

AUTHORIZED REPRESENTATIVE FOR CVS PHARMACY #8824

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Karlo Nikko Arceo
[redacted]
Las Vegas, NV [redacted]

Karlo Nikko Arceo
[redacted]
Henderson, NV [redacted]

CVS Pharmacy #8824
4411 E Bonanza Rd
Las Vegas, NV 89110

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

5B

FILED
APR 22 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **CVS PHARMACY #8824,** **Pharmacy License No. PH00947, and** **KARLO NIKKO ARCEO, RPH,** **Certificate of Registration No. 19679,** **Respondents.**	**CASE NOS. 22-509-PH-S** **22-509-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

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JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these Respondents because at the time of the events alleged herein, Respondent Karlo Nikko Arceo, RPh (Arceo), Certificate of Registration No. 19679, was a pharmacist registered with the Board, and Respondent CVS Pharmacy #8824, Pharmacy License No. PH00947, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Arceo was employed as a staff pharmacist by CVS Pharmacy #8824 at the time of the events alleged herein.

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Failure to Provide Medication Counseling to Patient/Unprofessional Conduct

(Respondent Arceo)

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8. Respondent Arceo violated NRS 639.266 and/or NAC 639.707(1) and/or (4) and/or engaged in unprofessional conduct as defined in NAC 639.945(1)(i) when he failed to provide medication counseling to K.M. for prescription nos. 2554970 and 2554971, neither of which had previously been dispensed from CVS Pharmacy #8824, and is therefore subject to discipline pursuant to NRS 639.210(4) and (12).

COUNT TWO

Pharmacy/Pharmacy Owner Responsibility

(Respondent CVS Pharmacy #8824)

9. Any violation of any of the provisions of NRS Chapter 639 by a managing pharmacist or by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5); NAC 639.702. Further, the owner of any business

or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

10. As the pharmacy/pharmacy owner at which the violations of law alleged herein occurred, Respondent CVS Pharmacy #8824 is responsible for those violations, including all errors and omissions of Respondent Arceo, pursuant to NRS 639.230(5), NAC 639.702 and/or NAC 639.945(3).

WHEREFORE, it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license and certificate of registration of these Respondents.

Signed this 22nd day of April 2025

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

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BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KARLO NIKKO ARCEO, RPH,** **Certificate of Registration No. 19679,** **Respondent.**	**Case No. 22-509-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

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2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

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Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **KARLO NIKKO ARCEO, RPH,** **Certificate of Registration No. 19679,** **Respondent.**	**Case No. 22-509-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

KARLO NIKKO ARCEO, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Karlo Nikko Arceo
[redacted]
Las Vegas, NV [redacted]

Karlo Nikko Arceo
[redacted]
Henderson, NV [redacted]

CVS Pharmacy #8824
4411 E Bonanza Rd
Las Vegas, NV 89110

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RODELYN ARCEO, APRN,** **Certificate of Registration No. CS30228,** **Respondent.**	**CASE NO. 23-353-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Rodelyn Arceo, APRN, held a Nevada controlled substance registration, Certificate of Registration No. CS30228, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent served as medical director of Natural Beauty International LLC, DBA New U Natural Beauty (Natural Beauty), located at 4860 W Desert Inn Rd #1, in Las Vegas, Nevada, during the relevant times frames herein. Olivia Pernsteiner and Jiwen He owned Natural Beauty and are not Nevada-licensed practitioners.

3. A Board investigation in August 2023 revealed that Respondent permitted Pernsteiner and registered nurses (RNs) at both Natural Beauty to have independent access to the

3. A Board investigation in August 2023 revealed that Respondent permitted Pernsteiner and registered nurses (RNs) at both Natural Beauty to have independent access to the medication storage containing dangerous drugs, and to access those medications outside Respondent's presence and without Respondent's supervision.

4. The investigation revealed that Respondent permitted RNs at Natural Beauty to independently access, possess, furnish and administer dangerous drugs to patients, to provide on-site medical treatment at Natural Beauty, including the administration of dangerous drugs by injection, specifically cosmetic injectable fillers, including, without limitation, Botox and Dysport, without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug was medically necessary.

APPLICABLE LAW

5. No person may possess, furnish or administer a dangerous drug in Nevada without specific statutory authority to do so. NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321; NRS 454.356; NRS 639.100(1).

6. A practitioner may give an RN limited authority to possess and administer dangerous drugs pursuant to NRS 454.213(1)(c), which states in relevant part:

> A drug or medicine referred to in NRS 454.181 to 454.371, inclusive, may be possessed and administered by . . . a registered nurse licensed to practice professional nursing or licensed practical nurse, at the direction of a prescribing physician, physician assistant licensed pursuant to chapter 630 or 633 of NRS, dentist, podiatric physician or advanced practice registered nurse, or pursuant to a chart order, for administration to a patient at another location.

Chart orders are patient-specific and medication-specific. *See* NRS 454.0041; NRS 639.004.

7. All controlled substances and dangerous drugs in the possession of an advanced practice registered nurse must be kept in a locked storage area with access restricted to authorized persons. NAC 639.898(1).

8. The Board may suspend or revoke the certificate of registration of an advanced practice registered nurse that has failed to maintain the security of his or her drug supply. NAC 639.900(12).

9. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

10. Aiding or abetting a person in unlicensed practice constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(j) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

11. Dispensing a drug to any patient with whom the practitioner does not have a bona fide therapeutic relationship constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(n) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4); NAC 639.900(4).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs, including, without limitation, any provision of chapter 453, 454,585 or 639 of NRS or any regulation pertaining thereto, is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12); NAC 639.900(14).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.226 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violations of State Law - Failure to Maintain Security of Dangerous Drugs

14. By permitting Pernsteiner and RNs to have unrestricted access to her inventory of dangerous drugs at Natural Beauty as alleged in paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NAC 639.898(1), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), NAC 639.900(12) and (14) and/or NRS 639.210(12).

COUNT TWO

Violations of State Law - Unlawful Possession & Administration of Dangerous Drugs

15. By permitting RNs at Natural Beauty to independently access, possess, furnish and administer dangerous drugs without direct practitioner supervision, to patients with whom Respondent had not established a bona fide therapeutic relationship, and for whom Respondent had neither diagnosed nor determined that a dangerous drug medically was medically necessary, as alleged in paragraph 4 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 454.213, NRS 454.217, NRS 454.221, NRS 454.316, NRS 454.321, NRS 454.356 and/or NRS 639.100(1), and is subject to discipline pursuant to NAC 639.900(14) and/or NRS 639.210(12).

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COUNT THREE

Unprofessional Conduct - Unlawful Possession & Administration of Dangerous Drugs

16. By her conduct as alleged in paragraphs 3-4 herein, Respondent performed her duties as the holder of a controlled substance registrations in an incompetent, unskillful or negligent manner, aided and abetted unlicensed practice, and engaged in, or aided and abetted others to engage in, unprofessional conduct as defined in NAC 639.945(i), (j) and (n), and is subject to discipline pursuant to NRS 639.210(4) and/or NAC 639.900(4).

COUNT FOUR

Commission of Acts that Render Registration Inconsistent with the Public Interest

17. By her conduct as alleged in paragraphs 3-4 herein, Respondent has committed acts that render registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 22nd day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RODELYN ARCEO, APRN,** **Certificate of Registration No. CS30228,** **Respondent.**	**Case No. 23-353-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 22nd day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RODELYN ARCEO, APRN,** **Certificate of Registration No. CS30228,** **Respondent.**	**Case No. 23-353-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

RODELYN ARCEO, APRN

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Rodelyn Arceo
[redacted]
Las Vegas, NV [redacted]

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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FILED
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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HILL-ROM COMPANY, INC.,** **License No. MP00038,** **Respondent.**	**CASE NOS. 24-500-MP-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300 and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Hill-Rom Company, Inc., License No. MP00038, was a medical products provider licensed by the Board.

FACTUAL ALLEGATIONS

2. On or about November 8, 2023, the Board conducted an inspection of Respondent's facility and determined that Respondent was engaged in the business of selling, leasing, supplying and/or distributing medical devices to hospitals and other licensed care facilities in this State without a license to engage in business as a wholesaler.

3. On or about November 26, 2024, the Board conducted an inspection of Respondent's facility and determined that Respondent continued to engage in the business of selling, leasing, supplying and/or distributing medical devices to hospitals and other licensed care facilities in this State without a license to engage in business as a wholesaler.

4. On or about February 13, 2025, Board staff issued a cease-and-desist order with a citation and $5000 fine against Respondent pursuant to NRS 639.2895 for Respondent engaging in the business of selling, leasing, supplying and/or distributing medical devices to hospitals and

other licensed care facilities in this State without a license to engage in business as a wholesaler in violation of NRS 639.100(1), NRS 639.233 and NAC 639.593.

APPLICABLE LAW

5. Any person who engages in the business of selling, leasing, supplying and/or distributing medical devices, that are restricted by federal law to sale by or on the order of a physician, to any health care facility, agency, practitioner or provider in this State must be licensed as a wholesaler pursuant to NRS 639.100(1), NRS 639.233 and NAC 639.593. *See also* NAC 639.6937 ("medical products wholesaler" defined).

6. Performing any duties as the owner of a business or an entity licensed by the Board or as the employee of any such business in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

7. Performing any act, task or operation for which licensure, certification or registration is required without the required license, certificate or registration constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(k) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

8. Violating any law or regulation relating to the practices of a medical products provider constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.6941(1)(a) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

9. The Board may suspend or revoke a license if the holder has violated, attempted to violate, assisted or abetted in the violation of or conspired to violate any provision of Chapter 639 of the Nevada Revised Statutes. NRS 639.210(12).

10. The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ. NAC 639.945(3). A medical

products provider is responsible for the acts of his or her business administrator and employees. NAC 639.6941(2).

COUNT ONE

Violation of State Law – Unlicensed Wholesale Distribution of Medical Products

11. By engaging in the business of selling, leasing, supplying and/or distributing medical devices to hospitals and other licensed care facilities in this State without a license to engage in business as a wholesaler, as alleged herein, Respondent, Respondent's owner(s), and/or Respondent's personnel violated NRS 639.100(1), NRS 639.233 and/or NAC 639.593, and Respondent therefore subject to discipline pursuant to NAC 639.6941(2), NAC 639.945(3) and NRS 639.210(12).

COUNT TWO

Unprofessional Conduct

2. By engaging in the business of selling, leasing, supplying and/or distributing medical devices to hospitals and other licensed care facilities in this State without a license to engage in business as a wholesaler, as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.6941(1)(a), NAC 639.945(1)(i) and/or NAC 639.945(1)(k) and is subject to discipline pursuant to NRS 639.210(4).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the license of this respondent.

Signed this 21st day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HILL-ROM COMPANY, INC.,** **License No. MP00038,** **Respondent.**	**Case No. 24-500-MP-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 21st day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **HILL-ROM COMPANY, INC.,** **License No. MP00038,** **Respondent.**	**Case No. 24-500-MP-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR HILL-ROM COMPANY, INC.

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

HILL-ROM COMPANY, INC.
1889 E Maule #C
Las Vegas, NV 89119

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

HILL-ROM COMPANY, INC.
1889 E Maule #C
Las Vegas, NV 89119

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, Pharmacy License No. PH02028,** **and** **CHRISTOPHER PETERS, RPH, Certificate of Registration No. 16325,** **Respondents.**	**Case Nos. 23-175-PH-S** **23-175-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over Respondent Christopher Peters ("Respondent Peters") because the Board has issued to Respondent Peters a certificate of registration authorizing him to engage in the practice of pharmacy.

2. The Board has jurisdiction over Respondent Partell Specialty Pharmacy ("Respondent Partell") because the Board has licensed Respondent Partell to operate a pharmacy at 5835 South Eastern Avenue #101, in Las Vegas, Nevada.

FACTUAL ALLEGATIONS

3. Respondent Partell dispenses nonsterile compounded drug products among other prescription drugs.

4. In 2023, Respondent Peters was a registered pharmacist employed by Respondent Partell at its pharmacy location on South Eastern Avenue in Las Vegas, Nevada.

5. In April 2023, Respondent Partell received a prescription for 0.1% retinoic acid cream, written by Nilofar Kuraishi, M.D., a Las Vegas physician.

6. Respondent Peters advised Dr. Kuraishi that the pharmacy was unable to lawfully compound the prescription as written because the 0.1% concentration of retinoic acid was commercially available.

7. After speaking with Respondent Peters, Dr. Kuraishi reissued the prescription for 0.11% retinoic acid cream. Dr. Kuraishi authorized one refill.

8. In April 2023, Respondent Partell filled and dispensed the prescription for 0.11% retinoic acid cream. However, in May 2023, the patient requested that the refill be transferred to the National Specialty Pharmacy, a licensed pharmacy located at 3022 West Post Road in Las Vegas, Nevada.

9. On May 12, 2023, Brian Ford, a registered pharmacist with the National Specialty Pharmacy, called Respondent Peters to tell him that the patient wished to transfer the prescription to the National Specialty Pharmacy. Respondent Peters refused to transfer the prescription, telling Pharmacist Ford to call Dr. Kuraishi to obtain the prescription.

10. Respondent Peters refused to transfer the prescription to the National Specialty Pharmacy based on his belief that Dr. Kuraishi had given Respondent Partell the exclusive right to compound 0.11% retinoic acid cream.

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APPLICABLE LAW

11. The Board may revoke or suspend the registration of any pharmacist who has been guilty of unprofessional conduct or conduct contrary to the public interest. NRS 639.210(4); NRS 639.255.

12. The Board may revoke or suspend the registration of any pharmacist who has violated Nevada law relating to prescription drugs. NRS 639.210(12); NRS 639.255.

13. Aside from revoking or suspending a pharmacist's registration, the Board may impose fines and/or a public reprimand as a disciplinary measure. NRS 639.255; NAC 639.955.

14. A pharmacist's conduct is deemed unprofessional if the pharmacist uses secret formulas. NAC 639.945(1)(c).

15. At the request of a patient, a pharmacist must transfer a prescription to another registered pharmacist. NRS 639.2357(1). The Board has adopted regulations that set forth the procedures and methods that a pharmacy must follow when transferring a prescription. *See* NAC 639.713 to 639.7145.

16. A pharmacy is responsible for the acts and/or omissions of its pharmacists. NRS 639.230(5); NAC 639.707; NAC 639.945(3).

COUNT ONE
Unprofessional Conduct
(Respondent Peters and Respondent Partell)

17. As alleged above, Respondent Peters refused to transfer a prescription at the request of a patient. Respondent Peters refused to transfer the prescription because he mistakenly believed that the prescribing practitioner, Dr. Kuraishi, had given his employer, Respondent Partell, the exclusive right to compound 0.11% retinoic acid cream.

18. By asserting the pharmacy's exclusive right to compound 0.11% retinoic acid cream, Respondent Peters attributed "secret formula" status to 0.11% retinoic acid cream.

19. Because it is unprofessional to use secret formulas, *see* NAC 639.945(1)(c), Respondent Peters engaged in unprofessional conduct when he refused to transfer Dr. Kuraishi's prescription for 0.11% retinoic acid cream. Therefore, Respondent Peters is subject to discipline pursuant to NRS 629.210(4) and NAC 639.945(1)(c).

20. As the owner/operator of the pharmacy at which Respondent Peters was employed, Respondent Partell is responsible for Respondent Peters' conduct as alleged above. Accordingly, the Board may discipline Respondent Partell pursuant to NRS 639.230(5) and NAC 639.945(3).

COUNT TWO
Violation of NRS 639.2357(1)
(Respondent Peters and Respondent Partell)

21. As alleged above, Respondent Peters refused to transfer a prescription at the request of a patient. By refusing to transfer the prescription, Respondent Peters violated NRS 639.2357(1).

22. Having violated NRS 639.2357(1), Respondent Peters is subject to discipline pursuant to NRS 639.210(12), NRS 639.255.

23. As the owner/operator of the pharmacy at which Respondent Peters was employed, Respondent Partell is responsible for Respondent Peters' conduct as alleged above. Accordingly, the Board may discipline Respondent Partell pursuant to NRS 639.230(5), NRS 639.255, NAC 639.945(3), and NAC 639.955.

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WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent Peters and the pharmacy license of Respondent Partell.

DATED this 3rd day of FEBRUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY,** **Pharmacy License No. PH02028,** **Respondent.**	**Case No. 23-175-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of FEBRUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, Pharmacy License No. PH02028,** **Respondent.**	**Case No. 23-175-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR PARTELL SPECIALTY PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 3rd day of February 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave #101
Las Vegas, NV 89119

Christopher Peters, Rph
[redacted]
Henderson, NV [redacted]

Christopher Peters, Rph
c/o Partell Specialty Pharmacy
5835 S Eastern Ave #101
Las Vegas, NV 89119

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028** **-and-** **JEFFREY LANG, RPH, Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **SECOND AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because the Board has licensed Respondent Pharmacy to operate a pharmacy on South Eastern Avenue in Las Vegas, Nevada.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because the Board has issued Respondent Lang a certificate of registration authorizing him to engage in the practice of pharmacy in Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang (Respondents) dispensed Nutlin to patient T.S. with directions to mix Nutlin with 2mL DMSO and

administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondents also dispensed Thymulin to patient T.S. with instructions to mix with 2mL saline and administer 6.25mg intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060592.

6. Respondents also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

7. Respondents purchased the drugs used for these prescriptions from Biopeptek Pharmaceuticals, a drug manufacturer based in Malvern, Pennsylvania.

8. Biopeptek Pharmaceuticals was then registered with the Food and Drug Administration (FDA) as a manufacturer. *See* 21 U.S.C. § 360.

9. Registration with the FDA does not suggest or imply that Biopeptek's drug products are approved by the FDA for distribution in the United States. *See* 21 U.S.C. § 355 (concerning the approval of new drugs under new drug applications or abbreviated new drug applications).

10. Biopeptek Pharmaceuticals has never been licensed or registered by the Board to distribute or dispense drugs in Nevada.

11. Neither Nutlin, Thymulin, nor Pooled Peptides has a *United States Pharmacopeia – National Formulary* Monograph.

12. Neither Nutlin, Thymulin, nor Pooled Peptides contains components of drugs approved by the FDA.

13. Neither Nutlin, Thymulin, nor Pooled Peptides appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

14. Nutlin, Thymulin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

15. Neither Nutlin, Thymulin, nor Pooled Peptides is considered an investigational drug under Nevada law.

16. Biopeptek Pharmaceuticals delivered Nutlin, Thymulin, and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that the drugs were experimental, potentially dangerous, and/or not approved by the FDA.

17. Biopeptek Pharmaceuticals delivered Nutlin, Thymulin, and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that they were bulk drug substances or active pharmaceutical ingredients intended to be compounded and then administered intravenously, or by way of intramuscular injection.

18. Respondents dispensed these bulk drug substances to patient T.S. in their solid state.

19. Respondents were not approved by the Board to perform sterile compounding.

20. Respondents did not seek nor obtain the Board's approval to compound drugs products using bulk drug substances described in NAC 639.757(2).

21. On information and belief, neither patient T.S. nor her practitioner was qualified or competent to perform sterile compounding.

22. Respondents dispensed bulk drug substances to patient T.S. when they knew or should have known that an injectable drug product or parenteral solution could not be safely administered to patient T.S. unless those bulk drug substances were compounded with other active pharmaceutical ingredients using sterile compounding methods and protocols.

23. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy.

APPLICABLE LAW

24. The term "drug" includes "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

25. "'Dispense' means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery." NRS 639.0065.

26. "'Compounding' includes, without limitation, the combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug." NAC 639.6911.

27. The terms "bulk drug substance' and "active pharmaceutical ingredient" are synonymous. These terms refer to any "substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." 21 C.F.R. § 207.1. *See also* NAC 639.6611 (defining "active ingredient").

28. "'Investigational drug, biological product or device' means a drug, biological product or device that: . . . (1) Has successfully completed Phase 1 of a clinical trial; . . . (2) Has not been approved by the United States Food and Drug Administration; and . . . (3) Is currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

29. A person may not engage in the wholesale distribution of drugs in Nevada unless the person is properly licensed pursuant to NRS 639.233 and the regulations promulgated thereunder.

30. It is unlawful for any person to engage in or permit the wholesale distribution of drugs unless that person holds a wholesaler license issued by the Board. NRS 639.100(1); NRS 639.233; NAC 639.593.

31. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284(1).

32. To perform sterile compounding in Nevada, a pharmacy and/or its pharmacists must demonstrate competency in the practice of sterile compounding. NAC 639.67013.

33. Under both state and federal law, except as provided in NAC 639.757(2), a compounded drug product cannot be dispensed by a pharmacy or pharmacist unless it is compounded using bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopeia (USP)

or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the FDA; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. 353a(b)(1); NAC 639.757(1).

34. Under NAC 639.757(2), a pharmacist may compound drug products using an active pharmaceutical ingredient that does not meet the criteria set forth in paragraph 33 above if the pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient.

35. The furnishing of prescription blanks that bear the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2).

36. The Board may discipline the holder of a license or registration if the holder of said license or registration assists or abets in the violation of any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

37. The Board may discipline the holder of a license or registration if the holder of said license or registration violates any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

38. The Board may discipline the holder of a license or registration if the holder of said license or registration "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

39. Unprofessional conduct includes "[p]erforming any...duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

40. Unprofessional conduct includes "[m]anufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations." NAC 639.945(1)(a).

41. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

COUNT ONE
Purchasing Drugs from an Unlicensed Wholesaler
(Respondent Pharmacy & Respondent Lang)

42. As alleged above, Respondents purchased bulk drug substances from Biopeptek Pharmaceuticals.

43. Biopeptek Pharmaceuticals was engaged in "wholesale distribution" as that term is defined at NRS 639.0155.

44. Biopeptek Pharmaceuticals was not licensed by the Board to engage in wholesale distribution in Nevada.

45. A pharmacy or pharmacist may be disciplined for assisting or abetting in a violation of Nevada law involving the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

46. Respondents knew or should have known, based upon the facts and circumstances surrounding their dealings with Biopeptek Pharmaceuticals, that the company was not licensed to engage in the wholesale distribution of drugs or bulk drug substances in Nevada.

47. Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased bulk drug substances from an unlicensed wholesaler under the circumstances described above. NRS 639.210(4); NAC 639.945(1)(i).

48. Respondents assisted or abetted in a violation by Biopeptek Pharmaceuticals of Nevada's prohibition against engaging in the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

49. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

50. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT TWO
Dispensing a Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

51. As alleged above, Respondents dispensed Nutlin to patient T.S., listed as prescription number 0090060591.

52. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

53. Nutlin does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

54. Nutlin has not been approved by the Board for use in compounding pursuant to NAC 639.757(2).

55. Respondents have not demonstrated their competency to perform sterile compounding.

56. For any one or more of the reasons noted above, Nutlin cannot lawfully be compounded by Respondents under state or federal law.

57. Instead of compounding Nutlin for patient T.S., Respondents dispensed Nutlin to patient T.S. with directions to compound it herself.

58. Because Nutlin cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

59. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. This amounted to a breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

60. Having engaged in unprofessional conduct as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

61. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT THREE
Dispensing Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

62. As alleged above, Respondents dispensed Thymulin to patient T.S., listed as prescription number 0090060592.

63. Thymulin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

64. Thymulin does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

65. Thymulin has not been approved by the Board for use in compounding pursuant to NAC 639.757(2).

66. Respondents have not demonstrated their competency to perform sterile compounding.

67. For any one or more of the reasons noted above, Thymulin cannot lawfully be compounded by Respondents under state or federal law.

68. Instead of compounding Thymulin for patient T.S., Respondents dispensed Thymulin to patient T.S. with directions to compound it herself.

69. Because Thymulin cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

70. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. This amounted to a breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

71. Having engaged in unprofessional conduct as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

72. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT FOUR
Dispensing Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

73. As alleged above, Respondents dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593.

74. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

75. Pooled Peptides does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

76. Pooled Peptides has not been approved by the Board for use in compounding pursuant to NAC 639.757(2).

77. Respondents have not demonstrated their competency to perform sterile compounding.

78. For any one or more of the reasons noted above, Pooled Peptides cannot lawfully be compounded by Respondents under state or federal law.

79. Instead of compounding Pooled Peptides for patient T.S., Respondents dispensed Pooled Peptides to patient T.S. with directions to compound it herself.

80. Because Pooled Peptides cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

81. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. in breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

82. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

83. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT FIVE
Permitting Drugs to be Compounded by a Non-Pharmacist
(Respondent Pharmacy and Respondent Lang)

84. As alleged above, Respondents dispensed bulk drug substances to patient T.S. with instructions to compound them herself.

85. Respondent Pharmacy is the licensed proprietor of a pharmacy that is not approved by the Board to perform sterile compounding.

86. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284.

87. By dispensing bulk drug substances to patient T.S. with instructions to compound them herself, Respondent Pharmacy permitted the compounding of drugs or prescriptions by a person other than a registered pharmacist or intern pharmacist in violation of NRS 639.284.

88. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondent Lang assisted or abetted in the violation by Respondent Pharmacy of NRS 639.284.

89. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner.

90. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT SIX
Furnishing Preprinted Prescription Blanks
(Respondent Pharmacy)

91. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks bearing the name of Respondent Pharmacy. This indicates that Respondent Pharmacy, or its agent, furnished patient T.S.'s practitioner with prescription blanks bearing the name of Respondent Pharmacy.

92. It is unlawful for a pharmacy to furnish a practitioner with prescription blanks bearing the name or name and address of the pharmacy. NRS 639.264(2).

93. By furnishing prescription blanks as described above, Respondent Pharmacy violated NRS 639.264.

94. Having engaged in the conduct described above, Respondent Pharmacy is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Respondent Pharmacy and the certificate of registration of Respondent Lang.

DATED this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case Nos. 23-239-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case No. 23-239-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

AUTHORIZED REPRESENTATIVE FOR PARTELL SPECIALTY PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave., #101
Las Vegas, NV 89119

Jeffrey Lang, RPH
[redacted]
Las Vegas, NV [redacted]

Joey Gilbert, Esq.
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
JAN 2 3 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028** **-and-** **JEFFREY LANG, RPH, Certificate of Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because the Board has licensed Respondent Pharmacy to operate a pharmacy on South Eastern Avenue in Las Vegas, Nevada.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because the Board has issued Respondent Lang a certificate of registration authorizing him to engage in the practice of pharmacy in Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang (Respondents) dispensed Nutlin to patient T.S. with directions to mix Nutlin with 2mL DMSO and

administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondents also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

6. Respondents purchased the drugs used for these prescriptions from Biopeptek Pharmaceuticals, a drug manufacturer based in Malvern, Pennsylvania.

7. Biopeptek Pharmaceuticals was then registered with the Food and Drug Administration (FDA) as a manufacturer. *See* 21 U.S.C. § 360.

8. Registration with the FDA does not suggest or imply that Biopeptek's drug products are approved by the FDA for distribution in the United States. *See* 21 U.S.C. § 355 (concerning the approval of new drugs under new drug applications or abbreviated new drug applications).

9. Biopeptek Pharmaceuticals has never been licensed or registered by the Board to distribute or dispense drugs in Nevada.

10. Neither Nutlin nor Pooled Peptides have a *United States Pharmacopeia – National Formulary* Monograph.

11. Neither Nutlin nor Pooled Peptides contain components of drugs approved by the FDA.

12. Neither Nutlin nor Pooled Peptides appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

13. Both Nutlin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

14. Neither Nutlin nor Pooled Peptides are considered investigational drugs under Nevada law.

15. Biopeptek Pharmaceuticals delivered Nutlin and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that the drugs were experimental, potentially dangerous, and/or not approved by the FDA.

16. Biopeptek Pharmaceuticals delivered Nutlin and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that they were bulk drug substances or active pharmaceutical ingredients intended to be compounded and then administered intravenously, or by way of intramuscular injection.

17. Respondents dispensed these bulk drug substances to patient T.S. in their solid state.

18. Respondents were not approved by the Board to perform sterile compounding.

19. Neither patient T.S. nor her practitioner were qualified or competent to perform sterile compounding.

20. Respondents dispensed bulk drug substances to patient T.S. when they knew or should have known that an injectable drug product or parenteral solution could not be safely administered to patient T.S. unless those bulk drug substances were compounded with other active pharmaceutical ingredients using sterile compounding methods and protocols.

21. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy.

APPLICABLE LAW

22. The term "drug" includes "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

23. "'Dispense' means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery." NRS 639.0065.

24. "'Compounding' includes, without limitation, the combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug." NAC 639.6911.

25. The terms "bulk drug substance' and "active pharmaceutical ingredient" are synonymous. These terms refer to any "substance that is intended for incorporation into a finished drug

product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." 21 C.F.R. § 207.1. *See also* NAC 639.6611 (defining "active ingredient").

26. "'Investigational drug, biological product or device' means a drug, biological product or device that: . . . (1) Has successfully completed Phase 1 of a clinical trial; . . . (2) Has not been approved by the United States Food and Drug Administration; and . . . (3) Is currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

27. A person may not engage in the wholesale distribution of drugs in Nevada unless the person is properly licensed pursuant to NRS 639.233 and the regulations promulgated thereunder.

28. It is unlawful for any person to engage in or permit the wholesale distribution of drugs unless that person holds a wholesaler license issued by the Board. NRS 639.100(1); NRS 639.233; NAC 639.593.

29. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284(1).

30. To perform sterile compounding in Nevada, a pharmacy and/or its pharmacists must demonstrate competency in the practice of sterile compounding. NAC 639.67013.

31. Under both state and federal law, a compounded drug product cannot be dispensed by a pharmacy or pharmacist unless it is compounded using bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the FDA; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. 353a(b)(1); NAC 639.757(1).

32. The furnishing of prescription blanks that bear the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2)..

33. The Board may discipline the holder of a license or registration if the holder of said license or registration assists or abets in the violation of any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

34. The Board may discipline the holder of a license or registration if the holder of said license or registration violates any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

35. The Board may discipline the holder of a license or registration if the holder of said license or registration "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

36. Unprofessional conduct includes "[p]erforming any…duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

37. Unprofessional conduct includes "[m]anufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations." NAC 639.945(1)(a).

38. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

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COUNT ONE

Purchasing Drugs from an Unlicensed Wholesaler
(Respondent Pharmacy & Respondent Lang)

39. As alleged above, Respondents purchased bulk drug substances from Biopeptek Pharmaceuticals.

40. Biopeptek Pharmaceuticals was engaged in "wholesale distribution" as that term is defined at NRS 639.0155.

41. Biopeptek Pharmaceuticals was not licensed by the Board to engage in wholesale distribution in Nevada.

42. A pharmacy or pharmacist may be disciplined for assisting or abetting in a violation of Nevada law involving the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

43. Respondents knew or should have known, based upon the facts and circumstances surrounding their dealings with Biopeptek Pharmaceuticals, that the company was not licensed to engage in the wholesale distribution of drugs or bulk drug substances in Nevada.

44. Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased bulk drug substances from an unlicensed wholesaler under the circumstances described above. NRS 639.210(4); NAC 639.945(1)(i).

45. Respondents assisted or abetted in a violation by Biopeptek Pharmaceuticals of Nevada's prohibition against engaging in the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

46. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

47. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT TWO
Dispensing a Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

48. As alleged above, Respondents dispensed Nutlin to patient T.S., listed as prescription number 0090060591.

49. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

50. Nutlin does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

51. Respondents have not demonstrated their competency to perform sterile compounding.

52. For any one or more of the reasons noted above, Nutlin cannot lawfully be compounded by Respondents under state or federal law.

53. Instead of compounding Nutlin for patient T.S., Respondents dispensed Nutlin to patient T.S. with directions to compound it herself.

54. Because Nutlin cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

55. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. This amounted to a breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

56. Having engaged in unprofessional conduct as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

57. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

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COUNT THREE
Dispensing Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

58. As alleged above, Respondents dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593.

59. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

60. Pooled Peptides does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

61. Respondents have not demonstrated their competency to perform sterile compounding.

62. For any one or more of the reasons noted above, Pooled Peptides cannot lawfully be compounded by Respondents under state or federal law.

63. Instead of compounding Pooled Peptides for patient T.S., Respondents dispensed Pooled Peptides to patient T.S. with directions to compound it herself.

64. Because Pooled Peptides cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

65. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. in breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

66. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

67. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT FOUR
Permitting Drugs to be Compounded by a Non-Pharmacist
(Respondent Pharmacy and Respondent Lang)

68. As alleged above, Respondents dispensed bulk drug substances to patient T.S. with instructions to compound them herself.

69. Respondent Pharmacy is the licensed proprietor of a pharmacy that is not approved by the Board to perform sterile compounding.

70. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284.

71. By dispensing bulk drug substances to patient T.S. with instructions to compound them herself, Respondent Pharmacy permitted the compounding of drugs or prescriptions by a person other than a registered pharmacist or intern pharmacist in violation of NRS 639.284.

72. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondent Lang assisted or abetted in the violation by Respondent Pharmacy of NRS 639.284.

73. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner.

74. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

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COUNT FIVE
Furnishing Preprinted Prescription Blanks
(Respondent Pharmacy)

75. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks bearing the name of Respondent Pharmacy. This indicates that Respondent Pharmacy, or its agent, furnished patient T.S.'s practitioner with prescription blanks bearing the name of Respondent Pharmacy.

76. It is unlawful for a pharmacy to furnish a practitioner with prescription blanks bearing the name or name and address of the pharmacy. NRS 639.264(2).

77. By furnishing prescription blanks as described above, Respondent Pharmacy violated NRS 639.264.

78. Having engaged in the conduct described above, Respondent Pharmacy is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Respondent Pharmacy and the certificate of registration of Respondent Lang.

DATED this 23rd day of January 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case Nos. 23-239-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of January 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case No. 23-239-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR PARTELL SPECIALTY PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 3RD day of FEBRUARY 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave., #101
Las Vegas, NV 89119

Jeffrey Lang, RPH
[redacted]
Las Vegas, NV [redacted]

Joey Gilbert, Esq.
405 Marsh Ave.
Reno, NV 89509

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
OCT 09 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028, and** **JEFFREY LANG, RPH, Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because Respondent Pharmacy, at the time of the violations alleged herein, held License No. PH02028 issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy. Since June 29, 2007, Respondent Pharmacy has held this license to operate a pharmacy issued by the Board pursuant to NRS 639.230.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because Respondent Lang, at the time of the violations alleged herein, held Certificate of Registration No. 17503 issued by the Board pursuant to NRS 639.127, authorizing Respondent to engage in the practice of pharmacy. Since November 6, 2008, Respondent Lang has held this registration to practice pharmacy issued by the Board pursuant to NRS 639.127.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang dispensed Nutlin to patient T.S. with direction to mix Nutlin with 2mL DMSO and administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondent Pharmacy and Respondent Lang also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

6. Respondent Pharmacy and Respondent Lang purchased the drugs used for these prescriptions from an unlicensed wholesaler/manufacturer called Biopeptek Pharmaceuticals.

7. Neither Nutlin nor Pooled Peptides have a *United States Pharmacopeia – National Formulary* Monograph.

8. Neither Nutlin nor Pooled Peptides have components of drugs approved by the Food and Drug Administration.

9. Both Nutlin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

10. Neither Nutlin nor Pooled Peptides are considered investigational drugs under Nevada law.

APPLICABLE LAW

11. The definition of drug includes, "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

12. "Investigational drug, biological product or device" means a drug, biological product or device that: (1) [h]as successfully completed Phase 1 of a clinical trial; (2) [h]as not been approved by

the United States Food and Drug Administration; and (3) [i]s currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

13. The Board may discipline the holder of a license or registration if the holder of said license or registration, "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

14. "Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter." NRS 639.233(1).

15. "For the purpose of this section, a person is "engaged in the business of furnishing" if the person: (a) Solicits or accepts orders for drugs or devices whose sale in this State is restricted by this chapter or chapter 453 or 454 of NRS; or (b) Receives, stores or ships such drugs or devices." NRS 639.233(2).

16. "The furnishing to a practitioner by a pharmacist or a pharmacy of prescription blanks bearing the name or name and address of any pharmacy is an unearned rebate and an inducement to refer patients to such pharmacist or pharmacy." NRS 639.264(2).

17. Prescription drugs may only be sold if the sale is a bona fide transaction. NRS 639.595(1).

18. A transaction is not a bona fide transaction if the circumstances of the purchase do not reasonably indicate that the drug was purchased from a source prohibited by law. NRS 639.595(5)(a)(2).

19. "A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if... the active ingredients used to compound the drugs: (1) [h]ave a monograph in and meet or exceed the standards of the United States Pharmacopoeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670; (2) [h]ave been components of drugs approved by the Food and Drug Administration; or (3) [a]re authorized to be used in pharmacy

compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto." NAC 639.757(1).

20. Unprofessional conduct includes, "[p]erforming any…duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

21. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

22. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Respondent Pharmacy and Respondent Lang purchased drugs from Biopeptek Pharmaceuticals. Biopeptek Pharmaceuticals was not licensed as a wholesaler in Nevada. NRS 639.233. Nevada law imposes a duty on parties to transactions involving prescription drugs, to engage in bona fide transactions. NRS 639.595(1). By purchasing drugs from an unlicensed wholesaler, Respondent Pharmacy and Respondent Lang purchased drugs from a source prohibited by law. *See* NRS 639.210(4); NRS 639.233; NRS 639.595(5)(a)(2); and NAC 639.945(1)(i).

24. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased drugs from an unlicensed wholesaler, breaching the duty imposed on them by Nevada law. NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

26. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration (Respondent Pharmacy and Respondent Lang)

27. Respondent Pharmacy and Respondent Lang filled and dispensed Nutlin to patient T.S., listed as prescription number 0090060591. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

28. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

29. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

30. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration
(Respondent Pharmacy and Respondent Lang)

31. Respondent Pharmacy and Respondent Lang filled and dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

32. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

33. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

34. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

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COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy
(Respondent Pharmacy and Respondent Lang)

35. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy. The furnishing of prescription blanks that contain the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2).

36. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they furnished or allowed to be furnished on their behalf prescription blanks that contain the name or name and address of their pharmacy. NRS 639.210(4); NRS 639.264(2); and NAC 639.945(1)(i).

37. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

38. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case No. 23-239-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028,** **Respondent.**	**Case No. 23-239-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

AUTHORIZED REPRESENTATIVE FOR PARTELL SPECIALTY PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave., #101
Las Vegas, NV 89119

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD OF PHARMACY

JOSEPH S. GILBERT, ESQ.- SBN #. 9033
Joey Gilbert Law
405 Marsh Avenue
Reno, Nevada 89509
Telephone: (775) 284-7700
Attorney for Respondent

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, PARTELL SPECIALTY PHARMACY, License No. PH02028, and JEFFREY LANG, RPH, Registration No. 17503. Respondent.	Case No.: 23-239-PH-S 23-239-RPH-S **ANSWER AND NOTICE OF DEFENSE**

COMES NOW, Respondents, PARTELL SPECIALTY PHARMACY and JEFFREY LANG, RPH (hereinafter referred to as "Respondents") by and through their counsel of record, JOSEPH S. GILBERT, ESQ. of JOEY GILBERT LAW, and answers the Notice of Intended Action and Accusation filed on October 9, 2024 as follows:

JURISDICTION

1. Responding to Paragraph 1 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Partell Specialty Pharmacy.

2. Responding to Paragraph 2 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Jeffrey Lang, RPH.

3. Responding to Paragraph 3 of the Notice of Intended Action and Accusation, Respondents admit that the Nevada State Board of Pharmacy has jurisdiction over the subject matter of this accusation.

FACTUAL ALLEGATIONS

4. Responding to Paragraph 4 of the Notice of Intended Action and Accusation, Respondents admit to the allegation.

5. Responding to Paragraph 5 of the Notice of Intended Action and Accusation, Respondents admit to the allegations.

6. Responding to Paragraph 6 of the Notice of Intended Action and Accusation, Respondents admit to the allegation that they purchased Nutlin and Pooled Peptides from Biopeptek Pharmaceuticals. Respondents deny the allegation that they knew Biopeptek was an unlicensed wholesale/manufacturer.

7. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

8. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

9. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

10. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

APPLICABLE LAW

11. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

12. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

13. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

14. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

15. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

16. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

17. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

18. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

19. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

20. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

21. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

22. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Responding to Paragraph 23 of the Notice of Intended Action and Accusation, Respondents admit to purchasing drugs from Biopeptek. Respondents deny all remaining allegations.

24. Responding to Paragraph 24 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Responding to Paragraph 25 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

26. Responding to Paragraph 26 of the Notice of Intended Action and Accusation, Respondent admits to the allegation.

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

27. Responding to Paragraph 27 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

28. Responding to Paragraph 28 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

29. Responding to Paragraph 29 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

30. Responding to Paragraph 30 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

31. Responding to Paragraph 31 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

32. Responding to Paragraph 32 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

33. Responding to Paragraph 33 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

34. Responding to Paragraph 34 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy (Respondent Pharmacy and Respondent Lang)

35. Responding to Paragraph 35 of the Notice of Intended Action and Accusation, Respondent Pharmacy denies furnishing prescription blanks in violation of Nevada law (NRS 639.264(2)).

36. Responding to Paragraph 36 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

37. Responding to Paragraph 37 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

38. Responding to Paragraph 38 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and through their counsel of record, Joseph S. Gilbert, Esq. of Joey Gilbert Law, assert that they have consistently met their professional obligations, including full cooperation with the NVBOP's inquiries, transparency regarding their relabeling practices, and adherence to applicable regulations. Respondents further state that during a 2023 visit by Joe Dodge and a male investigator from the NVBOP, they received no indication that their practices were non-compliant or improper. When asked if the pharmacy was compounding these items, Respondents explained the relabeling process, clarifying that the items were not compounded at Partell but were manufactured by the FDA-registered Biopeptek. Respondents' staff also proactively inquired whether there was any issue with this process or if relabeling should be discontinued. The investigator did not suggest any changes or raise any compliance concerns. Respondents remain fully committed to maintaining the highest standards of professional conduct and strict compliance with all relevant laws and regulations.

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

JOSEPH S. GILBERT, ESQ.
Attorney for Respondent,

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

PARTELL SPECIALTY PHARMACY

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **Answer and Notice of Defense** was served upon the following person by electronic transmission and/or by mailing a copy to their last known address, first class mail, postage prepaid for non-registered users, on this 1st day of November, 2024 as follows:

Nevada Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521
Email: TeamBC@pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

Nancy Vazquez

Nancy Vazquez, Legal Assistant

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028** **-and-** **JEFFREY LANG, RPH, Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **SECOND AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because the Board has licensed Respondent Pharmacy to operate a pharmacy on South Eastern Avenue in Las Vegas, Nevada.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because the Board has issued Respondent Lang a certificate of registration authorizing him to engage in the practice of pharmacy in Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang (Respondents) dispensed Nutlin to patient T.S. with directions to mix Nutlin with 2mL DMSO and

administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondents also dispensed Thymulin to patient T.S. with instructions to mix with 2mL saline and administer 6.25mg intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060592.

6. Respondents also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

7. Respondents purchased the drugs used for these prescriptions from Biopeptek Pharmaceuticals, a drug manufacturer based in Malvern, Pennsylvania.

8. Biopeptek Pharmaceuticals was then registered with the Food and Drug Administration (FDA) as a manufacturer. *See* 21 U.S.C. § 360.

9. Registration with the FDA does not suggest or imply that Biopeptek's drug products are approved by the FDA for distribution in the United States. *See* 21 U.S.C. § 355 (concerning the approval of new drugs under new drug applications or abbreviated new drug applications).

10. Biopeptek Pharmaceuticals has never been licensed or registered by the Board to distribute or dispense drugs in Nevada.

11. Neither Nutlin, Thymulin, nor Pooled Peptides has a *United States Pharmacopeia – National Formulary* Monograph.

12. Neither Nutlin, Thymulin, nor Pooled Peptides contains components of drugs approved by the FDA.

13. Neither Nutlin, Thymulin, nor Pooled Peptides appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

14. Nutlin, Thymulin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

15. Neither Nutlin, Thymulin, nor Pooled Peptides is considered an investigational drug under Nevada law.

16. Biopeptek Pharmaceuticals delivered Nutlin, Thymulin, and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that the drugs were experimental, potentially dangerous, and/or not approved by the FDA.

17. Biopeptek Pharmaceuticals delivered Nutlin, Thymulin, and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that they were bulk drug substances or active pharmaceutical ingredients intended to be compounded and then administered intravenously, or by way of intramuscular injection.

18. Respondents dispensed these bulk drug substances to patient T.S. in their solid state.

19. Respondents were not approved by the Board to perform sterile compounding.

20. Respondents did not seek nor obtain the Board's approval to compound drugs products using bulk drug substances described in NAC 639.757(2).

21. On information and belief, neither patient T.S. nor her practitioner was qualified or competent to perform sterile compounding.

22. Respondents dispensed bulk drug substances to patient T.S. when they knew or should have known that an injectable drug product or parenteral solution could not be safely administered to patient T.S. unless those bulk drug substances were compounded with other active pharmaceutical ingredients using sterile compounding methods and protocols.

23. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy.

APPLICABLE LAW

24. The term "drug" includes "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

25. "'Dispense' means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery." NRS 639.0065.

26. "'Compounding' includes, without limitation, the combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug." NAC 639.6911.

27. The terms "bulk drug substance' and "active pharmaceutical ingredient" are synonymous. These terms refer to any "substance that is intended for incorporation into a finished drug product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." 21 C.F.R. § 207.1. *See also* NAC 639.6611 (defining "active ingredient").

28. "'Investigational drug, biological product or device' means a drug, biological product or device that: . . . (1) Has successfully completed Phase 1 of a clinical trial; . . . (2) Has not been approved by the United States Food and Drug Administration; and . . . (3) Is currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

29. A person may not engage in the wholesale distribution of drugs in Nevada unless the person is properly licensed pursuant to NRS 639.233 and the regulations promulgated thereunder.

30. It is unlawful for any person to engage in or permit the wholesale distribution of drugs unless that person holds a wholesaler license issued by the Board. NRS 639.100(1); NRS 639.233; NAC 639.593.

31. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284(1).

32. To perform sterile compounding in Nevada, a pharmacy and/or its pharmacists must demonstrate competency in the practice of sterile compounding. NAC 639.67013.

33. Under both state and federal law, except as provided in NAC 639.757(2), a compounded drug product cannot be dispensed by a pharmacy or pharmacist unless it is compounded using bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopeia (USP)

or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the FDA; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. 353a(b)(1); NAC 639.757(1).

34. Under NAC 639.757(2), a pharmacist may compound drug products using an active pharmaceutical ingredient that does not meet the criteria set forth in paragraph 33 above if the pharmacist establishes the purity and safety of the ingredient by reasonable means, satisfactory to the Board, which include, without limitation, analysis of the lot in which the ingredient was packaged, the reputation of the manufacturer of the ingredient and the reliability of the source of the ingredient.

35. The furnishing of prescription blanks that bear the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2).

36. The Board may discipline the holder of a license or registration if the holder of said license or registration assists or abets in the violation of any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

37. The Board may discipline the holder of a license or registration if the holder of said license or registration violates any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

38. The Board may discipline the holder of a license or registration if the holder of said license or registration "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

39. Unprofessional conduct includes "[p]erforming any…duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

40. Unprofessional conduct includes "[m]anufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations." NAC 639.945(1)(a).

41. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

COUNT ONE
Purchasing Drugs from an Unlicensed Wholesaler
(Respondent Pharmacy & Respondent Lang)

42. As alleged above, Respondents purchased bulk drug substances from Biopeptek Pharmaceuticals.

43. Biopeptek Pharmaceuticals was engaged in "wholesale distribution" as that term is defined at NRS 639.0155.

44. Biopeptek Pharmaceuticals was not licensed by the Board to engage in wholesale distribution in Nevada.

45. A pharmacy or pharmacist may be disciplined for assisting or abetting in a violation of Nevada law involving the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

46. Respondents knew or should have known, based upon the facts and circumstances surrounding their dealings with Biopeptek Pharmaceuticals, that the company was not licensed to engage in the wholesale distribution of drugs or bulk drug substances in Nevada.

47. Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased bulk drug substances from an unlicensed wholesaler under the circumstances described above. NRS 639.210(4); NAC 639.945(1)(i).

48. Respondents assisted or abetted in a violation by Biopeptek Pharmaceuticals of Nevada's prohibition against engaging in the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

49. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

50. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT TWO
Dispensing a Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

51. As alleged above, Respondents dispensed Nutlin to patient T.S., listed as prescription number 0090060591.

52. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

53. Nutlin does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

54. Nutlin has not been approved by the Board for use in compounding pursuant to NAC 639.757(2).

55. Respondents have not demonstrated their competency to perform sterile compounding.

56. For any one or more of the reasons noted above, Nutlin cannot lawfully be compounded by Respondents under state or federal law.

57. Instead of compounding Nutlin for patient T.S., Respondents dispensed Nutlin to patient T.S. with directions to compound it herself.

58. Because Nutlin cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

59. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. This amounted to a breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

60. Having engaged in unprofessional conduct as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

61. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT THREE
Dispensing Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

62. As alleged above, Respondents dispensed Thymulin to patient T.S., listed as prescription number 0090060592.

63. Thymulin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

64. Thymulin does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

65. Thymulin has not been approved by the Board for use in compounding pursuant to NAC 639.757(2).

66. Respondents have not demonstrated their competency to perform sterile compounding.

67. For any one or more of the reasons noted above, Thymulin cannot lawfully be compounded by Respondents under state or federal law.

68. Instead of compounding Thymulin for patient T.S., Respondents dispensed Thymulin to patient T.S. with directions to compound it herself.

69. Because Thymulin cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

70. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. This amounted to a breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

71. Having engaged in unprofessional conduct as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

72. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT FOUR
Dispensing Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

73. As alleged above, Respondents dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593.

74. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

75. Pooled Peptides does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

76. Pooled Peptides has not been approved by the Board for use in compounding pursuant to NAC 639.757(2).

77. Respondents have not demonstrated their competency to perform sterile compounding.

78. For any one or more of the reasons noted above, Pooled Peptides cannot lawfully be compounded by Respondents under state or federal law.

79. Instead of compounding Pooled Peptides for patient T.S., Respondents dispensed Pooled Peptides to patient T.S. with directions to compound it herself.

80. Because Pooled Peptides cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

81. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. in breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

82. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

83. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT FIVE
Permitting Drugs to be Compounded by a Non-Pharmacist
(Respondent Pharmacy and Respondent Lang)

84. As alleged above, Respondents dispensed bulk drug substances to patient T.S. with instructions to compound them herself.

85. Respondent Pharmacy is the licensed proprietor of a pharmacy that is not approved by the Board to perform sterile compounding.

86. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284.

87. By dispensing bulk drug substances to patient T.S. with instructions to compound them herself, Respondent Pharmacy permitted the compounding of drugs or prescriptions by a person other than a registered pharmacist or intern pharmacist in violation of NRS 639.284.

88. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondent Lang assisted or abetted in the violation by Respondent Pharmacy of NRS 639.284.

89. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner.

90. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

COUNT SIX
Furnishing Preprinted Prescription Blanks
(Respondent Pharmacy)

91. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks bearing the name of Respondent Pharmacy. This indicates that Respondent Pharmacy, or its agent, furnished patient T.S.'s practitioner with prescription blanks bearing the name of Respondent Pharmacy.

92. It is unlawful for a pharmacy to furnish a practitioner with prescription blanks bearing the name or name and address of the pharmacy. NRS 639.264(2).

93. By furnishing prescription blanks as described above, Respondent Pharmacy violated NRS 639.264.

94. Having engaged in the conduct described above, Respondent Pharmacy is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Respondent Pharmacy and the certificate of registration of Respondent Lang.

DATED this 11th day of March 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 11th day of MARCH 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 12th day of March 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave., #101
Las Vegas, NV 89119

Jeffrey Lang, RPH
[redacted]
Las Vegas, NV [redacted]

Joey Gilbert, Esq.
[redacted]
Reno, NV [redacted]

ERIN MILLER
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR II

FILED
JAN 2 3 2025
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028** **-and-** **JEFFREY LANG, RPH, Certificate of Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **FIRST AMENDED NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because the Board has licensed Respondent Pharmacy to operate a pharmacy on South Eastern Avenue in Las Vegas, Nevada.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because the Board has issued Respondent Lang a certificate of registration authorizing him to engage in the practice of pharmacy in Nevada.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang (Respondents) dispensed Nutlin to patient T.S. with directions to mix Nutlin with 2mL DMSO and

administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondents also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

6. Respondents purchased the drugs used for these prescriptions from Biopeptek Pharmaceuticals, a drug manufacturer based in Malvern, Pennsylvania.

7. Biopeptek Pharmaceuticals was then registered with the Food and Drug Administration (FDA) as a manufacturer. *See* 21 U.S.C. § 360.

8. Registration with the FDA does not suggest or imply that Biopeptek's drug products are approved by the FDA for distribution in the United States. *See* 21 U.S.C. § 355 (concerning the approval of new drugs under new drug applications or abbreviated new drug applications).

9. Biopeptek Pharmaceuticals has never been licensed or registered by the Board to distribute or dispense drugs in Nevada.

10. Neither Nutlin nor Pooled Peptides have a *United States Pharmacopeia – National Formulary* Monograph.

11. Neither Nutlin nor Pooled Peptides contain components of drugs approved by the FDA.

12. Neither Nutlin nor Pooled Peptides appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

13. Both Nutlin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

14. Neither Nutlin nor Pooled Peptides are considered investigational drugs under Nevada law.

15. Biopeptek Pharmaceuticals delivered Nutlin and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that the drugs were experimental, potentially dangerous, and/or not approved by the FDA.

16. Biopeptek Pharmaceuticals delivered Nutlin and/or Pooled Peptides to Respondents with labels and/or package inserts indicating that they were bulk drug substances or active pharmaceutical ingredients intended to be compounded and then administered intravenously, or by way of intramuscular injection.

17. Respondents dispensed these bulk drug substances to patient T.S. in their solid state.

18. Respondents were not approved by the Board to perform sterile compounding.

19. Neither patient T.S. nor her practitioner were qualified or competent to perform sterile compounding.

20. Respondents dispensed bulk drug substances to patient T.S. when they knew or should have known that an injectable drug product or parenteral solution could not be safely administered to patient T.S. unless those bulk drug substances were compounded with other active pharmaceutical ingredients using sterile compounding methods and protocols.

21. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy.

APPLICABLE LAW

22. The term "drug" includes "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

23. "'Dispense' means to deliver a controlled substance or dangerous drug to an ultimate user, patient or subject of research by or pursuant to the lawful order of a practitioner, including the prescribing by a practitioner, administering, packaging, labeling or compounding necessary to prepare the substance for that delivery." NRS 639.0065.

24. "'Compounding' includes, without limitation, the combining, admixing, mixing, pooling, reconstituting or other altering of a drug or bulk drug substance, as defined in 21 C.F.R. § 207.3, to create a drug." NAC 639.6911.

25. The terms "bulk drug substance' and "active pharmaceutical ingredient" are synonymous. These terms refer to any "substance that is intended for incorporation into a finished drug

product and is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease, or to affect the structure or any function of the body." 21 C.F.R. § 207.1. *See also* NAC 639.6611 (defining "active ingredient").

26. "'Investigational drug, biological product or device' means a drug, biological product or device that: . . . (1) Has successfully completed Phase 1 of a clinical trial; . . . (2) Has not been approved by the United States Food and Drug Administration; and . . . (3) Is currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

27. A person may not engage in the wholesale distribution of drugs in Nevada unless the person is properly licensed pursuant to NRS 639.233 and the regulations promulgated thereunder.

28. It is unlawful for any person to engage in or permit the wholesale distribution of drugs unless that person holds a wholesaler license issued by the Board. NRS 639.100(1); NRS 639.233; NAC 639.593.

29. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284(1).

30. To perform sterile compounding in Nevada, a pharmacy and/or its pharmacists must demonstrate competency in the practice of sterile compounding. NAC 639.67013.

31. Under both state and federal law, a compounded drug product cannot be dispensed by a pharmacy or pharmacist unless it is compounded using bulk drug substances that: (1) comply with the standards of an applicable United States Pharmacopeia (USP) or National Formulary (NF) monograph, if a monograph exists, and the USP chapter on pharmacy compounding; (2) if such a monograph does not exist, are drug substances that are components of drugs approved by the FDA; or (3) if such a monograph does not exist and the drug substance is not a component of a drug approved by the FDA, appears on a list developed by the FDA through regulations issued pursuant to 503A of the federal Food, Drug and Cosmetic Act. *See* 21 U.S.C. 353a(b)(1); NAC 639.757(1).

32. The furnishing of prescription blanks that bear the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2).

33. The Board may discipline the holder of a license or registration if the holder of said license or registration assists or abets in the violation of any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

34. The Board may discipline the holder of a license or registration if the holder of said license or registration violates any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

35. The Board may discipline the holder of a license or registration if the holder of said license or registration "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

36. Unprofessional conduct includes "[p]erforming any...duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

37. Unprofessional conduct includes "[m]anufacturing, compounding, selling, dispensing or permitting to be manufactured, compounded, sold or dispensed substandard drugs or preparations." NAC 639.945(1)(a).

38. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

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COUNT ONE
Purchasing Drugs from an Unlicensed Wholesaler
(Respondent Pharmacy & Respondent Lang)

39. As alleged above, Respondents purchased bulk drug substances from Biopeptek Pharmaceuticals.

40. Biopeptek Pharmaceuticals was engaged in "wholesale distribution" as that term is defined at NRS 639.0155.

41. Biopeptek Pharmaceuticals was not licensed by the Board to engage in wholesale distribution in Nevada.

42. A pharmacy or pharmacist may be disciplined for assisting or abetting in a violation of Nevada law involving the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

43. Respondents knew or should have known, based upon the facts and circumstances surrounding their dealings with Biopeptek Pharmaceuticals, that the company was not licensed to engage in the wholesale distribution of drugs or bulk drug substances in Nevada.

44. Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased bulk drug substances from an unlicensed wholesaler under the circumstances described above. NRS 639.210(4); NAC 639.945(1)(i).

45. Respondents assisted or abetted in a violation by Biopeptek Pharmaceuticals of Nevada's prohibition against engaging in the unlicensed wholesale distribution of drugs or bulk drug substances. NRS 639.210(12); NRS 639.100.

46. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

47. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT TWO
Dispensing a Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

48. As alleged above, Respondents dispensed Nutlin to patient T.S., listed as prescription number 0090060591.

49. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

50. Nutlin does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

51. Respondents have not demonstrated their competency to perform sterile compounding.

52. For any one or more of the reasons noted above, Nutlin cannot lawfully be compounded by Respondents under state or federal law.

53. Instead of compounding Nutlin for patient T.S., Respondents dispensed Nutlin to patient T.S. with directions to compound it herself.

54. Because Nutlin cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

55. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. This amounted to a breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

56. Having engaged in unprofessional conduct as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

57. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

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COUNT THREE

Dispensing Substandard Drug Product
(Respondent Pharmacy and Respondent Lang)

58. As alleged above, Respondents dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593.

59. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the FDA.

60. Pooled Peptides does not appear on a list developed by the FDA through a regulation issued pursuant to 503A of the federal Food, Drug and Cosmetic Act.

61. Respondents have not demonstrated their competency to perform sterile compounding.

62. For any one or more of the reasons noted above, Pooled Peptides cannot lawfully be compounded by Respondents under state or federal law.

63. Instead of compounding Pooled Peptides for patient T.S., Respondents dispensed Pooled Peptides to patient T.S. with directions to compound it herself.

64. Because Pooled Peptides cannot be safely compounded by Respondents, it cannot safely be compounded by patient T.S. or her practitioner.

65. By dispensing a bulk drug substance to patient T.S. under the circumstances described above, Respondents delivered a substandard drug product to patient T.S. in breach of their duty to treat their patients with competence and professionalism. NRS 639.210(4); NAC 639.945(1)(a) and 639.945(1)(i).

66. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

67. Respondent Pharmacy is responsible for the acts of all personnel in the company's employ. NAC 639.945(3).

COUNT FOUR
Permitting Drugs to be Compounded by a Non-Pharmacist
(Respondent Pharmacy and Respondent Lang)

68. As alleged above, Respondents dispensed bulk drug substances to patient T.S. with instructions to compound them herself.

69. Respondent Pharmacy is the licensed proprietor of a pharmacy that is not approved by the Board to perform sterile compounding.

70. It is unlawful for the licensed proprietor of a pharmacy to permit the compounding or dispensing of drugs or prescriptions by any person other than a registered pharmacist or intern pharmacist. NRS 639.284.

71. By dispensing bulk drug substances to patient T.S. with instructions to compound them herself, Respondent Pharmacy permitted the compounding of drugs or prescriptions by a person other than a registered pharmacist or intern pharmacist in violation of NRS 639.284.

72. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondent Lang assisted or abetted in the violation by Respondent Pharmacy of NRS 639.284.

73. By dispensing bulk drug substances to patient T.S. under the circumstances described above, Respondents performed their duties as the holder of a license or registration issued by the Board in an incompetent, unskillful or negligent manner.

74. Having engaged in the conduct described above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.210(12); NRS 639.255; NAC 639.945; and NAC 639.955.

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COUNT FIVE
Furnishing Preprinted Prescription Blanks
(Respondent Pharmacy)

75. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks bearing the name of Respondent Pharmacy. This indicates that Respondent Pharmacy, or its agent, furnished patient T.S.'s practitioner with prescription blanks bearing the name of Respondent Pharmacy.

76. It is unlawful for a pharmacy to furnish a practitioner with prescription blanks bearing the name or name and address of the pharmacy. NRS 639.264(2).

77. By furnishing prescription blanks as described above, Respondent Pharmacy violated NRS 639.264.

78. Having engaged in the conduct described above, Respondent Pharmacy is subject to discipline by the Board. NRS 639.210(12); NRS 639.255; NAC 639.955.

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the pharmacy license of Respondent Pharmacy and the certificate of registration of Respondent Lang.

DATED this 23rd day of January 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **zunino@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of January 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 3RD day of FEBRUARY 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave., #101
Las Vegas, NV 89119

Jeffrey Lang, RPH
[redacted]
Las Vegas, NV [redacted]

Joey Gilbert, Esq.
405 Marsh Ave.
Reno, NV 89509

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
OCT 09 2024
NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, License No. PH02028, and** **JEFFREY LANG, RPH, Registration No. 17503.** **Respondents.**	**Case Nos. 23-239-PH-S** **23-239-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has personal jurisdiction over Respondent Partell Specialty Pharmacy (Respondent Pharmacy), because Respondent Pharmacy, at the time of the violations alleged herein, held License No. PH02028 issued by the Board pursuant to NRS 639.230, authorizing the business to operate as a pharmacy. Since June 29, 2007, Respondent Pharmacy has held this license to operate a pharmacy issued by the Board pursuant to NRS 639.230.

2. The Board has personal jurisdiction over Respondent Jeffrey Lang, RPh, (Respondent Lang), because Respondent Lang, at the time of the violations alleged herein, held Certificate of Registration No. 17503 issued by the Board pursuant to NRS 639.127, authorizing Respondent to engage in the practice of pharmacy. Since November 6, 2008, Respondent Lang has held this registration to practice pharmacy issued by the Board pursuant to NRS 639.127.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

3. The Board has jurisdiction over the subject matter of this accusation because the alleged violations involve the dispensing of poisons, drugs, chemicals and medicines and the regulation of the practice of pharmacy. NRS 639.070.

FACTUAL ALLEGATIONS

4. On or about February 28, 2023, Respondent Pharmacy and Respondent Lang dispensed Nutlin to patient T.S. with direction to mix Nutlin with 2mL DMSO and administer .5mL up to 1mL intramuscularly or IV per administration protocol. This prescription was given prescription number 0090060591.

5. Respondent Pharmacy and Respondent Lang also dispensed Pooled Peptides to patient T.S. with instructions to inject 1mL daily per administration protocol. This prescription was given prescription number 0090060593.

6. Respondent Pharmacy and Respondent Lang purchased the drugs used for these prescriptions from an unlicensed wholesaler/manufacturer called Biopeptek Pharmaceuticals.

7. Neither Nutlin nor Pooled Peptides have a *United States Pharmacopeia – National Formulary* Monograph.

8. Neither Nutlin nor Pooled Peptides have components of drugs approved by the Food and Drug Administration.

9. Both Nutlin and Pooled Peptides were prescribed in this instance to cure, mitigate, and/or treat cancer.

10. Neither Nutlin nor Pooled Peptides are considered investigational drugs under Nevada law.

APPLICABLE LAW

11. The definition of drug includes, "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in humans or other animals." NRS 639.007(2).

12. "Investigational drug, biological product or device" means a drug, biological product or device that: (1) [h]as successfully completed Phase 1 of a clinical trial; (2) [h]as not been approved by

the United States Food and Drug Administration; and (3) [i]s currently being tested in a clinical trial that has been approved by the United States Food and Drug Administration." NRS 454.690(10)(c).

13. The Board may discipline the holder of a license or registration if the holder of said license or registration, "is guilty of unprofessional conduct or conduct contrary to the public interest." NRS 639.210(4).

14. "Any person, including a wholesaler or manufacturer, who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of this chapter." NRS 639.233(1).

15. "For the purpose of this section, a person is "engaged in the business of furnishing" if the person: (a) Solicits or accepts orders for drugs or devices whose sale in this State is restricted by this chapter or chapter 453 or 454 of NRS; or (b) Receives, stores or ships such drugs or devices." NRS 639.233(2).

16. "The furnishing to a practitioner by a pharmacist or a pharmacy of prescription blanks bearing the name or name and address of any pharmacy is an unearned rebate and an inducement to refer patients to such pharmacist or pharmacy." NRS 639.264(2).

17. Prescription drugs may only be sold if the sale is a bona fide transaction. NRS 639.595(1).

18. A transaction is not a bona fide transaction if the circumstances of the purchase do not reasonably indicate that the drug was purchased from a source prohibited by law. NRS 639.595(5)(a)(2).

19. "A pharmacy or pharmacist is not required to obtain a license as a manufacturer to compound drugs if... the active ingredients used to compound the drugs: (1) [h]ave a monograph in and meet or exceed the standards of the United States Pharmacopoeia - National Formulary, as adopted by reference in paragraph (c) of subsection 1 of NAC 639.670; (2) [h]ave been components of drugs approved by the Food and Drug Administration; or (3) [a]re authorized to be used in pharmacy

compounding pursuant to 21 U.S.C. § 353a(b)(1) or the regulations adopted pursuant thereto." NAC 639.757(1).

20. Unprofessional conduct includes, "[p]erforming any…duties as the holder of a license, certificate or registration issued by the Board, or as the owner of a business or an entity licensed by the Board, in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

21. "The owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employ." NAC 639.945(3).

22. In lieu of a suspension or revocation, the Board may impose a fine of up to $10,000 for each violation committed. NRS 639.255(1)(f) and (3).

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Respondent Pharmacy and Respondent Lang purchased drugs from Biopeptek Pharmaceuticals. Biopeptek Pharmaceuticals was not licensed as a wholesaler in Nevada. NRS 639.233. Nevada law imposes a duty on parties to transactions involving prescription drugs, to engage in bona fide transactions. NRS 639.595(1). By purchasing drugs from an unlicensed wholesaler, Respondent Pharmacy and Respondent Lang purchased drugs from a source prohibited by law. *See* NRS 639.210(4); NRS 639.233; NRS 639.595(5)(a)(2); and NAC 639.945(1)(i).

24. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they purchased drugs from an unlicensed wholesaler, breaching the duty imposed on them by Nevada law. NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

26. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration (Respondent Pharmacy and Respondent Lang)

27. Respondent Pharmacy and Respondent Lang filled and dispensed Nutlin to patient T.S., listed as prescription number 0090060591. Nutlin does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

28. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

29. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

30. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product that Does not have a *United States Pharmacopeia – National Formulary* Monograph or Components of Drugs Approved by the Food and Drug Administration (Respondent Pharmacy and Respondent Lang)

31. Respondent Pharmacy and Respondent Lang filled and dispensed Pooled Peptides to patient T.S., listed as prescription number 0090060593. Pooled Peptides does not have a *United States Pharmacopeia – National Formulary* Monograph, nor have its components been approved by the U.S. Food and Drug Administration. NAC 639.757(1).

32. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they filled and dispensed a drug product with an active ingredient that does not have a *United States Pharmacopeia – National Formulary* Monograph, or components that have been approved by the U.S. Food and Drug Administration. NRS 639.210(4); NAC 639.757(1); and NAC 639.945(1)(i).

33. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

34. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

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COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy (Respondent Pharmacy and Respondent Lang)

35. Respondent Pharmacy received both prescriptions at issue in this case via prescription blanks that contained the name of Respondent Pharmacy. The furnishing of prescription blanks that contain the name or name and address of a pharmacy is prohibited by Nevada law. NRS 639.264(2).

36. Respondents performed their duties as the holder of a license and registration issued by the Board in an incompetent, unskillful or negligent manner because they furnished or allowed to be furnished on their behalf prescription blanks that contain the name or name and address of their pharmacy. NRS 639.210(4); NRS 639.264(2); and NAC 639.945(1)(i).

37. Having engaged in conduct contrary to the public interest as alleged above, Respondents are subject to discipline by the Board. NRS 639.210(4); NRS 639.255; NAC 639.945; and NAC 639.955.

38. Respondent Pharmacy is responsible for the acts of all personnel in his or her employ. NAC 639.945(3).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Respondent.

DATED this 9th day of October 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH,** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, December 4, 2024, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov **and** **gvanderdonck@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 9th day of OCTOBER 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JEFFREY LANG, RPH** **Certificate of Registration No. 17503,** **Respondent.**	**Case No. 23-239-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2024.

_____

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of October 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Jeffrey Lang, RPH
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
NOV 04 2024
NEVADA STATE BOARD OF PHARMACY

JOSEPH S. GILBERT, ESQ.- SBN #. 9033
Joey Gilbert Law
405 Marsh Avenue
Reno, Nevada 89509
Telephone: (775) 284-7700
Attorney for Respondent

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, Petitioner, PARTELL SPECIALTY PHARMACY, License No. PH02028, and JEFFREY LANG, RPH, Registration No. 17503. Respondent.	Case No.: 23-239-PH-S 23-239-RPH-S **ANSWER AND NOTICE OF DEFENSE**

COMES NOW, Respondents, PARTELL SPECIALTY PHARMACY and JEFFREY LANG, RPH (hereinafter referred to as "Respondents") by and through their counsel of record, JOSEPH S. GILBERT, ESQ. of JOEY GILBERT LAW, and answers the Notice of Intended Action and Accusation filed on October 9, 2024 as follows:

JURISDICTION

1. Responding to Paragraph 1 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Partell Specialty Pharmacy.

2. Responding to Paragraph 2 of the Notice of Intended Action and Accusation, Respondent admits that the Nevada State Board of Pharmacy has personal jurisdiction over Respondent Jeffrey Lang, RPH.

3. Responding to Paragraph 3 of the Notice of Intended Action and Accusation, Respondents admit that the Nevada State Board of Pharmacy has jurisdiction over the subject matter of this accusation.

FACTUAL ALLEGATIONS

4. Responding to Paragraph 4 of the Notice of Intended Action and Accusation, Respondents admit to the allegation.

5. Responding to Paragraph 5 of the Notice of Intended Action and Accusation, Respondents admit to the allegations.

6. Responding to Paragraph 6 of the Notice of Intended Action and Accusation, Respondents admit to the allegation that they purchased Nutlin and Pooled Peptides from Biopeptek Pharmaceuticals. Respondents deny the allegation that they knew Biopeptek was an unlicensed wholesale/manufacturer.

7. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

8. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

9. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

10. This Paragraph contains no allegations. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

APPLICABLE LAW

11. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

12. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

13. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

14. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

15. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

16. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

17. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

18. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

19. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

20. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

21. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

22. This Paragraph contains no allegations. Respondents acknowledge this as the Applicable Law in Nevada. If the paragraph is found to contain an allegation against the Respondents, Respondents deny the same.

COUNT ONE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Purchasing Drugs from an Unlicensed Wholesaler (Respondent Pharmacy & Respondent Lang)

23. Responding to Paragraph 23 of the Notice of Intended Action and Accusation, Respondents admit to purchasing drugs from Biopeptek. Respondents deny all remaining allegations.

24. Responding to Paragraph 24 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NRS 639.595(1); NRS 639.595(5)(a)(2); NAC 639.945(1)(i).

25. Responding to Paragraph 25 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

26. Responding to Paragraph 26 of the Notice of Intended Action and Accusation, Respondent admits to the allegation.

COUNT TWO

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

27. Responding to Paragraph 27 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

28. Responding to Paragraph 28 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

29. Responding to Paragraph 29 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

30. Responding to Paragraph 30 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT THREE

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner when Compounding and Dispensing a Product with an Active Ingredient that does not have a United States Pharmacopeia-National Formulary Monograph or Components of Drugs Approved by the Food and Drug Administration

(Respondent Pharmacy and Respondent Lang)

31. Responding to Paragraph 31 of the Notice of Intended Action and Accusation, Respondents admit solely to dispensing Nutlin to patient T.S., listed as prescription number 0090060591. Accordingly, Respondents deny all remaining allegations herein.

32. Responding to Paragraph 32 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

33. Responding to Paragraph 33 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

34. Responding to Paragraph 34 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

COUNT FOUR

Unprofessional Conduct – Performing Duties as a Licensee and Registrant in an Incompetent, Unskillful, or Negligent Manner by Furnishing Prescription Blanks Bearing the Name or Name and Address of Respondent Pharmacy (Respondent Pharmacy and Respondent Lang)

35. Responding to Paragraph 35 of the Notice of Intended Action and Accusation, Respondent Pharmacy denies furnishing prescription blanks in violation of Nevada law (NRS 639.264(2)).

36. Responding to Paragraph 36 of the Notice of Intended Action and Accusation, Respondents deny performing their duties in an incompetent, unskillful, or negligent manner under NRS 639.210(4); NAC 639.757(1); NAC 639.945(1)(i).

37. Responding to Paragraph 37 of the Notice of Intended Action and Accusation, Respondents deny that they engaged in conduct contrary to the public interest and deny that they are subject to discipline by the Board.

38. Responding to Paragraph 38 of the Notice of Intended Action and Accusation, Respondents admit the allegations.

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and

WHEREFORE, Respondent respectfully submits this response to the Notice of Intended Action and Accusation. Respondents, Partell Specialty Pharmacy and Jeffrey Lang, RPH, by and through their counsel of record, Joseph S. Gilbert, Esq. of Joey Gilbert Law, assert that they have consistently met their professional obligations, including full cooperation with the NVBOP's inquiries, transparency regarding their relabeling practices, and adherence to applicable regulations. Respondents further state that during a 2023 visit by Joe Dodge and a male investigator from the NVBOP, they received no indication that their practices were non-compliant or improper. When asked if the pharmacy was compounding these items, Respondents explained the relabeling process, clarifying that the items were not compounded at Partell but were manufactured by the FDA-registered Biopeptek. Respondents' staff also proactively inquired whether there was any issue with this process or if relabeling should be discontinued. The investigator did not suggest any changes or raise any compliance concerns. Respondents remain fully committed to maintaining the highest standards of professional conduct and strict compliance with all relevant laws and regulations.

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

JOSEPH S. GILBERT, ESQ.
Attorney for Respondent,

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

PARTELL SPECIALTY PHARMACY

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this 1st day of November, 2024.

JEFFREY LANG, RPH

CERTIFICATE OF SERVICE

I hereby certify that copies of the foregoing **Answer and Notice of Defense** was served upon the following person by electronic transmission and/or by mailing a copy to their last known address, first class mail, postage prepaid for non-registered users, on this 1st day of November, 2024 as follows:

Nevada Board of Pharmacy
985 Damonte Ranch Parkway Suite 206
Reno, NV 89521
Email: TeamBC@pharmacy.nv.gov and gvanderdonck@pharmacy.nv.gov

DATED this 1st day of November, 2024.

JOEY GILBERT LAW

Nancy Vazquez

Nancy Vazquez, Legal Assistant

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, Pharmacy License No. PH02028,** **v.** **ROBERT SEIK, RPH, Certificate of Registration No. 13574, and** **DAVID WHITEHOUSE, RPH, Certificate of Registration No. 13635,** **Respondents.**	**Case Nos. 23-429-PH-S** **23-429-RPH-A-S** **23-429-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Robert Seik (Seik), Certificate of Registration No. 13574, and Respondent David Whitehouse (Whitehouse), Certificate of Registration No. 13635, were pharmacists registered with the Board, and Respondent Partell Pharmacy (Partell Pharmacy), Pharmacy License No. PH02028, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Seik owns Partell Pharmacy and served as the managing pharmacist of Partell Pharmacy from August 21, 2023, to September 19, 2023, and from January 6, 2024, to present.

3. Whitehouse served as the managing pharmacist of Partell Pharmacy from September 20, 2023, to January 5, 2024.

4. Partell Pharmacy contracted with The Wellness Company (TWC), based in Boca Raton, Florida, to dispense various prescription drug products to TWC patients.

5. One product was an "Emergency Kit" including: 1) Amoxicillin-Clavulanate 875-125mg (28 tablets); 2) Azithromycin 250mg (12 tablets); 3) Bactrim DS 800mg-160mg (28 tablets); 4) Doxycycline Hyclate 100mg (60 capsules); 5) Fluconazole 150mg (2 tablets); 6) Ivermectin 18mg (7 capsules); 7) Metronidazole 500mg (30 tablets); and 8) Ondansetron 4mg (6 tablets).

6. Another product was a "COVID Kit" including: 1) Hydroxychloroquine 200mg (20 tablets); 2) Azithromycin 250mg (12 tablets); 3) Budesonide .5mg (10 vials); and 4) Ivermectin 12mg (25 capsules).

7. Each prescription transmitted to Partell Pharmacy only indicated that the pharmacy was to dispense an "Emergency Kit" or "COVID Kit" to the patient – the drugs in each kit were not identified on the prescription.

8. When a practitioner associated with TWC prescribed either of the two kits, Partell Pharmacy staff used a mutually agreed upon "pharmacy script" template that specified the drugs to be included in each kit.

9. Partell Pharmacy dispensed at least 512 prescriptions issued for an "Emergency Kit" or "COVID Kit" under this scheme.

10. Partell Pharmacy regularly substituted Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without consulting the prescribing practitioner, and continued billing TWC for the cost of Budesonide while substituting cheaper medications.

11. None of the counseling materials for each kit included any information on Medrol DosePaks or Albuterol. No further action was taken by Partell Pharmacy, Seik or Whitehouse to correct the counseling materials or provide any information regarding the substituted medications.

APPLICABLE LAW

12. A prescription must contain in pertinent part "[t]he name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled." NRS 639.2353(2)(d). A prescription must be written in such a manner that any registered pharmacist would be able to dispense it. NRS 639.2353(4).

13. Billing for the cost of a prescription drug while substituting cheaper medications constitutes fraud and is a felony offense. 18 U.S.C. § 1347; NRS 629.071; NRS 686A.2815.

14. A pharmacist shall provide medication counseling to a patient when dispensing a prescription and a pharmacy shall maintain documentation of medication counseling in conformance with NRS 639.266, NAC 639.707 and NAC 639.708.

15. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug prescribed, unless the express permission of the prescriber is obtained, constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(b) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

16. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

17. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

18. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

19. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(15); NRS 639.220(1).

21. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employment. NAC 639.945(3).

COUNT ONE
Violations of State Law – Dispensing Invalid Prescriptions

22. By dispensing at least 512 invalid prescriptions issued for an "Emergency Kit" or "COVID Kit" for which the drugs in each kit were not identified on the prescription, as alleged herein, Respondents Partell Pharmacy, Seik and Whitehouse violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.2353(2)(d) and (4), and are subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO
Unprofessional Conduct - Dispensing a Different Drug Without Permission

23. By substituting Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner, as alleged in Paragraph 9 herein, Respondents Partell Pharmacy, Seik and Whitehouse engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(b), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT THREE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

24. By substituting Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner, as alleged in Paragraph 10 herein, Respondents Partell Pharmacy, Seik and Whitehouse were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT FOUR
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

25. By their conduct as alleged herein, Respondents Partell Pharmacy, Seik and Whitehouse have performed their duties as licensees/registrants in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT FIVE
Violations of State Law – Failure to Provide Counseling to Patient for Substituted Medications

26. By failing to correct the counseling materials for each kit to include the necessary information on Medrol DosePaks or Albuterol or to otherwise provide any counseling regarding the substituted medications, as alleged in Paragraph 11 herein, Respondents Partell Pharmacy, Seik and Whitehouse violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.266, NAC 639.707 and/or NAC 639.708, and are subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT SIX
Violations of State Law – Fraudulent Billing Practices

27. By billing TWC for the cost of Budesonide while substituting cheaper medications, as alleged in Paragraph 10 herein, Respondents Partell Pharmacy, Seik and Whitehouse engaged in fraudulent billing practices and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1347, NRS 629.071 and/or NRS 686A.2815, and are subject to discipline pursuant to NRS 639.210(11), (12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and licenses of these Respondents.

DATED this 3rd day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, Pharmacy License No. PH02028,** **Respondent.**	**Case No. 23-429-PH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of FEBRUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, Pharmacy License No. PH02028,** **Respondent.**	**Case No. 23-429-PH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

AUTHORIZED REPRESENTATIVE FOR PARTELL SPECIALTY PHARMACY

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 3rd day of February 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave #101
Las Vegas, NV 89119

Robert Seik
5835 S Eastern Ave #101
Las Vegas, NV 89119

Robert Seik
[redacted]
Las Vegas, NV [redacted]

David Whitehouse
5835 S Eastern Ave #101
Las Vegas, NV 89119

David Whitehouse
[redacted]
Lakeport, CA [redacted]

Darlene Nases
DARLENE NASES
BOARD COORDINATOR

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NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, Pharmacy License No. PH02028,** **v.** **ROBERT SEIK, RPH, Certificate of Registration No. 13574, and** **DAVID WHITEHOUSE, RPH, Certificate of Registration No. 13635,** **Respondents.**	**Case Nos. 23-429-PH-S** **23-429-RPH-A-S** **23-429-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Robert Seik (Seik), Certificate of Registration No. 13574, and Respondent David Whitehouse (Whitehouse), Certificate of Registration No. 13635, were pharmacists registered with the Board, and Respondent Partell Pharmacy (Partell Pharmacy), Pharmacy License No. PH02028, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Seik owns Partell Pharmacy and served as the managing pharmacist of Partell Pharmacy from August 21, 2023, to September 19, 2023, and from January 6, 2024, to present.

3. Whitehouse served as the managing pharmacist of Partell Pharmacy from September 20, 2023, to January 5, 2024.

4. Partell Pharmacy contracted with The Wellness Company (TWC), based in Boca Raton, Florida, to dispense various prescription drug products to TWC patients.

5. One product was an "Emergency Kit" including: 1) Amoxicillin-Clavulanate 875-125mg (28 tablets); 2) Azithromycin 250mg (12 tablets); 3) Bactrim DS 800mg-160mg (28 tablets); 4) Doxycycline Hyclate 100mg (60 capsules); 5) Fluconazole 150mg (2 tablets); 6) Ivermectin 18mg (7 capsules); 7) Metronidazole 500mg (30 tablets); and 8) Ondansetron 4mg (6 tablets).

6. Another product was a "COVID Kit" including: 1) Hydroxychloroquine 200mg (20 tablets); 2) Azithromycin 250mg (12 tablets); 3) Budesonide .5mg (10 vials); and 4) Ivermectin 12mg (25 capsules).

7. Each prescription transmitted to Partell Pharmacy only indicated that the pharmacy was to dispense an "Emergency Kit" or "COVID Kit" to the patient – the drugs in each kit were not identified on the prescription.

8. When a practitioner associated with TWC prescribed either of the two kits, Partell Pharmacy staff used a mutually agreed upon "pharmacy script" template that specified the drugs to be included in each kit.

9. Partell Pharmacy dispensed at least 512 prescriptions issued for an "Emergency Kit" or "COVID Kit" under this scheme.

10. Partell Pharmacy regularly substituted Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without consulting the prescribing practitioner, and continued billing TWC for the cost of Budesonide while substituting cheaper medications.

11. None of the counseling materials for each kit included any information on Medrol DosePaks or Albuterol. No further action was taken by Partell Pharmacy, Seik or Whitehouse to correct the counseling materials or provide any information regarding the substituted medications.

APPLICABLE LAW

12. A prescription must contain in pertinent part "[t]he name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled." NRS 639.2353(2)(d). A prescription must be written in such a manner that any registered pharmacist would be able to dispense it. NRS 639.2353(4).

13. Billing for the cost of a prescription drug while substituting cheaper medications constitutes fraud and is a felony offense. 18 U.S.C. § 1347; NRS 629.071; NRS 686A.2815.

14. A pharmacist shall provide medication counseling to a patient when dispensing a prescription and a pharmacy shall maintain documentation of medication counseling in conformance with NRS 639.266, NAC 639.707 and NAC 639.708.

15. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug prescribed, unless the express permission of the prescriber is obtained, constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(b) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

16. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

17. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

18. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

19. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(15); NRS 639.220(1).

21. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employment. NAC 639.945(3).

COUNT ONE
Violations of State Law – Dispensing Invalid Prescriptions

22. By dispensing at least 512 invalid prescriptions issued for an "Emergency Kit" or "COVID Kit" for which the drugs in each kit were not identified on the prescription, as alleged herein, Respondents Partell Pharmacy, Seik and Whitehouse violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.2353(2)(d) and (4), and are subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO
Unprofessional Conduct - Dispensing a Different Drug Without Permission

23. By substituting Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner, as alleged in Paragraph 9 herein, Respondents Partell Pharmacy, Seik and Whitehouse engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(b), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT THREE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

24. By substituting Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner, as alleged in Paragraph 10 herein, Respondents Partell Pharmacy, Seik and Whitehouse were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT FOUR
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

25. By their conduct as alleged herein, Respondents Partell Pharmacy, Seik and Whitehouse have performed their duties as licensees/registrants in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT FIVE
Violations of State Law – Failure to Provide Counseling to Patient for Substituted Medications

26. By failing to correct the counseling materials for each kit to include the necessary information on Medrol DosePaks or Albuterol or to otherwise provide any counseling regarding the substituted medications, as alleged in Paragraph 11 herein, Respondents Partell Pharmacy, Seik and Whitehouse violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.266, NAC 639.707 and/or NAC 639.708, and are subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT SIX
Violations of State Law – Fraudulent Billing Practices

27. By billing TWC for the cost of Budesonide while substituting cheaper medications, as alleged in Paragraph 10 herein, Respondents Partell Pharmacy, Seik and Whitehouse engaged in fraudulent billing practices and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1347, NRS 629.071 and/or NRS 686A.2815, and are subject to discipline pursuant to NRS 639.210(11), (12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and licenses of these Respondents.

DATED this 3rd day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ROBERT SEIK, RPH,** **Certificate of Registration No. 13574,** **Respondent.**	**Case No. 23-429-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of FEBRUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **ROBERT SEIK, RPH,** **Certificate of Registration No. 13574** **Respondent.**	**Case No. 23-429-RPH-A-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

ROBERT SEIK, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 3rd day of February 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave #101
Las Vegas, NV 89119

Robert Seik
5835 S Eastern Ave #101
Las Vegas, NV 89119

Robert Seik
[redacted]
Las Vegas, NV [redacted]

David Whitehouse
5835 S Eastern Ave #101
Las Vegas, NV 89119

David Whitehouse
[redacted]
Lakeport, CA [redacted]

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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FILED
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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **PARTELL SPECIALTY PHARMACY, Pharmacy License No. PH02028,** **v.** **ROBERT SEIK, RPH, Certificate of Registration No. 13574, and** **DAVID WHITEHOUSE, RPH, Certificate of Registration No. 13635,** **Respondents.**	**Case Nos. 23-429-PH-S** **23-429-RPH-A-S** **23-429-RPH-B-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter and these respondents because at the time of the events alleged herein, Respondent Robert Seik (Seik), Certificate of Registration No. 13574, and Respondent David Whitehouse (Whitehouse), Certificate of Registration No. 13635, were pharmacists registered with the Board, and Respondent Partell Pharmacy (Partell Pharmacy), Pharmacy License No. PH02028, was a pharmacy licensed by the Board.

FACTUAL ALLEGATIONS

2. Seik owns Partell Pharmacy and served as the managing pharmacist of Partell Pharmacy from August 21, 2023, to September 19, 2023, and from January 6, 2024, to present.

3. Whitehouse served as the managing pharmacist of Partell Pharmacy from September 20, 2023, to January 5, 2024.

4. Partell Pharmacy contracted with The Wellness Company (TWC), based in Boca Raton, Florida, to dispense various prescription drug products to TWC patients.

5. One product was an "Emergency Kit" including: 1) Amoxicillin-Clavulanate 875-125mg (28 tablets); 2) Azithromycin 250mg (12 tablets); 3) Bactrim DS 800mg-160mg (28 tablets); 4) Doxycycline Hyclate 100mg (60 capsules); 5) Fluconazole 150mg (2 tablets); 6) Ivermectin 18mg (7 capsules); 7) Metronidazole 500mg (30 tablets); and 8) Ondansetron 4mg (6 tablets).

6. Another product was a "COVID Kit" including: 1) Hydroxychloroquine 200mg (20 tablets); 2) Azithromycin 250mg (12 tablets); 3) Budesonide .5mg (10 vials); and 4) Ivermectin 12mg (25 capsules).

7. Each prescription transmitted to Partell Pharmacy only indicated that the pharmacy was to dispense an "Emergency Kit" or "COVID Kit" to the patient – the drugs in each kit were not identified on the prescription.

8. When a practitioner associated with TWC prescribed either of the two kits, Partell Pharmacy staff used a mutually agreed upon "pharmacy script" template that specified the drugs to be included in each kit.

9. Partell Pharmacy dispensed at least 512 prescriptions issued for an "Emergency Kit" or "COVID Kit" under this scheme.

10. Partell Pharmacy regularly substituted Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without consulting the prescribing practitioner, and continued billing TWC for the cost of Budesonide while substituting cheaper medications.

11. None of the counseling materials for each kit included any information on Medrol DosePaks or Albuterol. No further action was taken by Partell Pharmacy, Seik or Whitehouse to correct the counseling materials or provide any information regarding the substituted medications.

APPLICABLE LAW

12. A prescription must contain in pertinent part "[t]he name, strength and quantity of the drug prescribed and the number of days that the drug is to be used, beginning on the day on which the prescription is filled." NRS 639.2353(2)(d). A prescription must be written in such a manner that any registered pharmacist would be able to dispense it. NRS 639.2353(4).

13. Billing for the cost of a prescription drug while substituting cheaper medications constitutes fraud and is a felony offense. 18 U.S.C. § 1347; NRS 629.071; NRS 686A.2815.

14. A pharmacist shall provide medication counseling to a patient when dispensing a prescription and a pharmacy shall maintain documentation of medication counseling in conformance with NRS 639.266, NAC 639.707 and NAC 639.708.

15. Dispensing or causing to be dispensed a different drug or brand of drug in place of the drug or brand of drug prescribed, unless the express permission of the prescriber is obtained, constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(b) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

16. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

17. Performing any duties as the holder of a registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

18. The Board may suspend or revoke a license if the holder has violated any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs. NRS 639.210(11).

19. The Board may suspend or revoke a license if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

20. A managing pharmacist is responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. NRS 639.210(15); NRS 639.220(1).

21. Any violation of any of the provisions of NRS Chapter 639 or NAC Chapter 639 by personnel of the pharmacy is cause for the suspension or revocation of the license of the pharmacy by the Board. NRS 639.230(5). Further, the owner of any business or facility licensed, certified or registered by the Board is responsible for the acts of all personnel in his or her employment. NAC 639.945(3).

COUNT ONE
Violations of State Law – Dispensing Invalid Prescriptions

22. By dispensing at least 512 invalid prescriptions issued for an "Emergency Kit" or "COVID Kit" for which the drugs in each kit were not identified on the prescription, as alleged herein, Respondents Partell Pharmacy, Seik and Whitehouse violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.2353(2)(d) and (4), and are subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT TWO
Unprofessional Conduct - Dispensing a Different Drug Without Permission

23. By substituting Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner, as alleged in Paragraph 9 herein, Respondents Partell Pharmacy, Seik and Whitehouse engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(b), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT THREE
Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

24. By substituting Budesonide in the "COVID Kit" with a Medrol DosePak and Albuterol without the knowledge or consent of the prescribing practitioner, as alleged in Paragraph 10 herein, Respondents Partell Pharmacy, Seik and Whitehouse were party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT FOUR
Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

25. By their conduct as alleged herein, Respondents Partell Pharmacy, Seik and Whitehouse have performed their duties as licensees/registrants in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and are subject to discipline pursuant to NRS 639.210(4), NRS 639.230(5) and/or NAC 639.945(3).

COUNT FIVE
Violations of State Law – Failure to Provide Counseling to Patient for Substituted Medications

26. By failing to correct the counseling materials for each kit to include the necessary information on Medrol DosePaks or Albuterol or to otherwise provide any counseling regarding the substituted medications, as alleged in Paragraph 11 herein, Respondents Partell Pharmacy, Seik and Whitehouse violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.266, NAC 639.707 and/or NAC 639.708, and are subject to discipline pursuant to NRS 639.210(12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

COUNT SIX
Violations of State Law – Fraudulent Billing Practices

27. By billing TWC for the cost of Budesonide while substituting cheaper medications, as alleged in Paragraph 10 herein, Respondents Partell Pharmacy, Seik and Whitehouse engaged in fraudulent billing practices and violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1347, NRS 629.071 and/or NRS 686A.2815, and are subject to discipline pursuant to NRS 639.210(11), (12) and/or (15), NRS 639.220(1) and/or NRS 639.230(5).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificates of registration and licenses of these Respondents.

DATED this 3rd day of February 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID WHITEHOUSE, RPH,** **Certificate of Registration No. 13635,** **Respondent.**	**Case No. 23-429-RPH-A-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, March 5, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **bkandt@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 3rd day of FEBRUARY 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **DAVID WHITEHOUSE, RPH,** **Certificate of Registration No. 13635,** **Respondent.**	**Case No. 23-429-RPH-B-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

DAVID WHITEHOUSE, RPH

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 3rd day of February 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Partell Specialty Pharmacy
5835 S Eastern Ave #101
Las Vegas, NV 89119

Robert Seik
5835 S Eastern Ave #101
Las Vegas, NV 89119

Robert Seik
[redacted]
Las Vegas, NV [redacted]

David Whitehouse
5835 S Eastern Ave #101
Las Vegas, NV 89119

David Whitehouse
[redacted]
Lakeport, CA [redacted]

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL BROGAN, RPh,** **Certificate of Registration No. 18710,** **Respondent.**	**Case No. 23-183-RPH-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Respondent Michael Brogan, RPh ("Respondent") Certificate of Registration No. 18710, was a pharmacist registered with the Board.

FACTUAL ALLEGATIONS

2. Respondent failed to submit the 30 required continuing education (CE) hours required by Nevada law by both the October 31, 2019, and October 31, 2021, biennial registration renewal deadlines.

3. The Board performed an audit on Respondent's continuing education requirements and found that he failed his 2019 and 2021 audits. For 2019, Respondent was 3 credits short and had not completed his law CE requirement. For 2021, Respondent was 0.5 credits short and had not completed all his general CE requirement.

4. The Board alerted Respondent via email on September 2, 2022, that he had failed his CE audits. Respondent replied on September 30, 2022, and admitted that he was short 0.5 credits for the November 1, 2019, to October 31, 2021, biennial registration period. Respondent

failed to submit the full required 30 CE hours for each deficient audit cycle by the September 31, 2022 deadline.

APPLICABLE LAW

5. Performing any duties as a license or registration holder in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license issued by the Board. NRS 639.210(4).

6. The Board may suspend or revoke a license or registration if the holder has violated any law or regulation relating to drugs, the manufacture or distribution of drugs or the practice of pharmacy. NRS 639.210(12).

7. "The Board shall adopt regulations necessary to carry out the purposes of NRS 639.2171 to 639.2176, inclusive, which must include the methods of determining accredited programs, the number of hours of continuing professional education necessary to constitute a continuing education unit, the number of units required of each pharmacist during the period for which a certificate is issued and such other regulations consistent with NRS 639.2171 to 639.2176, inclusive, as the Board may determine to be necessary." NRS 639.2176.

8. "The Board will not issue a certificate as a registered pharmacist to any person pursuant to NRS 639 .127, or renew the certificate of any registered pharmacist, until the applicant submits proof to the Board of receipt of 30 continuing education units within the biennium immediately preceding the current renewal period." NAC 639.330(1).

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COUNT ONE

Unprofessional Conduct – Failure to Comply with Continuing Education Requirements

9. Respondent failed to provide proof to the Board that he completed his CE hours for two audit cycles/biennial registration renewal periods. NRS 639.2174; NAC 639.330(1); NRS 639.100(1)(b).

10. By these actions, Respondent performed his duties as the holder of a pharmacist registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct as defined in NAC 639.945(i) and is subject to discipline pursuant to NRS 639.210(4).

COUNT TWO

Violations of State Law – Failure to Comply with Continuing Education Requirements

11. By failing to provide proof to the Board that he completed his CE hours for two audit cycles/biennial registration renewal periods, Respondent violated NRS 639.100(1)(b), NRS 639.2174 and/or NAC 639.330(1) and is subject to discipline pursuant to NRS 639.210(12).

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to Respondent's Certificate of Registration No. 18710.

Signed this 29th day of April 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL BROGAN, RPh,** **Certificate of Registration No. 18710,** **Respondent.**	**Case No. 23-183-RPH-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 17th day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MICHAEL BROGAN, RPh,** **Certificate of Registration No. 18710,** **Respondent.**	**Case No. 23-183-RPH-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

MICHAEL BROGAN, RPh

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Michael Brogan, RPh
[redacted]
Las Vegas, NV [redacted]

Meta Pharmacy Services
c/o Michael Brogan, RPh
8352 W Warm Springs Rd #120
Las Vegas, NV 89103

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Gary DeShazo, DO,** **Certificate of Registration No. CS03830,** **Respondent.**	**Case No. 23-450-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter because, at the time of the events alleged herein, Robert DeShazo, DO ("Respondent") held a registration issued by the Board, Certificate of Registration No. CS03830.

FACTUAL ALLEGATIONS

2. Respondent was licensed by the Nevada State Board of Osteopathic Medicine (Osteopathic Board) as an osteopathic physician and surgeon until April 11, 2023.

3. Pursuant to a Settlement Agreement and Order in the Osteopathic Board's Case No. PB1407002 (Order), approved on April 11, 2023, Respondent voluntarily surrendered his license with the Osteopathic Board. The Order included a provision that Respondent shall not apply for a new license or reinstatement until at least five years from the effective date of the Order.

4. On or about November 8, 2023, after learning that Respondent had voluntarily suspended his license, the Board placed Respondent's certificate of registration to prescribe controlled substances on inactive status. That Board did so pursuant to pursuant to NRS 639.2107.

5. According to the terms of the Order, Respondent admitted that his prescribing of controlled substances was in violation of NRS 639.2391-639.23914 and was below the standard of care either for a family medicine and general practice physician or for a pain management physician, thus constituting violations of NRS 633.511(a) and NRS 633.511(1)(w) and NRS 633.131(1)(f)(2) and NRS 633.131.(1)(g).

6. Furthermore, the Order stated that expert physicians reviewed documents provided by Osteopathic Board staff and indicated concerns that Respondent was prescribing opioids without compliance with NRS 639.2391-639.23914, that Respondent was prescribing opioids in conjunction with benzodiazepines, and that Respondent's prescribing was below the standard of care for a reasonably prudent osteopathic physician practicing either family medicine and general practice physician and practicing pain management.

7. The Order was supported by documentation, including the expert opinions, PMP reports, and patient treatment agreements.

APPLICABLE LAW

8. The Board may revoke or suspend the registration of any practitioner who has violated, attempted to violate, assisted, or abetted in the violation of, or conspired to violate any of the provisions of NRS chapter 639 or any state or federal law or regulation relating to drugs, the manufacture or distribution of drugs, or the practice of pharmacy. *See* NRS 639.210(12); NRS 453.231(1)(b); NRS 453.236(1)(e).

9. A prescription for a controlled substance may be issued only for a legitimate medical purpose and in conformance with the requirements of NRS 639.2391-.23914, *inclusive*.

10. .. The Board may revoke or suspend the registration of any practitioner who is guilty of unprofessional conduct or conduct contrary to the public interest. *See* NRS 639.210(4); NRS 453.231(1)(h).

11. A practitioner's conduct is deemed to be unprofessional and contrary to the public interest if the practitioner performs "any of his or her duties as the holder of a license, certificate

or registration issued by the Board . . . in an incompetent, unskillful or negligent manner." NAC 639.945(1)(i).

12. The Board may revoke or suspend the registration of any practitioner who "[h]as had a certificate, license or permit suspended or revoked in another state on grounds which would cause suspension or revocation of a certificate, license or permit in this State." NRS 639.210(14).

COUNT ONE

Violations of State Law relating to Prescriptions for Certain Controlled Substances

13. As alleged above, by violating NRS Chapter 633 as detailed in the Osteopathic Board's Order in Case No. PB1407002, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.2391-.23914, *inclusive*, and is subject to discipline pursuant to NRS 639.210(12) and/or NRS 639.23916(3)(b).

COUNT TWO

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

14. As alleged above, by violating NRS Chapter 633 as detailed in the Osteopathic Board's Order in Case No. PB14070021, and by violating NRS 639.2391-.23914, *inclusive*, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1)(e), NRS 639.210(4) and/or NRS 639.23916(3)(b).

COUNT THREE

Commission of Acts that Render Registration Inconsistent with the Public Interest

15. As alleged above, by violating NRS Chapter 633 as detailed in the Osteopathic Board's Order in Case No. PB14070021, and by violating NRS 639.2391-.23914, *inclusive*, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1)(e).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of Gary DeShazo.

DATED this 23rd day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Gary DeShazo, DO,** **Certificate of Registration No. CS03830,** **Respondent.**	**Case No. 23-450-CS-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 23rd day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **Gary DeShazo, DO,** **Certificate of Registration No. CS03830,** **Respondent.**	**Case No. 23-450-CS-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

Gary DeShazo, DO

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 23rd day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Gary DeShazo
[redacted]
Las Vegas, NV [redacted]

Gary DeShazo
[redacted]
Las Vegas, NV [redacted]

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Gary DeShazo
[redacted]
White Plains, MO [redacted]

JESSETTE PHAYNARIKHONE
ADMINISTRATIVE ASSISTANT,
BOARD COORDINATOR I

FILED
MAY 15 2025
NEVADA STATE BOARD
OF PHARMACY

From: Gary Deshazo
To: Laura Tucker
Subject: Re: Nevada State Board of Pharmacy v. Gary DeShazo, DO - Case No. 23-450-CS-S
Date: Thursday, May 15, 2025 10:09:11 AM

WARNING - This email originated from outside the State of Nevada. Exercise caution when opening attachments or clicking links, especially from unknown senders.

Laura Tucker:

I appreciate you reaching out to me and for the opportunity to submit my response and concerns to you. I am not physically able to travel 1500 miles from Missouri to Las Vegas on June 4. I suffered a left brain infarction on August 15, 2024, that left me with speech impairment (dysarthria) and right sided weakness (hemiparesis). I also was diagnoses with an aggressive form of prostate cancer in November 2024.Please allow me to submit my Answer and Notice of Defense:

1. J. David Wuest, R.Ph., executive secretary Nevada State Board of Pharmacy,listed charges of prosecution similar to those disciplined by the Nevada State Board of Osteopathic Medicine-case number PB1407002 that was settled on April 11, 2023. This disciplinary action was reported to the National Practitioner Data Bank in April of 2023. Therefore, counts one, two, and three listed in the charging document were already adjudicated over two years ago. I voluntarily surrender my Federal DEA license and Nevada Controlled registration followed on November 8, 2023, I have not had an active license in Nevada since.

2. The investigation resulting in the Settlement Agreement Order PB 1407002 was prompted by a referral from the Nevada Board of Pharmacy to the Osteopathic Board. I was informed by Richard Dreitzer, general counsel for the Osteopathic Board, that the Pharmacy Board's "High Prescriber List" program surveyed my PMP and reported to the Osteopathic Board that I was in the "top ten" of prescribers of benzodiazepines in the state. This was the only reason the Osteopathic Board opened the investigation into my license. There were no patient complaints, reported adverse reactions, or malpractice issues to initiate an investigation.

3. Timeline: The Osteopathic Board began the investigation into my license during Covid in 2021 and finished in June, 2022, when Sandra Reed, ex.dir., notified me of the result and offered the Settlement Agreement. On September 23, 2022, I lost my 25 year old son to Fentanyl poisoning. I took an extended bereavement leave of absence until after Thanksgiving of 2022. Due to persistent sorrow I decided to surrender my license and retire on January 26, 2023 and moved to Missouri where all my family lives.

4. Attributes of moral character and professional competency: I served two years 1990-1992 as president of the Nevada Osteopathic Medical Association arranging continuing medical educational events and promoting osteopathic medicine in the state. I also served as a preceptor in training to numerous nurse practitioner students. Before retirement I donated my clinic to a nonprofit, Safe Harbor Medical, in order that my patients had affordable medical care in the future.

In summary, I respectfully request that the charges be dropped against me with prejudice because of the reasons listed above. To continue to prosecute me for charges listed in the charging document would be akin to Double Jeopardy. It isn't reasonable to bring these charges two years after resolution of the Settlement Agreement Order of April 11, 2023. There is no further risk to the public in that I have no license to practice or prescribe controlled substances in the state and will never again seek status to do so in Nevada. I am retired and physically disabled.

Thank you for this opportunity to defend myself:

Gary DeShazo

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FILED
APR 29 2025
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MASHAYLA COLEMAN, PT,** **Certificate of Registration No. PT16852,** **Respondent.**	**Case No. 23-505-PT-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, files the following document that will serve as both a notice of intended action under NRS 233B.127(3) and an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy ("Board") has jurisdiction over this matter and this Respondent because, at the time of the events alleged herein, Respondent Mashayla Coleman ("Respondent"), Certificate of Registration No. PT16852, was registered with the Board.

FACTUAL ALLEGATIONS

2. For approximately one and a half years until December 2020, Respondent was employed as a pharmaceutical technician at CVS Pharmacy #5144, located at 1425 W. Lake Mead Boulevard, Las Vegas, NV 89108. CVS Pharmacy #5144 has since closed.

3. On or around February 4, 2021, CVS Pharmacy #5144 sent documentation notifying the Board of the significant loss or theft of a controlled substance after an investigation produced evidence that Respondent diverted 863 Alprazolam tablets and 2,057 mg of promethazine with codeine syrup.

4. On or around December 2020, following an investigation into the theft, CVS terminated Respondent's employment and filed a police report with the Las Vegas Metropolitan Police Department against Respondent.

5. On or around November 10, 2020, CVS opened in investigation when the pharmacy manager of CVS Pharmacy #5144 discovered that the pharmacy's counts of alprazolam 2mg tablets appeared to be inconsistent.

6. On or around December 28, 2020, during an interview with CVS related to the investigation, Respondent admitted to having removed alprazolam and promethazine with codeine from the pharmacy about once or twice a month by placing the bottles of promethazine with codeine and loose tablets of alprazolam in her pocket. Respondent said that she took the bottles and tablets during her shifts on or around August 2020 until November 2020 for the purpose of selling them to pay her past due bills. Respondent provided a written statement to CVS confirming the information from the interview.

7. On December 20, 2023, during a Board investigation, Respondent confirmed the information contained in her written statement to CVS.

APPLICABLE LAW

8. The Board may revoke or suspend the registration of a registrant who has violated any provision of state or federal law relating to prescription drugs or controlled substances. NRS 639.210(12).

9. The Board may revoke or suspend the registration of a registrant who has engaged in unprofessional conduct. NRS 639.210(4). "Unprofessional conduct" includes performing or in any way being a party to any fraudulent or deceitful practice or transaction. NAC 639.945(1)(h).

10. Under Nevada law, it is unlawful for a person knowingly or intentionally to acquire or obtain or attempt to acquire or obtain possession of a dangerous drug by misrepresentation, fraud, forgery, deception, subterfuge, or alteration. NRS 454.311.

11. Under federal law, it is unlawful for a person to knowingly or intentionally possess a controlled substance unless such substance was obtained directly, or pursuant to a valid prescription or order, from a practitioner, while acting in the course of his professional practice. 21 U.S.C. § 844.

12. Supplying or diverting drugs which are legally sold in pharmacies constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(g) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

13. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(4).

14. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(11).

15. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 639.210(12).

16. It is a felony offense to acquire a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 843(a)(3); 21 U.S.C. § 846; NRS 453.331(1)(d); NRS 453.391(1).

17. It is a felony offense to possess a controlled substance except as authorized by law. 21 U.S.C. § 841(a); 21 U.S.C. § 844; 21 U.S.C. § 846; NRS 453.336(1); NRS 453.381(8)

18. It is a criminal offense to use a controlled substance except as authorized by law. 42 U.S.C. § 12210; NRS 453.411(1).

19. The Drug Enforcement Agency lists alprazolam as a Schedule IV controlled substance. 21 U.S.C. § 1308.14(c)(2). The Board also recognizes alprazolam as a Schedule IV controlled substance under Nevada law. NAC 453.540.

20. Because promethazine with codeine contains codeine in combination with one or more active, nonnarcotic ingredients in sufficient proportion to confer upon the compound, mixture, or preparation valuable medicinal qualities other than those possessed by narcotic drugs alone, the Drug Enforcement Divisions lists promethazine with codeine as a Schedule V controlled substance. 21 U.S.C. § 1308.15(c). The Board also recognizes promethazine with codeine as a Schedule V controlled substance under Nevada law because it contains codeine and one or more nonnarcotic active medicinal ingredients in sufficient proportion to confer upon the compound, mixture or preparation valuable medicinal qualities other than those possessed by the narcotic drug alone. NAC 453.550(2).

COUNT ONE
Unlawful Obtaining of Controlled Substances

21. Between August and November 2020, by diverting and acquiring controlled substances as alleged herein, Respondent violated or attempted to violate 21 U.S.C. § 841(a), 21 U.S.C. § 843(a)(3), 21 U.S.C. § 846, NRS 453.331(1)(d) and/or NRS 453.391(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT TWO
Unlawful Possession of Controlled Substance

22. Between August and November 2020, by diverting and possessing controlled substances as alleged herein, Respondent violated or attempted to violate 21 U.S.C. § 841(a), 21 U.S.C. § 844, 21 U.S.C. § 846, NRS 453.336(1), NRS 453.381(8) and/or NRS 454.316(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT THREE
Unlawful Use of Controlled Substances

23. Between August and November 2020, by diverting and using controlled substances as alleged herein, Respondent violated or attempted to violate 42 U.S.C. § 12210 and/or NRS 453.411(1), and is subject to discipline pursuant to NRS 639.210(11) and/or (12).

COUNT FOUR
Unprofessional Conduct – Diversion

24. Between August and November 2020, by diverting controlled substances as alleged herein, Respondent engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(g) and is subject to discipline pursuant to NRS 639.210(4).

COUNT FIVE
Unprofessional (Deceitful) Conduct

Between August and November 2020, by diverting controlled substances as alleged herein, Respondent was a party to a fraudulent or deceitful practice or transaction, engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 639.210(4).WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to Respondent's Certificate of Registration No. PT16852.

WHEREFORE it is requested that the Nevada State Board of Pharmacy impose appropriate discipline with respect to Respondent's Certificate of Registration No. PT16852.

DATED this 29th day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). You have the right to a hearing before the Board to answer the Notice of Intended Action and Accusation and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3). The hearing shall be conducted pursuant to NRS 639.241 through NRS 639.258. To be entitled to a hearing, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, within twenty (20) days of your receipt of this Notice of Intended Action and Accusation. NRS 622A.320; NRS 639.243. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MASHAYLA COLEMAN, PT,** **Certificate of Registration No. PT16852,** **Respondent.**	**Case No. 23-505-PT-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

1. Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy ("Board") by NRS 639.241 to NRS 639.2576, inclusive, and NRS chapter 233B and 622A, a Notice of Intended Action and Accusation ("Accusation") has been filed with the Board by the Petitioner, J. David Wuest, Executive Secretary for the Board, alleging grounds for imposition of disciplinary action by the Board against you.

2. **A hearing on the Accusation filed against you has been scheduled before the Board for Wednesday, June 4, 2025, at 9:00 AM PST, or soon thereafter at the following location:**

Hilton Garden Inn Las Vegas Strip South
7830 S. Las Vegas Blvd
Las Vegas, NV 89123

3. At the hearing, you have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 233B.127(3). At the hearing, you are entitled to present argument and evidence including witness testimony on all issues involved, either personally or through counsel. NRS 233B.121; NRS 233B.127(3); NRS 622A.300(1) and (3); NRS 639.241; NRS 639.246. To do so, you must complete, and file two (2) copies of the Answer and Notice of Defense served herewith, within twenty (20) days of your receipt of this Statement and Notice, and the Accusation. NRS 622A.320; NRS 639.243.

You may file your answer electronically by emailing a copy of your Answer and Notice of Defense to the Board's coordinating staff and its prosecuting attorney at the email addresses below:

TeamBC@Pharmacy.nv.gov and **L.tucker@pharmacy.nv.gov**

Alternatively, you may file your Answer and Notice of Defense by mailing two (2) copies to Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521. Upon receipt of your Answer and Notice of Defense, a file-stamped copy will be returned to you.

4. Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

5. Your failure to timely file an Answer and Notice of Defense constitutes an admission of the charges and waiver of the right to a hearing. NRS 639.244. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350.

DATED this 24th day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **MASHAYLA COLEMAN, PT,** **Certificate of Registration No. PT16852,** **Respondent.**	**Case No. 23-505-PT-S** **ANSWER AND NOTICE OF DEFENSE**

Respondent above named, in answer to the Notice of Intended Action and Accusation filed in the above-entitled matter before the Nevada State Board of Pharmacy, declares:

1. That his/her objection to the Notice of Intended Action and Accusation as being incomplete or failing to state clearly the charges against him/her, is hereby interposed on the following grounds: (State specific objections or insert "none").

2. That, in answer to the Notice of Intended Action and Accusation, he/she admits, denies and alleges as follows:

I hereby declare, under penalty of perjury, that the foregoing Answer and Notice of Defense, and all facts therein stated, are true and correct to the best of my knowledge.

DATED this _____ day of _____ 2025.

_____

MASHAYLA COLEMAN, PT

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 29th day of April 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Mashayla Coleman, PT
[redacted]
Las Vegas, NV [redacted]

[redacted]
Las Vegas, NV [redacted]

Darlene Nases
DARLENE NASES
BOARD COORDINATOR

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **JULIO A. OROZCO,** **Respondent.**	**Case No. 24-375-MP-S** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED, PLEASE TAKE NOTICE THAT:

On or about December 27, 2024, pursuant to NRS 639.2895, the Nevada State Board of Pharmacy (the "Board") imposed upon the above-named Respondent, Julio A. Orozco ("Respondent"), a fine of One Thousand and No/100s Dollars ($1,000.00). By letter received February 10, 2025, Respondent requested a hearing before the Board. For purposes of said hearing, it is alleged that:

FACTUAL ALLEGATIONS

1. At all times mentioned herein, Respondent was the owner and manager of LV Med Brace, LLC, a Nevada limited-liability company doing business as FutureCare ("FutureCare").

2. In May 2023, on behalf of Future Care, Respondent applied to the Board for a license to conduct business as a medical products provider.

3. Respondent applied to the Board to serve as FutureCare's administrator.

4. On August 3, 2023, the Board approved the above applications, thereby authorizing FutureCare to conduct business as a medical products provider with Respondent as its administrator.

5. From and after August 3, 2023, Respondent served as FutureCare's administrator. As used herein, "administrator" refers to a person described in NAC 639.694.

6. On November 11, 2024, Board Inspector Leo Basch contacted Respondent in anticipation of performing an inspection of FutureCare's facility, located at 222 S. Rainbow Road #216 in Las Vegas, Nevada.

7. Respondent informed Inspector Basch that he had sold the business of FutureCare in November 2023.

8. Respondent refused to produce records for Inspector Basch related to the operation and alleged sale of the business of FutureCare.

9. Respondent refused to speak with Board Investigator Kenneth Scheuber regarding the operation and alleged sale of the business of FutureCare.

10. During a telephone conversation, Respondent told Investigator Scheuber to speak with his attorney, but then he hung up the telephone without providing the alleged attorney's name or contact information.

11. Respondent refused to return telephone calls and respond to email correspondence from the Board's representatives.

12. Respondent refused to provide credible information regarding the identity and whereabouts of the person to whom he allegedly sold the business of FutureCare.

13. Respondent refused to provide credible information regarding the identity and whereabouts of his alleged attorney.

14. Respondent failed to maintain the records described in NAC 639.6949.

15. In light of the foregoing, Board staff cited Respondent for having violated NAC 639.695 and NAC 639.6947.

16. By letter received February 10, 2025, Respondent requested a hearing before the Board. Respondent's request was not timely submitted to the Board.

17. To date, Respondent has not provided the Board's representatives with information or records concerning the operation and alleged sale of FutureCare.

APPLICABLE LAW

18. Any person who engages in business as a medical products provider must obtain a license from the Board. NRS 639.233; NAC 639.6942. Such a license is non-transferable. NAC 639.6942(4).

19. "Medical products provider" means a person licensed pursuant to NAC 639.693 to 639.6958, inclusive, to sell, lease or otherwise provide medical products to a consumer in Nevada.

20. "Medical products" includes medical devices, equipment, supplies and gases intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease. NAC 639.6935.

21. A medical products provider must employ an administrator who has the qualifications set forth at NAC 639.694.

22. The owner of a medical products provider is responsible for the acts of his or her administrator and employees.

23. A medical products provider must "ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules." NAC 639.694(2); NAC 639.6941(2).

24. A medical products provider must maintain records related to the operation of the business and must produce such records at the request of any person conducting an inspection or investigation on behalf of the Board. NAC 639.695.

25. A medical products provider is subject to discipline for having performed his or her duties in an incompetent, unskillful or negligent manner. NRS 639.210(4); NAC 639.945(1)(i).

26. A medical products provider is subject to discipline for having failed to comply with any regulation adopted by the Board. NRS 639.2895; NRS 639.100(1)(b).

27. To appeal a citation, the recipient must submit a written request for a hearing to the Board not later than 30 days after the date of issuance of the citation. NRS 639.2895(2).

COUNT ONE
(Failure to Maintain and/or Produce Records)

28. As alleged above, Respondent refused to produce records and to answer questions concerning the operation and alleged sale of FutureCare.

29. Respondent failed to maintain the records described in NAC 639.6949.

30. As the owner, manager, and administrator of FutureCare, Respondent had a duty to maintain and produce records, and to answer questions concerning the operation and alleged sale of FutureCare.

31. By refusing to produce records and answer questions, Respondent violated NAC 639.695.

32. By failing to maintain the records described in NAC 639.6949, Respondent performed his duties in an incompetent, unskillful or negligent manner.

33. For any one or more of the acts or omissions stated above, Respondent is subject to an administrative fine not to exceed $5,000.00. NRS 639.2895.

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2); NRS 233B.127(3). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.127(3); NRS 622A.300(1) and (3). If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision. NRS 622A.350. A regulatory body may recover from a person reasonable attorney's fees and costs that are incurred by the regulatory body as a part of its

investigative, administrative, and disciplinary proceedings against the person if the regulatory body finds that the person has violated any provision of this title. NRS 622.400(1).

The Board has scheduled your hearing on this matter for June 4, 2025, at 9:00 a.m. or soon thereafter. The hearing will occur at the at the Hilton Garden Inn, 7830 South Las Vegas Boulevard, Las Vegas, Nevada.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. You may request and the Board may at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session. NRS 241.030 and NRS 241.033.

DATED this 21st day of APRIL 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 22nd day of April, 2025, I personally served a true and correct copy of the foregoing **Statement to the Respondent and Notice of Hearing** by placing a copy in the United States Mail, postage prepaid, addressed to the following:

FutureCare
222 S Rainbow Blvd #216
Las Vegas, NV 89145

Darlene Nases
Darlene Nases
Board Coordinator

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **RXEED,** **Respondent.**	**Case No. 24-118-WH-O** **STATEMENT TO THE RESPONDENT AND NOTICE OF HEARING**

TO THE RESPONDENT ABOVE-NAMED: PLEASE TAKE NOTICE THAT:

Pursuant to the authority and jurisdiction conferred upon the Nevada State Board of Pharmacy (Board) by NRS 639.2895 and NRS 233B.121-.126, *inclusive*, on or about October 10, 2024, an Order to Cease-and-Desist/Citation and Fine was served upon Respondent Rxeed, alleging violations of Nevada law as set forth herein.

FACTUAL ALLEGATIONS

1. On or about April 10, 2024, during an annual inspection of First Choice Pharmacy, License No. PH04395, located in Las Vegas, a Board Inspector found supplier invoices and shipping confirmations demonstrating that Rxeed is soliciting and brokering the sales of prescription drug products between pharmacies in Nevada.

2. Rxeed, located in Illinois, is not licensed to engage in business as a wholesaler in Nevada.

3. Rxeed's website, located at www.rxeed.com, represents in pertinent part that:

> Rxeed is a secure online marketplace that brings together independent pharmacies, healthcare providers, and drug wholesalers. . . . Our platform provides a DSCSA compliant method for buying and selling small quantities of non-controlled, non-expired, FDA-approved prescription medications. We also offer a discounted wholesale marketplace . . .

4. On or about November 10, 2024, Rxeed appealed the Citation and Fine and requested a hearing before the Board.

APPLICABLE LAW

5. Any person who engages in the business of wholesale distribution or furnishing controlled substances, poisons, drugs, devices or appliances that are restricted by federal law to sale by or on the order of a physician to any person located within this State shall obtain a license pursuant to the provisions of NRS Chapter 639. NRS 639.100(3); NRS 639.233(1).

6. Every wholesale distributor who engages in wholesale distributions of prescription drugs in interstate commerce must be licensed by the state into which the drug is distributed. 21 U.S.C. § 353(e)(1)(A); 21 CFR § 205.4.

7. A person is "engaged in the business of furnishing" if the person solicits or accepts orders for drugs or devices whose sale in this State are restricted by chapters 453, 454 and/or 639 of the Nevada Revised Statutes. NRS 639.233(2).

8. "Wholesaler" means a wholesale distributor as defined by 21 CFR § 205.3(g), including brokers. NRS 639.016.

9. Wholesalers are subject to the licensing requirements specified in NRS 639.500, NRS 639.505, and NAC 639.593-5938, *inclusive*. Licensing of wholesalers is also subject to the requirements of federal law. 21 U.S.C. § 353(e)(1)(A); 21 CFR Part 205.

10. Engaging in the business of wholesale distribution without a license is a felony. NRS 639.100(2).

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COUNT ONE

Violation of Federal and State Law – Unlicensed Wholesale Distribution

11. By soliciting and brokering the sales of prescription drug products between pharmacies in Nevada, Rxeed violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 639.100(1), NRS 639.233(1) and/or 21 U.S.C. § 353(e)(1)(A) and 21 CFR Part 205.

NOTICE TO RESPONDENT

You have the right to show the Nevada State Board of Pharmacy that your conduct, as alleged above, complies with all lawful requirements. NRS 639.2895(2). You have the right to a hearing before the Board to answer the allegations and present evidence and argument on all issues involved, either personally or through counsel. NRS 233B.121. If you fail to appear at the hearing and the Board finds that you were given sufficient legal notice of the hearing, the Board may accept the allegations as true and may proceed to consider the case and render a decision.

The Board has scheduled your hearing on this matter for Wednesday, March 5, at 9:00 a.m. or soon thereafter. The hearing will occur at Hilton Garden Inn, 7830 S. Las Vegas Blvd., Las Vegas, Nevada 89123.

Pursuant to NRS 241.033 and 241.034, please be advised that the hearing is a public meeting, and the Board may, without further notice, take administrative action against you if the Board determines that such administrative action is warranted after considering your character, alleged misconduct, professional competence, or physical or mental health. The Board at its discretion may go into closed session to consider your character, alleged misconduct, professional competence, or physical or mental health. You may attend any closed session, have an attorney or other representative of your choosing present during any closed session, and

present written evidence, provide testimony, and present witnesses relating to your character, alleged misconduct, professional competence, or physical or mental health during any closed session.

DATED this 14th day of January 2025.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 13th day of January 2025, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

RXEED
10062 190th Place, Ste 205
Moken IL 60448

RXEED
9426 Corsair Road
Frankfort, IL 60423

Darlene Nases

DARLENE NASES
BOARD COORDINATOR

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **FINDINGS OF FACT, CONCLUSIONS OF LAW AND ORDER**

This matter came before the Nevada State Board of Pharmacy (Board) at its regularly scheduled meeting on Wednesday, September 4, 2024. Brett Kandt, Esq., prosecuted the case before the Board. Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, was represented by counsel, Libo Agwara, Esq. The Board heard the case and, based on the evidence presented, the Board makes the following Findings of Fact, Conclusions of Law and Order.

FINDINGS OF FACT

The Board finds that probative evidence exists in the record to establish each of the following facts by a preponderance of the evidence:

1. The Board has jurisdiction over this matter and this Respondent because, at the time of the events herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

2. Respondent pre-signed two (2) controlled substance prescriptions that were issued to patients by his staff - on February 28, 2017, for patient J.J., and on March 2, 2017, for patient D.R. - while he was engaged in overseas travel outside of the United States from February 25 to March 11, 2017.

3. Board staff incurred at least $4,268.097 in attorney's fees and recoverable costs investigating and prosecuting this administrative action. The attorney's fees are reasonable based upon legal counsel's professional qualities, the nature of this administrative enforcement action, the work performed, and the result as evidenced by this Order.

CONCLUSIONS OF LAW

Based on the forgoing findings of fact, the Board concludes as a matter of law:

1. The Board has jurisdiction over this matter and Respondent because, at the time of the events herein, Respondent held a controlled substance registration issued by the Board.

2. The applicable law in this matter is as follows:

A. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2353.

B. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

C. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

D. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

E. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or

revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

F. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

G. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

H. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

3. Respondent is GUILTY on Count One of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

4. Respondent is GUILTY on Count Two of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS 453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2353, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

5. Respondent is NOT GUILTY on Count Three of the Accusation.

6. Respondent is GUILTY on Count Four of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

7. Respondent is GUILTY on Count Five of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

8. Respondent is GUILTY on Count Six of the Accusation: By pre-signing controlled substance prescriptions that were issued to two (2) patients while he was engaged in overseas travel, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

ORDER

THEREFORE, THE BOARD HEREBY ORDERS AS FOLLOWS:

1. The certificate of registration of Respondent Festus Ebonka, APRN, Certificate of Registration No. CS23430, is revoked pursuant to NRS 453.241(1)(b). The revocation is stayed, and Respondent is placed on probation for a period of three (3) years pursuant to NRS 639.255(1)(b) subject to the following conditions:

A. Pursuant to NRS 622.400, Respondent shall pay Four Thousand Two Hundred Sixty-Eight Dollars and Ninety-Seven Cents ($4,268.97) to partially reimburse the Board

for reasonable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by due and payable by September 4, 2025;

B. Respondent shall complete two (2) hours of training from Board staff on Nevada Prescription Monitoring Program (PMP) compliance by September 4, 2025;

C. Respondent shall complete two (2) hours of continuing education (CE) on ethics by September 4, 2025; and

D. Respondent shall comply with all federal and state statutes and regulations regarding controlled substances and dangerous drugs, and have no additional charges filed against him while on probation.

Upon successful completion of probation, Respondent's Certificate of Registration No. CS23430 will be fully restored.

2. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board may lift the stay and immediately revoke Respondent's Certificate of Registration No. CS23430, and impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapters 453 and 639.

3. This Order constitutes a final decision in a contested case and a public record pursuant to NRS 639.255(5), and shall be reported to the National Practitioner Data Bank pursuant to 42 U.S.C. § 1396r–2 and 45 CFR Part 60.

4. This Order is effective immediately.

IT IS SO ORDERED.

Entered this 4th day of September, 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

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NEVADA STATE BOARD
OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** **v.** **FESTUS EBONKA, APRN,** **Certificate of Registration No. CS23430,** **Respondent.**	**Case No. 19-012-CS-S** **NOTICE OF INTENDED ACTION AND ACCUSATION**

J. David Wuest, in his official capacity as Executive Secretary of the Nevada State Board of Pharmacy, makes the following that will serve as both a notice of intended action under NRS 233B.127(3) and as an accusation under NRS 622A.300(1) and NRS 639.241.

JURISDICTION

1. The Nevada State Board of Pharmacy (Board) has jurisdiction over this matter because at the time of the events alleged herein, Respondent Festus Ebonka, APRN, held a controlled substance registration, Certificate of Registration No. CS23430, issued by the Board.

FACTUAL ALLEGATIONS

2. Respondent pre-signed controlled substance prescriptions that were issued to patients by his staff while he was engaged in overseas travel. Respondent traveled outside of the United States on the following dates: July 14, 2016 – July 25, 2016; February 25, 2017 – March 11, 2017; September 27, 2017 – October 2, 2017; December 22, 2017 – December 28, 2017; and November 9, 2018 – November 30, 2018. Prescriber records and prescriptions document one-hundred and twenty-six (126) controlled substance prescriptions authorized by Respondent during these periods.

3. Respondent caused other practitioners who treated his patients to use his National Provider Identifier (NPI) while he was outside of the country to falsely bill Medicaid and other

commercial health insurance plans for services that Respondent did not personally provide, and received reimbursement for those services.

APPLICABLE LAW

4. It is unlawful for a practitioner to prescribe a controlled substance except as authorized by law. 21 U.S.C. § 822(a)(2); 21 U.S.C. § 823(f); 21 CFR §§ 1306.03-1306.05; NRS 453.226(1); NRS 453.321(1)(a); NRS 453.381(1); NRS 639.100(1); NRS 639.235(1); NRS 639.2355.

5. Falsifying a prescription for a controlled substance and the possession of signed prescription blanks are felony offenses. 21 U.S.C. § 841(a); 21 U.S.C. § 842(a); NRS 453.331(1)(f), (h) and (i).

6. Conspiring to violate the Controlled Substances Act is a felony offense. 21 U.S.C. § 846; NRS 453.401(l)(a).

7. Medicaid fraud is a felony offense. 18 U.S.C. § 1347; 42 U.S.C.A. § 1320a-7b; NRS 422.540(1).

8. Insurance fraud is a felony offense. NRS 686A.2815; NRS 686A.291.

9. Performing or in any way being a party to any fraudulent or deceitful practice or transaction constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(h) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

10. Performing any duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner constitutes unprofessional conduct or conduct contrary to the public interest pursuant to NAC 639.945(1)(i) and is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(4).

11. Violating any provision of the Federal Food, Drug and Cosmetic Act or any other federal law or regulation relating to prescription drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(11).

12. Violating, attempting to violate, assisting or abetting in the violation of or conspiring to violate any law or regulation relating to drugs is grounds for suspension or revocation of any license or registration issued by the Board. NRS 453.236(1) and NRS 639.210(12).

13. The Board may suspend or revoke a registration issued pursuant to NRS 453.231 to prescribe or otherwise dispense a controlled substance upon a finding that the registrant has committed an act that would render registration inconsistent with the public interest. NRS 453.236(1)(e) and NRS 453.241(1).

COUNT ONE

Violation of Federal Controlled Substances Act – Issuing Fraudulent Controlled Substance Prescriptions

14. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 21 U.S.C. § 822(a)(2), 21 U.S.C. § 823(f), 21 U.S.C. § 841(a), 21 U.S.C. § 842(a), 21 U.S.C. § 846, 21 CFR § 1306.03(a)(1), 21 CFR § 1306.04(a) and/or 21 CFR § 1306.05(a), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11).

COUNT TWO

Violations of State Law – Issuing Fraudulent Controlled Substance Prescriptions

15. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in Paragraph 2 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate NRS 453.226(1), NRS 453.321(1)(a), NRS 453.331(1) (f), (h) and (i), NRS 453.381(1), NRS

453.401(l)(a), NRS 639.100(1), NRS 639.235(1) and/or NRS 639.2355, and is subject to discipline pursuant to NRS 453.236(1), NRS 453.241(1) and/or NRS 639.210(12).

COUNT THREE

Violations of Federal and State Law – Medicaid Fraud/Insurance Fraud

16. By falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent violated, attempted to violate, assisted or abetted in the violation of or conspired to violate 18 U.S.C. § 1347, 42 U.S.C.A. § 1320a-7b, NRS 422.540(1), NRS 686A.2815 and/or NRS 686A.291, and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(11) and/or (12).

COUNT FOUR

Unprofessional Conduct - Fraudulent/Deceitful Practice/Transaction

17. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent was party to a fraudulent or deceitful practice or transaction and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(h), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1) and/or NRS 639.210(4).

COUNT FIVE

Unprofessional Conduct – Incompetent, Unskillful or Negligent Performance of Duties

18. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3

herein, Respondent has performed his duties as the holder of a controlled substance registration in an incompetent, unskillful or negligent manner and engaged in unprofessional conduct and conduct contrary to the public interest as defined in NAC 639.945(1)(i), and is subject to discipline pursuant to NRS 453.236(1)(e), NRS 453.241(1), and/or NRS 639.210(4).

COUNT SIX

Commission of Acts that Render Registration Inconsistent with the Public Interest

19. By pre-signing controlled substance prescriptions that were issued to patients while he was engaged in overseas travel as alleged in paragraph 2 herein, and by falsely billing Medicaid and other commercial health insurance plans for services that Respondent did not personally provide, and receiving reimbursement for those services, as alleged in Paragraph 3 herein, Respondent has committed acts that render his registration inconsistent with the public interest and is subject to discipline pursuant to NRS 453.236(1) and NRS 453.241(1).

WHEREFORE it is requested that the Nevada State Board of Pharmacy take appropriate disciplinary action with respect to the certificate of registration of this Respondent.

Signed this 25th day of January 2024.

J. David Wuest, R.Ph., Executive Secretary
Nevada State Board of Pharmacy

8

8A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		■ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Inspire Prosthetics and Orthotics

MDEG Physical Address: 3233 W Charleston Blvd, Suite 111

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725-222-4476 Website: inspireprosthetics.com

Email: chante.hp@inspireprosthetics.com

Name of MDEG Administrator (NAC 639.694): Elden Henry-Pottinger

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8am-5pm	■ Tue: 8am-5pm	■ Wed: 8am-5pm	■ Thurs: 8am-5pm	■ Fri: 8am-5pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?	✓	
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name:	Elden Henry-Pottinger	Credentials:	BOCPO	%:	25
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: Inspire Prosthetics and Orthotics

Mailing Address: 3233 W Charleston Blvd, Suite 111

City: Las Vegas State: NV Zip: 89102

Telephone: 725-222-4476 Email: chante.hp@inspireprosthetics.com

Contact Person Name: Chante Henry-Pottinger

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Chante Henry-Pottinger

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

Date 2/20/25 2/19/25

Board Use Only	Date Received: 3/3/25	Amount: $500cc

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG INSPIRE PROSTHETICS and ORTHOTICS MDEG License # (if applicable) _____

Physical Address 3233 West Charleston Blvd. #111

City LAS VEGAS State NV Zip 89102

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 725.222.4476 Website www.inspireprosthetics.com

Licensing Company Email elden.hp@inspireprosthetics.com

Section 2: Personal Information

First ELDEN Middle RODOLFO Last HENRY-POTTINGER

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email elden.hp@inspireprosthetics.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✔	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
PACIFIC UNION COLLEGE		09/92 - 06/96	
Address	**City**	**State**	**Zip**
1 ANGWIN AVE.	ANGWIN	CA	94508
Diploma/Degree obtained, if any			
BUSINESS-PRE LAW			

School Name		From - To (MM/YY – MM/YY)	
BIRMINGHAM HIGH SCHOOL		09/88 -06/92	
Address	**City**	**State**	**Zip**
17000 HAYNES STREET	VAN NUYS	CA	91406
Diploma/Degree obtained, if any			
HIGH SCHOOL			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21 - PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
04/20 - 0421		LAS VEGAS	NV	
01/20 - 04/20		LAS VEGAS	NV	
11/14 - 01/20		NORTH LAS VEGAS	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
POP Prosthetics			09/18 - 01/25	
Business Address		**City**	**State**	**Zip**
526 SOUTH TONOPAH DRIVE #120		LAS VEGAS	NV	89106
Phone	**Title**		**Number of Employed Hours**	
702.243.7671	BOARD CERTIFIED PROSTHETIS/ORTHOTIST		14,560	
Description of Duties				
I specialize in the design, fitting, and management of prosthetic and orthotic devices for patients. Following the initial fitting, I provide comprehensive education on device usage, modifications and adjustments as needed.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✔

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

03.17.25
Date

I, ELDEN R. HENRY-POTTINGER, BOCPO, **certify that as the MDEG Administrator for**

INSPRIRE PROSTHETICS AND ORTHOTICS,

that I (initial that you have read and meet the following requirements):

1. EHP Have a high school diploma or its equivalent;
2. EHP Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. EHP Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. EHP Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ELDEN HENRY-POTTINGER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03.17.25

Date

Board Use Only	Date Received:

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/28/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Wayde Kitchens	
Scott Held Insurance Agency 5855 Avenida Encinas Ste. 145 Carlsbad CA 92008	PHONE (A/C, No, Ext): (858) 332-2220	FAX (A/C, No):
	E-MAIL ADDRESS: wayde@srhinsurance.com	
	INSURER(S) AFFORDING COVERAGE	NAIC #
	INSURER A : Property & Casualty Ins Co of Hartford	34690
INSURED Inspire Prosthetics & Orthotics LLC 3233 W CHARLESTON BLVD, Unit #110 LAS VEGAS NV 89102-1923	INSURER B : Lloyds of London	
	INSURER C :	
	INSURER D :	
	INSURER E :	
	INSURER F :	

COVERAGES **CERTIFICATE NUMBER:** **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			72SBABM8JGR	12/31/2024	12/31/2025	EACH OCCURRENCE	$ 2,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 10,000
							PERSONAL & ADV INJURY	$ 2,000,000
							GENERAL AGGREGATE	$ 4,000,000
							PRODUCTS - COMP/OP AGG	$ 4,000,000
								$
A	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] OWNED AUTOS ONLY [ ] SCHEDULED AUTOS [X] HIRED AUTOS ONLY [X] NON-OWNED AUTOS ONLY			72SBABM8JGR	12/31/2024	12/31/2025	COMBINED SINGLE LIMIT (Ea accident)	$ 2,000,000
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY Y / N ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? [ ] N / A (Mandatory in NH) If yes, describe under DESCRIPTION OF OPERATIONS below						[ ] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$
							E.L. DISEASE - EA EMPLOYEE	$
							E.L. DISEASE - POLICY LIMIT	$
B	Errors & Omissions			5171092	2/28/2025	2/28/2026	Aggregate	1,000,000
							Per Occurrence	1,000,000
							Deductible	2,500

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

Proof of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Wayde Kitchens

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SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Inspire Prosthetics and Orthotics LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 05/13/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/21/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502215458784
You may verify this certificate online at https://www.nvsilverflume.gov/home

EXHIBIT A
MEMBERS

The Members of the Company and their respective addresses, Capital Contributions, and Ownership Interests are set forth below. The Members agree to keep this Exhibit A current and updated in accordance with the terms of this Agreement, including, but not limited to, Sections 2.1, 2.3, 2.4, 7.1, 7.2, and 10.1.

Members	**Capital Contribution**	**Percentage Interest**
Elden Henry-Pottinger 5940 S Rainbow Blvd Ste 400 #639434 Las Vegas, Nevada 89118	_____	25%
Wilfredo Christie 5940 S Rainbow Blvd Ste 400 #639434 Las Vegas, Nevada 89118	_____	25%
Jennifer Daniels 5940 S Rainbow Blvd Ste 400 #639434 Las Vegas, Nevada 89118	_____	25%
Chante Henry-Pottinger 5940 S Rainbow Blvd Ste 400 #639434 Las Vegas, Nevada 89118	_____	25%

25 /.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Inspire Prosthetics and Orthotics

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3233 W Charleston Blvd, Suite 111

City: Las Vegas State: Nevada Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725-222-4476 Website: www.inspireprosthetics.com

Licensing Company Email: _____

Section 2: Personal Information

First: Chante Middle: Marie Last: Henry-Pottinger

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: chante.hp@inspireprosthetics.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Desert Pines High School		1999 - 2003	
Address	**City**	**State**	**Zip**
	Las Vegas	NV	
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Pima Medical Institute		2003-2004	
Address	**City**	**State**	**Zip**
3333 E Flamingo Road	Las Vegas	NV	
Diploma/Degree obtained, if any			
Certificate of Completion in Medical Assisting			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21 - Current	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)		City	State	
04/20 - 04/21		Las Vegas	NV	
From - To (MM/YY – MM/YY)		City	State	
03/15 - 04/20		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Inspire Prosthetics and Orthotics			01/25 - current	
Business Address		**City**	**State**	**Zip**
3233 W Charleston Blvd Suite 111		Las Vegas	NV	89102
Phone	**Title**			
725-222-4476	Director of Operations			
Description of Duties				
Day to day clinic operations				

Business Name			From - To (MM/YY – MM/YY)	
ForMotion			04/2019 - 01/25	
Business Address		**City**	**State**	**Zip**
Remote				
Phone	**Title**			
Description of Duties				
Compliance Related				

Business Name			From - To (MM/YY – MM/YY)	
Priority Health Group			2017 - 2019	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Unemployed			2015 - 2017	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
		NV	Henderson	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		City of Henderson		
Reason/Charge				
Domestic Battery				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Chante Torno				
Name of Business/Industry/Entity				

Provide explanation below:

Second Charge - Domestic Battery, NV Henderson, Clark County, City of Henderson - Chante Torno
Third Charge - Carrying a concealed weapon, pocketknife, VN, Las Vegas, Clark County, City of Las Vegas - Chante Torno

Since these incidents, I have made significant efforts to stay out of trouble and lead a responsible life. I have not had any further legal issues and have worked diligently to contribute positively to my community.

Original Signature (electronic, copies or stamps not accepted)

~~2/7/25~~ 2/19/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Chante Henry-Pottinger

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~02/05/2025~~ 2/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Chante Marie Henry-Pottinger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/19/25

Date

Subscribed and Sworn to before me this 19 day of February.

Notary Public Signature

MARIO DIAZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 19-1865-1
MY APPT. EXPIRES FEB. 25, 2027

(Seal)

Chante Henry-Pottinger
[redacted]
chante.hp@inspireprosthetics.com
[redacted]
March 25, 2025

Nevada State Board of Pharmacy
431 W Plumb Ln
Reno, NV 89509

Dear Members of the Nevada State Board of Pharmacy,

I am writing to provide an explanation of the charges listed on my arrest records from both the Las Vegas Metropolitan Police Department and the Henderson Police Department, as part of my application for a pharmacy license to open an orthotics and prosthetics clinic.

Henderson Police Department Records:

1. Arrest Date: December 19, 2010
    - Charge: Domestic Battery
    - Disposition: Fined, jail time, counseling, community service.
    - Additional Details: Due to the age of the case, I was only able to obtain a minimal amount of information from the Henderson Police Department. However, I do remember that all court requirements were met, including domestic violence classes and counseling.
2. Arrest Date: November 16, 2011
    - Charge: Domestic Battery (warrant)
    - Disposition: No further action taken.
    - Additional Details: This arrest, along with the arrests on May 18, 2012, and October 18, 2012, were all related to the same charge. Initially, I faced challenges in completing all the requirements set forth by the judge, but I eventually fulfilled all obligations.
3. Arrest Date: May 18, 2012
    - Charge: Domestic Battery (warrant)

- Disposition: No further action taken.
- Additional Details: This arrest was related to the same charge as the November 16, 2011, and October 18, 2012, arrests. The warrant was issued as a result of the challenges I faced with completing all the requirements set forth in a timely manner.

4. Arrest Date: October 18, 2012
    - Charge: Domestic Battery (warrant)
    - Disposition: No further action taken.
    - Additional Details: This arrest was related to the same charge as the November 16, 2011, and May 18, 2012, arrests. . The warrant was issued as a result of the challenges I faced with completing all the requirements set forth in a timely manner.

Las Vegas Metropolitan Police Department Records:

1. Arrest Date: November 12, 2011
    - Charge: Failure to Appear (Bench Warrant)
    - Offense: Expired License Plates
    - Disposition: No further action taken.
    - Additional Details: This arrest was due to my inability to pay a traffic ticket, which resulted in the ticket going into bench warrant status. Ultimately, this resulted in time served, and I was released.
2. Arrest Date: December 17, 2014
    - Charge 1: Carrying a Concealed Weapon Without a Permit (misdemeanor)
    - Disposition: Found guilty, fined $400.
    - Additional Details: The case (No. 14F19533X) was handled by the Las Vegas Justice Court. This charge was due to a folding pocket knife I had. I was sentenced to a suspended jail sentence of 30 days, required to stay out of trouble, complete 40 hours of community service, and forfeit the knife seized during the arrest. I successfully completed all requirements by December 8, 2015.

- Charge 2: Use/Possession of Drug Paraphernalia (misdemeanor)
- Disposition: Denied by the district attorney, and no charges were pursued.

3. Arrest Date: December 6, 2015
    - Charge: Failure to Appear (Bench Warrant)
    - Offense: Domestic Battery (1st offense, misdemeanor)
    - Disposition: Found guilty, sentenced to a fine and community service.
    - Additional Details: The case (No. 15M22413X) was handled by the Las Vegas Justice Court. I entered a plea of nolo contendere and was found guilty as charged. I was sentenced to a suspended jail sentence of 90 days, required to stay out of trouble, complete 26 domestic violence counseling sessions, and perform community service. I successfully completed all requirements by March 15, 2017.

The most recent of these arrests occurred ten years ago, demonstrating my rehabilitation and successful integration into the community. Since these incidents, I have been successful in turning my life around. I deeply regret these past incidents and have taken significant steps to address and rectify my behavior. I have completed all court-mandated requirements, including fines, community service, and counseling. Since these incidents, I have committed myself to personal growth and professional development.

I am passionate about opening an orthotics and prosthetics clinic to serve our community and provide essential healthcare services. I assure you that I have learned from my past mistakes and am dedicated to upholding the highest standards of professionalism and ethical conduct in my practice.

Thank you for considering my application. I am available to provide any additional information or clarification needed.

Sincerely,

Chante Henry-Pottinger

Chante Henry-Pottinger

CERTIFIED RECORDS CHECK

DATE: January 24, 2025

I declare under the penalty of perjury:

I am authorized to conduct a search of the criminal history records of the Las Vegas Metropolitan Police Department (LVMPD). I conducted a name search of LVMPD records for any criminal history record information relating to arrests, misdemeanor or felony convictions for **HENRY-POTTINGER, CHANTE MARIE**, DOB [redacted] Based on this search conducted on January 24, 2025, LVMPD records reflect the following information:

☒ The subject has a criminal history record with the LVMPD. See attached 2 pages.
☐ No arrests, misdemeanor or felony convictions with the LVMPD. No attachments.

Please be advised the identity of the above-named person was NOT VERIFIED by fingerprints.

For proper certification, the attached records must be attached.

I declare under penalty of perjury that the foregoing is true and correct.

KEVIN McMAHILL, *Sheriff*

M arellano

BY: Maria Arellano-Murillo P#: 20273
FOR: Jonathan Clark, Captain
Records and Fingerprint Bureau

Pursuant to Nevada Revised Statute, the Las Vegas Metropolitan Police Department is only authorized to release criminal history information from its own records. For information concerning other police departments or public agencies, contact the police department or agency directly or for complete state-wide background checks, contact the State of Nevada Central Repository at 775-684-6262.

SCOPE II - R211 ▸ Dissemination - Citizens

I HEREBY CERTIFY that this is a full true and correct copy of the original on file with the Las Vegas Metropolitan Police Department, except for the information that is privileged and confidential by law.

LVMPD CITIZENS REPORT

SCOPE RESPONSE

PERSON BASE RECORD

ID #: 2744118
NAM: CHRISTIE, CHANTE MARIE [redacted]
[redacted]
ADR: RS
[redacted]

AKA [2]

NAME	AGY	ENTRY DATE
TORNO, CHANTE MARIE	HENDERSON PD	3/25/2002
CHRISTIE, CHANTE MARIE	LAS VEGAS METRO PD	3/25/2002

ADDITIONAL DOB [1]

DOB	AGY	ENTRY DATE
[redacted]	LAS VEGAS METRO PD	3/25/2002

EVENT REPORTS [1]

TYPE:	ASSOCIATION:	AGY:	REPORTED:	ENTERED:	EVENT#:
CIT ENTRY	VICTIM	LAS VEGAS METRO PD	09/07/2015 00:00:00	09/10/2015 11:08:24	150907-2376

COMMENT [1]

COMMENT: CIT 1B **AGY:** LAS VEGAS METRO PD **COMMENT DATE:** 09/10/2015 11:08:43

CRIMINAL HISTORY **ARR [3] CIT [0] SUM [0]**

ARREST DATE: 12/6/2015 **AGY: LAS VEGAS METRO PD** **PCN#:** **BK#: -**

RN#: 0009 **CHARGE:** 1 **TYPE:** BW **FAIL TO:** APPEAR **OFF:** 50235 DOM BATTERY, (1ST) (M) **COUNTS:** 1 **EVT#:** 150717-4191
CCN: 15M22413X LAS VEGAS JUSTICE COURT **CREATED:** 12/7/2015 **UPDATED:** **JUV/CERT/ADULT:** ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:
12/22/2015 CCN: 15M22413X	50235 DOM BATTERY, (1ST) (M)	FOUND GUILTY

UPDATED:

FINE	EXCUSE	RESTITUTION
$	$	$

	MIN	YRS	MOS	DAYS	HRS		MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE						COMMUNITY SERVICE					
CREDIT TIME SERVED						PROBATION					

NO

RN#: 7 **CHARGE:** 2 **TYPE:** BW **FAIL TO:** APPEAR **OFF:** 57944 CARRY CONCEAL WEAP W/O PRMT (M) **COUNTS:** 1 **EVT#:** 141217-0001
CCN: 14F19533X LAS VEGAS JUSTICE COURT **CREATED:** 12/7/2015 **UPDATED:** **JUV/CERT/ADULT:** ADULT

PER NEVADA REVISED STATUTES, LAS VEGAS METRO PD IS AUTHORIZED TO RELEASE OUR AGENCY'S CRIMINAL HISTORY INFORMATION ONLY. FOR OTHER AGENCY INFORMATION, CONTACT THE AGENCY DIRECTLY - OR - FOR COMPLETE BACKGROUND CHECKS, CONTACT THE STATE OF NEVADA REPOSITORY.

LAS VEGAS METRO PD MARIA ARELLANO-MURILLO/M20273A 01/24/2025 10:56:47

RELEASE TO: HENRY POTTINGER, CHANTE MARIE

ARREST DATE: 12/17/2014 **AGY: LAS VEGAS METRO PD** **PCN#: 25538427** **BK#: -**

RN#: 0007 **CHARGE:** 1 **TYPE:** PC **OFF:** 51457 CARRY CONCEALED MACHETE W/O PERMIT, 1ST (G) **COUNTS:** 1 **EVT#:** 141217-0001

CCN: 14F19533X LAS VEGAS JUSTICE COURT **SEQ#:** 1 **CREATED:** 12/17/2014 **UPDATED:** **JUV/CERT/ADULT:** ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:
12/19/2014	57944 CARRY CONCEAL WEAP W/O PRMT (M)	FOUND GUILTY
CCN: 14F19533X		**UPDATED:**

FINE	EXCUSE	RESTITUTION
$400.00	$	$

	MIN	YRS	MOS	DAYS	HRS		MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE						COMMUNITY SERVICE					
CREDIT TIME SERVED					NO	PROBATION					

LEGACY DISPO: AMD MISD/STAY OUT OF TROUBLE

RN#: 0008 **CHARGE:** 2 **TYPE:** PC **OFF:** 51339 USE/POSS DRUG-PARA (M) **COUNTS:** 1 **EVT#:** 141217-0001

CCN: 14F19533X LAS VEGAS JUSTICE COURT **SEQ#:** 2 **CREATED:** 12/17/2014 **UPDATED:** **JUV/CERT/ADULT:** ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:
12/18/2014	51339 USE/POSS DRUG-PARA (M)	DENIED
CCN: 14F19533X		**UPDATED:**

FINE	EXCUSE	RESTITUTION
$	$	$

	MIN	YRS	MOS	DAYS	HRS		MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE						COMMUNITY SERVICE					
CREDIT TIME SERVED					NO	PROBATION					

ARREST DATE: 11/12/2011 **AGY: LAS VEGAS METRO PD** **PCN#:** **BK#: -**

RN#: 5 **CHARGE:** 2 **TYPE:** UNK **FAIL TO:** APPEAR **OFF:** 99999 OTHER () EXP LIC PLTS, WARRANT, BW-P-527679-B, MPD **COUNTS:** 1 **EVT#:** UNKNOWN
CREATED: 11/12/2011 **UPDATED:** 5/18/2013 **JUV/CERT/ADULT:** ADULT

RN#:	CHARGE:	TYPE:	FAIL TO:	OFF:	COUNTS:	EVT#:
6	1	UNK	APPEAR	99999 OTHER () FOLLOW T/CLOSE, WARRANT, BW-P-527679-A, MPD	1	UNKNOWN

CREATED: 11/12/2011 **UPDATED:** 5/18/2013 **JUV/CERT/ADULT:** ADULT

I HEREBY CERTIFY that this is a full true and correct copy of the original on file with the Las Vegas Metropolitan Police Department, except for the information that is privileged and confidential by law.

PER NEVADA REVISED STATUTES, LAS VEGAS METRO PD IS AUTHORIZED TO RELEASE OUR AGENCY'S CRIMINAL HISTORY INFORMATION ONLY. FOR OTHER AGENCY INFORMATION, CONTACT THE AGENCY DIRECTLY – OR – FOR COMPLETE BACKGROUND CHECKS, CONTACT THE STATE OF NEVADA REPOSITORY.

LAS VEGAS METRO PD MARIA ARELLANO-MURILLO/M20273A 01/24/2025 10:56:47

RELEASE TO: HENRY POTTINGER, CHANTE MARIE

HENDERSON POLICE DEPARTMENT

BACKGROUND LETTER

HPD 0040

CERTIFIED RECORDS CHECK

I am authorized to conduct a search of the criminal history records of the Henderson Police Department.

I conducted a name search of Henderson Police Department's records on **3/25/2025** for **Chante Henry-Pottinger (Torno; Christie)** [redacted]

Henderson Police Department's records reflect the following information:

☒ The subject has a criminal history record with the Henderson Police Department. See attached.

☐ No misdemeanor, gross misdemeanor, or felony arrests/citations with the Henderson Police Department.

Please be advised the identity of the above-named person was not verified by fingerprints.

For non-criminal traffic infraction/citation information, please contact the issuing court.

I declare under penalty of perjury that the foregoing is true and correct.
Executed on **3/25/2025**

V. Pando

BY: V. Pando P#: 3007
Law Enforcement Support Specialist, Records Section

For Information concerning other police departments or public agencies, contact the department or agency directly. For state or nationwide background checks, visit https://rccd.nv.gov/FeesForms/Criminal/RecordsRequest/ for more information.

SCOPE II - II211 ▸ Dissemination - Citizens

CITIZENS REPORT

SCOPE RESPONSE

PERSON BASE RECORD

ID #: 2744118

NAM: CHRISTIE, CHANTE MARIE **DOB:** [redacted]

ADR: RS [redacted]

AKA [2]

NAME	AGY	ENTRY DATE
TORNO, CHANTE MARIE	HENDERSON PD	3/25/2002
CHRISTIE, CHANTE MARIE	LAS VEGAS METRO PD	3/25/2002

ADDITIONAL DOB [1]

DOB	AGY	ENTRY DATE
[redacted]	LAS VEGAS METRO PD	3/25/2002

CRIMINAL HISTORY **ARR [4] CIT [0] SUM [0]**

ARREST DATE: 10/18/2012 **AGY: HENDERSON PD** **PCN#:** **BK#:** -

RN#:	CHARGE:	TYPE:	FAIL TO:	OFF:	COUNTS:	EVT#:
4	1	UNK	COMPLY HEN	99999 OTHER () BATT DOMESTIC VIOL, WARRANT, BW-12M07760,	1	12-18205

CREATED: 10/18/2012 **UPDATED:** 5/18/2013 **JUV/CERT/ADULT:** ADULT

ARREST DATE: 5/18/2012 **AGY: HENDERSON PD** **PCN#:** **BK#:** -

RN#:	CHARGE:	TYPE:	FAIL TO:	OFF:	COUNTS:	EVT#:
4	1	UNK	COMPLY HEN	99999 OTHER () BATT DOMESTIC VIOL, WARRANT, BW-12M01481,	1	12-08766

CREATED: 5/18/2012 **UPDATED:** 5/18/2013 **JUV/CERT/ADULT:** ADULT

ARREST DATE: 11/16/2011 **AGY: HENDERSON PD** **PCN#:** **BK#:** -

RN#:	CHARGE:	TYPE:	FAIL TO:	OFF:	COUNTS:	EVT#:
4	1	UNK	PAY HEN	99999 OTHER () BATT DOMESTIC VIOL, WARRANT, BW-11M05657,	1	11-21208

CREATED: 11/16/2011 **UPDATED:** 5/18/2013 **JUV/CERT/ADULT:** ADULT

ARREST DATE: 12/19/2010 **AGY: HENDERSON PD** **PCN#:** **BK#:** -

RN#: 4 **CHARGE:** 1 **TYPE:** UNK **OFF:** 99999 OTHER () BATT DOMESTIC VIOL **COUNTS:** 1 **EVT#:** 10-24529

CCN: 10CR018060 UNKNOWN **CREATED:** 12/19/2010 **UPDATED:** 5/18/2013 **JUV/CERT/ADULT:** ADULT

FINAL DISPO DATE:	FINAL OFF:	DISPO:
12/21/2010	99999 OTHER () BATT DOMESTIC VIOL	FINAL

CCN: 10CR018060 **UPDATED:** 5/18/2013

PER NEVADA REVISED STATUTES, HENDERSON PD IS AUTHORIZED TO RELEASE OUR AGENCY'S CRIMINAL HISTORY INFORMATION ONLY. FOR OTHER AGENCY INFORMATION, CONTACT THE AGENCY DIRECTLY – OR – FOR COMPLETE BACKGROUND CHECKS, CONTACT THE STATE OF NEVADA REPOSITORY.

HENDERSON PD VANESSA PARDO/VP5 03/25/2025 14:38:35

RELEASE TO: CHANTE HENRY-POTTINGER (TORNO)

	FINE	EXCUSE	RESTITUTION
	$	$	$

	MIN	YRS	MOS	DAYS	HRS
TERM OF SENTENCE					
CREDIT TIME SERVED				NO	

	MIN	YRS	MOS	DAYS	HRS
COMMUNITY SERVICE					
PROBATION					

LEGACY DISPO: FINED/JAIL/CNSV/COMM SVC/NFA

PER NEVADA REVISED STATUTES, HENDERSON PD IS AUTHORIZED TO RELEASE OUR AGENCY'S CRIMINAL HISTORY INFORMATION ONLY. FOR OTHER AGENCY INFORMATION, CONTACT THE AGENCY DIRECTLY – OR – FOR COMPLETE BACKGROUND CHECKS, CONTACT THE STATE OF NEVADA REPOSITORY.

HENDERSON PD VANESSA PARDO/VP5 03/25/2025 14:38:35

RELEASE TO: CHANTE HENRY-POTTINGER (TORNO)

REGISTER OF ACTIONS
CASE NO. 15M22413X

State of Nevada vs. Christie, Chante Marie

Case Type: **Misdemeanor**
Subtype: **DV Case**
Date Filed: **09/11/2015**
Location: **JC Department 10**

PARTY INFORMATION

Defendant **Christie, Chante Marie CHRISTIE, CHANTE MARIE**
Other Agency Numbers
2744118 Justice Court Scope ID Subject Identifier

Lead Attorneys
Public Defender
Retained
702-455-4685(W)

State of Nevada **State of Nevada**

CHARGE INFORMATION

Charges: Christie, Chante Marie	Statute	Level	Date
1. Dom battery, (1st) [50235]	200.485.1a	Misdemeanor	07/17/2015

EVENTS & ORDERS OF THE COURT

DISPOSITIONS

12/22/2015 **Plea** (Judicial Officer: Tobiasson, Melanie A.)
1. Dom battery, (1st) [50235]
Nolo Contendere

12/22/2015 **Disposition** (Judicial Officer: Tobiasson, Melanie A.)
1. Dom battery, (1st) [50235]
Guilty as Charged

06/24/2016 **Misdemeanor Sentence** (Judicial Officer: Pro Tempore, Judge)
1. Dom battery, (1st) [50235]
Condition - Adult:
1. Suspended Jail Sentence, 90 Days 12/22/2015, , Closed 03/15/2017
2. Stay Out of Trouble, 12/22/2015, , Satisfied 03/15/2017
3. Domestic Violence Counseling (6 Months), Safe Nest - TADC May continue at Safe Nest through CPS case with credit for any classes completed previously (possibly 3). 1/19/2016: 2 classes previously completed at ABC, defendant now attending at Safe Nest beginning today. - 03/25/2016 - 10 of 26 Completed - 06/22/2016 - 21 of 26 Completed - 08/02/2013 - Completed 12/22/2015 - 08/02/2016, , Satisfied 08/02/2016
4. Community Service Mandatory Hours DV1, CTS for 48 hours 12/22/2015, Closed 12/22/2015
5. Community Service - DV1, Defendant may do 35 hours of community service in lieu of $345 fine 12/22/2015, , Closed 03/15/2017
6. Defendant Sentenced to 2 Days Jail, with 2 Days Credit for Time Served 12/22/2015, Satisfied 12/22/2015
Fee Totals:

AA Fees	$105.00
County Fine-Criminal	$205.00
Domestic Violence AA Fee	$35.00
Fee Totals $	$345.00

OTHER EVENTS AND HEARINGS

09/10/2015 **CTRACK Track Assignment JC02**
09/10/2015 **CTRACK Case Modified**
Jurisdiction/DA;
09/11/2015 **Criminal Complaint**
09/11/2015 **Filed Under Seal**
09/11/2015 **Summons Issued In Lieu Of Arrest**
10/12/2015 **Arraignment** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.)
No bail posted
Result: Bench Warrant Issued
10/12/2015 **Minute Order - Department 10** (Judicial Officer: Tobiasson, Melanie A.)
10/12/2015 **Bench Warrant Ordered Issued - Defendant Failed to Appear** (Judicial Officer: Tobiasson, Melanie A.)
$5,000/ $5,000
10/12/2015 **Warrant Issued**
10/12/2015 **Bench Warrant Confidential**
10/12/2015 **Bench Warrant - Face Sheet**
10/26/2015 **Notice of Motion**
to quash warrant
10/27/2015 **Comment**
FTA- Initial Arraignment 10/12/2015

10/28/2015 **Arraignment** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.)
No Bail Posted
Result: Warrant Stands
10/28/2015 **Minute Order - Department 10** (Judicial Officer: Tobiasson, Melanie A.)
10/28/2015 **Motion to Quash Bench Warrant** (Judicial Officer: Tobiasson, Melanie A.)
Motion Denied
10/28/2015 **Warrant Stands** (Judicial Officer: Tobiasson, Melanie A.)
12/06/2015 **CTRACK Case Modified**
ArrestDate/12/06/2015;
12/06/2015 **Warrant Cleared (NCJIS)**
12/07/2015 **Warrant Service Slip**
12/07/2015 **Warrant Arrest Documents**
12/07/2015 **Comment**
Bench Warrant Return/ FTA- Initial Arraignment 10/12/2015
12/07/2015 **Comment**
Bail : $5,000/ $5,000
12/08/2015 **Arraignment** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.)
In Custody
Result: Matter Heard
12/08/2015 **Minute Order - Department 10**
12/08/2015 **Arraignment Completed**
Advised of Charges on Criminal Complaint, Waives Reading of Criminal Complaint
12/08/2015 **Public Defender Appointed**
12/08/2015 **Bail Stands - Cash or Surety**
Counts: 001 - $5,000.00/$5,000.00 Total Bail
12/22/2015 **Bench Trial** (10:00 AM) (Judicial Officer Tobiasson, Melanie A.)
In-Custody
Result: Matter Heard
12/22/2015 **Minute Order - Department 10**
12/22/2015 **Admonishment of Rights - BDV**
Signed in open court.
12/22/2015 **HELP of Southern Nevada Form**
Provided to defendant in open Court.
12/22/2015 **Judgment Entered**
12/22/2015 **Release Order - Court Ordered** (Judicial Officer: Tobiasson, Melanie A.)
Counts: 001
12/22/2015 **Status Check on Requirements**
12/22/2015 **Official Court Date Slip**
12/22/2015 **Notice of Disposition and Judgment**
12/22/2015 **Transcript of Proceedings**
01/06/2016 **DV - Court Compliance**
12/22/2015
01/19/2016 **Status Check** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.)
No Bail Posted
Result: Matter Heard
01/19/2016 **Minute Order - Department 10**
01/19/2016 **HELP of Southern Nevada Form - fees waived**
Provided to defendant in open court.
01/19/2016 **Status Check on Requirements**
Defendant has completed 2 classes at ABC and is starting her classes at Safenest today (1/19/2016). Defendant to have 6 classes completed at Safenest by the next court date.
01/19/2016 **Counseling Report**
03/23/2016 **Counseling Report**
8/26 SN Paid 2 classes @ ABC 10/26 Total
03/25/2016 **Status Check** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.)
No Bail Posted
Result: Matter Heard
03/25/2016 **Minute Order - Department 10**
03/25/2016 **Fine Payment In Court**
$50 Fine Payment in Court - $295 Balance due
03/25/2016 **Status Check on Requirements**
Defendant to have 20 total classes completed by the next court date.
06/17/2016 **Counseling Report**
19/26 SN Paid 2 Completed @ ABC Total 21/26
06/24/2016 **Status Check** (8:30 AM) (Judicial Officers Pro Tempore, Judge, Jansen, William D.)
No Bail Posted
Result: Matter Heard
06/24/2016 **Status Check on Requirements**
continued.
06/24/2016 **Minute Order - Department 10**
08/02/2016 **Counseling Report**
Completed & paid
09/23/2016 **Status Check** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.)
No Bail Posted
Result: Matter Heard
09/23/2016 **Minute Order - Department 10**
09/23/2016 **Presence Waived**
upon compliance of requirements.
09/23/2016 **Status Check**
on $295 court fine.
11/03/2016 **Status Check** (8:30 AM) (Judicial Officers Pro Tempore, Judge, Gubler, James L.)
No Bail Posted
Result: Matter Heard
11/03/2016 **Minute Order - Department 10**

11/03/2016	**Status Check** *on $295 court fine.*
11/10/2016	**Status Check** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.) *No Bail Posted* Result: Bench Warrant Issued
11/10/2016	**Defendant failed to appear**
11/10/2016	**Bench Warrant Ordered Issued - Defendant Failed to Appear** *295/00 total*
11/10/2016	**Minute Order - Department 10**
11/10/2016	**Bench Warrant - Face Sheet**
11/10/2016	**Bench Warrant Confidential**
11/10/2016	**Warrant Issued**
11/10/2016	**Warrant Recalled**
11/10/2016	**Warrant Issued**
03/10/2017	**Defendant's Notice of Motion and Motion** *to quash bench warrant.*
03/15/2017	**Motion** (8:30 AM) (Judicial Officer Tobiasson, Melanie A.) *No bail posted* Result: Motion Granted
03/15/2017	**Minute Order - Department 10**
03/15/2017	**Motion to Quash Bench Warrant** *Motion Granted.*
03/15/2017	**Warrant Ordered Quashed**
03/15/2017	**Case Closed - Requirement(s) Completed**
03/15/2017	**Warrant Recalled**
03/15/2017	**DV - Closed** *The defendant completed all requirements case closed*

Financial Information

Defendant Christie, Chante Marie

	Total Financial Assessment			355.00
	Total Payments and Credits			355.00
	Balance Due as of 03/25/2025			**0.00**
12/22/2015	Transaction Assessment			345.00
03/25/2016	Payment (Court)	Receipt # CRS-2016-01416	Christie, Chante Marie	(50.00)
01/13/2017	Web Criminal	Receipt # CCS-2017-00451	Christie, Chante Marie	(100.00)
01/13/2017	Transaction Assessment			5.00
01/13/2017	Web Criminal	Receipt # CCS-2017-00452	Christie, Chante Marie	(0.50)
01/13/2017	HPS Credit			(4.50)
02/23/2017	Web Criminal	Receipt # CCS-2017-02126	Christie, Chante Marie	(195.00)
02/23/2017	Transaction Assessment			5.00
02/23/2017	Web Criminal	Receipt # CCS-2017-02127	Christie, Chante Marie	(0.50)
02/23/2017	HPS Credit			(4.50)

REGISTER OF ACTIONS
CASE NO. 14F19533X

State of Nevada vs. Christie, Chante Marie

Case Type: **Gross Misdemeanor**
Date Filed: **12/18/2014**
Location: **JC Department 11**

PARTY INFORMATION

Defendant	**Christie, Chante Marie** Other Agency Numbers 2744118 Justice Court Scope ID Subject Identifier	**Lead Attorneys** **Public Defender** *Public Defender* 702-455-4685(W)
State of Nevada	**State of Nevada**	

CHARGE INFORMATION

Charges: Christie, Chante Marie	**Statute**	**Level**	**Date**
1. Carry Concealed Weapon W/O Permit [57944]	12.04.180	Misdemeanor	12/17/2014
999. Use/poss drug-para [51339]	453.566	Misdemeanor	12/17/2014

EVENTS & ORDERS OF THE COURT

DISPOSITIONS

12/19/2014 **Plea** (Judicial Officer: Goodman, Eric)
1. Carry Concealed Weapon W/O Permit [57944]
Guilty

12/19/2014 **Disposition** (Judicial Officer: Goodman, Eric)
1. Carry Concealed Weapon W/O Permit [57944]
Guilty of Lesser Offense

12/19/2014 **Misdemeanor Sentence** (Judicial Officer: Goodman, Eric)
1. Carry Concealed Weapon W/O Permit [57944]
Condition - Adult:
1. Stay Out of Trouble, 12/19/2014, Active 12/19/2014
2. Community Service, 40 Hours In Lieu of fine 12/19/2014, Active 12/19/2014
3. Property Forfeited, Knife Seized in Metro Event #1412170001 12/19/2014, Active 12/19/2014
4. Suspended Jail Sentence, 30 days 12/19/2014, Active 12/19/2014
Fee Totals:

AA Fees	$105.00
County Fine-Criminal	$295.00
Fee Totals $	$400.00

12/07/2015 **Disposition**
999. Use/poss drug-para [51339]
DA Denial

12/08/2015 **Amended Misdemeanor Sentence** (Judicial Officer: Goodman, Eric) Reason: Court Ordered
1. Carry Concealed Weapon W/O Permit [57944]
Condition - Adult:
1. Stay Out of Trouble, 12/19/2014, Closed 12/08/2015
2. Community Service, 40 Hours In Lieu of fine 12/19/2014, Closed 12/08/2015
3. Property Forfeited, Knife Seized in Metro Event #1412170001 12/19/2014, Closed 12/08/2015
4. Suspended Jail Sentence, 30 days 12/19/2014, Closed 12/08/2015
Fee Totals:

AA Fees	$105.00
County Fine-Criminal	$295.00
Fee Totals $	$400.00

OTHER EVENTS AND HEARINGS

12/17/2014 **Standard Bail Set**
Ct1: $2000 Cash/$2000 Surety
12/17/2014 **CTRACK Track Assignment JC11**
12/17/2014 **Standard Bail Set**
Ct2: $1000 Cash/$1000 Surety
12/18/2014 **48 Hour Probable Cause Review** (7:20 AM) (Judicial Officer Goodman, Eric)
Result: Signing Completed
12/18/2014 **CTRACK Case Modified**
Jurisdiction/DA;
12/18/2014 **Probable Cause Found** (Judicial Officer: Goodman, Eric)

12/18/2014	**Bail Stands** (Judicial Officer: Goodman, Eric) *Counts: 001; 999 -*
12/18/2014	**Minute Order - Department 11** (Judicial Officer: Goodman, Eric)
12/18/2014	**Custody Status Slip (No Custody Change)**
12/18/2014	**Probable Cause Arrest Documents**
12/18/2014	**Criminal Complaint**
12/18/2014	**Surety Bond**
12/18/2014	**Surety Bond Acceptance-Notice of Appearance**
12/19/2014	**Arraignment** (7:30 AM) (Judicial Officer Goodman, Eric) *Out of custody* Result: Matter Heard
12/19/2014	**Custody Status Slip (Release From Custody)**
12/19/2014	**Arraignment Completed** (Judicial Officer: Goodman, Eric) *Advised of Charges on Criminal Complaint, Waives Reading of Criminal Complaint*
12/19/2014	**Public Defender Appointed** (Judicial Officer: Goodman, Eric)
12/19/2014	**Surety Bond Ordered Exonerated** (Judicial Officer: Goodman, Eric) *FCS51433267*
12/19/2014	**Judgment Entered** (Judicial Officer: Goodman, Eric)
12/19/2014	**Status Check on Requirements** (Judicial Officer: Goodman, Eric)
12/19/2014	**Surety Bond Exonerated**
12/19/2014	**Minute Order - Department 11** (Judicial Officer: Goodman, Eric)
12/19/2014	**Official Court Date Slip**
12/19/2014	**Notice of Disposition and Judgment**
06/05/2015	**Status Check** (7:30 AM) (Judicial Officer Goodman, Eric) *No Bail Posted* Result: Matter Heard
06/05/2015	**Last Chance Warning Given by Court** (Judicial Officer: Goodman, Eric) *To have all requirements completed by next court hearing.*
06/05/2015	**Status Check on Requirements** (Judicial Officer: Goodman, Eric)
06/05/2015	**Minute Order - Department 11** (Judicial Officer: Goodman, Eric)
08/25/2015	**Community Service Report**
08/28/2015	**Status Check** (7:30 AM) (Judicial Officer Goodman, Eric) *No bail posted* Result: Matter Heard
08/28/2015	**Motion to Continue - Defense** (Judicial Officer: Goodman, Eric) *Defendant request one more time to complete requirements- Motion Granted*
08/28/2015	**Status Check on Requirements** (Judicial Officer: Goodman, Eric)
08/28/2015	**HELP of Southern Nevada Form - fees waived** (Judicial Officer: Goodman, Eric) *Provided to defendant in open court.*
08/28/2015	**Minute Order - Department 11** (Judicial Officer: Goodman, Eric)
12/01/2015	**Status Check** (7:30 AM) (Judicial Officer Goodman, Eric) *No bail posted* Result: Bench Warrant Issued
12/01/2015	**Bench Warrant Ordered Issued - Defendant Failed to Appear** *00/00*
12/01/2015	**Minute Order - Department 11**
12/01/2015	**Warrant Issued**
12/01/2015	**Bench Warrant Confidential**
12/01/2015	**Bench Warrant - Face Sheet**
12/06/2015	**Warrant Cleared (NCJIS)**
12/07/2015	**Warrant Service Slip**
12/07/2015	**Warrant Arrest Documents**
12/07/2015	**Comment** *$00/ 00 bail*
12/08/2015	**Bench Warrant Return Hearing** (7:30 AM) (Judicial Officer Goodman, Eric) *In Custody* Result: Matter Heard
12/08/2015	**Oral Motion** *To modify sentence- Motion Denied*
12/08/2015	**All Requirements Vacated**
12/08/2015	**Case Closed - Court Order**
12/08/2015	**Judgment Entered**
12/08/2015	**Minute Order - Department 11**
12/08/2015	**Notice of Disposition and Judgment**

Financial Information

	Defendant Christie, Chante Marie			
	Total Financial Assessment			450.00
	Total Payments and Credits			450.00
	Balance Due as of 03/25/2025			**0.00**
12/18/2014	Transaction Assessment			50.00
12/18/2014	Payment (Window)	Receipt # PT-2014-14611	Dad's Bail Bonds LLC	(50.00)
12/19/2014	Transaction Assessment			400.00
08/26/2015	Payment (Window)	Receipt # CCS-2015-07798	Christie, Chante Marie	(80.00)
12/08/2015	Requirements Vacated			(320.00)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

25 %.

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site INSPIRE PROSTHETICS & ORTHOTICS

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3233 WEST CHARLESTON BLVD. #111

City LAS VEGAS State NV Zip 89102

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 725.222.4476 Website www.inspireprosthetics.com

Licensing Company Email _____

Section 2: Personal Information

First Elden Middle Rodolfo Last Henry-Pottinger

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email elden.hp@inspireprosthetics.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✔	
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
PACIFIC UNION COLLEGE		09/92 - 06/96	
Address	**City**	**State**	**Zip**
1 ANGWIN AVENUE	ANGWIN	CA	94508
Diploma/Degree obtained, if any			
BUSINESS-PRE LAW			

School Name		From - To (MM/YY – MM/YY)	
BIRMINGHAM HIGH SCHOOL		09/88 - 06/92	
Address	**City**	**State**	**Zip**
17000 HAYNES STREET	VAN NUYS	CA	91406
Diploma/Degree obtained, if any			
HIGH SCHOOL			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/21-PRESENT	[redacted]	LAS VEGAS	NV	[redacted]
04/20-04/21		LAS VEGAS	NV	
01/20 - 04/20		LAS VEGAS	NV	
11/14 - 01/20		NORTH LAS VEGAS	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
INSPIRE PROSTHETICS & ORTHOTICS			01/25 - PRESENT
Business Address	**City**	**State**	**Zip**
3233 WEST CHARLESTON AVENUE #111	LAS VEGAS	NV	89102
Phone	**Title**		
725.222.4476	PRESIDENT & CHIEF CLINICAL OFFICER		

Description of Duties
Evaluate patients for prosthetic and orthotic devices. Design, fabricate and fit patients for prosthetic and orthotic devices.

Business Name			From - To (MM/YY – MM/YY)
POP PROSTHETICS			09/18 - 01/25
Business Address	**City**	**State**	**Zip**
526 SOUTH TONOPAH DRIVE #120	LAS VEGAS	NV	89106
Phone	**Title**		
702.243.7671	PROSTHETIST/ORTHOTIST		

Description of Duties
Evaluate patients for prosthetic and orthotic devices. Design, fabricate and fit patients for prosthetic and orthotic devices.

Business Name			From - To (MM/YY – MM/YY)
ADVANCED PROSTHETICS AND ORTHOTICS			11/14 - 09/18
Business Address	**City**	**State**	**Zip**
7455 WEST WASHINGTON AVENUE #215	LAS VEGAS	NV	89129
Phone	**Title**		
702.256.5265	ORTHOTIST		

Description of Duties
Evaluate patients for orthotic devices. Design, fabricate and fit patients for orthotic devices.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

N/A

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

ELDEN HENRY-POTTINGER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Elden Rodolfo Henry-Pottinger, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/19/25

Date

Subscribed and Sworn to before me this 19 day of February.

Notary Public Signature

MARIO DIAZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 19-1865-1
MY APPT. EXPIRES FEB. 25, 2027

(Seal)

25 1.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Inspire Prosthetics & Orthotics

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3233 W Charleston Blvd, Suite 111

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 725-222-4476 Website: inspireprosthetics.com

Licensing Company Email: _____

Section 2: Personal Information

First: Jennifer Middle: Wilikina Last: Daniels

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: jenny.d@inspireprosthetics.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Hawaii Manoa		09/97-12/99	
Address	**City**	**State**	**Zip**
2500 Campus Rd	Honolulu	HI	96822
Diploma/Degree obtained, if any			
Bachelor of Arts in Organizational Management			

School Name		From - To (MM/YY – MM/YY)	
University of Las Vegas		12/95-06/96	
Address	**City**	**State**	**Zip**
4505 S Maryland Parkway	Las Vegas	NV	89154
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
FIDM - Fashion Institute of Design & Merchandising		09/88-05/89	
Address	**City**	**State**	**Zip**
919 S Grand Ave	Los Angeles	CA	90015
Diploma/Degree obtained, if any			
Certificate in Merchandising			

School Name		From - To (MM/YY – MM/YY)	
University of Hawaii Maui College		09/86-05/88	
Address	**City**	**State**	**Zip**
310 W Ka'ahumanu Ave	Kahului	HI	96732
Diploma/Degree obtained, if any			
Associates of Arts			

School Name		From - To (MM/YY – MM/YY	
St. Anthony Jr and Sr. High School		08/80-05/86	
Address	**City**	**State**	**Zip**
1618 Lower Main St	Wailuku	HI	96793
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
01/25-Present	[redacted]	Las Vegas	NV	[redacted]
06/24-01/25		Wailuku	HI	
02/18-06/24		Discovery Bay	CA	
10/17-02/18		Concord	CA	
09/13-10/17		Wailuku	HI	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Inspire Prosthetics and Orthotics LLC			05/13/24-Present
Business Address	**City**	**State**	**Zip**
3233 W Charleston Blvd Suite 111	Las Vegas	NV	89102
Phone	**Title**		
725-222-4476	Administrative Director		

Description of Duties

Customer service which includes checking in patients and processing their paperwork, answering phones, scheduling patient appointments, being the liaison between our company and doctors' offices and insurance companies, AR & AP

Business Name			From - To (MM/YY – MM/YY)
Lele Consulting LLC			11/24-Present
Business Address	**City**	**State**	**Zip**
268 Halenani Dr	Wailuku	HI	96793
Phone	**Title**		
808-866-6760	Owner/President		

Description of Duties

Provide administrative services, streamlining processes and improving effeciency for clients.

Business Name			From - To (MM/YY – MM/YY)
Aloha Consulting Services, LLC			04/18-12/24
Business Address	**City**	**State**	**Zip**
14850 Highway 4 Suite A-227	Discovery Bay	CA	94505
Phone	**Title**		
808-866-6760	Owner/President		

Description of Duties

Provide administrative services, streamlining processes and improving effeciency for clients.

Business Name			From - To (MM/YY – MM/YY)
County of Maui			01/11-10/17
Business Address	**City**	**State**	**Zip**
200 S High St	Wailuku	HI	96793
Phone	**Title**		
808-270-7877	Office Manager for the Office of the Mayor		

Description of Duties

Managed all the personnel in the Office of the Mayor. My duties also ncluded human resource, payroll and office events. I was responsible for scheduling Mayor's travel arrangements and hotel accomodations when traveling to outer islands, the continental United States and foreign countries.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	✔	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1,3,4 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
2:13-CR-0203-JCM-CWH	

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Because this case is sealed, I am unable to provide further details about it. Please note, however, that it was never related to patient care or to the medical industry in any way.

On the other hand, my personal integrity reflects the highest ethical and moral standards of accountability: demonstrated by the most responsible members of the community I seek to serve.

In addition to those professional standards, my commitment to "giving back" to the community is reflected in my active volunteer efforts to support the unsheltered, and often overlooked, individuals of our society. My passion to make a meaningful impact on those, who are in need, reiterates my belief in second chances, and the importance of uplifting each other.

Original Signature (electronic copies or stamps not accepted)

02/19/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jennifer Daniels

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Daniels Wilkina Jennifer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/19/25

Date

Subscribed and Sworn to before me this 19 day of February.

Notary Public Signature

MARIO DIAZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 19-1865-1
MY APPT. EXPIRES FEB. 25, 2027

(Seal)

Jennifer Daniels
[redacted]
jenny.d@inspireprosthetics.com
[redacted]

March 25, 2025

Nevada State Board of Pharmacy
431 W Plumb Ln
Reno, NV 89509

Dear Members of the Nevada State Board of Pharmacy,

I am writing to provide an explanation regarding a matter from my past. Although the case is sealed and there is no public record on file, I believe in being fully transparent. I understand the importance of accountability in the healthcare profession and would like to offer a detailed account of the circumstances surrounding this incident.

During the financial crisis of 2008, I was affiliated with a mortgage company that, following an FBI investigation, was found to have engaged in wire fraud, bank fraud, and mail fraud. Due to my association with the company, I was among those convicted in connection with these charges. While I did not plan or direct the fraudulent activities, I fully acknowledge my involvement and take complete responsibility for my actions during that time.

As part of the legal proceedings, I cooperated with federal prosecutors, providing assistance in their case against the company's owners and other involved parties, and ultimately entered into a plea agreement.

In 2013, I was charged with conspiracy to commit bank fraud, mail fraud, and wire fraud (Case No. 2:13-cr-00203-JCM-CWH). The charge was based on allegations that, between August 2003 and February 2006, I conspired with others to defraud financial institutions by submitting false information on mortgage loan applications.

The specific allegations included:

1. Submitting loan applications with materially false information about borrowers' income and intent to occupy the homes as their primary residences.
2. Using the United States Postal Service and interstate wire communications to transmit fraudulent loan applications and supporting documents.
3. Causing financial institutions to disburse mortgage loan funds based on the false information provided.

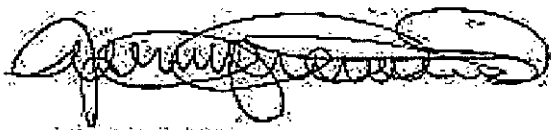
On October 30, 2017, I was sentenced to time served and two years of supervised release. I, along with the other defendants, were ordered to pay restitution totaling $19,356,074.00 to various financial institutions affected by the fraud. I have complied with all the conditions of my supervised release, including participating in a mental health treatment program (if needed) and providing financial information to the probation officer.

I deeply regret my involvement in this matter and have taken significant steps to ensure that such an event does not occur again. This experience has taught me valuable lessons, and I have made positive changes in my life to prevent any future occurrences. I am committed to maintaining the highest standards of conduct and professionalism in my career.

I respectfully request that the Board consider this explanation and the steps I have taken to address the situation. I am dedicated to upholding the integrity of the healthcare profession and am fully committed to serving the community with the utmost responsibility and care.

Thank you for your understanding and consideration.

Sincerely,



Jennifer Daniels

DANIEL G. BOGDEN
United States Attorney
District of Nevada
SARAH E. GRISWOLD
BRIAN PUGH
Assistant United States Attorneys
333 Las Vegas Boulevard South
Suite 5000
Las Vegas, Nevada 89101
702-388-6336
Fax: 702-388-5087

UNITED STATES DISTRICT COURT
DISTRICT OF NEVADA

-oOo-

UNITED STATES OF AMERICA, Plaintiff, vs. JENNIFER DANIELS, Defendant.	Case No.: 2:13-CR-0203-GMN-CWH **CRIMINAL INFORMATION** **VIOLATION:** 18 U.S.C. § 1349 – Conspiracy To Commit Bank Fraud, Mail Fraud, and Wire Fraud

THE UNITED STATES ATTORNEY CHARGES THAT:

INTRODUCTION

At all times relevant to this Information:

1. Purchasers of homes typically finance their purchases by submitting loan applications to lending institutions to obtain mortgages. Loan applications require borrowers to truthfully disclose certain information for the lender to decide whether the borrower will be willing and able to repay the loan. This information includes, but is not limited to, such information as the borrower's income and whether the home to be purchased will be the borrower's primary residence. This information is material to the decision of the financial

institution to loan money to the borrower, the amount of any such loan, and the terms of the loan, such as the interest rate the borrower will pay.

COUNT ONE
Conspiracy To Commit Bank Fraud, Mail Fraud, and Wire Fraud

2. From in or about August 2003, to in or about February 2006, in the State and Federal District of Nevada,

JENNIFER DANIELS,

defendant herein, did knowingly and willfully combine, conspire, and agree with Derrick Phelps, Cynthia Phelps, Linda Mack, and others known and unknown to the grand jury:

a. To devise a scheme and artifice to defraud and to obtain money and property under the custody and control of federally insured financial institutions, by means of materially false and fraudulent pretenses, representations and promises that would cause a bank to part with money and property, in violation of Title 18, United States Code, Section 1344;

b. To use the United States Postal Service and commercial interstate carriers to send and deliver mortgage loan applications and other supporting documentation, for purposes of executing a scheme and artifice to defraud and for obtaining money and property by means of materially false and fraudulent pretenses, representations, and promises, in violation of Title 18, United States Code, Section 1341; and

c. To transmit and cause to be transmitted by means of wire communications in interstate commerce, funds and documents, for purposes of executing a scheme and artifice to defraud and for obtaining money and property by means of materially false and fraudulent pretenses, representations, and promises, in violation of Title 18, United States Code, Section 1343.

///

The Objectives of the Conspiracy and Scheme to Defraud

3. The objective of the conspiracy and scheme was to obtain mortgage loans from financial institutions by causing materially false information to be placed in the buyers' mortgage loan applications and supporting documentation. Defendant and her coconspirators obtained money and property from financial institutions by causing money from the mortgage loans to be disbursed to their own use and benefit and the use and benefit of their coconspirators.

Manner and Means

4. The manner and means by which the objectives of the conspiracy were accomplished include, but were not limited to, the following:

a. Defendant's coconspirators solicited persons with good credit ratings to purchase real estate. In some instances, defendant caused buyers to purchase multiple houses at or about the same time. By purchasing multiple houses in a short period of time, the prior purchases would not show up on the buyer's credit report and lenders would not be aware of the other purchases.

b. Defendant's coconspirators made offers to purchase properties above the sellers' asking prices.

c. Defendant caused buyers to apply for mortgage loans from financial institutions to purchase properties. Through these transactions, defendant and her coconspirators obtained money from financial institutions by causing money from the mortgage loans to be paid to defendant's coconspirators' companies in the form of commissions and fees.

d. Defendant placed in buyers' loan applications and supporting documentation material false and fraudulent representations about buyers' qualifications, including but not limited to one or more of the following: the buyers' income and intent to

occupy the homes as their primary residences, when defendant then and there well knew that the representations were false and fraudulent.

e. Defendant's coconspirators caused the sellers to agree that part of the excess funds be redirected to the buyers under the pretense of making upgrades and repairs to the properties. Defendant and her coconspirators knowingly and intentionally concealed from financial institutions the identities of the recipients of these disbursements and the true purpose of the disbursements, when defendant and her coconspirators then and there well knew that the representations made to financial institutions were false and fraudulent.

f. Defendant caused lenders and escrow companies to transmit money and documents by means of U.S. mail, interstate commercial carriers, and interstate wire communications to complete the transactions.

g. Defendant and her coconspirators defaulted on the mortgage loans which caused the properties to go into foreclosure.

h. Defendants' conspiracy to violate Title 18, United States Code, Sections 1341 and 1343 affected a federally insured financial institution.

Overt Acts

5. On or about the dates identified below, in the State and Federal District of Nevada, for the purpose of executing and attempting to execute the scheme to defraud and to obtain money and property, defendant did knowingly cause to be submitted to the federally insured financial institutions identified below, loan applications and supporting documents containing materially false and fraudulent pretenses, representations and promises in order to cause the financial institutions to loan money to fund the purchase of the properties identified below:

Dates	Property	Financial Institution
5/10/04 to 6/2/04	355 Pure April Ave. Las Vegas, Nevada	Fremont Investment and Loan
11/17/04 to 12/15/04	7800 License St. Las Vegas, Nevada	Pacific Mercantile Bank
11/18/04 to 12/22/04	11131 Tuscolana St. Las Vegas, Nevada	Pacific Mercantile Bank
3/8/05 to 4/6/05	7224 Rustic Meadow St. Las Vegas, Nevada	Fremont Investment and Loan
3/8/05 to 4/2/05	5600 Windy Gorge St. Las Vegas, Nevada	Pacific Mercantile Bank
5/5/05 to 6/3/05	9221 Steel Tree St. Las Vegas, Nevada	Fremont Investment and Loan

All in violation of Title 18, United States Code, Section 1349.

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FORFEITURE ALLEGATION ONE
Conspiracy To Commit Mail Fraud, Wire Fraud, and Bank Fraud

1. The allegations of Count One of this Criminal Information are hereby realleged and incorporated herein by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c).

2. Upon conviction of the felony offense charged in Count One of this Criminal Information,

JENNIFER DANIELS,

defendant herein, shall forfeit to the United States of America, any property, real or personal, which constitutes or is derived from proceeds traceable to violations of Title 18, United States Code, Sections 1341, 1343, and 1344, specified unlawful activities as defined in Title 18, United States Code, Sections 1956(c)(7)(A) and 1961(1)(B), or Title 18, United States Code, Section 1349, conspiracy to commit such offenses, an *in personam* criminal forfeiture money judgment of $181,046.23 in United States Currency.

3. If any property being subject to forfeiture pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c), as a result of any act or omission of the defendant –

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property that cannot be divided without difficulty;

it is the intent of the United States of America, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any properties of the defendant for the *in personam* criminal forfeiture money judgment of $181,046.23 in United States Currency.

All pursuant to Title 18, United States Code, Section 981(a)(1)(C) and Title 28, United States Code, Section 2461(c); Title 18, United States Code, Sections 1341, 1343, and 1344, specified unlawful activities as defined in Title 18, United States Code, Sections 1956(c)(7) and 1961(1)(B); Title 18, United States Code, Section 1349; and Title 21, United States Code, Section 853(p).

FORFEITURE ALLEGATION TWO
Conspiracy To Commit Mail Fraud, Wire Fraud, and Bank Fraud

1. The allegations of Count One of this Criminal Information are hereby realleged and incorporated herein by reference for the purpose of alleging forfeiture pursuant to Title 18, United States Code, Section 982(a)(2)(A).

2. Upon conviction of the felony offense charged in Count of this Criminal Information,

JENNIFER DANIELS,

defendant herein, shall forfeit to the United States of America, any property constituting, or derived from, proceeds obtained directly or indirectly as a result of violations of Title 18, United States Code, Sections 1341, 1343, 1344, and 1349, conspiracy to violate such offenses, an *in personam* criminal forfeiture money judgment of $181,046.23 in United States Currency.

3. If any property being subject to forfeiture pursuant to Title 18, United States Code, Section 982(a)(2)(A), as a result of any act or omission of the defendant –

a. cannot be located upon the exercise of due diligence;

b. has been transferred or sold to, or deposited with, a third party;

c. has been placed beyond the jurisdiction of the court;

d. has been substantially diminished in value; or

e. has been commingled with other property that cannot be divided without difficulty;

it is the intent of the United States of America, pursuant to Title 21, United States Code, Section 853(p), to seek forfeiture of any properties of the defendant for the *in personam* criminal forfeiture money judgment of $181,046.23 in United States Currency.

All pursuant to Title 18, United States Code, Sections 982(a)(2)(A), 1341, 1343, 1344, and 1349; and Title 21, United States Code, Section 853(p).

DATED: this 24th day of May, 2013.

DANIEL G. BOGDEN
United States Attorney

SARAH E. GRISWOLD
BRIAN PUGH
Assistant United States Attorneys

AO 245B (Rev. 10/17) Judgment in a Criminal Case
Sheet 1

UNITED STATES DISTRICT COURT

District of Nevada

UNITED STATES OF AMERICA
v.
JENNIFER DANIELS

SEALED JUDGMENT IN A CRIMINAL CASE

Case Number: 2:13-CR-0203-JCM-CWH **SEALED**

USM Number: 48173-048

MARGARET STANISH, ESQ.
Defendant's Attorney

THE DEFENDANT:

☑ pleaded guilty to count(s) ONE (1) OF THE INFORMATION

☐ pleaded nolo contendere to count(s) which was accepted by the court.

☐ was found guilty on count(s) after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
18 USC§1349,1344,1341 and 1343	Conspiracy to Commit Bank Fraud, Mail Fraud and Wire Fraud	2/2006	1

The defendant is sentenced as provided in pages 2 through 14 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s)

☐ Count(s) ☐ is ☐ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

10/30/2017
Date of Imposition of Judgment

James C. Mahan
Signature of Judge

JAMES C. MAHAN, U.S. DISTRICT JUDGE
Name and Title of Judge

October 31, 2017
Date

DEFENDANT: JENNIFER DANIELS
CASE NUMBER: 2:13-CR-0203-JCM-CWH **SEALED**

IMPRISONMENT

The defendant is hereby committed to the custody of the Federal Bureau of Prisons to be imprisoned for a total term of:

TIME SERVED

☐ The court makes the following recommendations to the Bureau of Prisons:

☐ The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on _____.

☐ as notified by the United States Marshal.

☐ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☐ before 2 p.m. on _____.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

a _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

AO 245B (Rev. 10/17) Judgment in a Criminal Case
Sheet 3 — Supervised Release

DEFENDANT: JENNIFER DANIELS
CASE NUMBER: 2:13-CR-0203-JCM-CWH **SEALED**

SUPERVISED RELEASE

Upon release from imprisonment, you will be on supervised release for a term of: 2 YEARS.

MANDATORY CONDITIONS

1. You must not commit another federal, state or local crime.
2. You must not unlawfully possess a controlled substance.
3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court, not to exceed 104 tests annually.
   ☑ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(check if applicable)*
4. ☑ You must make restitution in accordance with 18 U.S.C. §§ 3663 and 3663A or any other statute authorizing a sentence of restitution. *(check if applicable)*
5. ☑ You must cooperate in the collection of DNA as directed by the probation officer. *(check if applicable)*
6. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (42 U.S.C. § 16901, *et seq.*) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(check if applicable)*
7. ☐ You must participate in an approved program for domestic violence. *(check if applicable)*

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

DEFENDANT: JENNIFER DANIELS
CASE NUMBER: 2:13-CR-0203-JCM-CWH **SEALED**

STANDARD CONDITIONS OF SUPERVISION

As part of your supervised release, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of your release from imprisonment, unless the probation officer instructs you to report to a different probation office or within a different time frame.
2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.
3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.
4. You must answer truthfully the questions asked by your probation officer.
5. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.
7. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
8. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.
9. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.
10. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchakus or tasers).
11. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting the permission of the court.
12. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the risk and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the risk.
13. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's Signature _____ Date _____

DEFENDANT: JENNIFER DANIELS
CASE NUMBER: 2:13-CR-0203-JCM-CWH **SEALED**

ADDITIONAL STANDARD CONDITIONS OF SUPERVISION

1. You must notify the court of any material change in your economic circumstances that might affect your ability to pay restitution, fines, or special assessments.

DEFENDANT: JENNIFER DANIELS
CASE NUMBER: 2:13-CR-0203-JCM-CWH **SEALED**

SPECIAL CONDITIONS OF SUPERVISION

1. Search and Seizure – You must submit your person, property, house, residence, vehicle, papers, computers (as defined in 18 U.S.C. § 1030(e)(1)), other electronic communications or data storage devices or media, or office, to a search conducted by a United States Probation Officer. Failure to submit to a search may be grounds for revocation of release. You must warn any other occupants that the premises may be subject to searches pursuant to this condition.

The probation officer may conduct a search under this condition only when reasonable suspicion exists that you have violated a condition of supervision and that the areas to be searched contain evidence of this violation. Any search must be conducted at a reasonable time and in a reasonable manner.

2. Mental Health Treatment – You must participate in a mental health treatment program and follow the rules and regulations of that program at the discretion of the probation officer.

3. Access to Financial Information – You must provide the probation officer access to any requested financial information and authorize the release of any financial information. The probation office will share financial information with the U.S. Attorney's Office.

4. Debt Obligations – You must not incur new credit charges, or open additional lines of credit without the approval of the probation officer.

5. No Contact – You must not communicate, or otherwise interact, with Derrick Phelps, Cynthia Phelps, Linda Mack, Daryll Reese, or Tai Keyster, either directly or through someone else, without first obtaining the permission of the probation office.

Note: A written statement of the conditions of release was provided to the Defendant by the Probation Officer in open court at the time of sentencing.

AO 245B (Rev. 10/17) Judgment in a Criminal Case
Sheet 5 — Criminal Monetary Penalties

DEFENDANT: JENNIFER DANIELS
CASE NUMBER: 2:13-CR-0203-JCM-CWH **SEALED**

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	JVTA Assessment*	Fine	Restitution
TOTALS	$ 100.00	$ 0.00	$ 0.00	$ 19,356,074.00

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss**	Restitution Ordered	Priority or Percentage
See restitution list attached.	19,356,074.00		

TOTALS	$ _____	$ _____

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

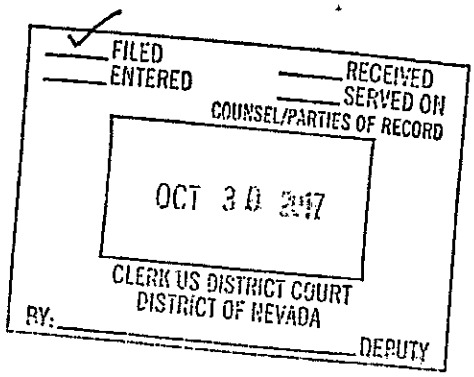
☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.
** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

U.S. vs JENNIFER DANIELS
2:13-cr-00203-JCM-CWH
Restitution List



Aegis Funding Corp 11381 Meadowglen Lane, Suite I Houston, TX 77082	280,500
American Mortgage Express Financial out of business	113,000
America's Servicing Company 7495 New Horizon Way Frederick, MD 21703	4,869,445
AMS Servicing, LLC 3374 Walden Avenue, Suite 120 Depew, NY 14043	255,000
Aurora Loan Services, LLC 10350 Park Meadows Drive Littleton, CO 80124	875,700
BAC Home Loans Servicing, LP 6400 Legacy Drive Plano, TX 75024	1,081,100
Central Mortgage Co 801 John Barrow Road, Ste 1 Little Rock, AR 72205	537,050
Chase Home Finance Inc. 343 Thornall Street Edison, NJ 08837	304,580
Colorado Federal Savings Bank 1952 Gallows Road Vienna, VA 22182	195,000
EMC Mortgage LLC 2780 Lake Vista Drive Lewisville, TX 75067	2,845,100
Entrust Mortgage, Inc 6795 East Tennessee Avenue, 5th Floor Denver, CO 80224	285,000

U.S. vs JENNIFER DANIELS
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Restitution List

Equity Link Financial 222 Las Colinas Blvd West, Suite 1650 Irving, TX 75039	150,000
Equity Title Company of Nevada 8850 W. Sunset Road, Suite 100 Las Vegas, NV 89148	337,800
Evergreen Lending, Inc 4936 Fairmont Ave Ste 201 Bethesda, MD 20814	142,000
FDIC Investigation Unit (RO) 1601 Bryan Street, MS 13.0 Dallas, TX 75201-3430 (re: Receiver for AmTrust Bank)	119,000
FDIC Investigation Unit (RO) 1601 Bryan Street, MS 13.0 Dallas, TX 75201-3430 (re: Receiver for IndyMac Bank)	387,900
First Franklin Out of business	525,000
Litton Loan Servicing, LP 2727 East Imperial Highway Brea, CA 92821	159,000
GMAC Mortgage, LLC out of business	102,600
HomeComings Financial out of business	75,000
National Title 4505 White Bear Pkwy White Bear Lake, MN 55110	200,750

U.S. vs JENNIFER DANIELS
2:13-cr-00203-JCM-CWH
Restitution List

Nevada Title Company 2500 N. Buffalo Drive, Suite 150 Las Vegas, NV 89128	169,000
New Century Mortgage Corp out of business	247,000
Ocwen Loan Servicing, LLC 1661 Worthington Road, Suite 100 West Palm Beach, FL 33409	535,700
Pacific Mercantile Bank 949 South Coast Drive, 3rd Floor Costa Mesa, CA 92626	88,000
Popular Mortgage Servicing, Inc 121 Woodcrest Rd. Cherry Hill, NJ 08003	134,352
Real Time Resolutions Inc 1750 Regal Row, Suite 120 Dallas, TX 75235	74,250
Saxon Mortgage Services, Inc. 4708 Mercantile Drive North Fort Worth, TX 76137	1,026,950
Silver State Financial Services Inc. out of business	246,595
Specialized Loan Servicing LLC 8742 Lucent Boulevard, Suite 300 Highlands Ranch, CO 80129-2386	1,775,000
Stonecreek Funding Corp 17295 Chesterfield Airport Rd Chesterfield, MO 63005	333,000
Sunset Mortgage out of business	111,500

U.S. vs JENNIFER DANIELS
2:13-cr-00203-JCM-CWH
Restitution List

WMC Mortgage LLC 6320 Canoga Avenue Woodland Hills, CA 91367	145,000
Wilshire Credit Corporation 14523 S.W. Millikan Way, Suite 200 Beaverton, OR 97005	629,202
TOTAL LOSS:	19,356,074

AO 245B (Rev. 10/17) Judgment in a Criminal Case
Sheet 6 — Schedule of Payments

DEFENDANT: JENNIFER DANIELS
CASE NUMBER: 2:13-CR-0203-JCM-CWH **SEALED**

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A ☑ Lump sum payment of $ 100.00 due immediately, balance due

☐ not later than _____, or
☐ in accordance with ☐ C, ☐ D, ☐ E, or ☑ F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☑ Special instructions regarding the payment of criminal monetary penalties:

It is further recommended that any unpaid balance shall be paid at a monthly rate of not less than 10% of any income earned during incarceration and/or gross income while on supervision, subject to adjustment by the Court based upon ability to pay.

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☑ Joint and Several

Defendant and Co-Conspirators Names and Case Numbers *(including defendant number)*, Total Amount, Joint and Several Amount, and corresponding payee, if appropriate.

Jennifer Daniels (1) - 2:13-cr-0203-JCM; Derrick Phelps (1) 2:13-cr-83-JCM; Cynthia Phelps (2) 2:13-cr-83-JCM; Linda Mack (3) 2:13-cr-83-JCM; Tai Keyster (4) 2:13-cr-83-JCM. **Total Amount: $19,356,074.00; Joint and Several Amount: $19,356.074.00.**

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

☑ The defendant shall forfeit the defendant's interest in the following property to the United States:
"FINAL ORDER OF FORFEITURE ATTACHED"

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) fine principal, (5) fine interest, (6) community restitution, (7) JVTA assessment, (8) penalties, and (9) costs, including cost of prosecution and court costs.

FILED ____ RECEIVED
ENTERED ____ SERVED ON
COUNSEL/PARTIES OF RECORD

OCT 30 2017

CLERK US DISTRICT COURT
DISTRICT OF NEVADA
BY: ____ DEPUTY

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

UNITED STATES OF AMERICA, Plaintiff, v. JENNIFER DANIELS, Defendant.	2:13-CR-203-JCM-(CWH) Final Order of Forfeiture

This Court found that Jennifer Daniels shall pay the in personam criminal forfeiture money judgment of $181,046.23 pursuant to Fed. R. Crim. P. 32.2(b)(1) and (2); Title 18, United States Code, Section 981(a)(1)(C) with Title 28, United States Code, Section 2461(c); Title 18, United States Code, Section 982(a)(2)(A); and Title 21, United States Code, Section 853(p). Criminal Information, ECF No. 8; Plea Agreement, ECF No. 10; Change of Plea, ECF No. __; Order of Forfeiture, ECF No. 11.

THEREFORE, IT IS HEREBY ORDERED, ADJUDGED, AND DECREED that the United States recover from Jennifer Daniels the in personam criminal forfeiture money judgment of $181,046.23 pursuant to Fed. R. Crim. P. 32.2(b)(4)(A) and (B); Title 18, United States Code, Section 981(a)(1)(C) with Title 28, United States Code, Section 2461(c); Title 18, United States Code, Section 982(a)(2)(A); and Title 21, United States Code, Section 853(p).

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IT IS FURTHER ORDERED, ADJUDGED, AND DECREED that the Clerk will provide three certified copies of this sealed order in a sealed envelope addressed: United States Attorney's Office, Attention Asset Forfeiture Unit.

DATED this 30th day of October, 2017.

UNITED STATES DISTRICT JUDGE

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

25-1-

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Inspire Prosthetics and Orthotics

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3233 W Charleston Blvd - STE 111

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (725) 222-4476 Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Wilfredo Middle: Antonio Last: Christie

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: wilfredo.c@inspireprosthetics.com

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	✔	
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
US Army Academy of Health Sciences		09-1982 to 03/1983	
Address	**City**	**State**	**Zip**
2250 Stanley Road - STE 251	Fort Sam Houston	TX	78234
Diploma/Degree obtained, if any			
Certificate of Completion, Ratiologic Technologist Program			

School Name		From - To (MM/YY – MM/YY)	
Clara Barton High School for Health Professions		09/1980 to 06/1982	
Address	**City**	**State**	**Zip**
901 Classon Avenue	Broolyn	NY	11225
Diploma/Degree obtained, if any			
Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/2024 - Present	[redacted]	Las Vegas	NV	[redacted]
10/2024 - 01/2025		Los Osos	CA	
07/2024 - 08/2024		Midland	TX	
02/2018 - 07/2024		Discovery Bay	CA	
10/2016 - 02/2018		Concord	CA	
12/2012 - 10/2016		Wailuku	HI	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Aequor Medical Staffing			10/2024 - 01/2025
Business Address	**City**	**State**	**Zip**
377 Hoes Lane - Ste 300	Piscataway	NJ	08854
Phone	**Title**		
(734) 354-8000	MRI Technologist		
Description of Duties			
Performed MRI imaging procedures in accordance with accepted standards of practice, including the administering contrast agents.			

Business Name			From - To (MM/YY – MM/YY)
RANG Technologies			7/2024 - 8/2024
Business Address	**City**	**State**	**Zip**
15 Corporate PL - Ste 356	Piscataway	NJ	08854
Phone	**Title**		
(732) 947-4119	MRI Technologist		
Description of Duties			
Managed technical factors and exam times to accommodate any unforeseen scheduling events.			

Business Name			From - To (MM/YY – MM/YY)
El Camino Health			03/2021 - 03/2024
Business Address	**City**	**State**	**Zip**
2500 Grant Road	Mountain View	CA	94040
Phone	**Title**		
(650) 940-7075	MRI Technologist		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Aureus Medical Staffing			03/2020 - 03/2021
Business Address	**City**	**State**	**Zip**
1010 N 102nd St - #300	Omaha	NE	68114
Phone	**Title**		
(402) 891-1118	MRI Technologist		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Bay Medical Imaging			10/2015 - 03/2020
Business Address	**City**	**State**	**Zip**
2125 Oak Grove Rd #200	Walnut Creek	CA	94598
Phone	**Title**		
(925) 296-7150	MRI Technologist		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	✔	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1 . Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
		NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Driving Under the Influence (DUI)				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

- First-time offense (misdemeanor) DUI

N/A

Original Signature (electronic, copies or stamps not accepted)

~~02/13/2025~~

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wilfredo Christie

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

~~02/18/2025~~ 2/19/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Wilfredo Antonio Christie, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02/19/25

Date

Subscribed and Sworn to before me this 19 day of February.

Notary Public Signature

MARIO DIAZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. No. 19-1865-1
MY APPT. EXPIRES FEB. 25, 2027

(Seal)

Wilfredo Christie
[redacted]
Wilfredo.c@inspireprosthetics.com
[redacted]
March 25, 2025

Nevada State Board of Pharmacy
431 W Plumb Ln
Reno, NV 89509

Dear Members of the Nevada State Board of Pharmacy,

I am writing to address two charges that appear on my record. I believe in the importance of transparency and wish to provide a clear account of these incidents.

1. DUI Charge

On October 13, 2010, I was arrested for driving under the influence of alcohol (Case No. 10M32430X). This offense was classified as a misdemeanor under statute 484.379. On July 19, 2011, I entered a plea of nolo contendere (no contest) and was found guilty.

The court mandated several conditions as part of my sentence, which included:

- Attending DUI school and a victim impact panel.
- Paying fines and fees amounting to $585.

I diligently completed all the required conditions, including attending the DUI school and the victim impact panel. The case was officially closed on December 15, 2011, after I fulfilled all the court's requirements.

2. Domestic Battery Charge

On November 30, 2006, I was involved in an incident that led to my arrest for domestic battery (Case No. PC06M29113X). The charge was classified as a misdemeanor under statute 200.481. I was required to post bail and ultimately, the charges were dropped.

At the time of the incident, I was in a very toxic marriage that significantly impacted my emotional and mental well-being. The relationship was fraught with conflict and stress, which culminated in the unfortunate event leading to my arrest. Shortly after this incident, the marriage ended, and I have not been in contact with my ex-wife since then.

I am now in a healthy and loving relationship that has lasted almost 20 years. This relationship has been a tremendous benefit to my life, providing stability, support, and happiness. The positive changes in my personal life have greatly contributed to my ability to maintain high standards of conduct and professionalism in my career.

In addition to these personal changes, I have had a very successful career as a radiology technician for 40 years. My extensive experience in the medical field has equipped me with the skills and knowledge necessary to excel in running my own orthotics and prosthetics clinic. Furthermore, I spent time in the army as a young adult, which instilled in me a strong sense of discipline, responsibility, and commitment to serving others.

I deeply regret my involvement in these matters and have proactively taken substantial measures to ensure that such events do not recur. These experiences have imparted invaluable lessons, prompting significant positive changes in my life to prevent any future occurrences. I am steadfastly committed to upholding the highest standards of conduct and professionalism in my career.

I respectfully request that the Board consider this explanation and the steps I have taken to address these situations. I am dedicated to upholding the integrity of the orthotics and prosthetics profession and am fully committed to serving the community with the utmost responsibility and care.

Thank you for your understanding and consideration.

Sincerely,

Wilfredo A. Christie

Wilfredo A. Christie

REGISTER OF ACTIONS
CASE NO. PC06M29113X

State of Nevada vs Christie, Wilfredo A §§§§§§

Case Type: **Misdemeanor**
Date Filed: **11/30/2006**
Location:

PARTY INFORMATION

		Lead Attorneys
Defendant	**Christie, Wilfredo A** Other Agency Numbers 1795849 Justice Court Scope ID Subject Identifier	
State of Nevada	**State of Nevada**	

CHARGE INFORMATION

Charges: Christie, Wilfredo A	Statute	Level	Date
1. BATTERY DOMESTIC VIOLENCE NO PRIOR CONVICTIONS	200.481	Misdemeanor	11/30/2006

EVENTS & ORDERS OF THE COURT

	OTHER EVENTS AND HEARINGS
11/30/2006	**Standard Bail Set** *Ct1: $3000.00 Cash/3000.00 Surety*
11/30/2006	**JCON Accounting Detail** *Rcpt #: 09722481 Deft Name: CHRISTIE, WILFREDO Payer Name: BAILBONDS.COM Deft ID: 01795849 Fund: 660 Payment Type: CSH Location: ITK Case #: 06M29113X*
11/30/2006	**CTRACK Track Assignment JC01**

REGISTER OF ACTIONS
CASE NO. 10M32430X

State of Nevada vs Christie, Wilfredo A

Case Type: **Citation**
Date Filed: **04/14/2011**
Location: **JC Department 6**

PARTY INFORMATION

Defendant	**Christie, Wilfredo A** *AKA* **Christie, Wilfredo** Other Agency Numbers 1795849 Justice Court Scope ID Subject Identifier	**Lead Attorneys** **Janet Kelleran** *Retained* 7023861070(W)
State of Nevada	**State of Nevada**	

CHARGE INFORMATION

Charges: Christie, Wilfredo A	**Statute**	**Level**	**Date**
1. DUI-ALCOHOL-1ST OFFENSE	484.379	Misdemeanor	10/13/2010
2. UNREGISTERED VEHICLE	482.545	Misdemeanor	04/14/2011
3. NO INSURANCE/SECURITY	485.187	Misdemeanor	04/14/2011

EVENTS & ORDERS OF THE COURT

DISPOSITIONS

07/19/2011 **Disposition** (Judicial Officer: Kephart, William)
1. DUI-ALCOHOL-1ST OFFENSE
PLEA NOLO/FOUND GUILTY

07/19/2011 **Disposition** (Judicial Officer: Kephart, William)
2. UNREGISTERED VEHICLE
DISMISSED PER NEGOTIATIONS

07/19/2011 **Disposition** (Judicial Officer: Kephart, William)
3. NO INSURANCE/SECURITY
DISMISSED PER NEGOTIATIONS

07/19/2011 **Plea** (Judicial Officer: Kephart, William)
1. DUI-ALCOHOL-1ST OFFENSE
GUILTY

07/19/2011 **Credit Time Served** (Judicial Officer: Kephart, William)
1. DUI-ALCOHOL-1ST OFFENSE
Condition - Adult:
1. DUI SCHOOL/VICTIM IMPACT PANEL, 07/19/2011, Active 07/19/2011
Comment (DATE: 07/19/2011 JC FINE: 0403 AA FINE: 122 JC TOTAL: 0585 JC EXCUSED:)
Comment (CONTRIBUTION: DRUGFEE: 060)
Comment (CTS (MOS): CTS (DAYS): 000 CTS (HRS):)

OTHER EVENTS AND HEARINGS

07/18/2010 **Minute Order**
10/13/2010 **COMPLETED BY JB**
MinuteCode1: COMPLETED BY JB MinuteCode3: COMPLETED BY JB
12/21/2010 **Notice of Confirmation of Counsel**
04/14/2011 **TRANSFERRED TO JC**
TRANSFERRED TO JC
04/14/2011 **COMPLETED BY LLO**
MinuteCode1: COMPLETED BY LLO MinuteCode3: COMPLETED BY LLO
04/14/2011 **CTRACK Track Assignment JC03**
04/15/2011 **Conversion Unknown** (Judicial Officer: Kephart, William)
OTHER
04/15/2011 **OTHER** (8:00 AM) (Judicial Officer Kephart, William)
Result: COMPLETED
04/15/2011 **Criminal Complaint**
04/15/2011 **Filed Under Seal**
04/15/2011 **Summons Issued In Lieu Of Arrest**
05/06/2011 **Returned Mail**
05/16/2011 **TRAFFIC ARRAIGNMENT COMPLETED** (Judicial Officer: Kephart, William)
SUMMONS RETURN
05/16/2011 **Summons Return Hearing** (8:00 AM) (Judicial Officer Kephart, William)
Result: COMPLETED
07/19/2011 **SEE CHARGE/DISPOSITION/SENT RECORDS** (Judicial Officer: Kephart, William)

	NONJURY TRIAL
07/19/2011	**COURTESY NOTICE OF DISPOSITION GENERATED**
	MinuteCode1: COURTESY NOTICE OF DISPOSITION GENERATED MinuteCode3: COURTESY NOTICE OF DISPOSITION GENERATED
07/19/2011	**Bench Trial** (8:00 AM) (Judicial Officer Kephart, William)
	Result: GUILTY/SENT
07/19/2011	**Admonishment of Rights - DUI**
07/19/2011	**Notice of Disposition and Judgment**
10/04/2011	**Transcript of Proceedings**
10/12/2011	**JCON Accounting Detail**
	Rcpt #: 10017131 Deft Name: CHRISTIE, WILFREDO Payer Name: CHRISTIE, WILFREDO Deft ID: 01795849 Fund: 309 Payment Type: CRE Location: CRM Case #: 10M32430X
10/12/2011	**JCON Accounting Detail**
	Rcpt #: 10017132 Deft Name: CHRISTIE, WILFREDO Payer Name: CHRISTIE, WILFREDO Deft ID: 01795849 Fund: 302 Payment Type: CRE Location: CRM Case #: 10M32430X
10/12/2011	**Receipt of Payment**
10/19/2011	**CONTINUED TO COMPLETE REQUIREMENTS** (Judicial Officer: Kephart, William)
	OTHER
10/19/2011	**OTHER** (8:00 AM) (Judicial Officer Kephart, William)
	Result: COMPLETED
10/19/2011	**Counseling Report**
11/16/2011	**Counseling Report**
11/22/2011	**CONTINUED TO COMPLETE REQUIREMENTS** (Judicial Officer: Kephart, William)
	OTHER
11/22/2011	**OTHER** (8:00 AM) (Judicial Officer Kephart, William)
	Result: COMPLETED
12/09/2011	**DUI Report**
12/15/2011	**REQUIREMENTS COMPLETED** (Judicial Officer: Kephart, William)
	OTHER
12/15/2011	**OTHER** (8:00 AM) (Judicial Officer Kephart, William)
	Result: COMPLETED
01/05/2012	**DUI Report**

8B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☒ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	☒ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
☒ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☒ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Optimal Embrace

MDEG Physical Address: 6050 S Fort Apache Rd #120, Las Vegas, NV 89148

City: Las Vegas State: Nevada Zip: 89148

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (702) 728-5735 Website: _____

Email: info@optimalptlv.com

Name of MDEG Administrator (NAC 639.694): Matt Figgins

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
☒ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☒ Orthotics and Prosthetics
	☐ Others:
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: Matt Figgins
	Telephone: 7028276384

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 8-6	■ Tue: 8-6	■ Wed: 8-6	■ Thurs: 8-6	■ Fri: 8-2
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Seek medicare and medicaid numbers after this application is approved

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Chelsea Jolley

Business Name: Optimal Embrace

Business Address: 6050 S Fort Apache Rd #120, Las Vegas, NV 89148

City: Las Vegas State: Nevada Zip: 89148

Telephone: (702) 728-5735 Email: info@optimalptlv.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Chelsea Jolley

Print Name of Authorized Person Submitting Application

Chelsea Jolley

Original signature of Authorized Person (copies or stamps not accepted)

1/08/2025

Date

Board Use Only	Date Received: 1/16/25	Amount: $520 ck 2116

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Optimal Embrace

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 6050 S Fort Apache Rd #120, Las Vegas, NV 89148

City Las Vegas State Nevada Zip 89148

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702) 728-5735 Website _____

Licensing Company Email _____

Section 2: Personal Information

First Chelsea Middle Ann Last Jolley

Alias(es, nicknames, name changes, etc.) Chelsea Ann Summers

Date of Birth [redacted] SSN or ITIN _____ Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City St George State Utah Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)	-	✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
BYU-IDAHO		09/2020 – 05/2024	
Address	**City**	**State**	**Zip**
101 E Viking St	Rexburg	ID	83460
Diploma/Degree obtained, if any			
BA - Communications			

School Name		From - To (MM/YY – MM/YY)	
Idasatch High School		08/1996 05/2000	
Address	**City**	**State**	**Zip**
930 500 E	Heber City	Ut	84032
Diploma/Degree obtained, if any			
High School			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
05/21 – Present	[redacted]	St. George	Ut	[redacted]
08/14 05/21		Pahrump	NV	

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Affiliated Physical Therapy			From - To (MM/YY – MM/YY): Now - 01/16
Business Address: 6050 S. Fort Apache Rd #120	City: Las Vegas	State: NV	Zip: 89148
Phone: 208 757 0391	Title: Public Relations		
Description of Duties: Business Development Referral Center Developer			
Business Name: Visa			From - To (MM/YY – MM/YY): 09/21 - 10/24
Business Address: 494 N Mall Dr	City: St. George	State: Ut	Zip: 84790
Phone: 435 628. 9201	Title: Aerobics Instructor		
Description of Duties: Teach Aerobic Classes -			
Business Name: Utah Tech University			From - To (MM/YY – MM/YY): 09/21 05/23
Business Address: 225 S. Univ Ave	City: St George	State: Ut.	Zip: 84770
Phone:	Title: Aerobics Instructor		
Description of Duties: Teach Aerobic Classes			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			
Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/12/2026
Date

5262

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Chelsea Jolley

Print Name (First, Last)

Chelsea Jolley

Original Signature (electronic, copies or stamps not accepted)

1/08/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Utah, ss. County of Washington

I, Chelsea Jolley, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Chelsea Jolley

Original Signature

1/9/25

Date

Subscribed and Sworn to before me this 9th day of January, 2025.

Kurtis Larsen

Notary Public Signature

NOTARY PUBLIC
KURTIS LARSEN
737611
MY COMMISSION EXPIRES
JUNE 06, 2028
STATE OF UTAH

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Optimal Embrace MDEG License # (if applicable) _____

Physical Address 6050 S. Fort Apache Rd #120, Las Vegas, NV 89148

City Las Vegas State NV Zip 89148

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone (702) 728-5735 Website _____

Licensing Company Email _____

Section 2: Personal Information

First Matthew Middle C Last Figgins

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN _____ Sex ■ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: AT Still University		From - To (MM/YY – MM/YY): 07/2017 - 07/2019	
Address: 5855 E. Still Circle Ste A	City: Mesa	State: Az	Zip: 85206
Diploma/Degree obtained, if any: Masters - Occupational therapy			
School Name: Utah Valley University		From - To (MM/YY – MM/YY): 09/2014 - 12/2016	
Address: 800 W. University Pkwy	City: Orem	State: UT	Zip: 84058
Diploma/Degree obtained, if any: Bachelors - Exercise Science			
School Name: Bonanza High School		From - To (MM/YY – MM/YY): 09/07 - 06/11	
Address: 6665 Del Rey Ave	City: Las Vegas	State: NV	Zip: 89146
Diploma/Degree obtained, if any: Advanced Honors Diploma			
School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/24 - present	[redacted]	Las Vegas	[redacted]	
03/21 - 07/24		Gilbert		
07/17 - 03/21		Gilbert		
12/16 - 07/17		Las Vegas		
08/15 - 12/16		Provo		
01/15 - 08/15		Provo		
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name		From - To (MM/YY – MM/YY)	
Desert Hand Therapy		02/20 - 06/24	
Business Address	**City**	**State**	**Zip**
3104 E. Indian School Rd #200A	Phoenix	AZ	85016
Phone	**Title**	**Number of Employed Hours**	
(602) 955-2302	Occupational therapist - Certified Hand Therapist	9,000	
Description of Duties			
Upper extremity rehabilitation & custom splint fabrication.			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**	**Number of Employed Hours**	
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Matthew Figgins, **certify that as the MDEG Administrator for** Optimal Embrace,

that I (initial that you have read and meet the following requirements):

1. MF Have a high school diploma or its equivalent;
2. MF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew Figgins
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/13/2025
Date

Board Use Only	Date Received: 3/4/25

HEALTHCARE PROVIDERS
PROFESSIONAL LIABILITY POLICY ENDORSEMENT

Scheduled Covered Subsidiaries

In consideration of the premium paid, and subject to the applicable limits of liability shown on the **certificate of insurance,** it is agreed as follows:

1. The following subsidiaries (hereafter referred to as **"subsidiary"**) are provided coverage under the Policy:

   Name(s) of Subsidiaries: Optimal Embrace
   6050 S Fort Apache Rd #120
   Las Vegas, NV 89148

2. Solely for the purposes of the coverage provided by this Endorsement, the definition of **You** in the Professional Liability Coverage Part is deleted in its entirety and replaced with the following:

   "You" or **"Your"** means the **named insured**, the Subsidiaries named above, and,

   1. any individual who, during the **policy period,** is or becomes a partner, officer, director, stockholder-employee, manager, member or an **employee** of the **named insured** or any **subsidiary,** but only while acting within the scope of their **professional services**; or
   2. any individual who, during the **policy period**, is or becomes a substitute health care provider that the **named insured** or any **subsidiary** contracts with, but only while acting within the scope of their **professional services.**
   3. any individual previously affiliated with the **named insured,** or any subsidiary named above, as its partner, officer, director, stockholder-employee, manager, member or **employee** but only for **professional services** performed on behalf of the **named insured** or any **subsidiary** during the course of such employment.

3. Solely for the purposes of the coverage provided by this Endorsement, the definition of **you** in the General Liability Coverage Part, or the Workplace Liability Coverage Part, as applicable, is deleted in its entirety and replaced with the following:

   "You" or **"Your"** means the **named insured** or any **subsidiary** and:

   1. any individual who, during the **policy period,** is or becomes an **employee** of the **named insured** or any **subsidiary,** but only while acting within the scope of their employment by the **named insured** or any **subsidiary**; or
   2. any individual who, during the **policy period**, is or becomes a substitute health care provider, other than a physician, dentist, nurse anesthetist, nurse mid-wife, chiropractor, self-employed perfusionist, or podiatrist, that the **named insured** or any **subsidiary** contracts with, but only while acting within the scope of their employment by the **named insured** or any **subsidiary;** or
   3. any individual previously affiliated with the **named insured** or any **subsidiary** as its **employee** but only while acting within the scope of their employment by the **named insured** or any **subsidiary,** during the course of such employment.

Must Be Completed	
Endt. No.	Policy No.
1	597328533

Completed Only When This Endorsement is Not Prepared with the Policy *Or* Is Not to be Effective with the Policy	
Issued to.	Effective Date
Affiliated Physical Therapy	01/29/25

G-141237-A (7/2001)

4. On the date during the **policy period**, that the **Named Insured's** direct or indirect ownership interest in any **subsidiary** becomes less than 50%, of the issued and outstanding voting stock, such corporation shall cease to be a **subsidiary** under the terms of this Policy. In such event, coverage will be provided under the Policy but only with respect to acts or omissions committed prior to such date in accordance with all other terms and conditions of this Policy. No coverage will be afforded under the Policy with respect to **claims** made against an **Insured** based on any act or omission committed or allegedly committed on or subsequent to such date.
5. This paragraph 5 applies only if this endorsement is attached to the Professional Liability Coverage Part – Claims Made (form G-121502-M3) and only if a prior acts date appears in the box below.
6. Solely with respect to each **subsidiary,** Section V, Exclusions, paragraph N.1. is deleted in its entirety and replaced with the following:

   N. any act, error or omission, including a **medical incident, Good Samaritan incident, placement services** or **personal injury:**

      1. that happened:

         a. prior to the prior acts date listed opposite such **subsidiary's** name; or

         b. after the prior acts date, if, on the inception date of this endorsement, **you** knew or had been told that it would result in a **claim**;

Subsidiary	Prior Acts Date

This endorsement is a part of **your** policy and takes effect on the effective date of **your** policy, unless another effective date is shown below. All other provisions of the policy remain unchanged.

Must Be Completed	
Endt. No.	Policy No.
1	597328533

Completed Only When This Endorsement Is Not Prepared with the Policy *Or* Is Not to be Effective with the Policy	
Issued to.	Effective Date
Affiliated Physical Therapy	01/29/25

G-141237-A (7/2001)

POLICY FORMS & ENDORSEMENTS

The following are the policy forms and endorsements that apply to your current professional liability policy.

COMMON POLICY FORMS & ENDORSEMENTS

FORM #	FORM NAME
G-121500-D (04-08)	Common Policy Conditions
G-121501-C (07-01)	Occurrence Policy Form
G-121503-C (07-01)	Workplace Liability Form
CNA82011 (04-15)	Related Claims Endorsement
G-145184-A (06-03)	Policyholder Notice - OFAC Compliance Notice
G-147292-A (03-04)	Policyholder Notice - Silica, Mold & Asbestos Disclosure
CNA81753 (03-15)	Coverage & Cap on Losses from Certified Acts Terrorism
CNA81758 (01-21)	Notice - Offer of Terrorism Coverage & Disclosure of Premium
GSL13424 (05-09)	Services to Animals
GSL13425 (05-09)	Business Owner Coverage Extension Endorsement
GSL15564 (10-09)	Sexual Misconduct Sublimits of Liability Professional Liability & Sexual Misconduct Exclusion
GSL15565 (03-10)	Healthcare Providers Professional Liability Assault Coverage
GSL17101 (02-10)	Exclusion of Specified Activities Reuse of Parenteral Devices and Supplies
CNA80052 (09-14)	Distribution or Recording of Material or Information in Violation of Law Exclusion Endorsement
CNA94164 (11-18)	Amendment Definition of Claim Endorsement
G-123816-C27 (12-01)	Nevada Amendatory Change
G-123846-C27 (07-01)	Nevada Cancellation and Non-Renewal
CNA79516 (07-14)	Enterprise Privacy Protection
CNA79575 (07-14)	Exclusion of Cosmetic Procedures
CNA89026 (05-17)	Media Expense Coverage
G-141236-A (07-01)	Exclusion of Activities
G-141237-A (07-01)	Scheduled Covered Subsidiaries
GSL13428 (05-09)	DBA or Specified Endorsements
GSL-6076 (12-06)	Office Sharing Exclusion
HP 2720-A (02-03)	Exclusion of Entity

PLEASE REFER TO YOUR CERTIFICATE OF INSURANCE FOR THE POLICY FORMS & ENDORSEMENTS SPECIFIC TO YOUR STATE AND YOUR POLICY PERIOD.

For NJ residents: The PLIGA surcharge shown on the Certificate of Insurance is the NJ Property & Liability Insurance Guaranty Association.

For KY residents: The Surcharge shown on the Certificate of Insurance is the KY Firefighters and Law Enforcement Foundation Program Fund and the Local Tax is the KY Local Government Premium Tax. As required by 806 Ky. Admin Regs. 2:100, this Notice is to advise you that a surcharge has been applied to your insurance premium and is separately itemized on the Declarations page or billing instrument attached to your policy, as required KRS. §136.392.

For WV residents: The surcharge shown on the Certificate of Insurance is the WV Premium Surcharge.

For FL residents:

CNA

HEALTHCARE PROVIDERS SERVICE
ORGANIZATION PURCHASING GROUP

HPSO

Certificate of Insurance

OCCURRENCE PROFESSIONAL LIABILITY POLICY FORM

Print Date: 12/09/2024

The application for the Policy and any and allsupplementary information, materials, and statements submitted therewith shall be maintained on file by us or our Program Administrator and will be deemed attached to and incorporated into the Policy as if physically attached.

PRODUCER	BRANCH	PREFIX	POLICY NUMBER	POLICY PERIOD
018098	970	HPG	0597328533	From: 12/12/24 to 12/12/25 at 12:01 AM Standard Time

Named Insured and Address:

Affiliated Physical Therapy
1333 N Buffalo Dr Unit 170
Las Vegas, NV 89128-3637

Program Administered by:

Healthcare Providers Service Organization
1100 Virginia Drive, Suite 250
Fort Washington, PA 19034
1-888-288-3534
www.hpso.com

Medical Specialty:	Code:	Insurance Provided by:
Physical Therapist Firm	80995	American Casualty Company of Reading, Pennsylvania 151 N. Franklin Street Chicago, IL 60606
Excludes Cosmetic Procedures		

Professional Liability $ 1,000,000 **each claim** $ 3,000,000 **aggregate**

Your professional liability limits shown above include the following:

* Good Samaritan Liability * Malplacement Liability * Personal Injury Liability
* Sexual Misconduct Included in the PL limit shown above subject to $ 25,000 aggregate sublimit

Coverage Extensions

License Protection	$ 25,000	per proceeding	$ 25,000	aggregate
Defendant Expense Benefit	$ 1,000	per day limit	$ 25,000	aggregate
Deposition Representation	$ 10,000	per deposition	$ 10,000	aggregate
Assault Includes Workplace Violence Counseling	$ 25,000	per incident	$ 25,000	aggregate
Medical Payments	$ 25,000	per person	$ 100,000	aggregate
First Aid	$ 10,000	per incident	$ 10,000	aggregate
Damage to the Property of Others	$ 10,000	per incident	$ 10,000	aggregate
Enterprise Privacy Protection - Claims Made Retroactive Date: 12/12/2015(Defense inside limits)	$ 25,000	per incident	$ 25,000	aggregate
Media Expense	$ 25,000	per incident	$ 25,000	aggregate

Workplace Liability

Workplace Liability	Included in Professional Liability Limit shown above
Fire & Water Legal Liability	Included in the PL limit shown above subject to $150,000 aggregate sublimit
Personal Liability	Excluded

Total $ 30,870.00

Base Premium $30,870.00

Policy Forms and Endorsements (Please see attached list of policy forms and endorsements)

Chairman of the Board **Secretary**

Keep this Certificate of Insurance in a safe place. It and proof of payment are your proof of coverage. There is no coverage in force unless the premium is paid in full. To activate your coverage, please remit premium in full by the effective date of this Certificate of Insurance.

Coverage Change Date: **Endorsement Date:** Master Policy: 188711433

CNA93692 (11-2018)

SECRETARY OF STATE

STATE OF NEVADA

DOMESTIC LIMITED-LIABILITY COMPANY (86) CHARTER

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **Optimal Embrace LLC** did, on 12/27/2024, file in this office the original Articles of Organization that said document is now on file and of record in the office of the Secretary of State of the State of Nevada, and further, that said document contains all the provisions required by the law of the State of Nevada.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 12/27/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate
Number: B202412275300830
You may verify this certificate
online at https://www.nvsilverflume.gov/home

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Optimal Embrace LLC

Nevada Business Identification # NV20243263311
Expiration Date: 12/31/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 12/27/2024.

Certificate Number: B202412275300831
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

8C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☑ Nevada	☐ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☑ Yes	☐ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices **or** appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		MDEG Business Type (check applicable box)
☑ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☑ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Silver State Medical Supply LLC

MDEG Physical Address: 2550 S. Jones

City: Las Vegas State: NV Zip: 89146

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-960-7003 Website: tcmedicare.com

Email: tawbincadymedical@gmail.com

Name of MDEG Administrator (NAC 639.694): Minnie Cady

Entities the MDEG will Serve	Type of MDEG products that will be sold (check all applicable)
☐ Patients by prescriptions	☑ Medical Gases**
☑ Pharmacies[a]	☑ Respiratory Equipment**
☑ Practitioners[a]	☑ Life-sustaining equipment**
☑ Hospitals/Clinics[a]	☑ Parenteral and Enteral Equipment**
☑ Clinics[a]	☑ Assistive Equipment
☑ Wholesalers[a]	☑ Diabetic Supplies
☐ Other business entities (specify)[a]:	☑ Orthotics and Prosthetics
	☐ Others:

This application is ONLY required if MDEG products will be sold to patients by prescription.

[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)

**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):

Name: Minnie Cady

Telephone: 702-501-3821

Check the Days the Business will be Opened and provide the Hours of Operation				
☑ Mon:	☑ Tue:	☐ Wed:	☐ Thurs:	☐ Fri:
☑ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner. (NAC 639.6942(4)(i))

TBD

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:
   a) A practicing health professional; or
   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.
2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any):

Corporation Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: N/A

Parent Company (if any):

Corporation/Organization Name:

Mailing Address:

City: State: Zip:

Telephone: Email:

Contact Person Name:

Section 7: Partnership

Partnership Name: Silver State Medical Supply LLC

Mailing Address: 2550 S. Jones

City: Las Vegas State: NV Zip: 89146

Telephone: 702-960-2003 Email: towbincaday medical@gmail.com

Contact Person Name: Rocco Towbin

Section 8: Sole Owner

Owner's Name: N/A

Business Name:

Business Address:

City: State: Zip:

Telephone: Email:

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin Caday

Print Name of Authorized Person Submitting Application

Original signature of Authorized Person (copies or stamps not accepted)

3/21/25

Date

Board Use Only	Date Received: 3/31/25	Amount: $500CC

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Silver State Medical Supply LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/30/2024, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/31/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412315311301
You may verify this certificate online at https://www.nvsilverflume.gov/home

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 2/11/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER	CONTACT NAME: Skyanne Wilkins
Leavitt Insurance Agency 7881 W. Charleston Blvd. Suite 140 Las Vegas NV 89117	PHONE (A/C, No, Ext): (702) 382-4010 FAX (A/C, No): (702) 947-4010 E-MAIL ADDRESS: skyanne-wilkins@leavitt.com

INSURED	INSURER(S) AFFORDING COVERAGE	NAIC #
Silver State Medical Supply LLC DBA: TC Medicore 2550 S Jones Blvd Las Vegas NV 89146	INSURER A: ACE Property and Casualty Insurance Co	20699
	INSURER B:	
	INSURER C:	
	INSURER D:	
	INSURER E:	
	INSURER F:	

COVERAGES **CERTIFICATE NUMBER:** 2025-2026 Master Cert **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	[X] COMMERCIAL GENERAL LIABILITY [ ] CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC [ ] OTHER:			D02845544/PKG	2/3/2025	2/3/2026	EACH OCCURRENCE	$ 1,000,000
							DAMAGE TO RENTED PREMISES (Ea occurrence)	$ 1,000,000
							MED EXP (Any one person)	$ 5,000
							PERSONAL & ADV INJURY	$ 1,000,000
							GENERAL AGGREGATE	$ 2,000,000
							PRODUCTS - COMP/OP AGG	$ Excluded
							Other than Products/Comp/OP Agg	$ 2,000,000
	AUTOMOBILE LIABILITY [ ] ANY AUTO [ ] ALL OWNED AUTOS [ ] SCHEDULED AUTOS [ ] HIRED AUTOS [ ] NON-OWNED AUTOS						COMBINED SINGLE LIMIT (Ea accident)	$
							BODILY INJURY (Per person)	$
							BODILY INJURY (Per accident)	$
							PROPERTY DAMAGE (Per accident)	$
								$
	[ ] UMBRELLA LIAB [ ] OCCUR [ ] EXCESS LIAB [ ] CLAIMS-MADE [ ] DED [ ] RETENTION $						EACH OCCURRENCE	$
							AGGREGATE	$
								$
A	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) Y/N [Y] N/A If yes, describe under DESCRIPTION OF OPERATIONS below			2671816397/WC	2/3/2025	2/3/2026	[X] PER STATUTE [ ] OTH-ER	
							E.L. EACH ACCIDENT	$ 1,000,000
							E.L. DISEASE - EA EMPLOYEE	$ 1,000,000
							E.L. DISEASE - POLICY LIMIT	$ 1,000,000

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

Coverage subject to policy terms, conditions, limitations, and exclusions.

CERTIFICATE HOLDER

Evidence of Insurance

CANCELLATION

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

Jordan Leavitt/SKWILK

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- List of all general and limited partner names and their percent ownership (NAC 639.6942)
    - Rocco Towbin 51%
    - Justin Caday 49%

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler SILVER STATE MEDICAL SUPPLY LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 2550 S. Jones

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) X

City X State X Zip X

Telephone 702-960-2003 Website TCMEDICORE.com

Licensing Company Email TOWBINCADAYMEDICAL@gmail.com

Section 2: Personal Information

First ROCCO Middle NMN Last TOWBIN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email ROCCO@TCMedicore.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Durango High School			8/16 - 5/18	
Address		City	State	Zip
7100 W Dewey Dr		las vegas	NV	89113
Diploma/Degree obtained, if any				
n/a				

School Name			From - To (MM/YY – MM/YY)	
Palo Verde High School			8/18 - 5/19	
Address		City	State	Zip
333 Pavilion center dr		Las Vegas	NV	89144
Diploma/Degree obtained, if any				
n/a				

School Name			From - To (MM/YY – MM/YY)	
n/a				
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
n/a				
Address		City	State	Zip
Diploma/Degree obtained, if any				

School Name			From - To (MM/YY – MM/YY)	
n/a				
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/13-08/16	[redacted]	Las Vegas	NV	[redacted]
08/16 - 10/19		Las Vegas	NV	
10/19 - 5/22		Las Vegas	NV	
05/22 - 03/25		Las Vegas	NV	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: Towbin Fiat Alfa Romeo			From - To (MM/YY – MM/YY): 6/18 - 1/20	
Business Address: 2550 S Jones	City: las vegas		State: NV	Zip: 89146
Phone: 702-900-3428	Title: Service Advisor			
Description of Duties: Sceduling and dispatching service for vehicles				

Business Name: Towbin Dodge Ram			From - To (MM/YY – MM/YY):	
Business Address: 275 AUTO MALL Dr	City: Las Vegas		State: NV	Zip: 89014
Phone: 702-957-1740	Title: USED CAR Manager			
Description of Duties: Overseeing all operations related to used car sales				

Business Name: n/a			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name: n/a			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Business Name: n/a			From - To (MM/YY – MM/YY):	
Business Address:	City:		State:	Zip:
Phone:	Title:			
Description of Duties:				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/a	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

n/a

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rocco Towbin

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3-27-2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Rocco Towbin, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3-27-2025

Date

Subscribed and Sworn to before me this 27th day of March 2025

Notary Public Signature

AMANDA LEIGH HANEY
Notary Public, State of Nevada
Appointment No. 18-4387-1
My Appt. Expires Nov 22, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/13/2022)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler SILVER STATE MEDICAL SUPPLY LLC

Pharmacy/MDEG/Wholesaler License # (if applicable) _____

Physical Address 2550 S. Jones

City LAS VEGAS State NV Zip 89146

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-960-2003 Website tcmedicore.com

Licensing Company Email towbincadaymedical@gmail.com

Section 2: Personal Information

First JUSTIN Middle JOLO Last CADAY

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City LAS VEGAS State NV Zip [redacted]

Telephone [redacted] Email jvstin@tcmedicore.com

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Durango High School		08/16 - 5/20	
Address	**City**	**State**	**Zip**
7100 W Dewey Dr, Las Vegas, NV	Las Vegas	NV	89113
Diploma/Degree obtained, if any			
College and Career Ready Diploma			

School Name		From - To (MM/YY – MM/YY)	
University of Nevada, Las Vegas		08/20 - 03/25	
Address	**City**	**State**	**Zip**
4505 S. Maryland Pkwy	Las Vegas	NV	89154
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
N/A			
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/12- 03/25	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section B: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?	N/A	
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/27/26
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Justin, Cadby

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/27/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Justin Jolo Cadby, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/27/25

Date

Subscribed and Sworn to before me this 27th day of March 2025

Notary Public Signature

AMANDA LEIGH HANEY
Notary Public, State of Nevada
Appointment No. 18-4387-1
My Appt. Expires Nov 22, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Silver State Medical Supply LLC MDEG License # (if applicable) _____

Physical Address 2550 S. Jones

City Las Vegas State NV Zip 89146

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-960-2003 Website tcmedicore.com

Licensing Company Email towbincadaymedical@gmail.com

Section 2: Personal Information

First Minnie Middle Puray Last Caday

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)
University of the Philippines College of Nursing		06/85 - 03/89
Address	**City**	**State** / **Zip**
Padre Faura ST	Manila	Philippines / 1000
Diploma/Degree obtained, if any		
BS Nursing		

School Name		From - To (MM/YY – MM/YY)
University of the Philippines Integrated School		06/79 - 03/83
Address	**City**	**State** / **Zip**
Ratiounan Road	Quezon City	Philippines / 1101
Diploma/Degree obtained, if any		
High School		

School Name		From - To (MM/YY – MM/YY)
N/A		
Address	**City**	**State** / **Zip**
Diploma/Degree obtained, if any		

School Name		From - To (MM/YY – MM/YY)
N/A		
Address	**City**	**State** / **Zip**
Diploma/Degree obtained, if any		

School Name		From - To (MM/YY – MM/YY)
N/A		
Address	**City**	**State** / **Zip**
Diploma/Degree obtained, if any		

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2012 - Present	[redacted]	Las Vegas	NV	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name: Sunrise Hospital			From - To (MM/YY – MM/YY): [redacted] 1996- Present
Business Address: 3186 Maryland Parkway	City: Las Vegas	State: NV	Zip: 89109
Phone: 702-961-7040	Title: RN		Number of Employed Hours: 36/week
Description of Duties: Read, acknowledge and verify doctors orders on medication and treatment modalities. Communicate with pharmacy regarding dispensation and delivery of medications. Administer medications as ordered.			
Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			
Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			
Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			
Business Name: N/A			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		Number of Employed Hours:
Description of Duties:			

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

3/27/25
Date

I, MINNIE CADAY, **certify that as the MDEG Administrator for** SILVER STATE MEDICAL SUPPLY LLC, **that I (initial that you have read and meet the following requirements):**

1. MC Have a high school diploma or its equivalent;
2. MC Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. MC Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. MC Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

MINNIE CADAY

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/27/25

Date

Board Use Only	Date Received: 3/31/25

8D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	■ Nevada	☐ Out-of-State
[a]**Is the business also a wholesaler? (NRS 639.016)**	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	■ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: HIGH VIBES MEDICAL SUPPLY LLC

MDEG Physical Address: 3430 E FLAMINGO RD #301

City: LAS VEGAS State: NV Zip: 89121

Mailing Address (if different from physical address): SAME

City: _____ State: _____ Zip: _____

Telephone: 682-331-0707 Website: _____

Email: cecily.fernandez@icloud.com

Name of MDEG Administrator (NAC 639.694): Cecily Fernandez

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	☐ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	☐ Assistive Equipment
☐ Wholesalers[a]	■ Diabetic Supplies
☐ Other business entities (specify)[a]:	■ Orthotics and Prosthetics
	■ Others: walkers, canes, commodes
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: _____
	Telephone: _____

Check the Days the Business will be Opened and provide the Hours of Operation				
■ Mon: 9:30am-4pm	■ Tue: 9:30am-4pm	■ Wed: 9:30am-4pm	■ Thurs: 9:30am-4pm	■ Fri: 9:30am-4pm
☐ Sat:	☐ Sun:	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
Pending Medicare

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: n/a _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: Cecily Fernandez

Business Name: HIGH VIBES MEDICAL SUPPLY LLC

Business Address: 3430 E FLAMINGO RD #301

City: LAS VEGAS State: NV Zip: 89121-5066

Telephone: 682-331-0707 Email: cecily.fernandez@icloud.com

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cecily Fernandez

Print Name of Authorized Person Submitting Application

Cecily Fernandez

Original signature of Authorized Person (copies or stamps not accepted)

01/24/2025

Date

Board Use Only	Date Received: 1/28/25	Amount: $500-CK 1095564350

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cecily Fernandez
Print Name (First, Last)

Cecily F
Original Signature (electronic, copies or stamps not accepted)

1/26/25
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Cecily Fernandez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Cecily F
Original Signature

1/25/25
Date

Subscribed and Sworn to before me this 25 day of Jan, 2025

Ben Gill
Notary Public Signature

Notary Public - State Of Nevada
COUNTY OF CLARK
BEN GILL
My Appointment Expires
July 9, 2025
No. 16-1938-1

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

100%

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: High Vibes Medical Supply LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3430 E Flamingo Rd

City: Las Vegas State: NV Zip: 89121

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 682-331-0707 Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Cecily Middle: G Last: Fernandez

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☐ F ☐ X

Mailing Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: National University			From - To (MM/YY – MM/YY): 3/12 - 11/13
Address	City: San Bernardino	State: CA	Zip: 92037
Diploma/Degree obtained, if any: Masters in Counseling			
School Name: Cajon High School			From - To (MM/YY – MM/YY):
Address	City: San Bernardino	State: CA	Zip: 92411
Diploma/Degree obtained, if any: High School			
School Name			From - To (MM/YY – MM/YY):
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY):
Address	City	State	Zip
Diploma/Degree obtained, if any			
School Name			From - To (MM/YY – MM/YY):
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 4/24 to Current	[redacted]	City: Henderson	State: NV	[redacted]
From - To (MM/YY – MM/YY): 8/23 to 4/24		City: Las Vegas	State: NV	
From - To (MM/YY – MM/YY): 3/21 to 8/23		City: Fort Worth	State: TX	
From - To (MM/YY – MM/YY): 5/15 to 3/21		City: Moreno Valley	State: CA	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name: High Vibes Therapy Circle			From - To (MM/YY – MM/YY): 1/23 to Current
Business Address: 3330 N Las Vegas	City: Las Vegas	State: NV	Zip: 89511
Phone: 682 331-0707	Title: ~~CEO~~ Owner		
Description of Duties: TeleHealth therapy			

Business Name: Dallas County Juvenile Detention			From - To (MM/YY – MM/YY): 3/21 to 1/23
Business Address: 2600 Lone Star dr	City: Dallas	State: TX	Zip: 75212
Phone: 214 698-2220	Title: Supervisor		
Description of Duties: Supervising staff, Safety & security			

Business Name: San Bernardino County CFS			From - To (MM/YY – MM/YY): 1/18 to 3/21
Business Address: 1032 s E street	City: San Bernardino	State: CA	Zip: 92408
Phone: 909-388-1900	Title: Investigator		
Description of Duties: Caseload, Investigations, Removals, Placements			

Business Name: San Bernardino County Department of Behavioral			From - To (MM/YY – MM/YY): 1/15 to 1/18
Business Address: 303 E Vanderbilt way	City: San Bernardino	State: CA	Zip: 92415
Phone: 855-743-1478	Title: Therapist		
Description of Duties: Mental Health Services			

Business Name:			From - To (MM/YY – MM/YY):
Business Address:	City:	State:	Zip:
Phone:	Title:		
Description of Duties:			

Continue on next page if additional space is needed.

Business Name			From - To (MM/YY – MM/YY)	
Business Address.		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		City	State	Zip
Phone	Title			
Description of Duties				

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court

Reason/Charge

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy

Name of Business/Industry/Entity

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted)

1/25/25
Date

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG: High Vibes Medical Supply LLC — MDEG License # (if applicable):

Physical Address: 3430 E Flamingo RD suite 301

City: Las Vegas — State: NV — Zip: 89121

Mailing Address (if different from physical address):

City: — State: — Zip:

Telephone: 682-331-0707 — Website:

Licensing Company Email: Cecily.fernandez@icloud.com

Section 2: Personal Information

First: Cecily — Middle: Ginnel — Last: Fernandez

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] — SSN or ITIN: [redacted] — Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Henderson — State: NV — Zip: [redacted]

Telephone: 682-331-0707 — Email: Cecily.fernandez@icloud.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. Use a separate piece of paper if additional space is needed.)

School Name: National University			From - To (MM/YY – MM/YY): 03/2012-11/2013	
Address	City: San Bernardino		State: CA	Zip: 92411
Diploma/Degree obtained, if any: MA in Counseling Psychology				
School Name: University of Phoenix			From - To (MM/YY – MM/YY)	
Address	City: San Bernardino		State: CA	Zip
Diploma/Degree obtained, if any: BA in Criminal Administration				
School Name: University of Phoenix			From - To (MM/YY – MM/YY)	
Address	City: San Bernardino		State: CA	Zip
Diploma/Degree obtained, if any: AA in Criminal Justice				
School Name: Cajon High School			From - To (MM/YY – MM/YY)	
Address	City: San Bernardino		State: CA	Zip
Diploma/Degree obtained, if any: High School Diploma				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY): 04/24 to current	[redacted]	City: Henderson		State: NV	[redacted]
From - To (MM/YY – MM/YY): 08/23 to 04/24		City: Las Vegas		State: NV	
From - To (MM/YY – MM/YY): 03/21 to 08/23		City: Fort Worth		State: TX	
From - To (MM/YY – MM/YY): 05/15 to 03/21		City: Moreno Valley		State: CA	
From - To (MM/YY – MM/YY)	Address	City		State	Zip
From - To (MM/YY – MM/YY)	Address	City		State	Zip
From - To (MM/YY – MM/YY)	Address	City		State	Zip
From - To (MM/YY – MM/YY)	Address	City		State	Zip
From - To (MM/YY – MM/YY)	Address	City		State	Zip
From - To (MM/YY – MM/YY)	Address	City		State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Family Medical Supply LLC			01/24 to 12/24	
Business Address		**City**	**State**	**Zip**
217 Arrowhead Blvd Suite D-2		Jonesboro	GA	30236
Phone	**Title**		**Number of Employed Hours**	
404-272-7140	Volunteer		120	

Description of Duties

Observing operations of a DME, Sales, medical equipment, patient charts, answering phones, filling orders

Business Name			From - To (MM/YY – MM/YY)	
San Bernardino County Children and Family Services			01/18 to 03/21	
Business Address		**City**	**State**	**Zip**
1032 S Est Street		San Bernardino	CA	92408
Phone	**Title**		**Number of Employed Hours**	
888-743-1478	Social Worker IIII		3,360	

Description of Duties

Removal of children from dangerous care, attending doctors appointments and providing recommended, dentist appointments, IEP's, changing diapers, changing bandages, appropriate wound care, toileting and toilet training, ADL's

Business Name			From - To (MM/YY – MM/YY)	
Riverside Mental Health Clinic			1/12 to 1/15	
Business Address		**City**	**State**	**Zip**
2085 Rustin Ave		Riverside	CA	92507
Phone	**Title**		**Number of Employed Hours**	
951-955-7270	Clinical Therapist/Direct Patient Care		3,840	

Description of Duties

Working with the severe mental health in public settings, doctors appointments, dentist appointments, ADL's,, explaining doctor recommendations and assisting with medical care, assisting with medication administering

Business Name			From - To (MM/YY – MM/YY)	
The Vosswood Nursing Home			01/92 to 3/95	
Business Address		**City**	**State**	**Zip**
815 S Voss Rd		Houston	TX	77057
Phone	**Title**		**Number of Employed Hours**	
713-827-0883	Certified Nurses Assistant		3,840	

Description of Duties

As assist patients with tasks like bathing, dressing, grooming, eating, and using the toilet. Help patients move around, including transferring them between beds, chairs, and other locations. Ensure patients are properly positioned in bed or

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in <u>any</u> state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in <u>any</u> state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		✓

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. <u>A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.</u>

This is in response to Question # _____. **Provide all the following *<u>where applicable</u>*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Cody J

Original Signature (electronic, copies or stamps not accepted)

4/23/25

Date

I, Cecily Fernandez, **certify that as the MDEG Administrator for**

High Vibes Medical Supply LLC,

that I (initial that you have read and meet the following requirements):

1. CF Have a high school diploma or its equivalent;
2. CF Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. CF Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. CF Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Cecily Fernandez
Print Name (First, Last)

Cecily
Original Signature (electronic, copies or stamps not accepted)

4/23/25
Date

Board Use Only	Date Received:

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **High Vibes Medical Supply LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 10/15/2024, and in good standing in this State.

I further certify that the above DOMESTIC LIMITED-LIABILITY COMPANY (86) has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/11/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502115430353

You may verify this certificate online at https://www.nvsilverflume.gov/home

STATE OF NEVADA

FRANCISCO V. AGUILAR
Secretary of State

RUBEN J. RODRIGUEZ
Deputy Secretary for Southern Nevada

2250 Las Vegas Blvd North, Suite 400
North Las Vegas, NV 89030
Telephone (702) 486-2880
Fax (702) 486-2452

OFFICE OF THE
SECRETARY OF STATE

GABRIEL DI CHIARA
Chief Deputy Secretary of State

DEANNA L. REYNOLDS
Deputy Secretary for Commercial Recordings

401 N. Carson Street
Carson City, NV 89701
Telephone (775) 684-5708
Fax (775) 684-7141

Cecily Fernandez
[redacted]

Work Order #: W2025021100586
February 11, 2025
Receipt Version: 1

Special Handling Instructions:

Submitter ID: 885980

Charges

Description	Fee Description	Filing Number	Filing Date/Time	Filing Status	Qty	Price	Amount
Certificates	Fees	20254659515	2/11/2025 9:56:49 AM	Approved	1	$50.00	$50.00
Total							$50.00

Payments

Type	Description	Payment Status	Amount
Credit Card	[redacted]	Success	$50.00
Credit Card	Service Fee	Success	$1.25
Total			$51.25

Credit Balance: $0.00

Cecily Fernandez
[redacted]

ACORD®

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY): 12/20/2024

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER
Next First Insurance Agency, Inc.
PO Box 60787
Palo Alto, CA 94306

CONTACT NAME:
PHONE (A/C, No, Ext): (855) 222-5919 **FAX (A/C, No):**
E-MAIL ADDRESS: support@nextinsurance.com

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : State National Insurance Company, Inc.	12831
INSURER B :	
INSURER C :	
INSURER D :	
INSURER E :	
INSURER F :	

INSURED
High Vibes Medical Supply LLC
3430 E Flamingo Rd Ste 301
Las Vegas, NV 89121

COVERAGES **CERTIFICATE NUMBER:** 753329044 **REVISION NUMBER:**

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE [X] OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: [X] POLICY [ ] PRO-JECT [ ] LOC OTHER:	X		NXT44CFKTR-00-GL	12/20/2024	12/20/2025	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$1,000,000.00 $100,000.00 $15,000.00 $1,000,000.00 $2,000,000.00 $2,000,000.00
	AUTOMOBILE LIABILITY ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY						COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $ $ $
	UMBRELLA LIAB [ ] OCCUR EXCESS LIAB [ ] CLAIMS-MADE DED [ ] RETENTION $						EACH OCCURRENCE AGGREGATE	$ $
	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANYPROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBEREXCLUDED? (Mandatory in NH) Y / N [ ] If yes, describe under DESCRIPTION OF OPERATIONS below	N / A					[ ] PER STATUTE [ ] OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	 $ $ $

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

The Certificate Holder is Board of Certification/Accreditation. This Certificate Holder is an Additional Insured on the General Liability policy with respect to ongoing operations. All Certificate Holder privileges apply only if required by written agreement between the Certificate Holder and the Insured, and are subject to policy terms and conditions.

CERTIFICATE HOLDER
Board of Certification/Accreditation
10461 Mill Run Cir Ste 1250
Owings Mills, MD 21117

LIVE CERTIFICATE
Click or scan to view

CANCELLATION
SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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NATIONAL UNIVERSITY
Office of the Registrar
11355 North Torrey Pines Road
La Jolla, CA 92037-1013
Phone: (858) 642-8260; 1-800-NAT-UNIV
Fax: (858) 642-8718

ACADEMIC TRANSCRIPT

Name: Fernandez,Cecily C
Student ID: [redacted]
Birthdate: [redacted]

Print Date: 01/15/2014

Degrees Awarded:

Degree: Master of Arts
Confer Date: 11/17/2013
Plan: Counseling Psychology
Sub-Plan: Specialization in Marriage and Family Therapy

External Degrees:
University of Phoenix - Phoenix Campus, Bachelor of Science 04/04/2011

Course Credit:
Course Credit Total Units from University of Phoenix - Phoenix Campus: 0.000

Beginning of Graduate Record

					Attempted	Earned	Grade	Points
2012-Mar	Course		Description					
	PSY	632A	Family Therapy A		4.500	4.500	A-	16.650
2012-Apr	Course		Description					
	PSY	632B	Couples Therapy B		4.500	4.500	A	18.000
2012-May	Course		Description					
	PSY	635	Childhood and Adolescence		4.500	4.500	B	13.500
2012-Jun	Course		Description					
	PSY	637	Culture in Counseling		4.500	4.500	B-	12.150
2012-Jul	Course		Description					
	PSY	624	Assess Techniques for MFT		4.500	4.500	A-	16.650
2012-Aug	Course		Description					
	CHD	640	Treatment of Addictions		4.500	4.500	B	13.500
2012-Sep	Course		Description					
	PSY	642	Relational Violence		4.500	4.500	A	18.000
2012-Oct	Course		Description					
	PSY	626	Human Sexuality in Psychothera		4.500	4.500	A	18.000
2012-Nov	Course		Description					
	PSY	655	Psychopharmacology		4.500	4.500	A-	16.650
2012-Dec	Course		Description					
	PSY	653	Research Critiques		4.500	4.500	B-	12.150
2013-Jan	Course		Description					
	PSY	629A	Adulthood and Aging		4.500	4.500	A	18.000
2013-Feb	Course		Description					
	PSY	631A	Counseling Practicum I		4.500	4.500	S	0.000
2013-Mar	Course		Description					
	PSY	623A	Clinical Assessment I		4.500	4.500	B	13.500
	PSY	631B	Counseling Practicum II		4.500	4.500	H	0.000
	Transcript Note:		Official Grade Change Approved					
	Transcript Note:		09/30/2013 Incomplete/IP Grade--Lapsed or removed					

Send To: CECILY FERNANDEZ
[redacted]

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Veronica Garcia, Registrar

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NATIONAL UNIVERSITY
Office of the Registrar
11355 North Torrey Pines Road
La Jolla, CA 92037-1013
Phone: (858) 642-8260; 1-800-NAT-UNIV
Fax: (858) 642-8718

ACADEMIC TRANSCRIPT

Name: Fernandez,Cecily C
Student ID: [redacted]

Print Date: 01/15/2014

	Course	Description	Attempted	Earned	Grade	Points
2013-Apr	PSY 623B	Clinical Assessment II	4.500	4.500	A	18.000
2013-May	PSY 628	Group Therapy	4.500	4.500	A-	16.650
2013-Jun	PSY 627	Legal & Ethical Issues	4.500	4.500	B+	14.850
2013-Jul	PSY 636	Child and Adolescent Therapy	4.500	4.500	A-	16.650

Graduate Career Totals

Cum GPA: 3.512	**Cum Totals:**	81.000	81.000	72.000	252.900

*** End of Official Transcript ***

Send To: CECILY FERNANDEZ
[redacted]

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Veronica Gonsa, Registrar

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9

9A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Medical Products Provider- Medical Devices, Equipment and Gases (MDEG) Application

Non-Refundable $500 fee

Rev (05/12/2022)

Where is the facility located?	☐ Nevada	■ Out-of-State
[a]Is the business also a wholesaler? (NRS 639.016)	☐ Yes	■ No

Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members.

Type of Application (check applicable box)		**MDEG Business Type (check applicable box)**
■ New MDEG	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9)
☐ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9)
☐ Name Change*		☐ Partnership (complete sections 1, 2, 3, 4, 7, 9)
☐ Location Change*	M _____	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9)

Section 1: General Information

Facility Name: Agile Medical LLC dba The CPAP Shop

MDEG Physical Address: 159 North Cooper Avenue

City: West Berlin State: NJ Zip: 08091

Mailing Address (if different from physical address): 555 E North Lane, Ste 5075

City: Conshohocken State: PA Zip: 19428

Telephone: 1-866-414-9700 Website: www.thecpapshop.com

Email: Credentialing@adapthealth.com

Name of MDEG Administrator (NAC 639.694): Karen Baldino

Entities the MDEG will Serve	**Type of MDEG products that will be sold (check all applicable)**
■ Patients by prescriptions	☐ Medical Gases**
☐ Pharmacies[a]	■ Respiratory Equipment**
☐ Practitioners[a]	☐ Life-sustaining equipment**
☐ Hospitals/Clinics[a]	☐ Parenteral and Enteral Equipment**
☐ Clinics[a]	■ Assistive Equipment
☐ Wholesalers[a]	☐ Diabetic Supplies
☐ Other business entities (specify)[a]:	☐ Orthotics and Prosthetics
	■ Others: Durable Medical Equipment
This application is ONLY required if MDEG products will be sold to patients by prescription.	**These products require you to have in place a mechanism to ensure continued care in the event of an emergency. Provide name and telephone number of Nevada contact (NAC 639.6954):
[a]If MDEG products will ALSO be sold to the Entities with an ([a]) above, then a Wholesaler license will ALSO be required. Find the Wholesaler Application here: Businesses (nv.gov)	Name: On-call services
	Telephone: 1-86-414-9700

Check the Days the Business will be Opened and provide the Hours of Operation				
▣ Mon: 8:30am-6:30p	▣ Tue: 8:30am-6:30pm	▣ Wed: 8:30am-6:30p	▣ Thurs: 8:30am-6:30p	▣ Fri: 8:30am-6:30pm
▣ Sat: 10am-4pm	☐ Sun: Closed	☐ Holidays:		

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been subject of an administrative action or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓
If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.		

Section 3: List all Medicare and Medicaid provider numbers registered to the business or its owner (NAC 639.6942(4)(i))
N/A

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name of the owner, their credentials and their percent ownership. (NAC 639.6943, NAC 693.6933)

Name: N/A Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

Name: _____ Credentials: _____ %: _____

1. The Board will not issue a license to conduct business as a medical products provider or medical products wholesaler to:

   a) A practicing health professional; or

   b) A partnership, corporation or association in which a practicing health professional has a controlling interest or in which ownership of 10 percent or more of the available stock is held by one or more practicing health professionals.

2. As used in this section, "practicing health professional" means a health professional who performs services within the scope of his or her licensure or registration in any capacity in a health care facility other than the facility of the medical products provider or medical products wholesaler.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PA

Parent Company (if any): AdaptHealth, LLC

Corporation/Organization Name: Agile Medical LLC

Mailing Address: 555 E North Lane, Ste 5075

City: Conshohocken State: PA Zip: 19428

Telephone: 610-424-4515 Email: Credentialing@adapthealth.com

Contact Person Name: Attn: Licensing & Credentialing

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List of all Officers and Directors.**	✓	✓		
• **List of all general and limited partner names and their percent ownership (NAC 639.6942).**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** obtained from the Secretary of State's Office in the State where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Medical products provider located outside of this State must submit evidence that the medical products provider is licensed, permitted, registered or otherwise lawfully authorized by the state of residence of the medical products provider to engage in the same business for which the medical products provider is seeking licensure in this State (NAC 639.6944). Provide a copy of the home state license, permit, registration or certification issued to the medical products provider (if applicable).**	✓	✓	✓	✓
• **Copy of proof of insurance (NAC 639.6946).** The MDEG provider shall maintain liability insurance of at least one million dollars ($1,000,000.00).	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/owner. Find form at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **MDEG Administrator Application (NAC 639.694).** Find form at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓
• [a]**Wholesaler Application** must be completed if the business will sell MDEG products to pharmacies, practitioners, hospitals, clinics, wholesalers or other business entities. Wholesaler" means a wholesale distributor as defined by 21 C.F.R. § 205.3(g) who supplies or distributes drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician to a person **other than the consumer or patient**. The term includes a person who derives, produces, prepares or repackages drugs, medicines or chemicals or devices or appliances that are restricted by federal law to sale by or on the order of a physician on sales orders for resale. The term does not include a nonprofit cooperative agricultural organization which supplies or distributes veterinary drugs and medicines only to its own members. Find the Wholesaler Application at http://bop.nv.gov/Services/newapps/Business/	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Joe Pailen

Print Name of Authorized Person Submitting Application

Joseph Pailen

Original signature of Authorized Person (copies or stamps not accepted)

01/10/2025

Date

Board Use Only	Date Received: 1/15/25	Amount: $500-a

Following are the officers:

Suzanne Foster, CEO
Jason Clemens, CFO
Wendy Russalesi, CCO

Nevada State Board of Pharmacy

2285 Renaissance Drive, Suite 206 • Reno, NV 89521
(775) 850-1440 • FAX (775) 850-1444
Email: Pharmacy@pharmacy.nv.gov • Web Page: bop.nv.gov

February 23, 2024

Via Certified and Regular U.S. Mail and Email

The CPAP Shop
158 Cooper Road
West Berlin, NJ 08091
Email: [redacted]@thecpapshop.com

CEASE AND DESIST and CITATION AND FINE ORDER, Case No. 24-0067-O
Unlicensed Furnishing of Medical Products

Greetings:

The Nevada State Board of Pharmacy (Board) has determined that The CPAP Shop was/is engaged in the business of furnishing prescription medical devices in Nevada without having secured a license as required by Nevada Revised Statute (NRS) 639.233. Pursuant to NRS 639.233, any person, including a wholesaler or manufacturer of prescription medical devices must secure a license from the Board before it sells, delivers, or accepts orders for drugs or devices which are to be sold in this State or delivered, distributed, or accepted for delivery in this State, unless such sale is restricted by law or by regulation of the Board. Under Nevada law, the term "drug" is defined to include "[a]rticles and devices intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in humans." See NRS 639.007. The terms "manufacturer" and "wholesaler" are defined at NRS 639.009 and NRS 639.015, respectively. The term "medical products provider" is defined at Nevada Administrative Code (NAC) 639.693. Nevada licensure is required of any person, including a medical products provider, who sells or ships drugs or medical devices that are restricted by federal law to sale by or on the order of a physician to any person located within this State. See NRS 639.233(1) and (2); NAC 639.694.

The CPAP Shop is engaged in the business of selling devices as that term is defined at 21 U.S.C. § 321(h). The product's purpose is for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals. Accordingly, at least some of the devices are "prescription devices" within the meaning of 21 CFR § 801.109. One of these devices is a ResMed AirSense 11 AutoSet CPAP Machine with Bluetooth, Humidifier and ClimateLineAir. ResMed's AirSense 11 User Guide explicitly states that in the United States, Federal law restricts the device to sale by or on the order of a physician.

Because these devices are not safe to use for their intended purpose except under the supervision of a qualified medical practitioner, they must bear a label indicating that they are prescription-only devices. See 21 CFR § 801.109(b). The relevant facts are as follows:

1

- During a routine inspection of Oxytech, located at 1544 Pittman Ave., Suite B, Sparks, NV 89431, Board Inspector Mui Lee located an invoice from The CPAP shop. The invoice was dated 12/21/2003 and was given order # 100485951. The invoice states that one ResMed AirSense 10 AutoSet CPAP Machine with Bluetooth, HumidAir and ClimateLineAir was sold and shipped by The CPAP Shop to Oxytech. ResMed's AirSense 10 User Guide explicitly states that in the United States, federal law restricts the device to sale by or on the order of a physician.

- Board Investigator Marilen S. Segedy attempted at least four (4) times to get in contact with The CPAP Shop's compliance personnel. They have yet to get back to her.

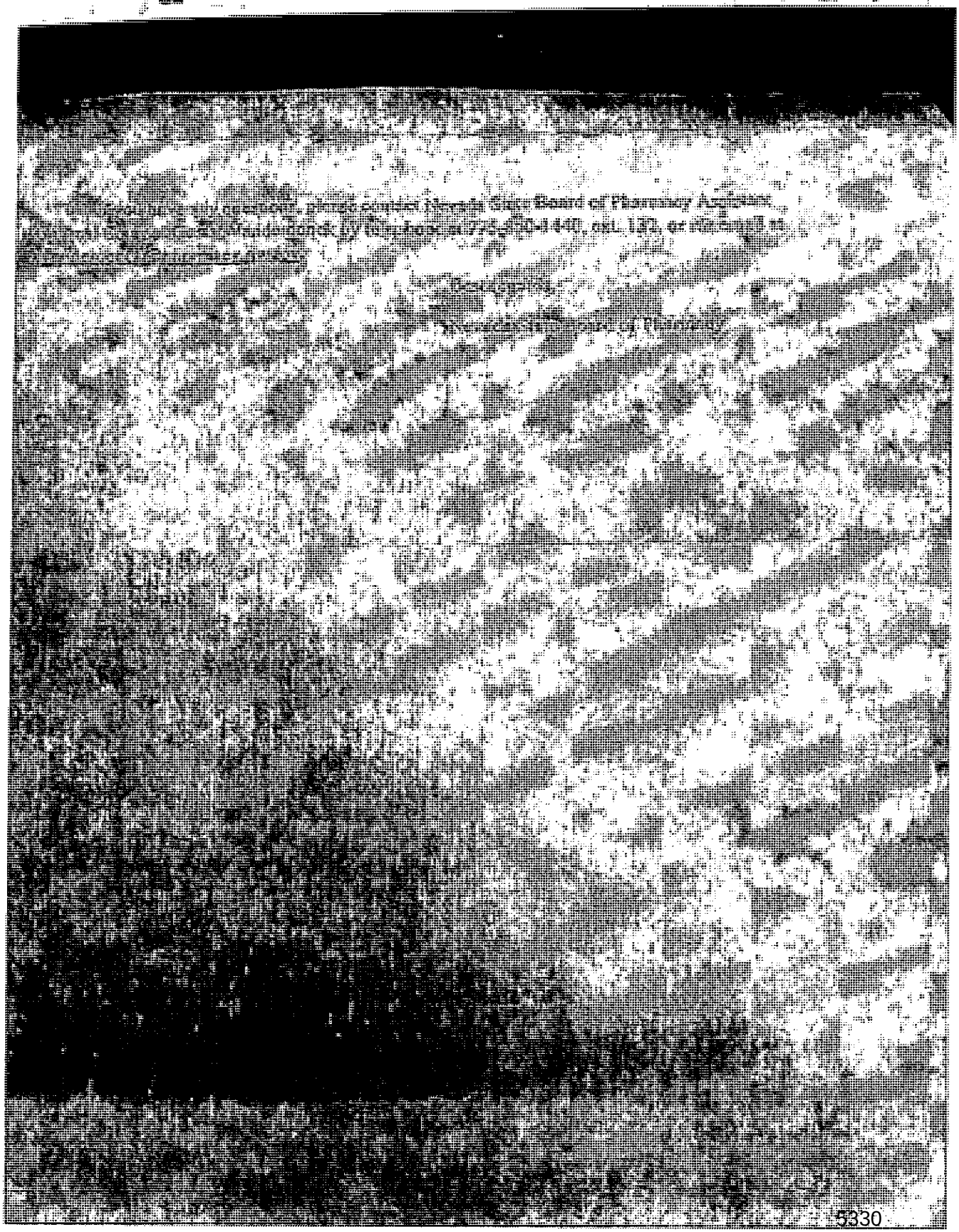
- Under Nevada law, the fact that there is a federal restriction on sale of the drug or device by or on the order of a physician requires any person to obtain a license with the Nevada Board of Pharmacy if they 1) solicit or accept orders for drugs or devices whose sale in this State is restricted; or 2) receive, store, or ship such drugs or devices. See 21 U.S.C. § 353(b)(1); 21 C.F.R. § 201.100(b)(1); 21 CFR § 801.109 and NRS 639.233.

- The Board has documentary evidence that The CPAP Shop solicited and/or accepted orders and shipped a prescription only medical device into Nevada without the required license to do so.

Accordingly, the Board hereby orders The CPAP Shop to immediately **CEASE and DESIST** furnishing to persons in Nevada any medical products, including drugs and/or devices that are restricted by federal law to sale by or on the order of a physician. Further, this notice shall serve as a **CITATION** pursuant to NRS 639.2895(2) for the unlicensed furnishing of medical devices to persons in Nevada. Pursuant to NRS 639.2895(3), the Board has assessed an **administrative fine** against The CPAP Shop in the amount of **Five Thousand and 00/100 Dollars ($5,000.00).**

If you do not intend to contest the above fine, please pay the fine within 30 days of receipt of this citation, or otherwise contact Board staff to request an alternative payment plan. Payment must be by *cashier's check, certified check* or *money order* made payable to "State of Nevada, Office of the Treasurer," to be received at the Board's Reno office, located at 985 Damonte Ranch Parkway – Suite 206, Reno, NV 89521. Additionally, please be advised that should you fail to comply with the terms of this citation and order, your noncompliance will be reported to the National Practitioner Data Bank and referred to the Nevada Controller's Office for collection pursuant to NRS 353C.195. *See* 45 C.F.R. §§ 60.3 and 60.5.

You may contest this citation by submitting to the Board, at the Reno address listed above, a written request for a public hearing. You must submit any such request not later than 30 days after receipt of this notice. *See* NRS 639.2895(2). Additionally, please be aware that issuance of the foregoing letter does not preclude the filing of an administrative disciplinary complaint, a civil suit, or criminal charges, if deemed appropriate based upon evidence not currently available to the Board's investigative staff.



adapthealth

555 E North Lane, Ste 5075, Conshohocken, PA 19428

AdaptHealth LLC owns 100% of Agile Medical LLC, 20-0965081

AdaptHealth LLC, 45-5553972

Wendy Russalesi, Chief Compliance Officer
[redacted]

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

AGILE MEDICAL LLC
0400226362

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named New Jersey Domestic Limited Liability Company was registered by this office on April 10, 2008.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

UNITED CORPORATE SERVICES, INC.
25 MAIN ST.
SUITE 202
HACKENSACK, NJ 07061

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 10th day of January, 2025

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6160602025

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

State of New Jersey
DEPARTMENT OF HEALTH
CONSUMER, ENVIRONMENTAL
AND OCCUPATIONAL HEALTH SERVICE
PO BOX 369
TRENTON, N.J. 08625-0369
www.nj.gov/health

PHILIP D. MURPHY
Governor

TAHESHA L. WAY
Lt. Governor

KAITLAN BASTON, MD, MSc, DFASAM
Commissioner

October 29, 2024

Re: Oversight of durable medical equipment providers

The New Jersey Department of Health, Wholesale Drug Project, does not register and/or license direct-to-patient durable medical equipment providers.

Sincerely,
Eric B. Lieberman, Esq.
Project Coordinator, Wholesale Drug Project
Public Health and Food Protection Program

The New Jersey Department of Health offers only a Wholesale Drug and Medical Device Registration option for which our business of providing durable medical equipment direct to patients does not qualify as stated in the Wholesale Drug or Medical Device Business Registration - Frequently Asked Questions noted below.

https://www.nj.gov/health/ceohs/phfpp/dmd/faq.shtml

APPLICATIONS FOR NEW REGISTRATIONS

Q: Does my business need to be registered with the Department?
This office is unable to offer legal advice to businesses and cannot evaluate for licensure without submission of application. Requirements for registration are based on the definitions and exemptions provided in NJAC 8:21-3A.3, NJSA 24:1-1 and NJSA 24:6B-14.

Q: Is this the correct registration for a Durable Medical Equipment provider?
The Drug and Medical Device Registration is not applicable to direct-to-patient equipment providers.

Durable Medical Equipment Provider means an entity that delivers durable medical equipment directly to the consumer or patient. Durable Medical Equipment Providers which do not conduct wholesale distribution business may not register. Licensure for Durable Medical Equipment Providers is not available through this office. Consult your local Medicare/Medicaid office for further guidance.

Wholesale Drug Rules (N.J.A.C. 8:21-3A and N.J.S.A. 24:6B):
https://www.nj.gov/health/ceohs/documents/food-drug-safety/Wholesale%20Drug%20Regulations.pdf

§ 8:21-3A.3 Definitions:

"Wholesale distribution" means the distribution of drugs or devices to persons other than a consumer or patient, but does not include:

1. Intracompany sales;
2. The purchase or other acquisition by a hospital or other health care entity that is a member of a group purchasing organization, of a drug or device for its own use from the group purchasing organization or from other hospitals or health care entities that are members of such organizations;
3. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device by a charitable organization described in section 501(c)(3) of the Internal Revenue Code of 1954 to a nonprofit affiliate of the organization to the extent otherwise permitted by law;
4. The sale, purchase, or trade of a drug or device or an offer to sell, purchase, or trade a drug or device among hospitals or other health care entities that are under common control; for purposes of this definition "common control" means the power to direct or cause the direction of the management and policies of a person or an organization, whether by ownership of stock, voting rights, by contract, or otherwise;
5. The sale, purchase or trade of a drug or device or an offer to sell, purchase, or trade a drug or device for emergency medical reasons; for purposes of this definition, "emergency medical reasons" includes transfers of prescription drugs by a retail pharmacy to another retail pharmacy to alleviate a temporary shortage;
6. The sale, purchase, or trade of a drug, an offer to sell, purchase, or trade a drug, or the dispensing of a drug pursuant to a prescription;
7. The distribution of drug or device samples by manufacturers' representatives or distributors' representatives; or
8. The sale, purchase, or trade of blood and blood components intended for transfusion.

"Wholesale distributor" means anyone engaged in wholesale distribution of drugs including, but not limited to, manufacturers; repackagers; own-label distributors; private label distributors; jobbers; brokers; warehouses, including manufacturers' and distributors' warehouses, chain drug warehouses, and wholesale drug warehouses; and independent wholesale drug traders, but does not include a retail pharmacy whose sales of prescription drugs to other than the ultimate user, including physicians for office use, nursing homes, institutions, etc. does not exceed five percent of the total gross annual sales of prescription drugs of the pharmacy.

CERTIFICATE OF LIABILITY INSURANCE

DATE (MM/DD/YYYY) 11/8/2025 | 5/14/2025

THIS CERTIFICATE IS ISSUED AS A MATTER OF INFORMATION ONLY AND CONFERS NO RIGHTS UPON THE CERTIFICATE HOLDER. THIS CERTIFICATE DOES NOT AFFIRMATIVELY OR NEGATIVELY AMEND, EXTEND OR ALTER THE COVERAGE AFFORDED BY THE POLICIES BELOW. THIS CERTIFICATE OF INSURANCE DOES NOT CONSTITUTE A CONTRACT BETWEEN THE ISSUING INSURER(S), AUTHORIZED REPRESENTATIVE OR PRODUCER, AND THE CERTIFICATE HOLDER.

IMPORTANT: If the certificate holder is an ADDITIONAL INSURED, the policy(ies) must have ADDITIONAL INSURED provisions or be endorsed. If SUBROGATION IS WAIVED, subject to the terms and conditions of the policy, certain policies may require an endorsement. A statement on this certificate does not confer rights to the certificate holder in lieu of such endorsement(s).

PRODUCER Lockton Companies, LLC DBA Lockton Insurance Brokers, LLC in CA CA license #0F15767 1185 Avenue of the Americas, Ste. 2010 New York NY 10036 (646) 572-7300	CONTACT NAME: PHONE (A/C, No, Ext): FAX (A/C, No): E-MAIL ADDRESS:
INSURED 1434385 Agile Medical LLC dba The CPAP Shop 159 Cooper Road, West Berlin NJ 08091	

INSURER(S) AFFORDING COVERAGE	NAIC #
INSURER A : Illinois Union Insurance Company	27960
INSURER B : Hartford Fire Insurance Company	19682
INSURER C : --- SEE ATTACHMENT ---	
INSURER D : Hartford Accident and Indemnity Company	22357
INSURER E : Twin City Fire Insurance Company	29459
INSURER F : XL Specialty Insurance Company	37885

COVERAGES **CERTIFICATE NUMBER:** 20583171 **REVISION NUMBER:** XXXXXXX

THIS IS TO CERTIFY THAT THE POLICIES OF INSURANCE LISTED BELOW HAVE BEEN ISSUED TO THE INSURED NAMED ABOVE FOR THE POLICY PERIOD INDICATED. NOTWITHSTANDING ANY REQUIREMENT, TERM OR CONDITION OF ANY CONTRACT OR OTHER DOCUMENT WITH RESPECT TO WHICH THIS CERTIFICATE MAY BE ISSUED OR MAY PERTAIN, THE INSURANCE AFFORDED BY THE POLICIES DESCRIBED HEREIN IS SUBJECT TO ALL THE TERMS, EXCLUSIONS AND CONDITIONS OF SUCH POLICIES. LIMITS SHOWN MAY HAVE BEEN REDUCED BY PAID CLAIMS.

INSR LTR	TYPE OF INSURANCE	ADDL INSD	SUBR WVD	POLICY NUMBER	POLICY EFF (MM/DD/YYYY)	POLICY EXP (MM/DD/YYYY)	LIMITS	
A	X COMMERCIAL GENERAL LIABILITY CLAIMS-MADE X OCCUR GEN'L AGGREGATE LIMIT APPLIES PER: X POLICY PRO-JECT LOC OTHER:	N	N	MLP G48980181 001	5/17/2025	5/17/2026	EACH OCCURRENCE DAMAGE TO RENTED PREMISES (Ea occurrence) MED EXP (Any one person) PERSONAL & ADV INJURY GENERAL AGGREGATE PRODUCTS - COMP/OP AGG	$ $1,000,000 $ $1,000,000 $ Not Applicable $ $1,000,000 $ $3,000,000 $ $3,000,000
B	AUTOMOBILE LIABILITY X ANY AUTO OWNED AUTOS ONLY HIRED AUTOS ONLY SCHEDULED AUTOS NON-OWNED AUTOS ONLY	N	N	39 CSE S65401	5/17/2025	5/17/2026	COMBINED SINGLE LIMIT (Ea accident) BODILY INJURY (Per person) BODILY INJURY (Per accident) PROPERTY DAMAGE (Per accident)	$ $2,000,000 $ XXXXXXX $ XXXXXXX $ XXXXXXX
C	UMBRELLA LIAB X OCCUR X EXCESS LIAB X CLAIMS-MADE DED RETENTION $	N	N	See Attached	5/17/2025	5/17/2026	EACH OCCURRENCE AGGREGATE	$ XXXXXXX $ XXXXXXX
D E	WORKERS COMPENSATION AND EMPLOYERS' LIABILITY ANY PROPRIETOR/PARTNER/EXECUTIVE OFFICER/MEMBER EXCLUDED? (Mandatory in NH) N If yes, describe under DESCRIPTION OF OPERATIONS below	N/A	N	39 WN S65400 39 WBR S65402 (MA &WI)	5/17/2025 5/17/2025	5/17/2026 5/17/2026	X PER STATUTE OTH-ER E.L. EACH ACCIDENT E.L. DISEASE - EA EMPLOYEE E.L. DISEASE - POLICY LIMIT	$ $1,000,000 $ $1,000,000 $ $1,000,000
F	Crime-Fidelity	N	N	ELU200697-24	11/8/2024	11/8/2025	$5,000,000/Ret: $50,000	
A	Professional Liability			MLP G48980181 001	5/17/2025	5/17/2026	$1,000,000 each incident/$3,000,000 agg	

DESCRIPTION OF OPERATIONS / LOCATIONS / VEHICLES (ACORD 101, Additional Remarks Schedule, may be attached if more space is required)

CERTIFICATE HOLDER

20583171
Evidence of Insurance

CANCELLATION See Attachments

SHOULD ANY OF THE ABOVE DESCRIBED POLICIES BE CANCELLED BEFORE THE EXPIRATION DATE THEREOF, NOTICE WILL BE DELIVERED IN ACCORDANCE WITH THE POLICY PROVISIONS.

AUTHORIZED REPRESENTATIVE

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Excess General Liability, Professional Liability, Employers Liability only

- Excess GL/PL/EL ($5M xs Primary)
    - **Policy Number:** XFL G48980193 001
    - **Policy Term:** 5/17/2025 to 5/17/2026
    - **Issuing Company:** Illinois Union Insurance Company
    - **Each Loss Limit:** $5,000,000
    - **Policy Aggregate Limit:** $5,000,000
    - **Abuse and Molestation Sub-Limit:** $2,000,000
- Excess GL/PL/EL ($5M xs $5M xs Primary)
    - **Policy Number:** UA25ZGOF8K1X
    - **Policy Term:** 5/17/2025 to 5/17/2026
    - **Issuing Company:** Ascot Underwriting Bermuda Syndicate 1414 at Lloyd's of London
    - **Each Loss Limit:** $5,000,000
    - **Policy Aggregate Limit:** $5,000,000

Excess Auto Only

- Excess Auto (2x2)
    - **Policy Number:** 22200001400
    - **Policy Term:** 5/17/2025 to 5/17/2026
    - **Issuing Company:** Lafayette Insurance Company
    - **Each Occurrence Limit:** $2,000,000
    - **Policy Aggregate Limit:** $2,000,000
- Excess Auto (1x4)
    - **Policy Number:** EXT30087204700

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Agile Medical LLC dba The CPAP Shop

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): Pending

Physical Address: 159 North Cooper Avenue

City: West Berlin State: NJ Zip: 08091

Mailing Address (if different from physical address): 555 E North Lane, Suite 5075

City: Conshohocken State: PA Zip: 19428

Telephone: 1-866-414-9700 Website: www.thecpapshop.com

Licensing Company Email: Credentialing@adapthealth.com

Section 2: Personal Information

First: Wendy Middle: Ann Last: Russalesi

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Toms River State: NJ Zip: [redacted]

Telephone: [redacted] Email: wendy.russalesi@adapthealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Thomas Edison State University			03/2009	
Address	City		State	Zip
111 W State St	Trenton		NJ	08608
Diploma/Degree obtained, if any				
Bachelors - Business Administration				
School Name			From - To (MM/YY – MM/YY)	
Woodbridge High School			09/1984 - 06/1988	
Address	City		State	Zip
1 Samuel Lopo Place	Woodbridge		NJ	07095
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/2022-Current	[redacted]	Toms River	NJ	
07/2013-06/2022		Jackson	NJ	[redacted]
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
AdaptHealth			07/2013-Current
Business Address	**City**	**State**	**Zip**
220 W. Germantown Pike, Suite 250	Plymouth Meeting	PA	19462-1437
Phone	**Title**		
610-424-4515	Chief Compliance Officer		

Description of Duties

design and implement internal controls to ensure compliance with applicable laws and regulations.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Wendy Russalesi
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

12/27/2024
Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Pinellas

I, Wendy Russalesi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

12/27/2024
Date

Subscribed and Sworn to before me this 27 day of December

Notary Public Signature

NATASCHA AMSTER
Commission # HH 093965
Expires February 17, 2025
Bonded Thru Troy Fain Insurance 800-385-7019

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Medical Products Provider and Wholesaler – Medical Devices, Equipment and Gases (MDEG) Administrator Application

Rev (06/21/2022)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of MDEG Agile Medical LLC dba The CPAP Shop MDEG License # (if applicable) _____

Physical Address 159 North Cooper Avenue

City West Berlin State NJ Zip 08091

Mailing Address (if different from physical address) 555 E North Lane, Ste 5075

City Conshohocken State PA Zip 19428

Telephone 866-414-9700 Website www.thecpapshop.com

Licensing Company Email Credentialing@adapthealth.com

Section 2: Personal Information

First Karen Middle _____ Last Baldino

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City West Deptford State NJ Zip [redacted]

Telephone [redacted] Email Karen.baldino@adapthealth.com

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Temple University		1985-1987	
Address	**City**	**State**	**Zip**
1801 N. Broad St	Philadelphia	PA	19122
Diploma/Degree obtained, if any			
No Degree			

School Name		From - To (MM/YY – MM/YY)	
Cherokee High School		1981-1985.	
Address	**City**	**State**	**Zip**
120 Tomlinson mill Rd	Marlton	NJ	08053
Diploma/Degree obtained, if any			
Graduated College Prep.			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2019-2023	[redacted]	Mt. Ephriam	NJ	[redacted]
2015-2019	[redacted]	Westmont	NJ	
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: An MDEG Administrator must provide proof that he or she has least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler. Beginning with the most current, list your hours of employment related to the above. (NAC 639.694)

Business Name			From - To (MM/YY – MM/YY)	
Agile Medical / Oxygen Concentrator supplies			2013-2024.	
Business Address		**City**	**State**	**Zip**
159 Cooper Rd		West Berlin	NJ	08091.
Phone	**Title**		**Number of Employed Hours**	
866 414-9708	Director of Operations		40+ hrs weekly	

Description of Duties
I manage both Customer Sva and our warehouse. We also have a retail store which presides under me. I not only observe calls FOR Suggestions but I manage all training for new & existing product

Business Name			From - To (MM/YY – MM/YY)	
I am also making sure the warehouse is stable and orders are				
Business Address		**City**	**State**	**Zip**
being shipped.				
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Section 8: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		X
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state? Include all public or private actions against a professional license, not limited to a suspension, revocation, surrender or other discipline.		X

Please use and make copies of this page (if necessary) to provide information as requested below regarding any questions, 1-3, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original Signature (electronic, copies or stamps not accepted) Date

I, Karen Baldino, **certify that as the MDEG Administrator for**

Agile Medical / Oxygen Concentrator Supplies,

that I (initial that you have read and meet the following requirements):

1. KB Have a high school diploma or its equivalent;
2. KB Have
   a. At least 1,500 hours of verifiable work experience relating to the products provided by the medical products provider or medical products wholesaler; or
   b. An associate's degree or higher degree from an accredited college or university in a field of study that is directly related to patient health care;
3. KB Will be employed by the medical products provider or medical products wholesaler at the place of business or facility of the employer at least 40 hours per week or during all regular business hours if the business or facility is regularly open less than 40 hours per week; and
4. KB Will ensure that the operation of the business or facility complies with all applicable federal, state and local laws, regulations and rules.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Karen Baldino

Print Name (First, Last)

Karen Baldino

Original Signature (electronic, copies or stamps not accepted)

6/25/2024

Date

Board Use Only	Date Received: 1/15/25

10

10A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
■ Ownership Change*	[redacted]194	■ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Coronado Surgery Center

Physical Address: 2779 W. Horizon Ridge Parkway Suite 140

City: Henderson State: NV Zip: 89052

Mailing Address (if different from physical address): 2779 W. Horizon Ridge Pkwy Suite 130

City: Henderson State: NV Zip: 89052

Telephone: (702)589-9250 Fax: (702)589-9257

Contact Email: lshields@coronadosurgery.com Website coronadosurgery.com

Nevada Business License # NV20081551293

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Dr. Michael J. Crovetti, Jr., D.O.

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Intermountain Orthopedic Holdings Nevada, LLC

Corporation/Organization Name: Coronado Surgery Center, LLC

Mailing Address: 2779 W. Horizon Ridge Pkwy Suite 130

City: Henderson State: NV Zip: 89052

Telephone: _____ Email: mcrovetti@crovettiortho.com

Contact Person Name: Dr. Michael J. Crovetti, Jr., D.O.

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Coronado Surgery Center :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle M McCarthy

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

1-12-25

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List <u>all</u> Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the <u>top four</u> stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List <u>all stockholders</u> who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dr. Michael J. Crovetti, Jr., D.O.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/13/25

Date

Board Use Only	Date Received: 1/22/25	Amount: $500.00

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **CORONADO SURGERY CENTER, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 01/10/2008, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/16/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412165271524
You may verify this certificate online at https://www.nvsilverflume.gov/home

Exhibit T

Officers and Stockholders

Officers:

- President – Michael J. Crovetti, Jr., D.O.

Top four stockholders: Intermountain Orthopedic Holdings Nevada, LLC

Stockholders with 10% or more of the shares: Intermountain Orthopedic Holdings Nevada, LLC

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
5381-ASC-19

Please display this license conspicuously

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to: https://nvdpbh.aithent.com/login.aspx.

This Is To Certify That

CORONADO SURGERY CENTER

2779 W HORIZON RIDGE PKWY STE 140
HENDERSON, NV 89052

Is hereby licensed as a(n)

SURGICAL CENTER FOR AMBULATORY PATIENTS

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

Facility Type : SURGICAL CENTER FOR AMBULATORY PATIENTS

Endorsement : CLASS - C

Bed Information : Operating Room - A - 2

MICHAEL ROSE / Administrator

CORONADO SURGERY CENTER, LLC.

Cody L Phinney / Administrator

If your license is not completely accurate, Please contact us at (775) 684-1030 so that we may resolve any problems.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site _____

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # _____

Physical Address _____

City _____

Mailing Address (if different from physical address) _____

City _____

Telephone _____ Website _____

Licensing Company Email _____

Coronado Surgical Recovery Suites ASC04428
2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052

Coronado Surgery Center ASC02494
2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052

Queensridge Surgical Recovery Suites RC04480
10040 Alta Dr #300, Las Vegas, NV 89145

Queensridge Surgery Center ASC04481
10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First Mitchell Middle Howard Last Cloward

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Weber State University		01/89-06/94	
Address	**City**	**State**	**Zip**
3848 Harrison Blvd	Ogden	UT	84403
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Texas Women's University		01-95-06/99	
Address	**City**	**State**	**Zip**
304 Administration Drive, Suite 102	Denton	TX	76204
Diploma/Degree obtained, if any			
Masters in Healthcare Administration			

School Name		From - To (MM/YY – MM/YY)	
David High School		08/83 - 05/86	
Address	**City**	**State**	**Zip**
325 South Main Street	Kaysville	UT	84037
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23-present	[redacted]			
5/13-7/23				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			7/23-President	
Business Address		**City**	**State**	**Zip**
6355 S. Buffalo Drive		Las Vegas	Nevada	89113
Phone	**Title**			
702-932-8550	Region President			
Description of Duties				
President SW Utah and Nevada Markets.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			3/22-7/23	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St George	UT	84790
Phone	**Title**			
435-251-2106	SW Utah Market President			
Description of Duties				
Market President – Desert South Utah and President of Intermountain St. George Regional Hospital.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			11/16-3/22	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Hospital Administrator			
Description of Duties				
Hospital Administrator for St. George Regional Hospital				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			05/13-11/16	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Operations Officer			
Description of Duties				
Guided surgical services, neurosciences, rehabilitation, lab and serving as on-site administrator of Dixie's 400 East Campus.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mitchell Cloward

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Mitchell Cloward, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/8/25

Date

Subscribed and Sworn to before me this 8 day of January

Notary Public Signature

KIM KANEALII
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-9158-01
MY APPT. EXPIRES OCTOBER 19, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site
Pharmacy/MDEG/Wholesaler/Dispensing Practitioner Licer
Physical Address
City
Mailing Address (if different from physical address)
City
Telephone Website
Licensing Company Email

Coronado Surgical Recovery Suites ASC04428
2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052
Coronado Surgery Center ASC02494
2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052
Queensridge Surgical Recovery Suites RC04480
10040 Alta Dr #300, Las Vegas, NV 89145
Queensridge Surgery Center ASC04481
10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First Michael Middle Last Crovetti
Alias(es, nicknames, name changes, etc.)
Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X
Mailing Address [redacted]
City Henderson State NV Zip [redacted]
Telephone [redacted] Email [redacted]
Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Medicine & Dentistry of NJ School of Medicine		01/94-06/95	
Address	**City**	**State**	**Zip**
One Medical Center Dr.	Stratford	NJ	08084
Diploma/Degree obtained, if any			
Internship, Surgery			

School Name		From - To (MM/YY – MM/YY)	
UMDNJ School of Osteopathic Medicine		01/90-01/94	
Address	**City**	**State**	**Zip**
One Medical Center Dr.	Stratford	NJ	08084
Diploma/Degree obtained, if any			
D.O.			

School Name		From - To (MM/YY – MM/YY)	
Albright College		01/84-01/88	
Address	**City**	**State**	**Zip**
1621 N. 13th St.	Reading	PA	19612
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Crovetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/09/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Michael Crovetti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/09/25

Date

Subscribed and Sworn to before me this 9th day of January

Sandra Brigandi

Notary Public Signature

SANDRA BRIGANDI
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 09-23-26
Certificate No: 22-2005-01

(Seal)

CURRICULUM VITAE
(as of May 2019)

Michael J. Crovetti, Jr. DO

[redacted]

Business Crovetti Bone & Joint Institute of Southern Nevada

dba Crovetti Orthopaedics and Sports Medicine
2779 W. Horizon Ridge Parkway, Suite 200
Henderson, NV 89052
702-990-2290
Aug. 2000 to current

Date of Birth [redacted]

Spouse [redacted]

Children [redacted]

EDUCATION

Institution	**Graduation/Degree**
Albright College Reading, PA	1988/B.S.
University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	8/90 – 6/94 DO

Internship

University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	7/94 – 6/95 Chief Intern

Residency

Ohio University – Dayton, OH	7/95 – 7/99 Chief Resident
Grandview Hospital and Medical Center	

Fellowship Subspecialty Training

Reconstruction of the Hip, Knee and Shoulder, Revision Surgery Todd Swanson, MD Desert Orthopedic Center Las Vegas, NV	8/99 – 7/00 Fellow

Consultant Positions

Previous
Cardo Medical, Beverly Hills, CA, Consultant for Total Joint Replacement
Stryker Orthopaedics, Mahwah, NJ, Consultant for Total Joint Replacement
Smith & Nephew, Memphis, TN, Consultant for Minimally Invasive Joint Replacement
DePuy Orthopaedics, Inc, Warsaw, IN, Consultant for Mini Incision Total Hip and Total Knee Arthroplasty
PLUS Orthopedics, San Diego, California, Consultant for the *Gliding Nail* for intramedullary nailing of peritrochanteric hip fractures.

Media Exposure

Summer 2014 – MyVegas Magazine – *Top Docs & Dentists Profile*

Summer 2014 – Las Vegas Life – *Top Doctors 2014*

May 2014 – Fox 5 More TV – *Patient testimonial following a double hip replacement*

February 2014 – Fox 5 More TV – *Coverage of patient walking 3 hours following Total Hip Replacement*

January 2014 – MyVegas Magazine Top Docs Profile

September-December 2013 – Spirit Magazine Health Issue with Advertorial

Fall 2013 – MyVegas Magazine – *Recovery: Crovetti Orthopaedics and Sports Medicine Celebrates Their 500th Patient*

Summer 2013 – MyVegas Magazine – *My Top Docs & Dentists*

Spring 2013 – Las Vegas Life – *Top Doctors 2013*

April 23, 2013 – Las Vegas Review Journal - *Las Vegas doctor streamlines popular knee, hip replacement procedures*

April 19, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

March 15, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

January 28, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

Spring, 2012, Las Vegas Life – *Top Doctors 2012*

May, 2012 – Vegas, Inc. – *Recovery Suites Model Takes Root In Las Vegas*

May, 2012 – Las Vegas Review Journal - *"Doctors look to control outcomes with own surgical centers, staff"*

2003-2005 Designer Platform Hip Stem, Smith and Nephew Orthopaedics

a. Royalty based agreement

2004-2006 Clinical Faculty Birmingham Hip Resurfacing Team

a. Designed and Implemented Cadaveric Training Program

b. Travelled internationally to learn technique in Belgium, Ireland, and Birmingham

2005-2010 Chairman, Co-Chairman and Clinical Faculty Stryker Orthopaedics Comet Hip Resurfacing Team

a. One of Four Surgeons commissioned to Introduce, Design and Implement Cadaveric training program

2005 – 2007 Consultant Designer HipStar Femoral Stem, Stryker Orthopaedics

2009 – 2010 Instrument and Implant Designer Consultant – CardoMedical, Inc

a. Designed Knee Replacement Instruments and Retractor System for Total Hip Arthroplasty
b. Design Input Poly Insert Total Knee Arthroplasty

2005 Guest Speaker Japanese Orthopedic Association Okinawa, Japan

a. Minimally Invasive Hip and Knee Replacement Surgery

2004 – 2010 Chairman Nevada Bioresearch Foundation, Medical Education And Research Institute of Nevada (MERIN)

a. Designed, Built, MERIN facility in Henderson, Nevada
b. Established Cadaveric Training program and Donation program for State of Nevada
c. MERIN trained more than 10,000 surgeons from 26 different countries

2005-2007 Team Physician UNLV Football, Las Vegas, Nevada

2005- Current Clinical Adjunct Professor of Orthopaedics Touro University, Henderson, Nevada

2006 – 2008 Chief of Surgery, St. Rose Dominican, San Martin Campus, Las Vegas, NV

Clinical and Scientific Presentations

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2013

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2012

Mahwah, NJ April 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ May 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ July 2009

"Hipstar DVD" Instructional DVD on how to complete implementation of Hipstar system.
Stryker
Mahwah,NJ June 2007

"North American Hip and Knee Symposium" Smith & Nephew Surgical Approached and Current Controversies
Copper, CO February 2006

"Japanese MIS Synergy Total Hip System Learning Center" Smith & Nephew
Henderson, NV January 2006

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV October 2005

"Minimally Invasive Hip and Knee Surgical Techniques". Smith & Nephew Innovations in MIS Joint Surgery.
New Orleans, LA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques", "Supartz: A Nonsurgical Option" Smith & Nephew Innovations in MIS Joint Surgery.
Santa Barbara, CA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV May 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV April 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Japan, February 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN December 2004

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.

Phoenix, AZ September 2003

"Minimally Invasive Hip Surgical Techniques" Led the cadaver labs. Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN July 2003

"Minimally Invasive Hip & Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2003

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beavercreek, CO January 2003

New Developments in Hip & Knee Arthroplasty- Smith & Nephew
Naples, FL November 2002

"Leg Length & Offset Restoration in Total Hip Arthroplasty"- Smith & Nephew The Great Lakes Joint Arthroplasty Symposium.
Onekama, MI September 2002

Joint Arthroplasty- Smith & Nephew
Coeur D'Alene, ID August 2002

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2002

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beaver Creek, CO February 2002

"Joint Reconstruction" Plus Orthopedics
12th International Symposium on Joint Reconstruction,
Ritz Carlton Hotel in Dana Point, CA. April 2001.

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented to the Arizona Orthopedic Society meeting.
Phoenix, AZ. November 2000

Mini-incision Total Hip Arthroplasty. Grand Rounds
Maricopa County Medical Center. Phoenix, AZ November 2000

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented at the 11Th International Zweymuller Symposium
Boston Harbor Hotel, Boston, MA. October 2000.
"Gliding Nail Workshop" Plus Orthopedics National Sales Meeting.
San Diego, CA. September 2000.

"Intramedullary Nailing of Stable and Unstable Peritrochanteric Hip Fractures;"
presented at University Medical Center of Fresno, CA, December 1999.

June 2010
4 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

June 2010
4 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

May 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

April 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Knee System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Hip System
Henderson, NV

March 2010
1 surgeon training on Cardo Unicompartmental Knee System

Utah

October 2007
3 surgeons training triathlon knee and accolade hip training
Utah

September 2007
1 surgeon training Accolade Hip System, Triathlon Knee and Comet Hip resurfacing system
Las Vegas, NV
1 surgeon skills development program
Fort Lauderdale, FL

August 2007
2 surgeon Presentation hip resurfacing
San Diego, CA
2 surgeons Presentation Triathlon Knee and Accolade Hip System
Mahwah,NJ
1 surgeon Training Comet implant
Los Angeles, CA

July 2007
1 surgeon presentation of hip resurfacing lab Miami Florida
15 surgeon presentation hip and knee replacement
Las Vegas, NV

June 2007
Stryker training session for development of an Activity Expectation Scoring system
1 surgeon training session on the Accolade Hip Stem
Arkansas
1 surgeon training with cadaver and detailed the benefits of Triathlon knee systems
1 surgeon training regarding Triathlon knee system
Phoenix, AZ

May 2007
Teaching seminar for the HIPStar implant program and resurfacing implant
5 surgeons Mahwah, NJ

Feb 2007
1 surgeon training seminar and cadaver interactive training
Los Angeles, CA

December 2007
1 surgeon from Colorado Springs, CO
1 surgeon from Fort Lauderdale, FI
15 surgeon seminar training Fort Lauderdale, FL

November 2006
1 surgeon from Michigan

June 2006

2 surgeons from Springfield, MO
1 surgeon from Houston, TX

June 2004
1 surgeon from Munster, IN

May 2004
1 surgeon from Scottsdale, AZ

March 2004
1 surgeon from Tuscaloosa, AL
1 surgeon from Birmingham, AL
1 surgeon from Lancing, MI

February 2004
2 surgeons from Jasper, AL
1 surgeon & 1 PA-C from Houston, TX
January 2004
2 surgeons from Decatur, AL

December 2003
1 surgeon from Australia
1 surgeon from Pleasanton, CA

September 2003
1 surgeon from MI

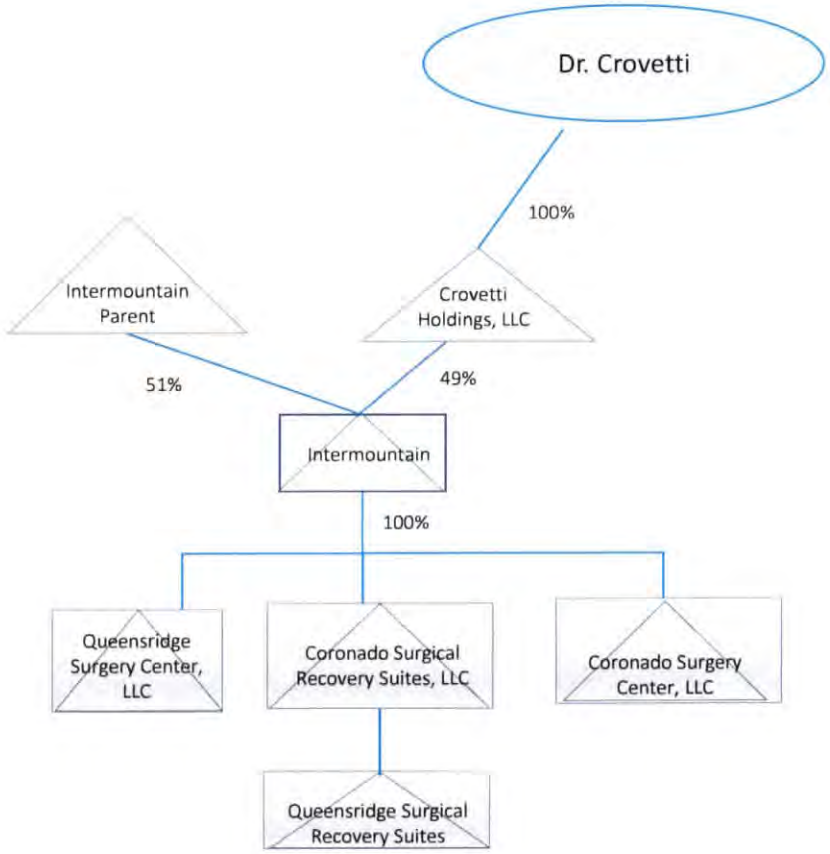
July 2003
1 surgeon from Birmingham, AL

March 2003
1 surgeon from Phoenix, AZ

February 2003
1 surgeon from Birmingham, AL

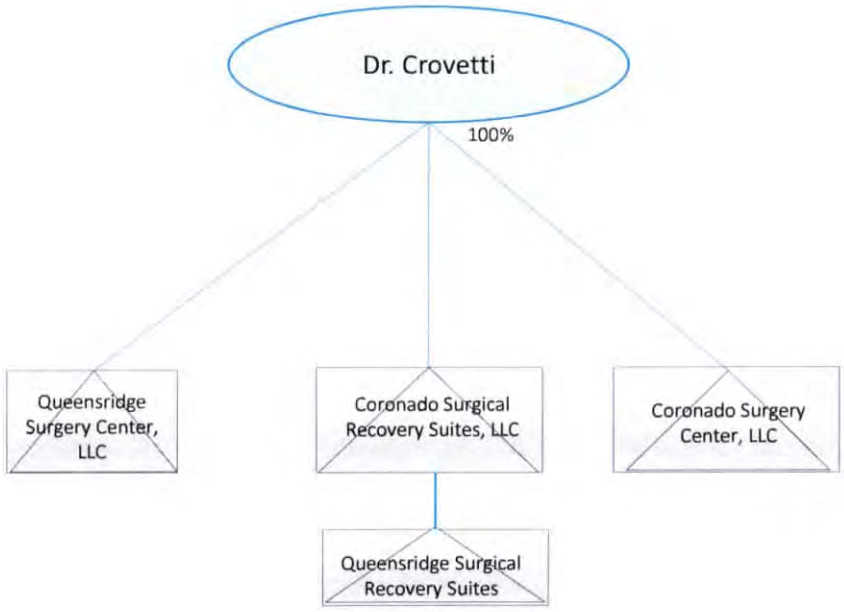
Post-reorganization

- Dr. Crovetti forms a JV holding company ("**Intermountain**")
- Intermountain Medical Holdings Nevada, Inc., a Delaware nonprofit nonstock corporation ("**Intermountain Parent**"), purchases 51% of Intermountain.
- Dr. Crovetti will remain in the structure as the ultimate 49% equity holder of each of the Facilities.



Pre-reorganization

- Dr. Crovetti holds 100% of the equity in each of the Facilities.



10B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

☐ Ambulatory Surgical Center (ASC)

☑ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☑ Ownership Change*		☑ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *	ASC04428	☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Coronado Surgical Recovery Suites

Physical Address: 2779 West Horizon Ridge Parkway Suite 130

City: Henderson State: NV Zip: 89052

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-932-8370 Fax: 702-331-2839

Contact Email: szimmerman@crovettiortho.com Website _____

Nevada Business License # NV20101218573

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Dr Michael J. Crovetti, Jr., D.O.

Days of Operation

☑ Monday	☑ Tuesday	☑ Wednesday	☑ Thursday	☑ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Intermountain Orthopedic Holdings Nevada, LLC

Corporation/Organization Name: Coronado Surgical Recovery Suites, LLC

Mailing Address: 2779 West Horizon Ridge Parkway Suite 130

City: Henderson State: NV Zip: 89052

Telephone: _____ Email: mcrovetti@crovettiortho.com

Contact Person Name: Dr Michael J. Crovetti, Jr., D.O.

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Coronado Surgical Recovery Suites :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle McCarty

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

1-12-25

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dr. Michael J. Crovetti, Jr., D.O.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

1/13/25

Date

Board Use Only	Date Received: 1/22/25	Amount: $500-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **CORONADO SURGICAL RECOVERY SUITES, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/25/2010, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/16/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412165271528
You may verify this certificate online at https://www.nvsilverflume.gov/home

Exhibit H

Officers and Stockholders

Officers:

- President – Michael J. Crovetti, Jr., D.O.

Top four stockholders: Intermountain Orthopedic Holdings Nevada, LLC

Stockholders with 10% or more of the shares: Intermountain Orthopedic Holdings Nevada, LLC

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
6188-RCF-18

Please display this license conspicuously

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to: https://nvdpbh.aithent.com/login.aspx.

This Is To Certify That

CORONADO SURGICAL RECOVERY SUITES

2779 W HORIZON RIDGE PKWY STE 130
HENDERSON, NV 89052

Is hereby licensed as a(n)

RECOVERY CENTER FACILITY

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

CORONADO SURGICAL RECOVERY SUITES

2779 W HORIZON RIDGE PKWY STE 130
HENDERSON, NV 89052

Facility Type : RECOVERY CENTER FACILITY

Endorsement :

Bed Information : BEDS - 6

If your license is not completely accurate, Please contact us at (775) 684-1030 so that we may resolve any problems.

SYVANA ZIMMERMAN / Administrator

MICHAEL CROVETTI, JR

Cody L Phinney / Administrator

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site _____

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # _____

Physical Address _____

City _____

Mailing Address (if different from physical address) _____

City _____

Telephone _____ Website _____

Licensing Company Email _____

Coronado Surgical Recovery Suites ASC04428
2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052

Coronado Surgery Center ASC02494
2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052

Queensridge Surgical Recovery Suites RC04480
10040 Alta Dr #300, Las Vegas, NV 89145

Queensridge Surgery Center ASC04481
10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First Mitchell Middle Howard Last Cloward

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Weber State University		01/89-06/94	
Address	City	State	Zip
3848 Harrison Blvd	Ogden	UT	84403
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Texas Women's University		01-95-06/99	
Address	City	State	Zip
304 Administration Drive, Suite 102	Denton	TX	76204
Diploma/Degree obtained, if any			
Masters in Healthcare Administration			

School Name		From - To (MM/YY – MM/YY)	
David High School		08/83 - 05/86	
Address	City	State	Zip
325 South Main Street	Kaysville	UT	84037
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23-present	[redacted]			
5/13-7/23				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			7/23-President	
Business Address		**City**	**State**	**Zip**
6355 S. Buffalo Drive		Las Vegas	Nevada	89113
Phone	**Title**			
702-932-8550	Region President			
Description of Duties				
President SW Utah and Nevada Markets.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			3/22-7/23	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St George	UT	84790
Phone	**Title**			
435-251-2106	SW Utah Market President			
Description of Duties				
Market President – Desert South Utah and President of Intermountain St. George Regional Hospital.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			11/16-3/22	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Hospital Administrator			
Description of Duties				
Hospital Administrator for St. George Regional Hospital				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			05/13-11/16	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Operations Officer			
Description of Duties				
Guided surgical services, neurosciences, rehabilitation, lab and serving as on-site administrator of Dixie's 400 East Campus.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mitchell Cloward

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

11/8/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Mitchell Cloward, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/8/25

Date

Subscribed and Sworn to before me this 8 day of January

Notary Public Signature

KIM KANEALII
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-9158-01
MY APPT. EXPIRES OCTOBER 19, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner Licer

Physical Address

City

Mailing Address (if different from physical address)

City

Telephone Website

Licensing Company Email

Coronado Surgical Recovery Suites ASC04428
2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052
Coronado Surgery Center ASC02494
2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052
Queensridge Surgical Recovery Suites RC04480
10040 Alta Dr #300, Las Vegas, NV 89145
Queensridge Surgery Center ASC04481
10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First Michael Middle Last Crovetti

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Henderson State NV Zip 89052

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Medicine & Dentistry of NJ School of Medicine			01/94-06/95	
Address		City	State	Zip
One Medical Center Dr.		Stratford	NJ	08084
Diploma/Degree obtained, if any				
Internship, Surgery				
School Name			From - To (MM/YY – MM/YY)	
UMDNJ School of Osteopathic Medicine			01/90-01/94	
Address		City	State	Zip
One Medical Center Dr.		Stratford	NJ	08084
Diploma/Degree obtained, if any				
D.O.				
School Name			From - To (MM/YY – MM/YY)	
Albright College			01/84-01/88	
Address		City	State	Zip
1621 N. 13th St.		Reading	PA	19612
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Crovetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/09/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Michael Crovetti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/09/25

Date

Subscribed and Sworn to before me this 9th day of January

Sandra Brigandi

Notary Public Signature

SANDRA BRIGANDI
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 09-23-26
Certificate No: 22-2005-01

(Seal)

CURRICULUM VITAE
(as of May 2019)

Michael J. Crovetti, Jr., DO

[redacted]

Business Crovetti Bone & Joint Institute of Southern Nevada

dba Crovetti Orthopaedics and Sports Medicine
2779 W. Horizon Ridge Parkway, Suite 200
Henderson, NV 89052
702-990-2290
Aug. 2000 to current

Date of Birth [redacted]

Spouse [redacted]

Children [redacted]

EDUCATION

Institution	**Graduation/Degree**
Albright College Reading, PA	1988/B.S.
University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	8/90 – 6/94 DO

Internship

University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	7/94 – 6/95 Chief Intern

Residency

Ohio University – Dayton, OH	7/95 – 7/99 Chief Resident
Grandview Hospital and Medical Center	

Fellowship Subspecialty Training

Reconstruction of the Hip, Knee and Shoulder, Revision Surgery Todd Swanson, MD Desert Orthopedic Center Las Vegas, NV	8/99 – 7/00 Fellow

Consultant Positions

Previous
Cardo Medical, Beverly Hills, CA, Consultant for Total Joint Replacement
Stryker Orthopaedics, Mahwah, NJ, Consultant for Total Joint Replacement
Smith & Nephew, Memphis, TN, Consultant for Minimally Invasive Joint Replacement
DePuy Orthopaedics, Inc, Warsaw, IN, Consultant for Mini Incision Total Hip and Total Knee Arthroplasty
PLUS Orthopedics, San Diego, California, Consultant for the *Gliding Nail* for intramedullary nailing of peritrochanteric hip fractures.

Media Exposure

Summer 2014 – MyVegas Magazine – *Top Docs & Dentists Profile*

Summer 2014 – Las Vegas Life – *Top Doctors 2014*

May 2014 – Fox 5 More TV – *Patient testimonial following a double hip replacement*

February 2014 – Fox 5 More TV – *Coverage of patient walking 3 hours following Total Hip Replacement*

January 2014 – MyVegas Magazine Top Docs Profile

September-December 2013 – Spirit Magazine Health Issue with Advertorial

Fall 2013 – MyVegas Magazine – *Recovery: Crovetti Orthopaedics and Sports Medicine Celebrates Their 500th Patient*

Summer 2013 – MyVegas Magazine – *My Top Docs & Dentists*

Spring 2013 – Las Vegas Life – *Top Doctors 2013*

April 23, 2013 – Las Vegas Review Journal - *Las Vegas doctor streamlines popular knee, hip replacement procedures*

April 19, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

March 15, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

January 28, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

Spring, 2012, Las Vegas Life – *Top Doctors 2012*

May, 2012 – Vegas, Inc. – *Recovery Suites Model Takes Root In Las Vegas*

May, 2012 – Las Vegas Review Journal - *"Doctors look to control outcomes with own surgical centers, staff"*

2003-2005 Designer Platform Hip Stem, Smith and Nephew Orthopaedics

a. Royalty based agreement

2004-2006 Clinical Faculty Birmingham Hip Resurfacing Team

a. Designed and Implemented Cadaveric Training Program

b. Travelled internationally to learn technique in Belgium, Ireland, and Birmingham

2005-2010 Chairman, Co-Chairman and Clinical Faculty Stryker Orthopaedics Comet Hip Resurfacing Team

a. One of Four Surgeons commissioned to Introduce, Design and Implement Cadaveric training program

2005 – 2007 Consultant Designer HipStar Femoral Stem, Stryker Orthopaedics

2009 – 2010 Instrument and Implant Designer Consultant – CardoMedical, Inc

a. Designed Knee Replacement Instruments and Retractor System for Total Hip Arthroplasty
b. Design Input Poly Insert Total Knee Arthroplasty

2005 Guest Speaker Japanese Orthopedic Association Okinawa, Japan
a. Minimally Invasive Hip and Knee Replacement Surgery

2004 – 2010 Chairman Nevada Bioresearch Foundation, Medical Education And Research Institute of Nevada (MERIN)

a. Designed, Built, MERIN facility in Henderson, Nevada
b. Established Cadaveric Training program and Donation program for State of Nevada
c. MERIN trained more than 10,000 surgeons from 26 different countries

2005-2007 Team Physician UNLV Football, Las Vegas, Nevada

2005- Current Clinical Adjunct Professor of Orthopaedics Touro University, Henderson, Nevada

2006 – 2008 Chief of Surgery, St. Rose Dominican, San Martin Campus, Las Vegas, NV

Clinical and Scientific Presentations

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2013

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2012

Mahwah, NJ April 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ May 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ July 2009

"Hipstar DVD", Instructional DVD on how to complete implementation of Hipstar system.
Stryker
Mahwah,NJ June 2007

"North American Hip and Knee Symposium" Smith & Nephew Surgical Approached and Current Controversies
Copper, CO February 2006

"Japanese MIS Synergy Total Hip System Learning Center" Smith & Nephew
Henderson, NV January 2006

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV October 2005

"Minimally Invasive Hip and Knee Surgical Techniques". Smith & Nephew Innovations in MIS Joint Surgery.
New Orleans, LA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques", "Supartz: A Nonsurgical Option" Smith & Nephew Innovations in MIS Joint Surgery.
Santa Barbara, CA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV May 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV April 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Japan, February 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN December 2004

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.

Phoenix, AZ September 2003

"Minimally Invasive Hip Surgical Techniques" Led the cadaver labs. Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN July 2003

"Minimally Invasive Hip & Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2003

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beavercreek, CO January 2003

New Developments in Hip & Knee Arthroplasty- Smith & Nephew
Naples, FL November 2002

"Leg Length & Offset Restoration in Total Hip Arthroplasty"- Smith & Nephew The Great Lakes Joint Arthroplasty Symposium.
Onekama, MI September 2002

Joint Arthroplasty- Smith & Nephew
Coeur D'Alene, ID August 2002

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2002

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beaver Creek, CO February 2002

"Joint Reconstruction" Plus Orthopedics
12th International Symposium on Joint Reconstruction,
Ritz Carlton Hotel in Dana Point, CA. April 2001.

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented to the Arizona Orthopedic Society meeting.
Phoenix, AZ. November 2000

Mini-incision Total Hip Arthroplasty. Grand Rounds
Maricopa County Medical Center. Phoenix, AZ November 2000

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented at the 11Th International Zweymuller Symposium
Boston Harbor Hotel, Boston, MA. October 2000.
"Gliding Nail Workshop" Plus Orthopedics National Sales Meeting.
San Diego, CA. September 2000.

"Intramedullary Nailing of Stable and Unstable Peritrochanteric Hip Fractures;"
presented at University Medical Center of Fresno, CA, December 1999.

June 2010
4 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

June 2010
4 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

May 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

April 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Knee System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Hip System
Henderson, NV

March 2010
1 surgeon training on Cardo Unicompartmental Knee System

Utah

October 2007
3 surgeons training triathlon knee and accolade hip training
Utah

September 2007
1 surgeon training Accolade Hip System, Triathlon Knee and Comet Hip resurfacing system
Las Vegas, NV
1 surgeon skills development program
Fort Lauderdale, FL

August 2007
2 surgeon Presentation hip resurfacing
San Diego, CA
2 surgeons Presentation Triathlon Knee and Accolade Hip System
Mahwah,NJ
1 surgeon Training Comet implant
Los Angeles, CA

July 2007
1 surgeon presentation of hip resurfacing lab Miami Florida
15 surgeon presentation hip and knee replacement
Las Vegas, NV

June 2007
Stryker training session for development of an Activity Expectation Scoring system
1 surgeon training session on the Accolade Hip Stem
Arkansas
1 surgeon training with cadaver and detailed the benefits of Triathlon knee systems
1 surgeon training regarding Triathlon knee system
Phoenix, AZ

May 2007
Teaching seminar for the HIPStar implant program and resurfacing implant
5 surgeons Mahwah, NJ

Feb 2007
1 surgeon training seminar and cadaver interactive training
Los Angeles, CA

December 2007
1 surgeon from Colorado Springs, CO
1 surgeon from Fort Lauderdale, FI
15 surgeon seminar training Fort Lauderdale, FL

November 2006
1 surgeon from Michigan

June 2006

2 surgeons from Springfield, MO
1 surgeon from Houston, TX

June 2004
1 surgeon from Munster, IN

May 2004
1 surgeon from Scottsdale, AZ

March 2004
1 surgeon from Tuscaloosa, AL
1 surgeon from Birmingham, AL
1 surgeon from Lancing, MI

February 2004
2 surgeons from Jasper, AL
1 surgeon & 1 PA-C from Houston, TX
January 2004
2 surgeons from Decatur, AL

December 2003
1 surgeon from Australia
1 surgeon from Pleasanton, CA

September 2003
1 surgeon from MI

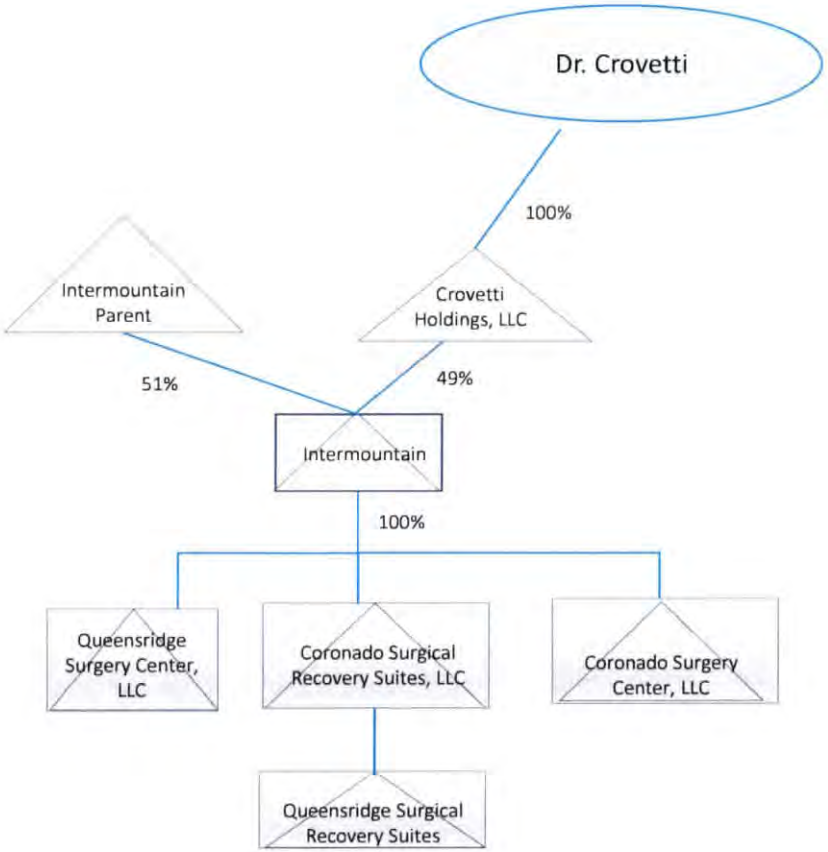
July 2003
1 surgeon from Birmingham, AL

March 2003
1 surgeon from Phoenix, AZ

February 2003
1 surgeon from Birmingham, AL

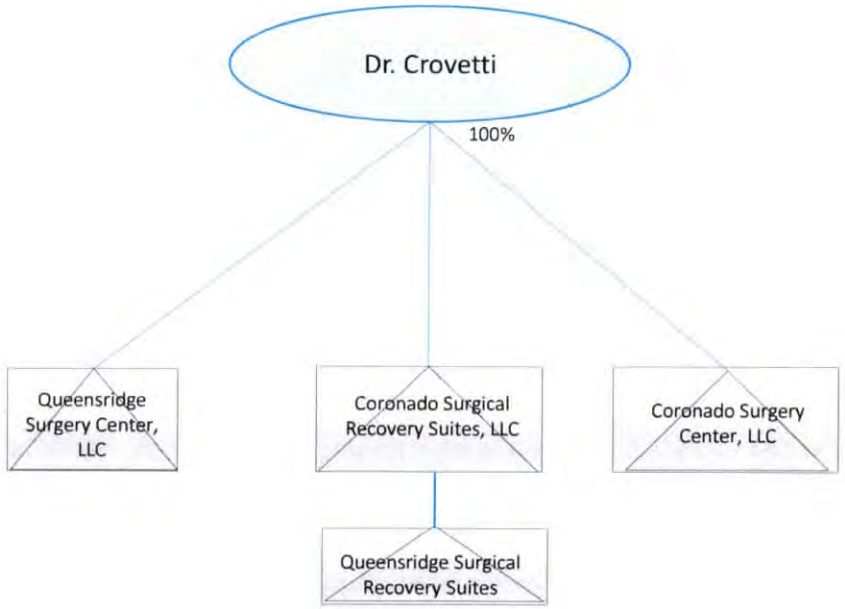
Post-reorganization

- Dr. Crovetti forms a JV holding company ("**Intermountain**")
- Intermountain Medical Holdings Nevada, Inc., a Delaware nonprofit nonstock corporation ("**Intermountain Parent**"), purchases 51% of Intermountain.
- Dr. Crovetti will remain in the structure as the ultimate 49% equity holder of each of the Facilities.



Pre-reorganization

- Dr. Crovetti holds 100% of the equity in each of the Facilities.



10C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility		
■ Ambulatory Surgical Center (ASC)		
☐ Recovery Center (RC)		
Type of Application (check applicable box)		**Ownership Type (check applicable box)**
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
■ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *	ASC02914	■ Partnership (complete sections 1, 2, 5, 7, 8, 9)
■ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Elkhorn Surgery Center

Physical Address: 7175 N Durango Suite 110

City: Las Vegas State: NV Zip: 89149

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-410-9800 Fax: 702-924-1520

Contact Email: administrator@reynoldscosmetics.com Website _____

Nevada Business License # NV20253294616

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Paul Reynolds

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 5: Partnership

Partnership Name: Elkhorn Surgery Center

Mailing Address: 7175 N Durango suite 110

City: Las Vegas State: NV Zip: 89149

Telephone: 702-410-9800 Email: brandonquayle@gmail.com

Contact Person Name: Brandon Reynolds

Please check type of partnership (NAC 639.214) ☐ General ■ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ■ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy, RPh NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Elkhorn Surgery Center :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle McCarty

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

2/25/2025

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.** Pending	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

BRANDON REYNOLDS

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/27/25

Date

Board Use Only	Date Received: 3/3/25	Amount: $300.00

Elkhorn Surgery Center LLC

Partnership over 10%

Brandon Reynolds

Robert Reynolds

Matthew Reynolds

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

Elkhorn Surgery Center LLC

Nevada Business Identification # NV20253294616
Expiration Date: 02/28/2026

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/18/2025.

Certificate Number: B202502185447518
You may verify this certificate online at https://www.nvsilverflume.gov/home

FRANCISCO V. AGUILAR
Secretary of State

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
7592-ASC-11

Please display this license conspicuously

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to: https://nvdpbh.aithent.com/login.aspx.

This Is To Certify That

SPRING VALLEY SURGERY CENTER

7175 N DURANGO DR STE 220
LAS VEGAS, NV 89149

Is hereby licensed as a(n)

SURGICAL CENTER FOR AMBULATORY PATIENTS

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

Facility Type : SURGICAL CENTER FOR AMBULATORY PATIENTS
AMBULATORY SURGERY CENTER CLASS C

Endorsement : CLASS - C

Bed Information : Operating Room - A - 2

If your license is not completely accurate, Please contact us at (775) 684-1030 so that we may resolve any problems.

DR. OKWUCHUKWU GINIKA OBI / Administrator

IMMACULATE CONCEPTION INTERNATIONAL LLC /

Cody L Phinney / Administrator

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Elkhorn Surgery Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 7175 N Durango Dr Suite 110

City: Las Vegas State: NV Zip: 89149

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-410-9800 Website:

Licensing Company Email: administrator@reynoldscosmetics.com

Section 2: Personal Information

First: Robert Middle: Harold Last: Reynolds

Alias(es, nicknames, name changes, etc.): Bob

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)	✔	✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	✔	✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name: NYU Law			From - To (MM/YY – MM/YY): 2000 – 2002	
Address: 40 Washington Square	City: NY		State: NY	Zip: 10012
Diploma/Degree obtained, if any: Juris Doctorate (JD)				
School Name: Brigham Young University			From - To (MM/YY – MM/YY): 92 – 99	
Address: BYU	City: Provo		State: UT	Zip: 84602
Diploma/Degree obtained, if any: English Major				
School Name: Bonanza High School			From - To (MM/YY – MM/YY): 5/88 – 6/92	
Address: 6665 Del Ray Ave	City: Las Vegas		State: NV	Zip:
Diploma/Degree obtained, if any: H.S. Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2023 – 2025	[redacted]			
2015 – 2023				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Robert Reynolds Management			2003 – 2025
Business Address 823 Las Vegas Blvd S	**City** Las Vegas	**State** NV	**Zip** 89101
Phone 7028074830	**Title** President		
Description of Duties Owner of Band mangent company			

Business Name			From - To (MM/YY – MM/YY)
Reynolds + Associates			2007 – 2025
Business Address 823 Las Vegas Blvd S	**City** Las Vegas	**State** NV	**Zip** 89101
Phone (702)807-4830	**Title** Lawyer / Associate		
Description of Duties Lawyer			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
	Settled	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
N/A		NV Federal Court		
Reason/Charge				
2 lawsuits re: music business with my client, both filed + settled				
Plaintiff/Defendant/Claimant/Respondent		**Lawsuit/Arbitration/Bankruptcy**		
Plzman / Merrick				
Name of Business/Industry/Entity				
Imagine Dragons LLC, The Killers LLC				

Provide explanation below:

Both bands have had internal flings, but both arbitrated and settled. One was with a former drummer, the other a former manager.

Original Signature (electronic, copies or stamps not accepted)

2/27/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert, Reynolds

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/28/2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, Robert Reynolds, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/28/2025

Date

Subscribed and Sworn to before me this 28th day of FEBRUARY, 2025

Keith Leah

Notary Public Signature

KEITH LEAH
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-05-27
Certificate No: 11-5485-5

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Elkhorn Surgery Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 7175 N Durango Dr Suite 110

City: Las Vegas State: NV Zip: 89149

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-410-9800 Website: _____

Licensing Company Email: administrator@reynoldscosmetics.com

Section 2: Personal Information

First: Matthew Middle: _____ Last: Reynolds

Alias(es, nicknames, name changes, etc.): Mac

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UCLA School of Law		9/2006 - 6/2008	
Address	**City**	**State**	**Zip**
385 Charles E Young Dr E	Los Angeles	CA	
Diploma/Degree obtained, if any			
J.D.			

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		9/2000 - 6/2006	
Address	**City**	**State**	**Zip**
Brigham Young University	Provo	UT	
Diploma/Degree obtained, if any			
B.A. English			

School Name		From - To (MM/YY – MM/YY)	
Bonanza High School		9/1996 - 6/2000	
Address	**City**	**State**	**Zip**
6665 Del Ray Ave	Las Vegas	NV	89146
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
12/22 - present	[redacted]			
1/15 - 12/22				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Night Street Games			1/22 - present	
Business Address		**City**	**State**	**Zip**
823 Las Vegas Blvd. So. #200		Las Vegas	NV	89101
Phone	**Title**			
7024457000	Owner and CEO			
Description of Duties				
Co-founded and leading a game studio.				

Business Name			From - To (MM/YY – MM/YY)	
Mac Reynolds Management			1/10 - present	
Business Address		**City**	**State**	**Zip**
823 Las Vegas Blvd. So. #200		Las Vegas	NV	89101
Phone	**Title**			
7024457000	Owner			
Description of Duties				
Artist manager.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Matthew, Reynolds

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/28/25

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, MATTHEW REYNOLDS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/28/2025

Date

Subscribed and Sworn to before me this 28th day of FEBRUARY 2025.

Notary Public Signature

KEITH LEAH
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-05-27
Certificate No: 11-5485-5

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Elkhorn Surgery Center

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 7175 N Durango Dr suite 110

City Las Vegas State NV Zip 89149

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone 702-410-9800 Website _____

Licensing Company Email administrator@reynoldscosmetics.com

Section 2: Personal Information

First Brandon Middle Quayle Last Reynolds

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITI [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Iowa Roy A Lucille J. Carver College of Medicine		2002 - 2006	
Address	**City**	**State**	**Zip**
451 Newton Road	Iowa City	IA	52242
Diploma/Degree obtained, if any			
Diplomat, Doctor of Medicine			

School Name		From - To (MM/YY – MM/YY)	
Brigham Young University		1996 - 2001	
Address	**City**	**State**	**Zip**
Brigham Young University	Provo	UT	84602
Diploma/Degree obtained, if any			
BS Zoology			

School Name		From - To (MM/YY – MM/YY)	
Bonanza High School		1992 - 1996	
Address	**City**	**State**	**Zip**
6665 Del Ray Ave	Las Vegas	NV	89146
Diploma/Degree obtained, if any			
H.S. Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20- 02/25	[redacted]			
08/13- 6/20	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Reynolds Plastic Surgery			07/12 - Present	
Business Address		**City**	**State**	**Zip**
5550 Painted Mirage Rd suite 217		Las Vegas	NV	89149
Phone	**Title**			
702-410-9800	Sole Proprietor			
Description of Duties				
Owner, Physician				

Business Name			From - To (MM/YY – MM/YY)	
Nevada Plastic Sugery			08/2016 - Present	
Business Address		**City**	**State**	**Zip**
5550 Painted Mirage RD suite 217		Las Vegas	NV	89149
Phone	**Title**			
702-410-9800	Sole Proprietor			
Description of Duties				
Partner, Physician				

Business Name			From - To (MM/YY – MM/YY)	
PREFcards LLC			01/20- Present	
Business Address		**City**	**State**	**Zip**
5550 Painted Mirage RD suite 217		Las Vegas	NV	89149
Phone	**Title**			
702-879-8030	Founder, Board Member			
Description of Duties				
Board Member				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Brandon, Reynolds

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/28/2025

Date

Please have this section completed in the presence of a Notary Public.

State of NEVADA, ss. County of CLARK

I, BRANDON REYNOLDS, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of ~~the license~~, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/28/2025

Date

Subscribed and Sworn to before me this 28th day of FEBRUARY 2025

Notary Public Signature

KEITH LEAH
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 08-05-27
Certificate No: 11-5485-5

(Seal)

10D

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
■ Ownership Change*		■ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *	ASC04451	☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Fort Apache Surgery Center, LLC

Physical Address: 6064 S Fort Apache Rd., Suite 110

City: Las Vegas State: NV Zip: 89148

Mailing Address (if different from physical address): N/A

City: State: Zip:

Telephone: (702) 940-8050 Fax: N/A

Contact Email: pb@releviumpain.com Website No website

Nevada Business License # NV20212234266

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Andrew Hall, M.D.

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy, RPh NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Fort Apache Surgery Center, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michael McCandless

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

2-27-25

Date

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): N/A

Corporation/Organization Name: Fort Apache Surgery Center, LLC

Mailing Address: 6064 S Fort Apache Rd., Suite 110

City: Las Vegas State: NV Zip: 89148

Telephone: (702) 940-8050 Email: pb@releviumpain.com

Contact Person Name: Pete Bekas

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ■ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Pete Bekas, CEO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/27/2025

Date

Board Use Only	Date Received: 3/3/25	Amount: $500cc

NEVADA STATE BOARD OF PHARMACY
Ambulatory Surgical Center ("ASC") Application

Section 9 – Additional Documents

1. Officers and Directors (Managers) of Fort Apache Surgery Center, LLC
   a. Andrew Hall, M.D. – Manager
   b. Pete Bekas – Chief Executive Officer

2. Stockholders (Members) and Percent Ownership for Fort Apache Surgery Center, LLC[1][2]
   a. ACA Relevium, LLC – 85%
   b. Andrew Hall M.D., PLLC – 15%

3. Certificate of Good Standing for Fort Apache Surgery Center, LLC
   a. See attached.

4. Personal History Record Application(s)
   a. See attached for application submitted on behalf of Andrew Hall, M.D. (sole owner of Andrew Hall, M.D., PLLC).

5. Copy of License for Fort Apache Surgery Center, LLC
   a. See attached for a copy of the Nevada Division of Public and Behavioral Health Laboratory License – Exempt Laboratory (License No. 12036-EXL-1).

[1] Ownership percentages are subject to change, as the transaction documents associated with the change of ownership have not yet been finalized.
[2] There are no direct or indirect individual/natural persons who directly or indirectly hold 10% or more of the stock in the owners of Fort Apache Surgery Center, LLC (ACA Relevium, LLC and Andrew Hall, M.D., PLLC) other than Andrew Hall, M.D.

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Fort Apache Surgery Center, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 09/22/2021, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/27/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502275475859
You may verify this certificate online at https://www.nvsilverflume.gov/home

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
10794-ASC-2

Please display t

This license w
licensing syste
VALID BY
nvdpbh.aither
License Verifi
Inspection Rep
up by licens
Number) to veri

Should you ha
Name, Adminis
of Ownership
https://nvdpbh

This Is To Certify That

FORT APACHE SURGERY CENTER

6064 S FORT APACHE RD 110
LAS VEGAS, NV 89148

Is hereby licensed as a(n)

SURGICAL CENTER FOR AMBULATORY PATIENTS

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

Facility Type : SURGICAL CENTER FOR AMBULATORY PATIENTS

Endorsement :

Bed Information : Operating Room - C - 2

If your license is
Please contact
that we may re

Pete Bekas
PETE BEKAS / Administrator

ANDREW HALL

Cody L Phinney
Cody L Phinney / Administrator

Effective Date : 11/09/2024
Expiration Date : 11/08/2026

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
12036-EXL-1

Please display this license conspicously

This Is To Certify That

FORT APACHE SURGERY CENTER
6064 SOUTH FORT APACHE RD STE 110
LAS VEGAS, NV 89148

Is hereby registered as an

EXEMPT LABORATORY

as provided for in Chapter 652 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following categorized tests:

WAIVED TESTS PURSUANT TO 42 C.F.R. PART 493, SUBPART A - Blood glucose tests, Urine pregnancy tests

This license was printed from an online licensing system.

VERIFY LICENSE IS VALID BY GOINC TO: https://nvdpbh.aithent.com/login.aspx

Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

ANDREW HALL
Director

ANDREW HALL
Owner

Cody L Phinney
Administrator

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Fort Apache Surgery Center, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): ASC04451

Physical Address: 6064 S Fort Apache Rd STE 110

City: Las Vegas State: NV Zip: 89148

Mailing Address (if different from physical address): PO Box # 400670

City: Las Vegas State: NV Zip: 89140

Telephone: 702.940.8050 Website:

Licensing Company Email: pb@releviumpain.com

Section 2: Personal Information

First: Andrew Middle: M Last: Hall

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✓

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of California, San Francisco		07/15 - 06/16	
Address	City	State	Zip
2255 Post St	San Francisco	CA	94143
Diploma/Degree obtained, if any			
Fellowship - Pain Medicine			

School Name		From - To (MM/YY – MM/YY)	
The University of Chicago		06/12 - 06/15	
Address	City	State	Zip
5841 S Maryland Ave	Chicago	IL	60637
Diploma/Degree obtained, if any			
Residency - Anesthesiology			

School Name		From - To (MM/YY – MM/YY)	
University of Illinois - Chicago		07/11 - 06/12	
Address	City	State	Zip
One Illini Drive	Peoria	IL	61605
Diploma/Degree obtained, if any			
Intership			

School Name		From - To (MM/YY – MM/YY)	
University of Illinois - Chicago		09/07 - 06/11	
Address	City	State	Zip
506 South Mathews	Urbana	IL	61801
Diploma/Degree obtained, if any			
Doctor of Medicine			

School Name		From - To (MM/YY – MM/YY	
Illinois Wesleyan University		09/03 - 05/07	
Address	City	State	Zip
1312 Park Stret	Bloomington	IL	61701
Diploma/Degree obtained, if any			
Bachelors of Science			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)				
03/22	[redacted]			
06/17 - 03/22				
07/16 - 06/17				
07/15 - 06/16				
06/12 - 06/15				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name		From - To (MM/YY – MM/YY)	
Relevium Pain Specialists		05/19 -	
Business Address	**City**	**State**	**Zip**
6064 S Fort Apache	Las Vegas	NV	89148
Phone	**Title**		
702.940.8007	Medical Director		
Description of Duties			
MD With Prescribing Authority - Nevada Pharmacy Board - CS24795 (Issued 07/21/2016)			

Business Name		From - To (MM/YY – MM/YY)	
Interventional Pain & Spine Institute (Now Closed)		04/17 - 04/19	
Business Address	**City**	**State**	**Zip**
851 S Rampart Blvd Ste 100	Las Vegas	NV	89148
Phone	**Title**		
702.357.8004	Pain Physician		
Description of Duties			
MD With Prescribing Authority - Nevada Pharmacy Board - CS24795 (Issued 07/21/2016)			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✓	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
12/2021		NV	Las Vegas	Clark

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
A-21-84600-C	Eighth Judicial District Court

Reason/Charge
Other Contract - Constructive Eviction

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
Andrew Hall & Andrew Hall MD, PLLC	Lawsuit

Name of Business/Industry/Entity
Lewel LLC - Defendant

Provide explanation below:

Beginning June of 2020, the landlord continued to make excessive amounts of noise on the suite next to the medical office. Some days, patients were not able to be heard because the music was so load. After several attempts to try fix the noise Issue and to terminate the lease mutually the landlord refused. The medical office Andrew Hall MD, PLLC DBA Relevium Pain Specialists relocated to a new office building and tried to settle the remaining term of the lease they landlord still refused. As such an active case to close the lease was flied.
Andrew Hall has 3 months of a personal guarantee on the lease

Andrew Hall MD PLLC has 2.25 years remaining on the term of the lease.

A confidential settlement agreement was entered into on July 28th, 2023.

Original Signature (electronic, copies or stamps not accepted)

02-27-2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Hall
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

02-27-2025
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Andrew Hall, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

02-27-2025
Date

Subscribed and Sworn to before me this 27 day of FEBRUARY

Notary Public Signature

SHATARA KING
Notary Public - State of Nevada
Appointment No. 23-8271-01
My Appointment Expires 03/23/2027

(Seal)

Electronically Filed
12/28/2021 5:01 PM
Steven D. Grierson
CLERK OF THE COURT

COMP
JOHN C. COURTNEY, ESQ.
Nevada Bar No. 11092
ANDREW P. DUNNING, ESQ.
Nevada Bar No. 13864
SEBASTIAN F. GAJARDO, ESQ.
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LBC LAW GROUP
3215 W. Charleston Blvd., Ste. 120
Las Vegas, Nevada 89102
Ph.: (702) 608-3030
Fax: (702) 463-4443
Info@LBCLawgroup.com
Attorneys for Plaintiffs

CASE NO: A-21-846000-C
Department 30

EIGHTH JUDICIAL DISTRICT COURT

CLARK COUNTY, NEVADA

ANDREW HALL MD, PLLC a Nevada limited-liability company, and ANDREW HALL MD, an individual, *Plaintiffs,* v. LEWEL, LLC, a Nevada limited-liability company; DOES I-X, and ROES XI-XX, *Defendants.*	Case No.: Dept. No.: **COMPLAINT** **Arbitration Exemption Requested:** Amount in Controversy Exceeds $50,000 Equitable Relief Sought **JURY TRIAL DEMANDED**

Plaintiffs Andrew Hall M.D., PLLC ("Relevium"), and Andrew Hall M.D. ("Dr. Hall," along with Relevium, "Plaintiffs"), by and through their attorneys of record, John C. Courtney, Esq. and Andrew P. Dunning, Esq. of LBC Law Group, allege and complain as follows:

PARTIES

1. Plaintiff Andrew Hall M.D., PLLC is, and was at all times relevant herein, a Nevada professional limited-liability company duly authorized to do business in Clark County, Nevada.

2. Plaintiff Andrew Hall M.D. is, and was at all times relevant herein, an individual residing in Clark County, Nevada.

3. Defendant Lewel, LLC ("Defendant") is, and was at all times relevant herein, a Nevada limited-liability company duly authorized to do business in Clark County, Nevada.

///

4. Plaintiffs are ignorant of the true names and capacities of Defendants sued herein as DOES I through X, inclusive, and ROE CORPORATIONS XI through XX, inclusive, and therefore sue these Defendants by such fictitious names (collectively with Defendant Lewel, LLC, the "Defendants"). Plaintiffs will amend their complaint to allege their true names and capacities when such are ascertained. Plaintiffs are informed and believe and thereon allege that each of the fictitiously named Defendants is responsible in some manner for the occurrences alleged in this complaint, and the Plaintiffs' damages as alleged were proximately caused by each Defendant's conduct.

5. At all relevant times, Defendants were agents, servants, employees or joint venturers of every other Defendant herein, and at all times mentioned herein were acting within the course and scope of said agency, employment, or joint venture, with knowledge and permission and consent of all other named Defendants.

JURISDICTION AND VENUE

6. The Eighth Judicial District Court of the State of Nevada has subject jurisdiction over this matter because:

a. The amount in controversy exceeds the jurisdictional minimum of $15,000.00; and

b. The events described herein, unless otherwise indicated, occurred in Clark County, Nevada.

7. The Eighth Judicial District Court of the State of Nevada is the appropriate venue for resolution of this matter because:

a. Plaintiffs and Defendant are individuals and/or entities located and domiciled in Clark County, Nevada; and

b. The events described herein, unless otherwise indicated, occurred in Clark County, Nevada.

c. The underlying agreements require that any related litigation be initiated in a state court of competent jurisdiction in the county where the subject leased premises are located.

GENERAL STATEMENT OF FACTS

8. On or about March 6, 2019, Relevium entered into a Standard Industrial/Commercial Multi-Tenant Lease with Defendant (the "Lease").

9. That Lease contemplated Relevium's use of certain real property located at 3975 South Durango Drive, Suite 107, Las Vegas, Nevada, 89147 (the "Property").

10. Section 1.8 of the Lease defined the "Agreed Use" of the Property as being "[g]eneral office use for a pain management clinic and other related lawful uses."

11. On or about March 6, 2019, Dr. Hall executed a Guaranty of Lease, which provided that Dr. Hall "shall guarantee the lease for the first 36 months of the lease term" (the "Guaranty").

12. The Lease identifies MDL Group, LLC, a domestic limited-liability company ("MDL") as the lessor's broker.

13. MDL operated as a property manager and tenant liaison for Plaintiffs for issues relating to the Lease.

14. The Property shares a wall with an adjoining Unit, 3975 South Durango Drive., Suite 104, Las Vegas, Nevada 89147 (the "Neighbor Unit").

15. Kraft-Sussman Funeral & Cremation Services ("KS") operates out of the Neighbor Unit; KS is a registered fictitious firm name of Kraft-Sussman Funeral Service, Inc., a dissolved and inactive domestic corporation owned and operated by Laura Sussman.

16. Defendant Lewel is also owned and operated by Laura Sussman, who is identified as its Managing Member in Nevada Secretary of State records.

17. Defendant Lewel, Laura Sussman, and KS all identify the Neighbor Unit as their respective addresses in Nevada Secretary of State records.

18. Shortly after entering into the Lease, Relevium took possession of the Property as agreed.

19. At all times relevant herein, Relevium performed under the Lease as agreed, and made timely rent payments as contemplated under the Lease.

20. At all times relevant herein, Dr. Hall performed under the Guaranty as agreed, and Relevium never defaulted under any of the Lease terms.

21. Section 38 of the Lease guarantees Relevium "quiet possession and quiet enjoyment of the [Property] during the term" of the Lease.

22. Section 6.1 of the Lease prevents tenants from creating a nuisance or using premises in a way that "disturbs occupants of or causes damage to neighboring premises or properties."

23. Beginning in June of 2020, Relevium experienced numerous disturbances, including sound intrusions, onto the Property from the Neighbor Unit.

24. Specifically, KS operated different funeral and memorial services from the Neighbor Unit during ordinary business hours, and those services often included loud chanting, ringing bells, live music, recorded music played over speaker systems, eulogies and spoken ceremonies on loudspeaker, and other noises (the "Disturbances").

25. These Disturbances were irregular and disruptive, permeating from the Neighbor Unit into the Property for Relevium's treaters, patients, and staff to hear.

26. Relevium immediately and repeatedly informed Defendant as well as its agent, Lewel, of these Disturbances, which would either remain unchanged or only superficially (and ultimately temporarily) addressed.

27. These Disturbances upset and distressed Relevium's patients, including those recovering from debilitating physical injuries and incapacitating pain, and disrupted appointments, forcing rescheduling and cancellation in some instances.

28. These Disturbances reflected poorly on Relevium and Dr. Hall's pain management practice, rendering their primary place of business unsuitable for the basic purposes for which the Property was leased.

29. Defendant underwent construction for "soundproofing" nearly a year after the Disturbances began, but these actions only compounded the interference with Relevium's business.

30. In March of 2021, and without any advanced notice to Relevium, Defendant had contractors begin work at the Neighbor Unit, resulting in loud drilling, hammering, and shouting during business hours.

31. The March 2021 construction did not resolve the Disturbances which remained ongoing from at least June of 2020.

32. In April of 2021, again without advanced notice to (or coordination with) Relevium, Defendant undertook additional construction at the Neighbor Unit during business hours, causing even further disruption.

33. Even after Defendant underwent the self-described "soundproofing" in March and April of 2021, KS continued with the Disturbances from the Neighbor Unit, unimpeded.

34. At or about the same time, Relevium began searching for property suitable for its business and which Relevium could reasonably use and enjoy without the Disturbances.

35. Defendant refused to discontinue these Disturbances, reduce volume to reduce the impact of these Disturbances, or modify the timing of these Disturbances so as to no impede Plaintiff's medical practice.

36. Despite Relevium's notice to Defendant and repeated communications regarding the disruptive and intrusive noises, these Disturbances continued.

37. Section 6.4 of the Lease permits Defendant and its agent MDL to enter the Property "at reasonable times" and "after reasonable notice" for the limited purpose of inspecting the conditions and ensuring Relevium's compliance with the terms of the Lease.

38. Beginning in the Spring of 2021, Relevium experienced numerous unauthorized intrusions on to the Property by Defendant's agent, MDL.

39. On multiple occasions, MDL employees arrived at the Property without prior notice to or consent from Relevium (the "Unauthorized Entries").

40. During these Unauthorized Entries, MDL employees would walk through the Property without regard to patient presence and/or treatment, and enter the private back offices maintained by Relevium's principals and treaters.

41. Relevium explained the importance of patient privacy and record confidentiality to Defendant and its agent MDL, as well as the Lease's restrictions against "drop-in" entries onto the Property.

42. Despite these communications, as well as a discussion of medical providers' HIPAA obligations, multiple Unauthorized Entries occurred.

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43. Sections 9.2, 9.6, and 36 concern Property destruction and loss, Property damage/use impairment, and certain hazardous substance conditions, and imposes certain repair, abatement, and liability obligations on the Defendant lessor.

44. Beginning in the Summer of 2021, Relevium experienced numerous noxious chemical and unpleasant scent intrusions onto the Property from the Neighbor Unit (the "Chemical Spills").

45. In August of 2021, rancid and pungent smells emanated from the Neighbor Unit and throughout the Property, causing queasiness, headaches, and unease in Relevium's staff and patients.

46. Upon information and belief, these Chemical Spills were caused by KS and/or Aquamation of Southern Nevada, LLC.

47. Relevium immediately informed Defendant and MDL of these Chemical Spills, unsure whether there were health concerns associated with biological and chemical agents used by KS in the Neighbor Unit.

48. MDL agreed to visit the property, only to show up hours later than promised with no information and no meaningful way to resolve the Chemical Spill; instead, a sole MDL employee showed up hours into the episode with only a "Febreze" brand air freshener spray.

49. The first instance of these Chemical Spills forced Relevium to close its business and relieve its patients and staff.

50. Specifically, Relevium was forced to reschedule certain patients following the Chemical Spill, and had to follow up with patients as well as staff about the nature of the incident and concerns relating to the same.

51. In November of 2021, Relevium again informed Defendant that the conditions at the Property were unresolved and unsustainable, and advised Defendant that Relevium would be vacating the Property in December of 2021.

52. That same month, Defendant responded by indicating that there were no breaches of the lease, that any such Disturbances, Unauthorized Entries, and Chemical Spills were cured, and

demanding over $80,000 in "termination fees" from Relevium as Relevium was being forced out of the Property.

53. Within days of that communication, Relevium experienced yet another one of KS's Chemical Spills; around that same time, Relevium learned that KS and its shared principal with Defendant, Laura Sussman, were subject to multiple ongoing compliance investigations by the Nevada State Funeral Board.

54. Despite notice from Relevium regarding the severity of these Chemical Spills, and despite scrutiny from the Nevada State Funeral Board regarding this issue, Defendant failed to prevent or resolve these conditions, and KS continued these intrusions from the Neighbor Unit into the Property.

55. In December of 2021, as soon as Relevium was able to transition to new premises from which to conduct its medical practice, Relevium vacated the Property.

56. At the time Relevium vacated the Property, Defendant had not cured its many prior breaches under the Lease, had not credited Relevium for the many impediments to Relevium's use and enjoyment of the Property, had not reimbursed Relevium for the many interruptions to Relevium's business, and had not abated their continuing breaches under the Lease.

57. Relevium continued to pay rents under the lease through December of 2021, even paying rent for weeks after Relevium vacated and cleaned the Property.

CAUSES OF ACTION

FIRST CAUSE OF ACTION
[Breach of Contract]

58. Plaintiffs repeat and reallege the allegations contained in preceding paragraphs as if fully restated herein.

59. The Lease and Guaranty are valid and enforceable contracts.

60. At all times relevant herein, Relevium performed all duties and conditions precedent required under the terms of the Lease.

61. At all times relevant herein, Dr. Hall performed all duties and conditions precedent required under the terms of the Guaranty.

62. Defendant repeatedly violated Relevium's contractual and common law entitlements to quiet possession and quiet enjoyment of the Property.

63. Defendant repeatedly refused to cure its violations of the Lease or address its continued intrusions onto the Property.

64. Defendant repeatedly violated the Lease's prohibition against unauthorized landlord access to the Property during the term of the Lease.

65. Defendant and its agent MDL refused to enforce the Lease terms against KS, which shares common ownership with Defendant.

66. Defendant refused to prevent and reasonably resolve spills involving noxious chemicals and biological agents, despite the Lease's many requirements that the Defendant lessor do so.

67. Defendant refused to afford rent credits, abatement, and/or damages payments for these Disturbances, Unauthorized Entries, and Chemical Spills.

68. As a result of Defendant's unlawful conduct, Plaintiffs have suffered damages in excess of $15,000.

69. As a result of Defendant's unlawful conduct, Plaintiffs have been forced to retain counsel and are entitled to an award of reasonable attorney's fees and costs in their favor.

SECOND CAUSE OF ACTION
[Breach of the Implied Covenant of Good Faith and Fair Dealing]

70. Plaintiffs repeat and reallege the allegations contained in preceding paragraphs as if fully restated herein.

71. Every contract in the State of Nevada contains an implied covenant to act in good faith and to engage in fair dealing in the performance and execution of that contract.

72. Because the Lease and the Guaranty are valid and enforceable contracts, each is bears the implied covenant of good faith and fair dealing.

73. Defendant's failure to perform under the agreements as promised, as well as Defendant's affirmative actions which deprived Plaintiffs of the benefit of their respective bargains, constitute breaches of the implied covenant of good faith and fair dealing.

74. As a result of Defendant's unlawful conduct, Plaintiffs have suffered damages in excess of $15,000.

75. As a result of Defendant's unlawful conduct, Plaintiffs have been forced to retain counsel and are entitled to an award of reasonable attorney's fees and costs in their favor.

THIRD CAUSE OF ACTION
[Declaratory Relief – NRS 30.010 et seq.*]*

76. Plaintiffs repeat and reallege the allegations contained in preceding paragraphs as if fully restated herein.

77. Controversies exist between Plaintiffs and Defendant on multiple issues, including the Parties' respective rights and obligations under the Lease and Guaranty.

78. Those issues are ripe for judicial determination as expressly authorized under NRS Chapter 30 and related Nevada procedural rules.

79. Plaintiffs are entitled to judicial declarations regarding Defendant's breaches of the Lease and Guaranty, as well as Defendant's actions which impeded Plaintiff's ability to remain in the Property for the duration of the term.

80. As a result of Defendant's unlawful conduct, Plaintiffs have been forced to retain counsel and are entitled to an award of reasonable attorney's fees and costs in their favor.

FOURTH CAUSE OF ACTION
[Constructive Eviction]

81. Plaintiffs repeat and reallege the allegations contained in preceding paragraphs as if fully restated herein.

82. Defendant's affirmative breaches of the Lease and continued failure to cure impeded Relevium's use of the Property.

83. Defendant's actions and failures to act rendered the Property, either in whole or in substantial part, unfit for occupancy for the purpose for which the Lease was entered into.

84. Specifically, Defendant rendered the Property unsuitable for the "[g]eneral office use for a pain management clinic and other related lawful uses" contemplated under the Lease.

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85. Relevium made repeated attempts to redress Defendant's actions and inaction to avoid having to vacate the Property, and provided Defendant with ample notice of, and a reasonable opportunity to cure, these defects.

86. Defendant's actions and inaction forced Relevium to locate and secure alternative premises which would be suitable for the agreed uses contemplated under the Lease.

87. Defendant's actions and inaction forced Relevium to vacate the Property in December of 2021 to relocate to a suitable property free of Defendant's unlawful conduct.

88. As a result of Defendant's unlawful conduct, Plaintiffs have been forced to retain counsel and are entitled to an award of reasonable attorney's fees and costs in their favor.

PRAYER FOR RELIEF

For the foregoing reasons, Plaintiffs pray for judgment in their favor and against Defendant as follows:

1. For an award of damages in excess of $15,000.00;
2. For preliminary and permanent injunctive relief as outlined herein;
3. For an award of reasonable attorney's fees and costs;
4. For interest on monetary damages, including awards of pre- and post-judgment interest;
5. For declaratory relief as outlined herein; and
6. For any other such relief the Court deems appropriate under the circumstances.

JURY DEMAND

Plaintiffs hereby demand to have their case heard by a jury.

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ARBITRATION EXEMPTION

The total of Plaintiffs' damages, exclusive of interests and costs, which the judge and/or jury is likely to award, exceeds $50,000. Additionally, Plaintiffs assert claims for declaratory relief, which may not be resolved in court-annexed arbitration. Accordingly, this case should be automatically exempted from the arbitration program.

Dated this 28th day of December 2021.

LBC LAW GROUP

/s/ Andrew P. Dunning

JOHN C. COURTNEY, ESQ.
Nevada Bar No. 11092
ANDREW P. DUNNING, ESQ.
Nevada Bar No. 13864
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Attorneys for Plaintiffs

TEMPORARY LIMITED POWER OF ATTORNEY FOR USE OF PHARMACY LICENSE, DEA AND OTHER REGISTRATION NUMBERS, AND DEA ORDER FORMS

February 28, 2025

Pursuant to that certain Equity Purchase Agreement, dated on or around March 17, 2025 (the "**Purchase Agreement**") by and among by and among Accident Care Alliance Holdco, LLC, a Delaware limited liability company ("**Buyer**"), Relevium Holdings, Inc., a Delaware corporation ("**Relevium Seller**"), Relevium ASC Holdings, Inc., a Delaware corporation ("**ASC Seller**" and together with Relevium Seller, the "**Sellers**" and each individually, a "**Seller**"), and Andrew Hall, MD, an individual ("**Beneficial Owner**"), and the other parties thereto, Sellers agreed to sell to Buyer, and Buyer agreed to purchase from Sellers, as of the Effective Time, certain Equity Interests of the Sellers as defined under the Purchase Agreement. Capitalized terms used in this Temporary Limited Power of Attorney but not otherwise defined herein shall have the meanings ascribed to such terms in the Purchase Agreement.

The registrant set forth on the signature page hereto (the "**Registrant**") operates an ambulatory surgery center located at the address set forth on Exhibit A (the "**Facility**"). In connection with the operation of the Facility prior to March 17, 2025 (the "**Effective Time**"), the Registrant obtained and has to date maintained licensure with the Nevada State Board of Pharmacy (the "**Board**") and registration with the United States Drug Enforcement Agency (the "DEA"), all as set forth in Exhibit A hereto (the "**Pharmacy Registrations**"). Registrant is authorized under the DEA controlled substance registration number set forth in Exhibit A to sign the current applications for registration and licensure as the registrant under the Controlled Substances Act (the "**Act**").

As of the Effective Time, approximately eighty-five percent (85%) of the Registrant's equity will be transferred to ACA Relevium, LLC, a Delaware limited liability company (the "**Agent**"). In connection with that transfer, Agent will file an original Ambulatory Surgical Center Application (the "**Application**") with the Board for registration under the Board's regulations, but the application will not be processed prior to the Effective Time.

In order to enable Agent to continue to make available pharmacy services, including controlled substances, to patients of Agent and to operate the Facility during the interim period between the Effective Time and approval of Agent's Application, it is necessary for Registrant to grant to Agent a Temporary Limited Power of Attorney to use the Pharmacy Registrations during the interim period.

Registrant desires to grant to Agent and Agent desires to accept from Registrant such Temporary Limited Power of Attorney upon the terms and conditions described herein.

In consideration of the mutual covenants and agreements herein set forth, Agent and Registrant do hereby covenant and agree as follows:

1. Temporary Limited Power of Attorney. In recognition of the need to continue to make available pharmacy services for treatment of Agent's patients and to continue to operate the Facility during the period from the Effective Time until approval of the Application, Registrant hereby makes, constitutes and appoints Agent as its full and lawful attorney-in-fact solely and

exclusively for the limited purpose of and with power to use the Pharmacy Registrations for purposes of ordering, storing, handling and dispensing drugs and taking all other actions reasonably necessary for operation of the Facility in the normal course of operations and in a manner consistent with operations prior to the Effective Time. Registrant further grants this limited power of attorney to Agent to act, effective as of the Effective Time, as the true and lawful agent and attorney-in-fact of Registrant, and to act in the name, place, and stead of Registrant, to execute applications for books of official order forms and to sign such order forms in requisition for Schedules I, II, III, IV and V controlled substances, but only in accordance with the applicable DEA registration and in accordance with Section 308 of the Act (21 U.S.C. § 828) and part 1305 of Title 21 of the Code of Federal Regulations, as is necessary for the treatment of Agent's patients.

2. Term. The rights, powers and authority granted to Agent hereunder as attorney-in-fact for Registrant shall become effective at the Effective Time and shall continue in effect until the earlier of the following events: (a) Agent receives all notices of the Board's approval of its Application and completes an inventory of all controlled substances then in its possession (the "**Notice**"); or (b) expiration of ninety (90) days following the Effective Time. Notwithstanding the foregoing, in the event Agent's commercially reasonable efforts to obtain a new pharmacy license is delayed, Registrant agrees to grant a reasonable extension of the term for a period of time deemed reasonable by Registrant and Agent which will cover the period until Agent, using commercially reasonable efforts to obtain such Notice, receives the Notice.

3. Liability. In accordance with the requirements of the DEA and the Board, Registrant acknowledges that Registrant remains liable for actions taken by Agent during the period this Temporary Limited Power of Attorney is in effect.

4. Covenants. Registrant grants this power of attorney based upon the following covenants and warranties of the Agent:

i. Agent shall follow and abide by all federal and state laws governing the regulation of controlled substances and pharmacy practice at all times while utilizing this Temporary Limited Power of Attorney;

ii. Agent shall defend, indemnify and hold Registrant harmless from and against any liability, loss, damage or expense (including, without limitation, reasonable counsel fees and expenses) arising out of or in connection with the Agent's use or misuse of this Temporary Limited Power of Attorney.

5. Entire Agreement; Amendment Governing Laws; Headings; Severability. This Temporary Limited Power of Attorney constitutes the entire agreement of the parties with respect to use of the Pharmacy Registrations. Any alteration or modification of the provisions of this Temporary Limited Power of Attorney shall not be effective unless reduced to writing or executed by the parties. This Temporary Limited Power of Attorney is governed by and shall be construed under the laws of the State of Delaware. Paragraph headings are for convenience of reference only and shall not be used in the interpretation of this Temporary Limited Power of Attorney. The terms and provisions of this Temporary Limited Power of Attorney are severable, and should any clause or provision hereof be unenforceable or be declared invalid for any reason whatsoever, this Temporary Limited Power of Attorney shall be construed and read as if such invalid or unenforceable clause or provision were omitted.

IN WITNESS WHEREOF, Registrant and Agent have executed this Temporary Limited Power of Attorney for use of the Pharmacy Registrations in multiple counterparts, each of which shall be considered an original, as of the date first written above.

AGENT:

ACA Relevium, LLC,
a Delaware limited liability company

By: _____
Name: Matthew Perelman
Title: Authorized Signatory

Witnesses:

1. _____

2. _____

REGISTRANT:

Fort Apache Surgery Center, LLC,
a Nevada limited liability company

By: _____
Name: Andrew Hall, M.D.
Title: Manager

Witnesses:

1. _____

2. _____

EXHIBIT A

Pharmacy Registration & Facility

Facility Address	License	Licensee	License No.	Issuing Agency	Expiration Date
6064 S Fort Apache Rd., Suite 110, Las Vegas, NV 89148	Pharmacy License	Fort Apache Surgery Center, LLC	ASC04451	Nevada State Board of Pharmacy	10/31/2026
	Controlled Substance Registration Certificate	Fort Apache Surgery Center, LLC	FF2304664	DEA	09/30/2025

10E

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ☒ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☒ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		☒ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Fresenius Vascular Care Henderson ASC, LLC

Physical Address: 3051 W. Horizon Ridge Pkwy, Suite #110

City: Henderson State: NV Zip: 89052-4690

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: (702) 640-5443 Fax: (702) 850-9585

Contact Email: Lynda.Teator@AzuraCare.com Website https://www.azuravascularcare.com/

Nevada Business License # NV20232689052

Employed/Contracted Pharmacist Name: Lee Dukes, PharmD NV Pharmacist License #: 19088

Medical Director Name: Rizwan Qazi, M.D.

Days of Operation

☐ Monday	☐ Tuesday	☒ Wednesday	☐ Thursday	☐ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 5: Partnership

Partnership Name: Fresenius Vascular Care Henderson ASC, LLC

Mailing Address: 920 Winter Street

City: Waltham State: MA Zip: 02451

Telephone: (267) 353-9145 Email: Rhonda.Palumbo@azuracare.com

Contact Person Name: Rhonda Palumbo

Please check type of partnership (NAC 639.214) ☐ General ■ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ■ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Lee Dukes, PharmD NV Pharmacist License #: 19088

As the employed/contracted pharmacist, for (ASC/RC Name): Fresenius Vascular Care Henderson ASC, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

2/21/2025
Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• For General Partnerships, list the name of each partner. NAC 639.214(2) • For Limited Partnerships, list the names of (NAC 639.214(3)): ○ All General Partners; ○ All Limited Partners who hold 10% or more of the interest.			✓	
• Certificate of Corporate Status or Certificate of Good Standing from the Secretary of State's Office where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• Personal History Record Application must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Gregg Miller, M.D.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

G. Miller MD — 2/25/25

Original signature of Authorized Person (copies or stamps not accepted) — Date

Board Use Only	Date Received: 3/2/25	Amount: $500cc

azura
vascular care

RECEIVED
3/3/25

VIA UPS NDA

February 26, 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206
Reno, NV 89521

Re: Fresenius Vascular Care Henderson ASC, LLC
3051 W Horizon Ridge Pkwy
Suite #110
Henderson, NV 89052-4690

Dear Sir/Madam:

Please find attached the Ambulatory Surgical Center (ASC) and Recovery Center Application for Fresenius Vascular Care Henderson ASC, LLC. The application and attachments are as follows:

1. Application – fully signed
2. The owners are as follows:
   a. Fresenius Vascular Care, Inc. 15.00%
   b. NKDHC (Rudnitsky), PLLC 28.33%
   c. Kidney Specialist Surgical Center SE, LLC 28.33%
   d. NNC VAC, LLC 28.33%
3. Certificate of Good Standing from the Nevada Secretary of State
4. Personal History Record Application is not required as there are no individuals with ownership in this entity.
5. Credit Card Authorization for $500 fee.

Please note that the certificate of occupancy and ASC license for the above-mentioned entity are expected to be received in April and June of this year.

Thank you for your attention to this request. If you have any questions, please contact Rhonda.palumbo@azuracare.com or by phone at 267-353-9145.

Sincerely,

Rhonda Palumbo
Director of Physician Services/Business Contracts

Enclosure

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Fresenius Vascular Care Henderson ASC, LLC** as a FOREIGN LIMITED-LIABILITY COMPANY duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 02/02/2023, and in good standing in this State.

I further certify that the above FOREIGN LIMITED-LIABILITY COMPANY has its formation or qualification document and no amendments on file in this office as of the date of this certificate.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 02/11/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502115429992
You may verify this certificate online at https://www.nvsilverflume.gov/home

10F

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility		
■ Ambulatory Surgical Center (ASC) ☐ Recovery Center (RC)		
Type of Application (check applicable box)		**Ownership Type (check applicable box)**
☐ New ASC/RC ■ Ownership Change* ☐ Location Change * ■ Name Change*	* If making a change, provide current license number: ASC02591	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9) ☐ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9) ■ Partnership (complete sections 1, 2, 5, 7, 8, 9) ☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Horizon Ridge Surgery Center, LLC

Physical Address: 10561 Jeffreys Street, Suite 130

City: Henderson State: NV Zip: 89044

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 702-824-8900 Fax: 702-982-8854

Contact Email: clussier@uspi.com Website _____

Nevada Business License # NV20201967762

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Vu Luu, MD

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: Horizon Ridge Surgery Center, LLC

Mailing Address: 10561 Jeffreys Street, Suite 130

City: Henderson State: NV Zip: 89044

Telephone: 702-824-8900 Email: clussier@uspi.com

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ■ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ■ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Horizon Ridge Surgery Center, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle McCurdy

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

3-24-25

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Crystal Lussier

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

3/24/25

Date

Board Use Only	Date Received: 3/27/25	Amount: $200 cc

Horizon Ridge Surgery Center, LLC

Partner List:

Owner Name	**% of Ownership**
Dignity/USP Las Vegas Surgery Centers, LLC 14201 Dallas Parkway Dallas, TX 75254	51 %
CDIN ASC, LLC 844 Fulfort Court Henderson, NV 89052	49%

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Horizon Ridge Surgery Center, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 12/16/2020, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 03/25/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202503255558987
You may verify this certificate online at https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Horizon Ridge Surgery Center, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): ASC02591

Physical Address: 10561 Jeffreys Street, Suite 130

City: Henderson State: NV Zip: 89052

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-724-8900 Website:

Licensing Company Email:

Section 2: Personal Information

First: Crystal Middle: Nadine Last: Lussier

Alias(es, nicknames, name changes, etc.): Crystal Nadine Duke

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City: Henderson State: NV Zi[redacted]

Telepho[redacted] Ema[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Mt. San Antonio College		08/00-06/05	
Address	City	State	Zip
1100 N. Grand Avenue	Walnut	CA	91789
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Etiwanda High School		08/96-06/00	
Address	City	State	Zip
13500 Victoria Street	Rancho Cucamonga	CA	91739
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
08/22-Current	[redacted]			
09/21-08/22				
02/05-09/21				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Horizon Ridge Surgery Center, LLC			09/21 to Current
Business Address	**City**	**State**	**Zip**
10561 Jeffreys Street, Ste 130	Henderson	NV	89052
Phone	**Title**		
702-724-8900	Administrator		

Description of Duties

Daily Operation of the facility is responsible for directing, coordinating, and controlling all aspects of the operating functions, processes, and staff of the facility.

Business Name			From - To (MM/YY – MM/YY)
Fullerton Surgical Center			04/18-09/21
Business Address	**City**	**State**	**Zip**
2240 N Harbor Blvd, Ste 100	Fullerton	CA	92835
Phone	**Title**		
714-870-8300	Administrator		

Description of Duties

Daily Operation of the facility is responsible for directing, coordinating, and controlling all aspects of the operating functions, processes, and staff of the facility.

Business Name			From - To (MM/YY – MM/YY)
Calisher & Associates / Spine and Sports Surgical Center			05/15-04/18
Business Address	**City**	**State**	**Zip**
555 Corporate Drive, Ste 115	Ladera Ranch	CA	92694
Phone	**Title**		
714-766-5880	Administrator		

Description of Duties

Daily Operation of the facility is responsible for directing, coordinating, and controlling all aspects of the operating functions, processes, and staff of the facility.

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		

Description of Duties

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Crystal Lussier

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/24/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Crystal Lussier, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/24/2025

Date

Subscribed and Sworn to before me this 24 day of March 2025

Notary Public Signature

Notary Public - State of Nevada
COUNTY OF CLARK
T. TREBICKA
My Appointment Expires
January 15, 2027
No. 23-4790-01

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Horizon Ridge Surgery Center, LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): ASC02591

Physical Address: 10561 Jeffreys Street, Suite 130

City: Henderson State: NV Zip: 89052

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-724-8900 Website:

Licensing Company Email:

Section 2: Personal Information

First: Andrew Middle: Insoo Last: Kim

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Henderson State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Chicago, Pritzker School of Medicine		10/98 to 06/02	
Address	**City**	**State**	**Zip**
924 E 57th St #104	Chicago	IL	60637
Diploma/Degree obtained, if any			
MD			

School Name		From - To (MM/YY – MM/YY)	
University of Pennsylvania		09/94 to 05/98	
Address	**City**	**State**	**Zip**
3451 Walnut St	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
BA			

School Name		From - To (MM/YY – MM/YY)	
Webster High School		09/90 to 06/94	
Address	**City**	**State**	**Zip**
875 Ridge Rd	Webster	NY	14580
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
10/14 to 03/25	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Kim Chen, PLLC			08/15 - current
Business Address	**City**	**State**	**Zip**
9260 W. Sunset Rd., Suite 306	Las Vegas	NV	89148
Phone	**Title**		
7024834483	Managing Partner, Physician		
Description of Duties			
Physician - evaluate and treat patients, oversee operations of practice			

Business Name			From - To (MM/YY – MM/YY)
CDIN ASC, LLC			03/2020 - current
Business Address	**City**	**State**	**Zip**
3430 East Flamingo Rd, Suite 232	Las Vegas	NV	89121
Phone	**Title**		
7024834483	Managing Partner, Physician		
Description of Duties			
Physician - evaluate and treat patients, oversee operations of practice			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Andrew Kim

Print Name (First, Last)

Original Signature ~~(electronic, copies or stamps not accepted)~~ Date 3/25/25

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Andrew J Kim, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature **Date** 3/25/25

Subscribed and Sworn to before me this 25 day of March 2025

Notary Public Signature

Notary Public - State of Nevada
COUNTY OF CLARK
PAMELA L. GREENWOOD
My Appointment Expires
February 1, 2026
No. 22-9524-01

(Seal)

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
10556-ASC-1

Please display

This license w
licensing syste
VALID BY
nvdpbh.aither
License Verifi
Inspection Rep
up by licens
Number) to veri

Should you ha
Name, Admini
of Ownership
https://nvdpbh

This Is To Certify That

HORIZON RIDGE SURGERY CENTER

10561 JEFFREYS ST. SUITE 130
HENDERSON, NV 89052

Is hereby licensed as a(n)

SURGICAL CENTER FOR AMBULATORY PATIENTS

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

Facility Type : SURGICAL CENTER FOR AMBULATORY PATIENTS

Endorsement : ENDOSCOPY ONLY

Bed Information : Operating Room - A - 2

If your license i
Please contact
that we may re

CRYSTAL LUSSIER / Administrator

ERIC BOON

Cody L Phinney / Administrator

SilverFlume
NEVADA'S BUSINESS PORTAL

BUSINESSINFORMATION

Entity Information

Entity Information

Entity Name: HORIZON RIDGE SURGERY CENTER, LLC
Entity Number: E11042772020-2
Entity Type: Domestic Limited-Liability Company (86)
Entity Status: Active
Formation Date: 12/16/2020
NV Business ID: NV20201967762
Termination Date:
Annual Report Due Date: 12/31/2025
Compliance Hold:
Series LLC: **Restricted LLC:**

Registered AGENT INFORMATION

Name of Individual or Legal Entity: C T CORPORATION SYSTEM**
Status: Active
CRA Agent Entity Type:
Registered Agent Type: Commercial Registered Agent
NV Business ID: NV20191497453
Office or Position:
Jurisdiction: DELAWARE
Street Address: 701 S CARSON ST STE 200, Carson City, NV, 89701, USA
Mailing Address:

OFFICER INFORMATION

☐ View Historical Data

Title	Name	Address	Last Updated	Status
Manager	Dignity/USP Las Vegas Surgery Centers, L.L.C.	14201 Dallas Parkway , Dallas, TX, 75254, USA	12/16/2020	Active

Page 1 of 1, records 1 to 1 of 1

Filing History | Name History | Mergers/Conversions

10G

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility		
☑ Ambulatory Surgical Center (ASC) ☐ Recovery Center (RC)		
Type of Application (check applicable box)		**Ownership Type (check applicable box)**
☐ New ASC/RC ☑ Ownership Change* ☐ Location Change * ☐ Name Change*	* If making a change, provide current license number: ASC04481	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9) ☑ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9) ☐ Partnership (complete sections 1, 2, 5, 7, 8, 9) ☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Queensridge Surgery Center

Physical Address: 10040 Alta Dr., #250

City: Las Vegas State: NV Zip: 89145

Mailing Address (if different from physical address): 2779 W. Horizon Ridge Pkwy Suite 130

City: Henderson State: NV Zip: 89052

Telephone: (702)640-0017 Fax: (702)331-1159

Contact Email: tfriend@queensridgesurgery.com Website queensridgesurgery.com

Nevada Business License # NV20253279140

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Dr. Michael J. Crovetti, Jr., D.O.

Days of Operation

☑ Monday	☑ Tuesday	☑ Wednesday	☑ Thursday	☑ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Intermountain Orthopedic Holdings Nevada, LLC

Corporation/Organization Name: Queensridge Surgery Center, LLC

Mailing Address: 2779 W. Horizon Ridge Pkwy Suite 130

City: Henderson State: NV Zip: 89052

Telephone: 702-640-0017 Email: mcrovetti@crovettiortho.com

Contact Person Name: Dr. Michael J. Crovetti, Jr., D.O.

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Queensridge Surgery Center, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle McCurdy
Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

1-12-2025
Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		
• **For General Partnerships, list the name of each partner. NAC 639.214(2)** • **For Limited Partnerships, list the names of (NAC 639.214(3)):** ○ **All General Partners;** ○ **All Limited Partners who hold 10% or more of the interest.**			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dr. Michael J. Crovetti, Jr., D.O.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/13/25

Date

Board Use Only	Date Received: _____	Amount: 500.00 / CC

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Queensridge Surgery Center, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 03/02/2021, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/16/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412165271511
You may verify this certificate online at https://www.nvsilverflume.gov/home

Exhibit N

Officers and Stockholders

Officers:

- President – Michael J. Crovetti, Jr., D.O.

Top four stockholders: Intermountain Orthopedic Holdings Nevada, LLC

Stockholders with 10% or more of the shares: Intermountain Orthopedic Holdings Nevada, LLC

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
10727-ASC-2

Please display this license conspicuously

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to: https://nvdpbh.aithent.com/login.aspx.

This Is To Certify That

QUEENSRIDGE SURGERY CENTER, LLC

10040 ALTA DRIVE, #250
LAS VEGAS, NV 89145

Is hereby licensed as a(n)

SURGICAL CENTER FOR AMBULATORY PATIENTS

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

Facility Type : SURGICAL CENTER FOR AMBULATORY PATIENTS

Endorsement : CLASS - A, CLASS - B, CLASS - C

Bed Information : Operating Room - C - 4

MICHAEL ROSE / Administrator

CALET PINEGAR,MICHAEL CROVETTI

Cody L Phinney / Administrator

If your license is not completely accurate, Please contact us at (775) 684-1030 so that we may resolve any problems.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Coronado Surgical Recovery Suites ASC04428

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License #: 2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052

Physical Address: Coronado Surgery Center ASC02494

City: 2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052

Mailing Address (if different from physical address): Queensridge Surgical Recovery Suites RC04480

City: 10040 Alta Dr #300, Las Vegas, NV 89145

Telephone: Website:

Licensing Company Email: Queensridge Surgery Center ASC04481

10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First: Mitchell Middle: Howard Last: Cloward

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ■ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ■ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Weber State University		01/89-06/94	
Address	City	State	Zip
3848 Harrison Blvd	Ogden	UT	84403
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Texas Women's University		01-95-06/99	
Address	City	State	Zip
304 Administration Drive, Suite 102	Denton	TX	76204
Diploma/Degree obtained, if any			
Masters in Healthcare Administration			

School Name		From - To (MM/YY – MM/YY)	
David High School		08/83 - 05/86	
Address	City	State	Zip
325 South Main Street	Kaysville	UT	84037
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
07/23-present	[redacted]			
5/13-7/23				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			7/23-President	
Business Address		**City**	**State**	**Zip**
6355 S. Buffalo Drive		Las Vegas	Nevada	89113
Phone	**Title**			
702-932-8550	Region President			
Description of Duties				
President SW Utah and Nevada Markets.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			3/22-7/23	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St George	UT	84790
Phone	**Title**			
435-251-2106	SW Utah Market President			
Description of Duties				
Market President – Desert South Utah and President of Intermountain St. George Regional Hospital.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			11/16-3/22	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Hospital Administrator			
Description of Duties				
Hospital Administrator for St. George Regional Hospital				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			05/13-11/16	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Operations Officer			
Description of Duties				
Guided surgical services, neurosciences, rehabilitation, lab and serving as on-site administrator of Dixie's 400 East Campus.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mitchell Cloward

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Mitchell Cloward, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/8/25

Date

Subscribed and Sworn to before me this 8 day of January

Notary Public Signature

KIM KANEALII
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-9158-01
MY APPT. EXPIRES OCTOBER 19, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner Licer

Physical Address

City

Mailing Address (if different from physical address)

City

Telephone Website

Licensing Company Email

Coronado Surgical Recovery Suites ASC04428
2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052
Coronado Surgery Center ASC02494
2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052
Queensridge Surgical Recovery Suites RC04480
10040 Alta Dr #300, Las Vegas, NV 89145
Queensridge Surgery Center ASC04481
10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First Michael Middle Last Crovetti

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Henderson State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Medicine & Dentistry of NJ School of Medicine			01/94-06/95	
Address		City	State	Zip
One Medical Center Dr.		Stratford	NJ	08084
Diploma/Degree obtained, if any				
Internship, Surgery				
School Name			From - To (MM/YY – MM/YY)	
UMDNJ School of Osteopathic Medicine			01/90-01/94	
Address		City	State	Zip
One Medical Center Dr.		Stratford	NJ	08084
Diploma/Degree obtained, if any				
D.O.				
School Name			From - To (MM/YY – MM/YY)	
Albright College			01/84-01/88	
Address		City	State	Zip
1621 N. 13th St.		Reading	PA	19612
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Crovetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/09/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Michael Crovetti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/09/25

Date

Subscribed and Sworn to before me this 9th day of January

Sandra Brigandi

Notary Public Signature

SANDRA BRIGANDI
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 09-23-26
Certificate No: 22-2005-01

(Seal)

CURRICULUM VITAE
(as of May 2019)

Michael J. Crovetti, Jr., DO

[redacted]

Business Crovetti Bone & Joint Institute of Southern Nevada

dba Crovetti Orthopaedics and Sports Medicine
2779 W. Horizon Ridge Parkway, Suite 200
Henderson, NV 89052
702-990-2290
Aug. 2000 to current

Date of Birth [redacted]

Spouse [redacted]

Children [redacted]

EDUCATION

Institution	Graduation/Degree
Albright College Reading, PA	1988/B.S.
University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	8/90 – 6/94 DO

Internship

University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	7/94 – 6/95 Chief Intern

Residency

Ohio University – Dayton, OH	7/95 – 7/99 Chief Resident
Grandview Hospital and Medical Center	

Fellowship Subspecialty Training

Reconstruction of the Hip, Knee and Shoulder, Revision Surgery Todd Swanson, MD Desert Orthopedic Center Las Vegas, NV	8/99 – 7/00 Fellow

Consultant Positions

Previous
Cardo Medical, Beverly Hills, CA, Consultant for Total Joint Replacement
Stryker Orthopaedics, Mahwah, NJ, Consultant for Total Joint Replacement
Smith & Nephew, Memphis, TN, Consultant for Minimally Invasive Joint Replacement
DePuy Orthopaedics, Inc, Warsaw, IN, Consultant for Mini Incision Total Hip and Total Knee Arthroplasty
PLUS Orthopedics, San Diego, California, Consultant for the *Gliding Nail* for intramedullary nailing of peritrochanteric hip fractures.

Media Exposure

Summer 2014 – MyVegas Magazine – *Top Docs & Dentists Profile*

Summer 2014 – Las Vegas Life – *Top Doctors 2014*

May 2014 – Fox 5 More TV – *Patient testimonial following a double hip replacement*

February 2014 – Fox 5 More TV – *Coverage of patient walking 3 hours following Total Hip Replacement*

January 2014 – MyVegas Magazine Top Docs Profile

September-December 2013 – Spirit Magazine Health Issue with Advertorial

Fall 2013 – MyVegas Magazine – *Recovery: Crovetti Orthopaedics and Sports Medicine Celebrates Their 500th Patient*

Summer 2013 – MyVegas Magazine – *My Top Docs & Dentists*

Spring 2013 – Las Vegas Life – *Top Doctors 2013*

April 23, 2013 – Las Vegas Review Journal - *Las Vegas doctor streamlines popular knee, hip replacement procedures*

April 19, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

March 15, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

January 28, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

Spring, 2012, Las Vegas Life – *Top Doctors 2012*

May, 2012 – Vegas, Inc. – *Recovery Suites Model Takes Root In Las Vegas*

May, 2012 – Las Vegas Review Journal - *"Doctors look to control outcomes with own surgical centers, staff"*

2003-2005 Designer Platform Hip Stem, Smith and Nephew Orthopaedics

a. Royalty based agreement

2004-2006 Clinical Faculty Birmingham Hip Resurfacing Team

a. Designed and Implemented Cadaveric Training Program

b. Travelled internationally to learn technique in Belgium, Ireland, and Birmingham

2005-2010 Chairman, Co-Chairman and Clinical Faculty Stryker Orthopaedics Comet Hip Resurfacing Team

a. One of Four Surgeons commissioned to Introduce, Design and Implement Cadaveric training program

2005 – 2007 Consultant Designer HipStar Femoral Stem, Stryker Orthopaedics

2009 – 2010 Instrument and Implant Designer Consultant – CardoMedical, Inc

a. Designed Knee Replacement Instruments and Retractor System for Total Hip Arthroplasty
b. Design Input Poly Insert Total Knee Arthroplasty

2005 Guest Speaker Japanese Orthopedic Association Okinawa, Japan

a. Minimally Invasive Hip and Knee Replacement Surgery

2004 – 2010 Chairman Nevada Bioresearch Foundation, Medical Education And Research Institute of Nevada (MERIN)

a. Designed, Built, MERIN facility in Henderson, Nevada
b. Established Cadaveric Training program and Donation program for State of Nevada
c. MERIN trained more than 10,000 surgeons from 26 different countries

2005-2007 Team Physician UNLV Football, Las Vegas, Nevada

2005- Current Clinical Adjunct Professor of Orthopaedics Touro University, Henderson, Nevada

2006 – 2008 Chief of Surgery, St. Rose Dominican, San Martin Campus, Las Vegas, NV

Clinical and Scientific Presentations

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2013

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2012

Mahwah, NJ April 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ May 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ July 2009

"Hipstar DVD" Instructional DVD on how to complete implementation of Hipstar system.
Stryker
Mahwah,NJ June 2007

"North American Hip and Knee Symposium" Smith & Nephew Surgical Approached and Current Controversies
Copper, CO February 2006

"Japanese MIS Synergy Total Hip System Learning Center" Smith & Nephew
Henderson, NV January 2006

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV October 2005

"Minimally Invasive Hip and Knee Surgical Techniques". Smith & Nephew Innovations in MIS Joint Surgery.
New Orleans, LA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques", "Supartz: A Nonsurgical Option" Smith & Nephew Innovations in MIS Joint Surgery.
Santa Barbara, CA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV May 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV April 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Japan, February 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN December 2004

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.

Phoenix, AZ September 2003

"Minimally Invasive Hip Surgical Techniques" Led the cadaver labs. Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN July 2003

"Minimally Invasive Hip & Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2003

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beavercreek, CO January 2003

New Developments in Hip & Knee Arthroplasty- Smith & Nephew
Naples, FL November 2002

"Leg Length & Offset Restoration in Total Hip Arthroplasty"- Smith & Nephew The Great Lakes Joint Arthroplasty Symposium.
Onekama, MI September 2002

Joint Arthroplasty- Smith & Nephew
Coeur D'Alene, ID August 2002

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2002

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beaver Creek, CO February 2002

"Joint Reconstruction" Plus Orthopedics
12th International Symposium on Joint Reconstruction,
Ritz Carlton Hotel in Dana Point, CA. April 2001.

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented to the Arizona Orthopedic Society meeting.
Phoenix, AZ. November 2000

Mini-incision Total Hip Arthroplasty. Grand Rounds
Maricopa County Medical Center. Phoenix, AZ November 2000

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented at the 11Th International Zweymuller Symposium
Boston Harbor Hotel, Boston, MA. October 2000.
"Gliding Nail Workshop" Plus Orthopedics National Sales Meeting.
San Diego, CA. September 2000.

"Intramedullary Nailing of Stable and Unstable Peritrochanteric Hip Fractures;"
presented at University Medical Center of Fresno, CA, December 1999.

June 2010
4 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

June 2010
4 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

May 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

April 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Knee System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Hip System
Henderson, NV

March 2010
1 surgeon training on Cardo Unicompartmental Knee System

Utah

October 2007
3 surgeons training triathlon knee and accolade hip training
Utah

September 2007
1 surgeon training Accolade Hip System, Triathlon Knee and Comet Hip resurfacing system
Las Vegas, NV
1 surgeon skills development program
Fort Lauderdale, FL

August 2007
2 surgeon Presentation hip resurfacing
San Diego, CA
2 surgeons Presentation Triathlon Knee and Accolade Hip System
Mahwah,NJ
1 surgeon Training Comet implant
Los Angeles, CA

July 2007
1 surgeon presentation of hip resurfacing lab Miami Florida
15 surgeon presentation hip and knee replacement
Las Vegas, NV

June 2007
Stryker training session for development of an Activity Expectation Scoring system
1 surgeon training session on the Accolade Hip Stem
Arkansas
1 surgeon training with cadaver and detailed the benefits of Triathlon knee systems
1 surgeon training regarding Triathlon knee system
Phoenix, AZ

May 2007
Teaching seminar for the HIPStar implant program and resurfacing implant
5 surgeons Mahwah, NJ

Feb 2007
1 surgeon training seminar and cadaver interactive training
Los Angeles, CA

December 2007
1 surgeon from Colorado Springs, CO
1 surgeon from Fort Lauderdale, FI
15 surgeon seminar training Fort Lauderdale, FL

November 2006
1 surgeon from Michigan

June 2006

2 surgeons from Springfield, MO
1 surgeon from Houston, TX

June 2004
1 surgeon from Munster, IN

May 2004
1 surgeon from Scottsdale, AZ

March 2004
1 surgeon from Tuscaloosa, AL
1 surgeon from Birmingham, AL
1 surgeon from Lancing, MI

February 2004
2 surgeons from Jasper, AL
1 surgeon & 1 PA-C from Houston, TX
January 2004
2 surgeons from Decatur, AL

December 2003
1 surgeon from Australia
1 surgeon from Pleasanton, CA

September 2003
1 surgeon from MI

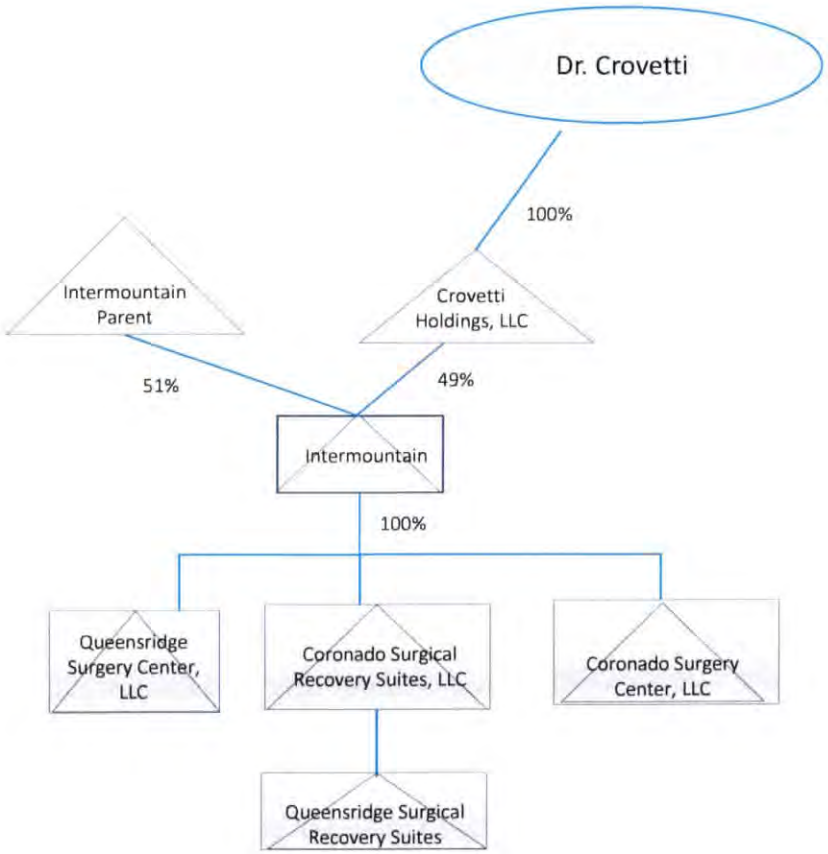
July 2003
1 surgeon from Birmingham, AL

March 2003
1 surgeon from Phoenix, AZ

February 2003
1 surgeon from Birmingham, AL

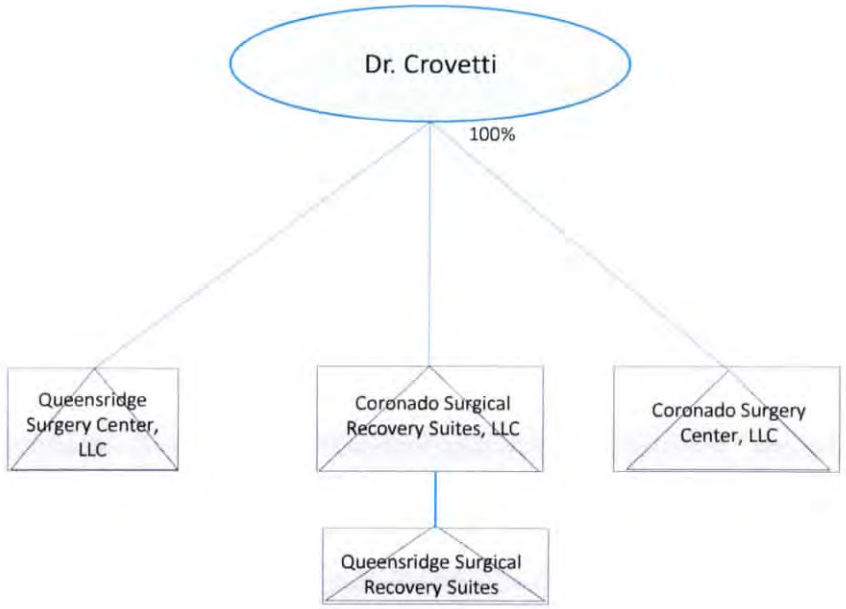
Post-reorganization

- Dr. Crovetti forms a JV holding company ("**Intermountain**")
- Intermountain Medical Holdings Nevada, Inc., a Delaware nonprofit nonstock corporation ("**Intermountain Parent**"), purchases 51% of Intermountain.
- Dr. Crovetti will remain in the structure as the ultimate 49% equity holder of each of the Facilities.



Pre-reorganization

- Dr. Crovetti holds 100% of the equity in each of the Facilities.



10H

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

☐ Ambulatory Surgical Center (ASC)

☒ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☒ Ownership Change*		☒ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *	RC04480	☐ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☒ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Queensridge Surgical Recovery Suites

Physical Address: 10040 Alta Dr., Ste 300

City: Las Vegas State: NV Zip: 89145

Mailing Address (if different from physical address): 2779 W. Horizon Ridge Pkwy Suite 130

City: Henderson State: NV Zip: 89052

Telephone: (702) 589-4975 Fax: (702) 331-2839

Contact Email: MSchilder@crovettiortho.com Website queensridgerurgery.com

Nevada Business License # NV20232839581

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: Dr. Michael J. Crovetti, Jr., D.O.

Days of Operation

☒ Monday	☒ Tuesday	☒ Wednesday	☒ Thursday	☒ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Nevada

Parent Company (if any): Coronado Surgical Recovery Suites, LLC

Corporation/Organization Name: Queensridge Surgical Recovery Suites, LLC

Mailing Address: 2779 W. Horizon Ridge Pkwy Suite 130

City: Henderson State: NV Zip: 89052

Telephone: _____ Email: mcrovetti@crovettiortho.com

Contact Person Name: Dr. Michael J. Crovetti, Jr., D.O.

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ■ No

Section 5: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Queensridge Surgical Recovery Suites :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✔
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle M Clark

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

1-22-25

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• For General Partnerships, list the name of each partner. NAC 639.214(2) • For Limited Partnerships, list the names of (NAC 639.214(3)): ○ All General Partners; ○ All Limited Partners who hold 10% or more of the interest.			✓	
• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months**.	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Dr. Michael J. Crovetti, Jr., D.O.

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

1/13/25

Date

Board Use Only	Date Received: 1/22/25	Amount: $500-cc

SECRETARY OF STATE

STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporations sole, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence **Queensridge Surgical Recovery Suites, LLC** as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, under and by virtue of the laws of the State of Nevada since 07/06/2023, and in good standing in this State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of this State, at my office on 12/16/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202412165271517
You may verify this certificate online at https://www.nvsilverflume.gov/home

Exhibit B

Officers and Stockholders

Officers:

- President – Michael J. Crovetti, Jr., D.O.

Top four stockholders: Intermountain Orthopedic Holdings Nevada, LLC

Stockholders with 10% or more of the shares: Intermountain Orthopedic Holdings Nevada, LLC

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
10728-RCF-2

Please display this license conspicuously

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to: https://nvdpbh.aithent.com/login.aspx.

This Is To Certify That

QUEENSRIDGE SURGICAL RECOVERY SUITES

10040 ALTA DRIVE 300
LAS VEGAS, NV 89145

Is hereby licensed as a(n)

RECOVERY CENTER FACILITY

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

QUEENSRIDGE SURGICAL RECOVERY SUITES

10040 ALTA DRIVE
LAS VEGAS, NV 89145

Facility Type : RECOVERY CENTER FACILITY

Endorsement :

Bed Information : BEDS - 10

If your license is not completely accurate, Please contact us at (775) 684-1030 so that we may resolve any problems.

MICHELLE SCHILDER / Administrator

MICHAEL CROVETTI

Cody L Phinney / Administrator

5525

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site _____

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # _____

Physical Address _____

City _____

Mailing Address (if different from physical address) _____

City _____

Telephone _____ Website _____

Licensing Company Email _____

Coronado Surgical Recovery Suites ASC04428
2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052

Coronado Surgery Center ASC02494
2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052

Queensridge Surgical Recovery Suites RC04480
10040 Alta Dr #300, Las Vegas, NV 89145

Queensridge Surgery Center ASC04481
10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First Mitchell Middle Howard Last Cloward

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Weber State University		01/89-06/94	
Address	City	State	Zip
3848 Harrison Blvd	Ogden	UT	84403
Diploma/Degree obtained, if any			
Bachelor's Degree			

School Name		From - To (MM/YY – MM/YY)	
Texas Women's University		01-95-06/99	
Address	City	State	Zip
304 Administration Drive, Suite 102	Denton	TX	76204
Diploma/Degree obtained, if any			
Masters in Healthcare Administration			

School Name		From - To (MM/YY – MM/YY)	
David High School		08/83 - 05/86	
Address	City	State	Zip
325 South Main Street	Kaysville	UT	84037
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	City	State	Zip
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	City	State	Zip
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
07/23-present				
From - To (MM/YY – MM/YY)				
5/13-7/23				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			7/23-President	
Business Address		**City**	**State**	**Zip**
6355 S. Buffalo Drive		Las Vegas	Nevada	89113
Phone	**Title**			
702-932-8550	Region President			
Description of Duties				
President SW Utah and Nevada Markets.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			3/22-7/23	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St George	UT	84790
Phone	**Title**			
435-251-2106	SW Utah Market President			
Description of Duties				
Market President – Desert South Utah and President of Intermountain St. George Regional Hospital.				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			11/16-3/22	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Hospital Administrator			
Description of Duties				
Hospital Administrator for St. George Regional Hospital				

Business Name			From - To (MM/YY – MM/YY)	
Intermountain Health			05/13-11/16	
Business Address		**City**	**State**	**Zip**
1380 E Medical Center Drive		St. George	UT	84790
Phone	**Title**			
435-251-2106	Operations Officer			
Description of Duties				
Guided surgical services, neurosciences, rehabilitation, lab and serving as on-site administrator of Dixie's 400 East Campus.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mitchell Cloward

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/8/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Mitchell Cloward, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/8/25

Date

Subscribed and Sworn to before me this 8 day of January

Notary Public Signature

KIM KANEALII
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-9158-01
MY APPT. EXPIRES OCTOBER 19, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner Licen

Physical Address

City

Mailing Address (if different from physical address)

City

Telephone Website

Licensing Company Email

Coronado Surgical Recovery Suites ASC04428
2779 W Horizon Ridge Pkwy #130, Henderson, NV 89052
Coronado Surgery Center ASC02494
2779 W Horizon Ridge Pkwy #140, Henderson, NV 89052
Queensridge Surgical Recovery Suites RC04480
10040 Alta Dr #300, Las Vegas, NV 89145
Queensridge Surgery Center ASC04481
10040 Alta Dr #250, Las Vegas, NV 89145

Section 2: Personal Information

First Michael Middle Last Crovetti

Alias(es, nicknames, name changes, etc.)

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City Henderson State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of Medicine & Dentistry of NJ School of Medicine		01/94-06/95	
Address	**City**	**State**	**Zip**
One Medical Center Dr.	Stratford	NJ	08084
Diploma/Degree obtained, if any			
Internship, Surgery			

School Name		From - To (MM/YY – MM/YY)	
UMDNJ School of Osteopathic Medicine		01/90-01/94	
Address	**City**	**State**	**Zip**
One Medical Center Dr.	Stratford	NJ	08084
Diploma/Degree obtained, if any			
D.O.			

School Name		From - To (MM/YY – MM/YY)	
Albright College		01/84-01/88	
Address	**City**	**State**	**Zip**
1621 N. 13th St.	Reading	PA	19612
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Michael Crovetti

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/09/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Michael Crovetti, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/09/25

Date

Subscribed and Sworn to before me this 9th day of January

Sandra Brigandi

Notary Public Signature

SANDRA BRIGANDI
NOTARY PUBLIC
STATE OF NEVADA
My Commission Expires: 09-23-26
Certificate No: 22-2005-01

(Seal)

CURRICULUM VITAE
(as of May 2019)

Michael J. Crovetti, Jr., DO

[redacted]

Business Crovetti Bone & Joint Institute of Southern Nevada

dba Crovetti Orthopaedics and Sports Medicine
2779 W. Horizon Ridge Parkway, Suite 200
Henderson, NV 89052
702-990-2290
Aug. 2000 to current

Date of Birth [redacted]

Spouse [redacted]

Children [redacted]

EDUCATION

Institution	**Graduation/Degree**
Albright College Reading, PA	1988/B.S.
University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	8/90 – 6/94 DO

Internship

University of Medicine and Dentistry of NJ School of Osteopathic Medicine Stratford, NJ	7/94 – 6/95 Chief Intern

Residency

Ohio University – Dayton, OH	7/95 – 7/99 Chief Resident
Grandview Hospital and Medical Center	

Fellowship Subspecialty Training

Reconstruction of the Hip, Knee and Shoulder, Revision Surgery Todd Swanson, MD Desert Orthopedic Center Las Vegas, NV	8/99 – 7/00 Fellow

Consultant Positions

Previous
Cardo Medical, Beverly Hills, CA, Consultant for Total Joint Replacement
Stryker Orthopaedics, Mahwah, NJ, Consultant for Total Joint Replacement
Smith & Nephew, Memphis, TN, Consultant for Minimally Invasive Joint Replacement
DePuy Orthopaedics, Inc, Warsaw, IN, Consultant for Mini Incision Total Hip and Total Knee Arthroplasty
PLUS Orthopedics, San Diego, California, Consultant for the *Gliding Nail* for intramedullary nailing of peritrochanteric hip fractures.

Media Exposure

Summer 2014 – MyVegas Magazine – *Top Docs & Dentists Profile*

Summer 2014 – Las Vegas Life – *Top Doctors 2014*

May 2014 – Fox 5 More TV – *Patient testimonial following a double hip replacement*

February 2014 – Fox 5 More TV – *Coverage of patient walking 3 hours following Total Hip Replacement*

January 2014 – MyVegas Magazine Top Docs Profile

September-December 2013 – Spirit Magazine Health Issue with Advertorial

Fall 2013 – MyVegas Magazine – *Recovery: Crovetti Orthopaedics and Sports Medicine Celebrates Their 500th Patient*

Summer 2013 – MyVegas Magazine – *My Top Docs & Dentists*

Spring 2013 – Las Vegas Life – *Top Doctors 2013*

April 23, 2013 – Las Vegas Review Journal - *Las Vegas doctor streamlines popular knee, hip replacement procedures*

April 19, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

March 15, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

January 28, 2013 – ABC Channel 13 Vegas Morning Blend – *Innovative Outpatient Hip and Knee Replacement*

Spring, 2012, Las Vegas Life – *Top Doctors 2012*

May, 2012 – Vegas, Inc. – *Recovery Suites Model Takes Root In Las Vegas*

May, 2012 – Las Vegas Review Journal - *"Doctors look to control outcomes with own surgical centers, staff"*

2003-2005 Designer Platform Hip Stem, Smith and Nephew Orthopaedics

a. Royalty based agreement

2004-2006 Clinical Faculty Birmingham Hip Resurfacing Team

a. Designed and Implemented Cadaveric Training Program

b. Travelled internationally to learn technique in Belgium, Ireland, and Birmingham

2005-2010 Chairman, Co-Chairman and Clinical Faculty Stryker Orthopaedics Comet Hip Resurfacing Team

a. One of Four Surgeons commissioned to Introduce, Design and Implement Cadaveric training program

2005 – 2007 Consultant Designer HipStar Femoral Stem, Stryker Orthopaedics

2009 – 2010 Instrument and Implant Designer Consultant – CardoMedical, Inc

a. Designed Knee Replacement Instruments and Retractor System for Total Hip Arthroplasty
b. Design Input Poly Insert Total Knee Arthroplasty

2005 Guest Speaker Japanese Orthopedic Association Okinawa, Japan
a. Minimally Invasive Hip and Knee Replacement Surgery

2004 – 2010 Chairman Nevada Bioresearch Foundation, Medical Education And Research Institute of Nevada (MERIN)

a. Designed, Built, MERIN facility in Henderson, Nevada
b. Established Cadaveric Training program and Donation program for State of Nevada
c. MERIN trained more than 10,000 surgeons from 26 different countries

2005-2007 Team Physician UNLV Football, Las Vegas, Nevada

2005- Current Clinical Adjunct Professor of Orthopaedics Touro University, Henderson, Nevada

2006 – 2008 Chief of Surgery, St. Rose Dominican, San Martin Campus, Las Vegas, NV

Clinical and Scientific Presentations

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2013

McDermott, Will and Emery, ASC Symposium, Additional revenue Streams in the Ambulatory Surgery Center, Miami, Fla., February, 2012

Mahwah, NJ April 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ May 2009

"Comet Hip Resurfacing Training Lab"
Stryker
Mahwah, NJ July 2009

"Hipstar DVD" Instructional DVD on how to complete implementation of Hipstar system.
Stryker
Mahwah,NJ June 2007

"North American Hip and Knee Symposium" Smith & Nephew Surgical Approached and Current Controversies
Copper, CO February 2006

"Japanese MIS Synergy Total Hip System Learning Center" Smith & Nephew
Henderson, NV January 2006

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV October 2005

"Minimally Invasive Hip and Knee Surgical Techniques". Smith & Nephew Innovations in MIS Joint Surgery.
New Orleans, LA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques", "Supartz: A Nonsurgical Option" Smith & Nephew Innovations in MIS Joint Surgery.
Santa Barbara, CA June 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV May 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Henderson, NV April 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Japan, February 2005

"Minimally Invasive Hip and Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN December 2004

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.

Phoenix, AZ September 2003

"Minimally Invasive Hip Surgical Techniques" Led the cadaver labs. Smith & Nephew Innovations in MIS Joint Surgery.
Memphis, TN July 2003

"Minimally Invasive Hip & Knee Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2003

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beavercreek, CO January 2003

New Developments in Hip & Knee Arthroplasty- Smith & Nephew
Naples, FL November 2002

"Leg Length & Offset Restoration in Total Hip Arthroplasty"- Smith & Nephew The Great Lakes Joint Arthroplasty Symposium.
Onekama, MI September 2002

Joint Arthroplasty- Smith & Nephew
Coeur D'Alene, ID August 2002

"Minimally Invasive Hip Surgical Techniques" Smith & Nephew Innovations in MIS Joint Surgery.
Los Cabos, Mexico June 2002

"MIS Joint Surgery" Smith & Nephew North American Hip & Knee Symposium
Beaver Creek, CO February 2002

"Joint Reconstruction" Plus Orthopedics
12th International Symposium on Joint Reconstruction,
Ritz Carlton Hotel in Dana Point, CA. April 2001.

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented to the Arizona Orthopedic Society meeting.
Phoenix, AZ. November 2000

Mini-incision Total Hip Arthroplasty. Grand Rounds
Maricopa County Medical Center. Phoenix, AZ November 2000

"Intramedullary Nailing of Peritrochanteric Hip Fractures,"
Presented at the 11th International Zweymuller Symposium
Boston Harbor Hotel, Boston, MA. October 2000.
"Gliding Nail Workshop" Plus Orthopedics National Sales Meeting.
San Diego, CA. September 2000.

"Intramedullary Nailing of Stable and Unstable Peritrochanteric Hip Fractures;"
presented at University Medical Center of Fresno, CA, December 1999.

June 2010
4 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

June 2010
4 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

May 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

May 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Total Hip System
Henderson, NV

April 2010
2 surgeons training on Cardo Unicompartmental Knee System
Henderson, NV

April 2010
2 surgeons training on Cardo Patellofemoral Arthroplasty System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Knee System
Henderson, NV

March 2010
1 surgeon training on Cardo Total Hip System
Henderson, NV

March 2010
1 surgeon training on Cardo Unicompartmental Knee System

Utah

October 2007
3 surgeons training triathlon knee and accolade hip training
Utah

September 2007
1 surgeon training Accolade Hip System, Triathlon Knee and Comet Hip resurfacing system
Las Vegas, NV
1 surgeon skills development program
Fort Lauderdale, FL

August 2007
2 surgeon Presentation hip resurfacing
San Diego, CA
2 surgeons Presentation Triathlon Knee and Accolade Hip System
Mahwah,NJ
1 surgeon Training Comet implant
Los Angeles, CA

July 2007
1 surgeon presentation of hip resurfacing lab Miami Florida
15 surgeon presentation hip and knee replacement
Las Vegas, NV

June 2007
Stryker training session for development of an Activity Expectation Scoring system
1 surgeon training session on the Accolade Hip Stem
Arkansas
1 surgeon training with cadaver and detailed the benefits of Triathlon knee systems
1 surgeon training regarding Triathlon knee system
Phoenix, AZ

May 2007
Teaching seminar for the HIPStar implant program and resurfacing implant
5 surgeons Mahwah, NJ

Feb 2007
1 surgeon training seminar and cadaver interactive training
Los Angeles, CA

December 2007
1 surgeon from Colorado Springs, CO
1 surgeon from Fort Lauderdale, FI
15 surgeon seminar training Fort Lauderdale, FL

November 2006
1 surgeon from Michigan

June 2006

2 surgeons from Springfield, MO
1 surgeon from Houston, TX

June 2004
1 surgeon from Munster, IN

May 2004
1 surgeon from Scottsdale, AZ

March 2004
1 surgeon from Tuscaloosa, AL
1 surgeon from Birmingham, AL
1 surgeon from Lansing, MI

February 2004
2 surgeons from Jasper, AL
1 surgeon & 1 PA-C from Houston, TX
January 2004
2 surgeons from Decatur, AL

December 2003
1 surgeon from Australia
1 surgeon from Pleasanton, CA

September 2003
1 surgeon from MI

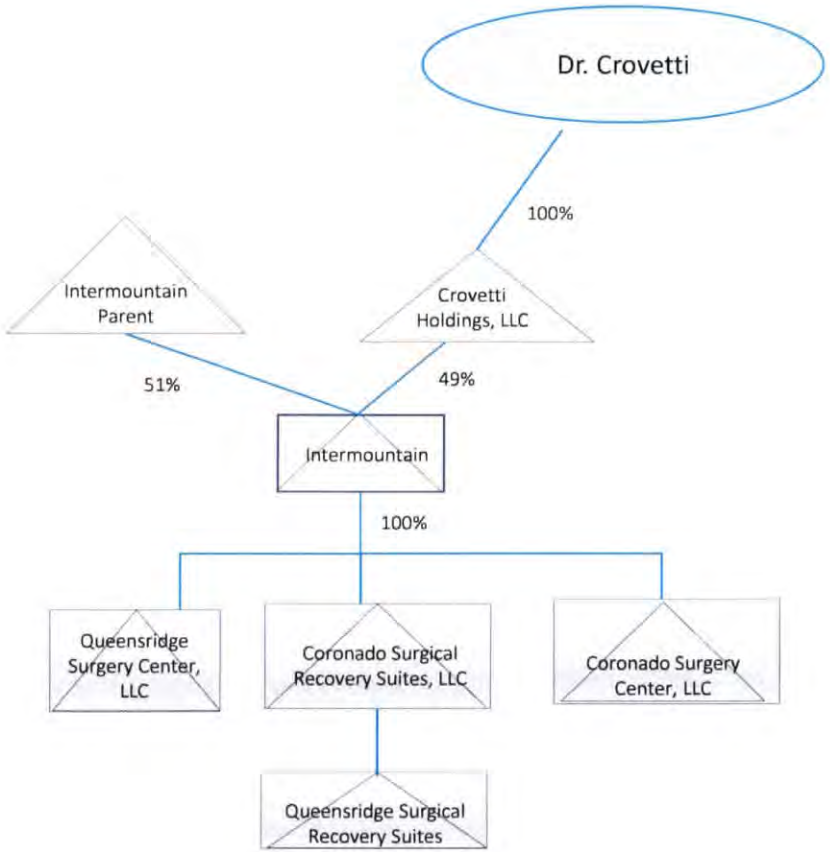
July 2003
1 surgeon from Birmingham, AL

March 2003
1 surgeon from Phoenix, AZ

February 2003
1 surgeon from Birmingham, AL

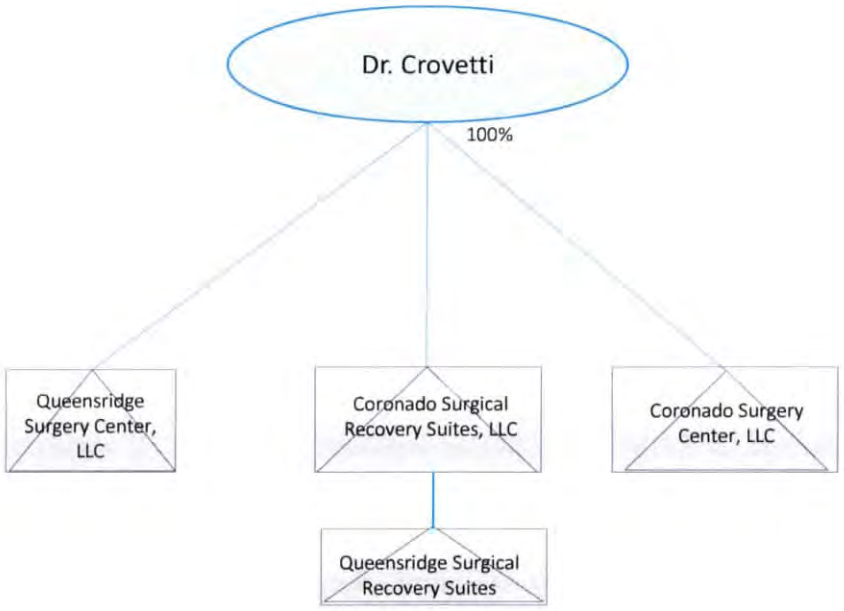
Post-reorganization

- Dr. Crovetti forms a JV holding company ("**Intermountain**")
- Intermountain Medical Holdings Nevada, Inc., a Delaware nonprofit nonstock corporation ("**Intermountain Parent**"), purchases 51% of Intermountain.
- Dr. Crovetti will remain in the structure as the ultimate 49% equity holder of each of the Facilities.



Pre-reorganization

- Dr. Crovetti holds 100% of the equity in each of the Facilities.



10l

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
☐ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
■ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *	ASC02422	■ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*		☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Sahara Surgery Center

Physical Address: 2401 Paseo Del Prado

City: Las Vegas State: NV Zip: 89102

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 702-362-7874 Fax: 702-362-3567

Contact Email: kelly.lorie@surgeryventures.com Website www.saharasurgery.com

Nevada Business License # NV19921011695

Employed/Contracted Pharmacist Name: Chike Okolo NV Pharmacist License #: 19267

Medical Director Name: Dr. Kevin Garth

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✓
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 5: Partnership

Partnership Name: Sahara Outpatient Surgery Center, Ltd., A Nevada Limited Partnership

Mailing Address: 2401 Paseo Del Prado

City: Las Vegas State: NV Zip: 89102

Telephone: 702-362-7874 Email: kelly.lorie@surgeryventures.com

Contact Person Name: Kelly Lorie

Please check type of partnership (NAC 639.214) ☐ General ■ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ■ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Chike Okolo NV Pharmacist License #: 19267

As the employed/contracted pharmacist, for (ASC/RC Name): Sahara Surgery Center ;

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

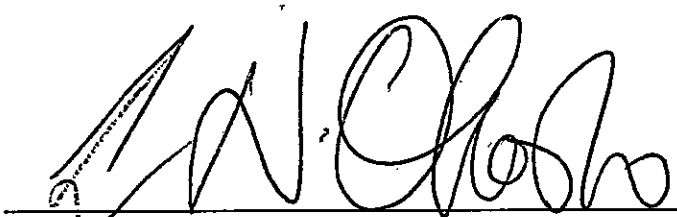
Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		Governing, licensing, Arresting Presiding Body/Agency/Court		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:



Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

3/11/2025

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)	✓	✓		
• List the top four stockholders and their percent ownership. NRS 639.231(3)	✓	✓		
• List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)		✓		
• For General Partnerships, list the name of each partner. NAC 639.214(2) • For Limited Partnerships, list the names of (NAC 639.214(3)): ○ All General Partners; ○ All Limited Partners who hold 10% or more of the interest.			✓	
• Certificate of Corporate Status or Certificate of Good Standing from the Secretary of State's Office where the business is domiciled, dated within the last 6 months.	✓	✓	✓	✓
• Personal History Record Application must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.	✓	✓	✓	✓

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Kelly Lorie

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Kelly Lorie

Original signature of Authorized Person (copies or stamps not accepted)

05/12/2025

Date

Board Use Only	Date Received: _____	Amount: _____

Limited Partnership Disclosures

Type of Partner	Name of Partner
General Partner	Surgicare of Las Vegas, Inc.
Limited Partner(s) with 10% or Greater Interest	No limited partner holds a 10% or greater ownership interest in the applicant.

SECRETARY OF STATE



STATE OF NEVADA

CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

SAHARA OUTPATIENT SURGERY CENTER LTD., A NEVADA LIMITED PARTNERSHIP

Organizational Documents on File	Filing Date
Amendment	10/20/1993
Registration-Limited Partnership (88)	12/28/1992

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence SAHARA OUTPATIENT SURGERY CENTER LTD., A NEVADA LIMITED PARTNERSHIP, as a DOMESTIC LIMITED PARTNERSHIP (88) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 12/28/1992, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 02/11/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202502115430934
You may verify this certificate online at
https://www.nvsilverflume.gov/home

ASC License

Please find enclosed on the following page the Ambulatory Surgical Center license issued to the applicant by the Nevada Department of Health and Human Services, Division of Public and Behavioral Health.

Effective Date : 01/01/2025
Expiration Date : 12/31/2025

State of Nevada
Department of Health and Human Services
Division of Public and Behavioral Health

License Number
466-ASC-31

Please display this license conspicuously

This license was printed from an online licensing system. VERIFY LICENSE IS VALID BY GOING TO: https://nvdpbh.aithent.com/login.aspx. Go to License Verification, Facility Locator & Inspection Reports "Click Here" and look up by license number (Credential Number) to verify that the license is active and valid.

Should you have any changes such as Name, Administrator, Location, Change of Ownership or Number of Beds go to: https://nvdpbh.aithent.com/login.aspx.

This Is To Certify That

SAHARA SURGERY CENTER

2401 PASEO DEL PRADO
LAS VEGAS, NV 89102

Is hereby licensed as a(n)

SURGICAL CENTER FOR AMBULATORY PATIENTS

as provided for in Chapters 439 and 449 of the Nevada Revised Statutes and the Nevada Administrative Code and the standards, rules and regulations adopted by the Board of Health.

This facility is licensed to provide the following:

Facility Type : SURGICAL CENTER FOR AMBULATORY PATIENTS
AMBULATORY SURGICAL CENTER
CLASS E

Endorsement : CLASS - E

Bed Information : Operating Room - A - 5

If your license is not completely accurate, Please contact us at (775) 684-1030 so that we may resolve any problems.

KELLY A LORIE / Administrator

SAHARA OUTPATIENT SURGERY CENTER

Cody L Phinney / Administrator

10J

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Ambulatory Surgical Center (ASC) and Recovery Center (RC) Application

Non-Refundable $500.00 Fee

Rev (09/02/2021)

Type of Facility

- ■ Ambulatory Surgical Center (ASC)
- ☐ Recovery Center (RC)

Type of Application (check applicable box)		Ownership Type (check applicable box)
■ New ASC/RC	* If making a change, provide current license number:	☐ Publicly Traded (complete sections 1, 2, 3, 7, 8, 9)
☐ Ownership Change*		☐ Non-Publicly Traded (complete sections 1, 2, 4, 7, 8, 9)
☐ Location Change *		■ Partnership (complete sections 1, 2, 5, 7, 8, 9)
☐ Name Change*	_____	☐ Sole Owner (complete sections 1, 2, 6, 7, 8, 9)

Section 1: General Information

ASC/RC Name: Summit Surgical Center LLC

Physical Address: 3820 S Hualapai Way Suite 100

City: Las Vegas State: NV Zip: 89147

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Fax: _____

Contact Email: admin@SummitSurgicalNV.com Website www.summitsurgicalNV.com

Nevada Business License # _____

Employed/Contracted Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

Medical Director Name: _____

Days of Operation

■ Monday	■ Tuesday	■ Wednesday	■ Thursday	■ Friday	☐ Saturday	☐ Sunday

Section 2: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?		✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

5557

Section 3: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 4: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: _____

Parent Company (if any): _____

Corporation/Organization Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Does the number of members or stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 5: Partnership

Partnership Name: Summit Surgical Center LLC

Mailing Address: 3820 S Hualapai Way Suite 100

City: Las Vegas State: NV Zip: 89147

Telephone: 954-258-7028 Email: JennTranMD@gmail.com

Contact Person Name: Jennifer Tran

Please check type of partnership (NAC 639.214) ☐ General ■ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ■ Yes ☐ No

Section 6: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 7: Employed/Contracted Pharmacist (MUST BE COMPLETED BY the Employed/Contracted Pharmacist)

Pharmacist Name: Michelle McCarthy NV Pharmacist License #: 22808

As the employed/contracted pharmacist, for (ASC/RC Name): Summit Surgical Center, LLC :

I understand that I am responsible for establishing policies and procedures which (NAC 639.4996):

a) Are consistent with the policies and procedures developed pursuant to NAC 639.447;
b) Require to maintain records in accordance with the provisions of NAC 639.485 and 639.485;
c) Address the purchase, storage, maintenance of records and dispensing of drugs and investigational drugs;
d) Require maintenance of a perpetual inventory of all controlled substances;
e) Prescribe the procedure for quarantining and destroying drugs and investigational drugs that are expired, adulterated, mislabeled or otherwise unsafe for human use;
f) Require the storage of drugs and investigational drugs in accordance with the specifications of the manufacturer;
g) Ensure that the ASC and RC dispenses drugs and investigational drugs pursuant to chart orders and in accordance with applicable state and federal laws; and
h) Ensure that all compounding is
    a. Performed by a registered pharmacist in accordance with the provisions of NRS and NAC 639; or
    b. If performed by an employee of the ASC or RC, other than a registered pharmacist, performed:
        i. In accordance with the provisions of NRS and NAC 639;
        ii. In a location designated for compounding that is clean and disinfected before each act of compounding; and
        iii. By a person who has completed training for the type of compounding that will be performed.

I understand that I shall (NAC 639.4998):

a) Visit the ASC or RC at least once each month to:
    a. Evaluate the effectiveness of the policies and procedures established pursuant to NAC 693.4996; and
    b. Confirm that the ASC or RC is complying with those policies and procedures, the below provisions.
b) Maintain documentation of each visit that the pharmacist makes;
c) Conduct an audit at least once each month using a sufficient number of records of the ASC or RC, including, without limitation, records of patients and records relating to the purchasing, storing and dispensing of drugs and investigational drugs, which must be randomly selected, to determine whether:
    a. The records indicate that the drugs and investigational drugs are dispensed in a safe and effective manner in accordance with accepted standards of practice and the specifications of the manufacturer;
    b. Drugs and investigational drugs are diluted in accordance with accepted standards of practice or pursuant to the specifications of the manufacturer;
    c. The records demonstrate:
        i. That a discrepancy does not exist in the number of drugs and investigational drugs that are in vials designated by the manufacturer for a single use which are dispensed and the number of patients who receive such drugs and investigational drugs; and
        ii. That drugs, not including investigational drugs, which are in vials designated by the manufacturer for a single use and any remaining medication in those vials are discarded after use;
    d. The records demonstrate that drugs, not including investigational drugs, which are in vials designated by the manufacturer for more than one use are discarded when the medication in the vials has expired or not more than 28 days after the initial breach of the vial;
    e. The employees of the ASC or RC properly maintain accurate records relating to drugs and investigational drugs; and
    f. The employees of the ASC or RC properly monitor and maintain the perpetual inventory required pursuant to paragraph (d) of subsection 1 of NAC 639.4996; and
d) Submit a written report, including, without limitation, a written explanation, to the Board not later than 5 business days after the pharmacist determines that:
    a. The ASC or RC is violating a state or federal law which affects the care and safety of a patient;
    b. There is a discrepancy of 5 percent or more between the actual quantity of a controlled substance in the possession of the ASC or RC and the amount of the controlled substance that should be in the possession of the ASC or RC according to the records of the ASC or RC, including, without limitation:
        i. Purchase orders and invoices for the controlled substance;
        ii. Records which indicate the removal of the controlled substance from the storage area;
        iii. Patient records;
        iv. Records which indicate the return of the controlled substance to the manufacturer;
        v. Records which indicate that the controlled substance was destroyed; and
        vi. Any other record for the controlled substance;
    c. The recovery center or surgical center has intentionally or recklessly failed to create or maintain a record required by the policies and procedures established pursuant to NAC 639.4996;
    d. The recovery center or surgical center is administering a drug or an investigational drug in violation of accepted standards of practice or the specifications of the manufacturer; or
    e. The recovery center or surgical center is engaged in a practice which endangers the health, safety or welfare of a patient or employee of the recovery center or surgical center.

Section 8: Personal and Professional History of the Employed/Contracted Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Name of Business/Industry/Entity				

Provide explanation below:

Michelle M Cundy

Original signature of Employed/Contracted Pharmacist (copies or stamps not accepted)

3-28-25

Date

Section 9: Provide all the applicable documents with your application based on your Business Type. Required documents are indicated by an "✓" on the right.	Publicly Traded	Non-publicly Traded	Partner-ship	Sole Owner
• **List all Officers and Directors. NRS 639.231(2)(b), NAC 639.214(5)(a)**	✓	✓		
• **List the top four stockholders and their percent ownership. NRS 639.231(3)**	✓	✓		
• **List all stockholders who hold 10% or more of the shares. NAC 639.214(4)(b)**		✓		

• **For General Partnerships, list the name of each partner. NAC 639.214(2)**
• **For Limited Partnerships, list the names of (NAC 639.214(3)):**
  ○ **All General Partners;**
  ○ **All Limited Partners who hold 10% or more of the interest.**
			✓	

• **Certificate of Corporate Status or Certificate of Good Standing** from the Secretary of State's Office where the business is domiciled, dated within the last **6 months.**	✓	✓	✓	✓
• **Personal History Record Application** must be completed by each shareholder/stockholder/partner/member/owner. Form found at http://bop.nv.gov/Services/newapps/Business/		✓	✓	✓
• **Submit a copy of your license, certification, permit or registration issued to your ASC or RC by the Nevada Division of Public and Behavioral Health of the Department of Health and Human Services.**	✓	✓	✓	✓

* still pending

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

My Linh J. Tran

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

4/3/2025

Date

Board Use Only	Date Received: 4/3/25	Amount: $500-cc

List of Partners for Summit Surgical Center

Jennifer Tran MD PLLC

Owners: My Linh Jennifer Tran, MD and Luis Velazquez, MD

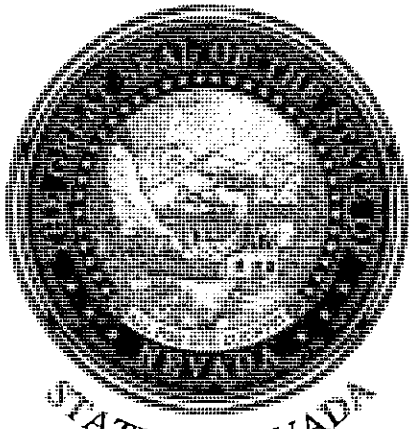
Rajah Ventures LLC

Owners: Hashim Qureshi, DO and Rehma Ehsan

Wzrost LLC

Owners: Mark Chmiela, MD and Olga Vallejos

SECRETARY OF STATE



CERTIFICATE OF EXISTENCE WITH STATUS IN GOOD STANDING

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that I am, by the laws of said State, the custodian of the records relating to filings by corporations, non-profit corporations, corporation soles, limited-liability companies, limited partnerships, limited-liability partnerships and business trusts pursuant to Title 7 of the Nevada Revised Statutes which are either presently in a status of good standing or were in good standing for a time period subsequent of 1976 and am the proper officer to execute this certificate.

I further certify, that the following is a list of all organizational or qualification, as applicable, documents on file in this office for

Summit Surgical Center LLC

Organizational Documents on File	Filing Date
Amendment to Articles of Organization	11/06/2024
Amendment to Articles of Organization	10/20/2024
Articles of Organization	03/01/2024

I further certify that the records of the Nevada Secretary of State, at the date of this certificate, evidence Summit Surgical Center LLC, as a DOMESTIC LIMITED-LIABILITY COMPANY (86) duly organized or formed and existing, or duly qualified or registered, as applicable, and by virtue of the laws of the State of Nevada since 03/01/2024, and is in good standing in this state.

SECRETARY OF STATE

STATE OF NEVADA

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 04/04/2025.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202504045599938
You may verify this certificate online at
https://www.nvsilverflume.gov/home

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Summit Surgical Center LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3820 S Hualapai Way Suite 100

City Las Vegas State NV Zip 89147

Mailing Address (If different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Luis Middle Alberto Last Velazquez

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☒ M ☐ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
University of South Florida COM		08/02-06/07	
Address	**City**	**State**	**Zip**
560 Channelside Dr	Tampa	FL	33602
Diploma/Degree obtained, if any			
MD			
School Name		**From - To (MM/YY – MM/YY)**	
Barry University		06/01-07/02	
Address	**City**	**State**	**Zip**
11300 NE 2nd Ave	Miami Shores	FL	33161
Diploma/Degree obtained, if any			
Masters In Biomedical Sciences			
School Name		**From - To (MM/YY – MM/YY)**	
University of Miami		08/97-05/01	
Address	**City**	**State**	**Zip**
1252 Memorial Drive	Coral Gables	FL	33146
Diploma/Degree obtained, if any			
BS			
School Name		**From - To (MM/YY – MM/YY)**	
Palmetto Senior High SChool		08/93-05/97	
Address	**City**	**State**	**Zip**
7431 SW 120th St	Pinecrest	FL	33156
Diploma/Degree obtained, if any			
HS diploma			
School Name		**From - To (MM/YY – MM/YY**	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20-current	[redacted]			
04/15- 3/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Luis Velazquez MD PLLC			08/2015- present	
Business Address	**City**	**State**	**Zip**	
848 N Rainbow Blvd #1328	las vegas	nv	89107	
Phone	**Title**			
702-960-4150	MD			
Description of Duties				
partner				

Business Name			From - To (MM/YY – MM/YY)	
Jennifer Tran MD PLLC			08/2024-present	
Business Address	**City**	**State**	**Zip**	
848 N Rainbow Blvd #1328	las vegas	NV	89107	
Phone	**Title**			
954-258-7028	MD			
Description of Duties				
owner				

Business Name			From - To (MM/YY – MM/YY)	
Chameleon Management			08	
Business Address	**City**	**State**	**Zip**	
848 N Rainbow Blvd #1328	las vegas	NV	89107	
Phone	**Title**			
305-924-5198	owner			
Description of Duties				
owner				

Business Name			From - To (MM/YY – MM/YY)	
Prosperity Realty Group LLC			03/2024-present	
Business Address	**City**	**State**	**Zip**	
848 N Rainbow Blvd #1328	Las Vegas	NV	89107	
Phone	**Title**			
954-258-7028	member			
Description of Duties				
partner				

Business Name			From - To (MM/YY – MM/YY)	
Summit Surgical Center LLC			03/2024-present	
Business Address	**City**	**State**	**Zip**	
3820 S Hualapai Way Suite 100	Las Vegas	NV	89147	
Phone	**Title**			
954-258-7028	member			
Description of Duties				
partner				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Luis Velazquez

Print Name (First, Last)

L. VELAZQUEZ — 3/28/25

Original Signature (electronic, copies or stamps not accepted) — Date

---

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Luis Velazquez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

L. VELAZQUEZ — 3/28/25

Original Signature — **Date**

Subscribed and Sworn to before me this 28th day of March, 2025.

ROSARIO GONZALEZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-1383-01
MY APPT. EXPIRES FEBRUARY 03, 2028

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Summit Surgical Center LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3820 S Hualapai Way Suite 100

City Las Vegas State NV Zip 89147

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First My Linh Middle Jennifer Last Tran

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☑ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Miami Miller School of Medicine			08/2005-06/2009	
Address		City	State	Zip
1600 NW 10th ave #1140		Miami	FL	33136
Diploma/Degree obtained, if any				
MD				
School Name			From - To (MM/YY – MM/YY)	
University of Miami			08/2003-06/2005	
Address		City	State	Zip
1252 Memorial Drive		CoralGables	FL	33146
Diploma/Degree obtained, if any				
BS				
School Name			From - To (MM/YY – MM/YY)	
Western High school			08/99-06/03	
Address		City	State	Zip
1200 SW 136th Ave		Davie	FL	33325
Diploma/Degree obtained, if any				
HS diploma				
School Name			From - To (MM/YY – MM/YY)	
Address		City	State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address		City	State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/20-current	[redacted]			
04/15- 3/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Luis Velazquez MD PLLC			08/2015- present
Business Address	**City**	**State**	**Zip**
848 N Rainbow Blvd #1328	las vegas	nv	89107
Phone	**Title**		
702-960-4150	MD		
Description of Duties			
partner			

Business Name			From - To (MM/YY – MM/YY)
Jennifer Tran MD PLLC			08/2015-present
Business Address	**City**	**State**	**Zip**
848 N Rainbow Blvd #1328	las vegas	NV	89107
Phone	**Title**		
954-258-7028	MD		
Description of Duties			
owner			

Business Name			From - To (MM/YY – MM/YY)
Tran Practice Management			08/2018- present
Business Address	**City**	**State**	**Zip**
848 N Rainbow Blvd #1328	las vegas	NV	89107
Phone	**Title**		
954-258-7028	owner		
Description of Duties			
owner			

Business Name			From - To (MM/YY – MM/YY)
Prosperity Realty Group LLC			03/2024-present
Business Address	**City**	**State**	**Zip**
848 N Rainbow Blvd #1328	Las Vegas	NV	89107
Phone	**Title**		
954-258-7028	member		
Description of Duties			
partner			

Business Name			From - To (MM/YY – MM/YY)
Summit Surgical Center LLC			03/2024-present
Business Address	**City**	**State**	**Zip**
3820 S Hualapai Way Suite 100	Las Vegas	NV	89147
Phone	**Title**		
954-258-7028	member		
Description of Duties			
partner			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

My Linh Jennifer TRAN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/28/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, My Linh J. TRAN, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/28/25

Date

Subscribed and Sworn to before me this 28th day of March, 2025

Notary Public Signature

ROSARIO GONZALEZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-1383-01
MY APPT. EXPIRES FEBRUARY 03, 2028

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Summit Surgical Center LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 3820 S Hualapai Way Suite 100

City: Las Vegas State: NV Zip: 89147

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Hashim Middle: Jehanzeb Last: Qureshi

Alias(es, nicknames, name changes, etc.):

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☒ M ☐ F ☐ X

Mailing Addres[redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone [redacted] Ema[redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Philadelphia College of Osteopathic Medicine		2009-2013	
Address	**City**	**State**	**Zip**
4170 City Ave	Philadelphia	PA	19131
Diploma/Degree obtained, if any			
Doctor of Osteopathic Medicine			

School Name		From - To (MM/YY – MM/YY)	
Drexel College of Medicine		2007-2009	
Address	**City**	**State**	**Zip**
2900 W Queen Ln	Philadelphia	PA	19129
Diploma/Degree obtained, if any			
Masters in Medical Science			

School Name		From - To (MM/YY – MM/YY)	
The George Washington University		2003-2007	
Address	**City**	**State**	**Zip**
2121 I St, NW	Washington	D.C.	20052
Diploma/Degree obtained, if any			
B.A. Psychology with minor in Biology			

School Name		From - To (MM/YY – MM/YY)	
Waynesboro High School		1999-2003	
Address	**City**	**State**	**Zip**
550 East Second Street	Waynesboro	PA	17268
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
2018-2019	[redacted]			
2017-2018				
2013-2017				
From - To (MM/YY – MM/YY)	Address			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
HRQ Medical LLC			12/21-Present	
Business Address		**City**	**State**	**Zip**
11700 W Charleston Blvd 170-473		Las Vegas	NV	89135
Phone	**Title**			
202-487-7636	Owner (50%)			
Description of Duties				
Manage Ownership of 25% share in Velazquez Pain Relief Center Marketing for continued growth in both the physician and legal communities				

Business Name			From - To (MM/YY – MM/YY)	
Luis Velazquez MD PLLC			2023-Present	
Business Address		**City**	**State**	**Zip**
3820 S Hualapai Way Suite 100		Las Vegas	NV	89147
Phone	**Title**			
702-960-4150	Owner (25%)			
Description of Duties				
Co-manage clinic operations, including financial oversight, staffing, and growth strategies, drive growth in personal injury, workers' compensation. Continuing to deliver care as a board certified and fellowship trained pain physician.				

Business Name			From - To (MM/YY – MM/YY)	
Raja Ventures LLC			10/24 - Present	
Business Address		**City**	**State**	**Zip**
11700 W Charleston Blvd 170-473		Las Vegas	NV	89135
Phone	**Title**			
202-487-7636	Owner (50%)			
Description of Duties				
Manage Ownership of 33% share in Summit Surgical Center LLC				

Business Name			From - To (MM/YY – MM/YY)	
HRQ Ventures LLC			05/23-Present	
Business Address		**City**	**State**	**Zip**
11700 W Charleston Blvd 170-473		Las Vegas	NV	89135
Phone	**Title**			
202-487-7636	Owner (50%)			
Description of Duties				
Real Estate Holding Company				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

HASHIM J. QURESHI

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

03/28/25

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Hashim J. Qureshi, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

03/29/25

Date

Subscribed and Sworn to before me this 29 day of March 2025

Notary Public Signature

Alyssa Pangelinan
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 22-7750-01
My Appt. Expires: March 10, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Summit Surgical Center LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable):

Physical Address: 3820 S Hualapai Way Suite 100

City: Las Vegas State: NV Zip: 89147

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: Website:

Licensing Company Email:

Section 2: Personal Information

First: Rehma Middle: Last: Ehsan

Alias(es, nicknames, name changes, etc.):

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		✔

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Drexel University School of Public Health		07/11-06/13	
Address	**City**	**State**	**Zip**
3215 Market Street	Philadelphia	PA	19104
Diploma/Degree obtained, if any			
Master of Public Health in Health Management and Policy			

School Name		From - To (MM/YY – MM/YY)	
University of Illinois Urbana Champaign		08/08-05/10	
Address	**City**	**State**	**Zip**
901 West Illinois Street	Urbana	IL	61801
Diploma/Degree obtained, if any			
Bachelor of Arts in Political Science; Minor in Psychology			

School Name		From - To (MM/YY – MM/YY)	
George Mason Univeristy		08/06-06/08	
Address	**City**	**State**	**Zip**
4400 University Dr	Fairfax	VA	22030
Diploma/Degree obtained, if any			
Transfered			

School Name		From - To (MM/YY – MM/YY)	
McLean High School			
Address	**City**	**State**	**Zip**
1633 Davidson Road	McLean	VA	22101
Diploma/Degree obtained, if any			
High School Diploma			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
present	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
HRQ Medical LLC			12/21-Present	
Business Address	**City**		**State**	**Zip**
11700 W Charleston Blvd 170-473	Las Vegas		NV	89135
Phone	**Title**			
571-232-3110	Owner (50%)			
Description of Duties				
Manage Ownership of 25% share in Velazquez Pain Relief Center Marketing for continued growth in both the physician and legal communities				

Business Name			From - To (MM/YY – MM/YY)	
Raja Ventures LLC			10/24-Present	
Business Address	**City**		**State**	**Zip**
11700 W Charleston Blvd 170-473	Las Vegas		NV	89135
Phone	**Title**			
571-232-3110	Owner (50%)			
Description of Duties				
Manage Ownership of 33% share in Summit Surgical Center LLC				

Business Name			From - To (MM/YY – MM/YY)	
HRQ Ventures LLC			05/23-Present	
Business Address	**City**		**State**	**Zip**
11700 W Charleston Blvd 170-473	Las Vegas		NV	89135
Phone	**Title**			
571-232-3110	Owner (50%)			
Description of Duties				
Real estate holding company				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address	**City**		**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations:	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Rehma Ehsan
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

3/28/25
Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Rehma Ehsan, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

3/29/25
Date

Subscribed and Sworn to before me this 29 day of March 2025

Notary Public Signature

Alyssa Pangelinan
NOTARY PUBLIC
STATE OF NEVADA
Appt. No. 22-7750-01
My Appt. Expires: March 10, 2026

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site: Summit Surgical Center LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable): _____

Physical Address: 3820 S. Hualapai Way Suite 100

City: Las Vegas State: NV Zip: 89147

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: _____ Website: _____

Licensing Company Email: _____

Section 2: Personal Information

First: Mark Middle: Adam Last: Chmiela

Alias(es, nicknames, name changes, etc.): _____

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X

Mailing Address: [redacted]

City: Las Vegas State: NV Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Cleveland Clinic Foundation		07/19 - 06/20	
Address	**City**	**State**	**Zip**
9500 Euclid Ave	Cleveland	OH	44195
Diploma/Degree obtained, if any			
Pain Medicine			
School Name		**From - To (MM/YY – MM/YY)**	
Cleveland Clinic Foundation		07/15 - 06/19	
Address	**City**	**State**	**Zip**
9500 Euclid Ave	Cleveland	OH	44195
Diploma/Degree obtained, if any			
Anesthesiology			
School Name		**From - To (MM/YY – MM/YY)**	
Jagiellonian University Medical College		09/11 - 05/15	
Address	**City**	**State**	**Zip**
Świętej Anny 12	Krakow, Poland		31-008
Diploma/Degree obtained, if any			
Medical Doctor (MD)			
School Name		**From - To (MM/YY – MM/YY)**	
University of Ottawa		09/06 - 04/10	
Address	**City**	**State**	**Zip**
75 Laurier Ave E	Ottawa	ON	K1N 6N5
Diploma/Degree obtained, if any			
Honours Bachelor of Science, Specialization in Biochemistry			
School Name		**From - To (MM/YY – MM/YY**	
Immaculata High School		09/02 - 06/06	
Address	**City**	**State**	**Zip**
140 Main St	Ottawa	ON	K1S 5P4
Diploma/Degree obtained, if any			
High School Diploma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
06/20 - Present	[redacted]			
05/16 - 06/20				
06/15 - 05/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
Velazquez Pain Relief Center			11/20 - Present	
Business Address		**City**	**State**	**Zip**
1815 East Lake Mead St 300		North Las Vegas	NV	89030
Phone	**Title**			
702-960-4150	Physician			
Description of Duties				
Interventional pain management doctor.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Mark Chmiela

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

04/01/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Mark Chmiela, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/1/2025

Date

Subscribed and Sworn to before me this 1st day of April, 2025

ROSARIO GONZALEZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-1383-01
MY APPT. EXPIRES FEBRUARY 03, 2028

Notary Public Signature

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site Summit Surgical Center LLC

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 3820 S Hualapai Way Suite 100

City Las Vegas State NV Zip 89147

Mailing Address (if different from physical address) _____

City _____ State _____ Zip _____

Telephone _____ Website _____

Licensing Company Email _____

Section 2: Personal Information

First Olga Middle Belinda Last Vallejos

Alias(es, nicknames, name changes, etc.) Olga Vallejos Chmiela

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☐ M ☒ F ☐ X

Mailing Address [redacted]

City Las Vegas State NV Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☐ Yes ☒ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
Western University			08/12-05/14	
Address	City		State	Zip
1151 Richmond Street	London		ON	N6A 3K7
Diploma/Degree obtained, if any				
Master of Science in Occupational Therapy				
School Name			From - To (MM/YY – MM/YY)	
Carleton University			09/05-05/10	
Address	City		State	Zip
1125 Colonel By Dr,	Ottawa		ON	K1S 5B6
Diploma/Degree obtained, if any				
Bachelor of Science in Integrated Sciences				
School Name			From - To (MM/YY – MM/YY)	
Immaculata High School			08/01- 06/05	
Address	City		State	Zip
140 Main St.	Ottawa		ON	K1S 5P4
Diploma/Degree obtained, if any				
High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City		State	Zip
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY	
Address	City		State	Zip
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper, if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
07/20-present				
From - To (MM/YY – MM/YY)				
06/15-07/20				
From - To (MM/YY – MM/YY)				
05/14- 06/15				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7. Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
Crystal Clinic Orthopaedic Center			06/19-12/20
Business Address	**City**	**State**	**Zip**
3975 Embassy Pkwy Suite 102	Fairlawn	OH	44333
Phone	**Title**		
(330) 668-4050	Occupational Therapist		
Description of Duties			
Occupational Therapist -Outpatient services			

Business Name			From - To (MM/YY – MM/YY)
Cleveland Clinic- Beachwood Rehabilitation Hospital-Select Medical			10/17-06/19
Business Address	**City**	**State**	**Zip**
3025 Science Park Dr	Cleveland	OH	89166
Phone	**Title**		
(216) 455-6400	Occupational Therapist		
Description of Duties			
Occupational Therapist- Rehabilitation inpatient services			

Business Name			From - To (MM/YY – MM/YY)
Cuyahoga County Board of Developmental Disabilities			08/15/-09/17
Business Address	**City**	**State**	**Zip**
1275 Lakeside Ave E	Cleveland	OH	44114
Phone	**Title**		
(216) 241-8230	Occupational Therapist		
Description of Duties			
Occupational Therapist- home health care services			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Olga Vallejos

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/2/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Nevada, ss. County of Clark

I, Olga Belinda Vallejos, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

05/03/2025

Date

Subscribed and Sworn to before me this 3rd day of April, 2025.

ROSARIO GONZALEZ
NOTARY PUBLIC
STATE OF NEVADA
APPT. NO. 20-1383-01
MY APPT. EXPIRES FEBRUARY 03, 2028

Notary Public Signature

(Seal)

11

11A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada ☐ Out-of-Nevada	☐ New Pharmacy ☑ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 02453	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☑ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☑ Non-sterile Compounding ☑ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☑ Other: Radiopharmaceuticals

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☑ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☑ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☑ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Las Vegas Radiopharmacy, Inc.

Physical Address: 1771 E Flamingo Rd., #A121

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): N/A

City: N/A State: N/A Zip: N/A

Telephone: 702-476-8600 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 702-750-1367 Contact Email: licensing@rls.bio

Website: https://rls.bio/

Nevada Business License # (if applicable) NV20243197775

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Southwick, RPh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 11480

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Christopher Southwick, RPh	NV Pharmacist Registration #: 11480
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Darren Patti	Credentials: Please see attached	%: 0
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Telix Pharmaceuticals (US) Inc.

Corporation/Organization Name: RLS (USA) Inc.

Mailing Address: 255 Primera Boulevard, Suite 440

City: Lake Mary State: FL Zip: 32746

Telephone: 813-285-3065 Email: licensing@rls.bio

Contact Person Name: David Miller

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Group Chief Operating Officer (title) for RLS (USA) Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Darren Patti

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/14/24

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Christopher Southwick Pharmacist Registration #: 11480

Pharmacy Name: RLS (USA) Inc.

Initial each statement below to indicate you have read and agree with the following:

CS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

CS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

CS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

CS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

CS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✔
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✔	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✔	

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
Stipulation	NV	07-18-2014	14-017-RPH-S

Criminal Action:	State:	Date:	Case #:	County:	Court:
N/A					

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Original signature of Managing Pharmacist (copies or stamps not accepted)

2/24/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Darren Patti

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/14/25

Date

Board Use Only	Date Received: 3/3/25	Amount: $500 CK 1000002077

Disciplinary Summary
RLS (USA) Inc. Pharmacies

RLS (USA) Inc., f/k/a Amersham Health Nuclear, Medical Pharmacy, 1 Naylon Place, Livingston, NJ 07039

March 8, 2004: New Jersey Board of Pharmacy issued a $225.00 penalty and requested a letter of corrective action as a result of violations of N.J.A.C 13:39-12.2(e) (Prescription label does not have the chemical form of the radioactive drug) and N.J.A.C 13:39-12.4(c) (Missing a current text in the category of "General Practice of Pharmacy") found during an inspection conducted on 12/19/2003. RLS (USA) Inc. satisfied all requirements of the corrective action, paid the fine, and remains in good standing with the New Jersey Board of Pharmacy.

RLS (USA) Inc., f/k/a/ Med-Physics, Inc., d/b/a/ GE Healthcare, 1 Naylon Place, Livingston, NJ 07039

May 19, 2017: New Jersey Board of Pharmacy issued a $5,500.00 penalty and requested a letter of corrective action as a result of violations of N.J.A.C 13:39-11.24(a)6 (Adequate efforts were not made to ensure the pharmacy's quality assurance program) and N.J.A.C 13:39-11.24(a)10 (When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards) found during an inspection conducted on 8/10/2016. The pharmacy paid the fine and met all requirements of the corrective action, and remains in good standing with the New Jersey Board of Pharmacy.

RLS (USA) Inc., 1283 Mountain View Alviso Road Ste. A - B, Sunnyvale, CA 94089

February 14, 2024: RLS (USA) Inc. failed to follow its written policies and procedures when, on dates ranging from 12/30/2022 to 6/26/2023, it failed to remove pharmacy equipment from use following microbial contamination. This resulted in a violation of California pharmacy law for which the Board issued a Citation. No fine was assessed and the pharmacy took corrective action to address the violations. The pharmacy remains in good standing with the California Board of Pharmacy.

RLS (USA) Inc., 16259 Stagg Street, Ste A, Van Nuys, CA 91406

October 11, 2024: RLS (USA) Inc. failed to timely notify the California Board of Pharmacy upon a change in the Pharmacist-in-Charge. RLS (USA) Inc. operated without an approved PIC for the pharmacy and was fined a total of $1500. RLS complied with all requirements of the citation and the pharmacy remains in good standing with the California Board of Pharmacy.

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. MCGREEVEY
Governor

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 8, 2004

John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Re: Inspection Report #8-1066.6
Inspection Date: 12/19/03

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated:

N.J.A.C. 13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.
$25.00

N.J.A.C. 13:39-12.4(c)
Missing a current text in the category of "General Practice of Pharmacy".
$200.00

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the attached acknowledgment and agree to the following:

1. Pay a penalty in the amount of **$225.00** and provide to the Board a Letter of Corrective Action. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively, you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973).504-6450.

The enclosed certification should be completed and returned to the Board **within fifteen (15) days following your receipt of this letter.** In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained here in shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: Joanne Boyer
Joanne Boyer
Executive Director

JB/mw

cc: Marianne Greenwald, Deputy Attorney General
[redacted]

5/26/04 Exhibit 10E (6)

CERTIFICATION

I, JOHN MARZOCCA, hereby acknowledge that I have read and reviewed the Board's letter dated March 8, 2004 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

☐ I acknowledge the conduct which has been charged and agree to:

1. Cease and desist in engaging in the conduct alleged and pay a penalty in the amount of **$225.00** (to be paid upon signing of this certification).

2. Send a **Letter of Corrective Action**, as requested by the Board, with this certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents.

☑ I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before the rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the certifications are public documents.

☐ I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.

(Signature)

Dated: 3/31/04

JOHN MARZOCCA
(Print Name)

Ref: John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Amersham Health
1 Naylpn Place
Livingston New Jersey 07039

March 31, 2004

Joanne Boyer
Executive Director
Division of Consumer Affairs
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Ms. Boyer:

We are in receipt of your letter dated 8 March 2004 concerning the alleged deficiencies sited during an inspection of our Livingston, New Jersey facility conducted 19 December 2003. T he alleged deficiencies as stated in your letter are listed below for ease of reference:

N.J.A.C.13:39-12.4(c)
Missing a current edition of a text in the category of "General Practice of Pharmacy".

We at Amersham Health believe that in the spirit of, and pursuant to, New Jersey State Board of Pharmacy Regulations, current texts via computer access, pertaining to the General Practice of Pharmacy meet these requirements of N.J.A.C.13:39-12.4(c). The two texts are USP/NF via internet access, and Pass Assured, a computer text used by our pharmacy technicians to prepare for the PTCB certification test. This computer text covers the following items in the general practice of pharmacy:

Pharmacy Law
Terminology
Calculations
Metric Conversions
Dosage Forms
Aseptic Techniques
Pharmacy Operations
Third Party Reimbursements.

The above notwithstanding, Amersham Health has also purchased a current edition of Remington's "The Science and Practice of Pharmacy" on 11 March 2004.

N.J.A.C.13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.

Amersham Health was unable to locate the definition of chemical form within New Jersey Board of Pharmacy Regulations so we reverted to the DOT interpretation. The Chemical form of a radioactive drug is required on all DOT Bills-of-Lading for radioactive deliveries and is addressed by the U.S D.O.T. under 49 CFR 172.203, and is defined as "a generic chemical description is acceptable for chemical form". Under these conditions Amersham Health can only interpret "chemical form" in NJAC 13:39-12.2(e) to be the name of the radiopharmaceutical drug. Attachment 1 contains an actual prescription label listing the name of the radionuclide (i.e., Tc-99m, In-111, etc...) along with the actual generic chemical (radiopharmaceutical/brand) name of the drug (i.e., Myoview, MAA, MDP, etc...). Amersham Health believes that if one interpreted "chemical form", as "inorganic salt", then all radioactive prescriptions have the potential of being "mislabeled". For example, Tc99mMyoview, Tc99mMDP, Tc99mMag 3, and Tc99mDTPA are "different" radiopharmaceutical drugs used to diagnose different organs within the body. Following the current board of pharmacy labeling

guidelines, and interpreting chemical form as inorganic salt, then all five prescription labels would read "Tc99m Inorganic Salt". The actual drug(brand) name would not have to appear on the label pursuant to regulation, which would cause all five prescriptions to be identical which in turn could be described as "mislabeled". Therefore the only way to assure that a radioactive prescription is not "mislabeled" is to interpret chemical form to be the name of the radiopharmaceutical. The name of the radiopharmaceutical currently appears on all Amersham Health prescriptions.

Based on this understanding Amersham Health respectfully requests that the both "deficiencies" be rescinded, and would like to request an informal meeting to discuss the matter with the board.

If you have any questions or require any additional information, please contact me at (973) 533-9109, or Richard Hughes, Corporate Radiation Safety Officer at (609) 514-6647.

Sincerely,

John Marzocca R.Ph
Pharmacist in charge

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-011
[redacted]
Nuclear Medicine

Order #2450929 Date 03/31/04

Tc-99m MAA
4.0000 mCi
0.5234 ml
9:30 On 03/31/04 Calibration Time

ADDRESS: 600 RIVER AVE., LAKEWOOD, NJ, 087
DOCTOR: Patel, Bharat
PATIENT: Per Physician's Order
PROCEDURE: Pulmonary Perfusion

ACT DISP: 4.0000 mCi 148.0000 MBq (+/- 10%)
LOT NO. 35-03/31/04 RX-2416608
ASSAY: 7.6423 mCi/ml MFGR: In-House Prep
EXP TIME: 15:05 EXP DATE: 03/31/04
LIC. NO. 29-14017-01 P.O. NO.: SO3000184
PIC: John Marzocca, R.Ph.

SPECIAL INSTRUCTIONS:
Mo-99 content < 0.15 uCi/mCi at expiration time Agitate Syringe Prior to Injection – Don't Use if Particles Visible.

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-015
[redacted]
Nuclear Medicine

Order #2447823 Date 03/31/04

Tc-99m MDP
25.0000 mCi
0.8236 ml
10:00 On 03/31/04 Calibration Time

ADDRESS: 495 NORTH 13TH STREET, NEWARK,
DOCTOR: Freyne,J
PATIENT: Per Physician's Order
PROCEDURE: Skeletal Imaging

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 18-03/31/04 RX-2413566
ASSAY: 30.3545 mCi/ml MFGR: In-House Prep
EXP TIME: 13:35 EXP DATE: 03/31/04
LIC. NO.: 29-07213-03 P.O. NO: C-0382
PIC: John Marzocca, R.Ph.

SPECIAL INSTRUCTIONS:
Mo-99 content < 0.15 uCi/mCi at expiration time Hydrate Patient Prior to Imaging.

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-015
[redacted]
Nuclear Medicine

Order #2450742 Date 03/31/04

Tc-99m DTPA
25.0000 mCi
0.8970 ml
14:00 On 03/31/04 Calibration Time

ADDRESS: 495 NORTH 13TH STREET, NEWARK,
DOCTOR: Freyne,J
PATIENT: Per Physician's Order
PROCEDURE: Renal Imaging

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 30-03/31/04 RX-2416421
ASSAY: 27.8707 mCi/ml MFGR: In-House Prep
EXP TIME: 20:35 EXP DATE: 03/31/04
LIC. NO.: 29-07213-03 P.O. NO.
PIC: John Marzocca, R.Ph.

SPECIAL INSTRUCTIONS
Mo-99 content < 0.15 uCi/mCi at expiration time

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-296
[redacted]
18

Order #2448221 Date 03/31/04

Tc-99m Myoview
25.0000 mCi
0.7774 ml
13:30 On 03/31/04 Calibration Time

ADDRESS: 585 NEW BRUNSWICK AVE, FORDS,
DOCTOR: SODHI,A
PATIENT: Per Physician's Order
PROCEDURE: Myocardial Perfusion

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 99-03/31/04 RX-2413964
ASSAY: 32.1585 mCi/ml MFGR: In-House Prep
EXP TIME: 20:05 EXP DATE: 03/31/04
LIC. NO.: 29-30100-01 P.O. NO.:
PIC: John Marzocca, R.Ph.

SPECIAL INSTRUCTIONS
Mo-99 content < 0.15 uCi/mCi at expiration time

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. MCGREEVEY
Governor

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

July 22, 2004

John Marzocca, RPIC GE
Amersham Health Nuclear 4463
1 Naylon Place
Livingston NJ 07039

RE: Inspection Report #8-1066.6

Dear Mr. Marzocca:

The Board reviewed your letter of March 31, 2004 in which you offered mitigation concerning the above referenced Inspection Report.

It was the decision of the Board at the May 26, 2004 meeting, to mitigate the following violation(s):

N.J.A.C.13:39-12.2(e) for $25.00 and deny the mitigation for N.J.A.C.13:39-12.4(c)for $200.00

Please submit the remaining balance in the amount of $200.00 along with a letter of corrective action.

Yours truly,

Joanne Boyer

Joanne Boyer, RPh
Executive Director

JB/sm

YHM-2017-03364

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

CHRISTOPHER S. PORRINO
Attorney General

STEVE C. LEE
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 19, 2017

John Marzocca, RPIC
Med-Physics, Inc., d/b/a GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039

Re: Inspection #8-1066-16-X
Date of Inspection: August 10, 2016

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

PAY A PENALTY IN THE AMOUNT OF $5,500.00 and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a reinspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the reinspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit

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determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification MUST be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____

Anthony Rubinaccio, RPh
Executive Director

AR/rh
(1/17)

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CERTIFICATION

I, JOHN MARZOCCA, hereby acknowledge that I have read and reviewed the Board's letter dated May 19, 2017 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[✓] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $5,500.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action,** as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[ ] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

(Signature)

Dated: 6/12/17

JOHN MARZOCCA
(Print Name)

Ref: John Marzocca, RPIC
Med-Physics, Inc., d/b/a GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
(28RS00446300)
Inspection #8-1066-16-X

AR/rh
(1/17)

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ATTACHMENT A

36. **Med-Physics, Inc., d/b/a GE Healthcare** - 1 Naylon Place, Livingston, New Jersey 07039
Pharmacist-In-Charge: John Marzocca
Bureau File #8-1066-16-X, **Period:** 8/10/16
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18, N.J.S.A.45:14-48(a)11&12 and a request from the Board to inspect all pharmacies that engage in compounding sterile preparations.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11.24(a)6	Adequate efforts were not made to ensure the pharmacy's quality assurance program. Specifically, on June 17, 2015, the pharmacy's internal surface sampling detected a total of twenty-two (22) Colony Forming Units (CFUs) from various locations, including support table used in sterile compounding, the prep room and the pass through. On January 11, 2016, internal surface sampling detected one (1) CFU from the ISO 5 hood, one (1) CFU from Tech Hood 2 and one (1) CFU from Biologic Safety Cabinet (BSC) 6. Sixty-nine (69) CFUs were detected at various testing sites, including support tables, support cars and the dispensing room. On June 27, 2016, according to the pharmacy's internal surface sampling, four (4) CFUs were detected at BSC support table 1, four (4) CFUs were detected at BSC support table 6, one (1) CFU at cart 2 and three (3) CFUs at a general support table. Additionally, a total of twenty-one (21) CFUs were found in the gowning room. On all of these occasions, the pharmacy failed to analyze the species to the genus level in order to exclude the possibility of the existence of highly pathogenic species. By reviewing the cleaning log for the month of June 2016, the pharmacy failed to specify the details of cleaning in the event of CFU detection.	**$3,000.00**

N.J.A.C.13:39-11.24(a)10	When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards. Specifically, on September 28, 2015, during the environmental monitoring tsts conducted by ENV Services, a laboratory equipment certification company, air sampling detected multiple CFUs in the dispensing room, the gowning room, the prep room, the White Blood Cell (WBC) anteroom and the WBC prep room. The nature of the CFUs detected in these areas was deemed non-highly pathogenic. The quantities of CFUs were below action level. Air Sample number 10 detected one (1) CFU in the center of the WBC Room and the species was identified as fungal in nature. This finding was deemed as Out-of-Compliance (OOC). On the following day, September 29, 2015, ENV Services detected one (1) CFU in the dispensing room, classified as ISO Class 7. The species was identified as fungal in nature. This finding was again deemed as OOC. John Marzocca, RPIC acknowledged that upon learning the test results on October 9, 2015, the pharmacy failed to cease using the affected equipment. The cleaning log for the month of October 2015 failed to indicate that the pharmacy performed triple cleaning in order to address these findings. On October 19, 2016, during a follow-up visit by Inv. Qi to the pharmacy, Mr. Marzocca stated that during the most recent environmental monitoring test performed by ENV Services, the maximum CFU count for two (2) ISO classified areas was exceeded. Air sampling detected one (1) CFU of genus in fungi nature from one of the BSC units, ISO Class 5, as well as thirteen (13) CFUs from one of the support tables. The CFUs detected were a highly pathogenic species. Mr. Marzocca stated that the pharmacy followed the N.J.A.C. regulation this time and ceased using the affected equipment.	**$2,500.00**

	Daily and weekly cleaning procedures were reviewed in detail. Upon review, it appeared that the pharmacy updated the cleaning frequency, cleaning methods and cleaning materials since my August 2016 visit.	
TOTAL: $5,500.00		

2/17

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

June 12, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated May 19, 2017 concerning inspection #8-1066-16-X, please find the enclosed signed certification letter with a check for $5500. Below are the corrective actions:

1. Contact plate surface samples are currently conducted in-house biannually. Any microbial recovery will be analyzed by an independent third party company, such as Nelson Labs 6280 South Redwood Road, Salt Lake City Utah. This is in addition to our cleanroom certification company (ENV) collecting and analyzing environmental air and surface samples biannually and identifying all recovered microbes to the genus level.
2. In 2016, we and our third-party certification vendor (ENV) enacted more stringent garbing, cleaning, and clean room entry procedures. Prior to these new protocols ENV would wheel in testing equipment from the street into our clean room without thoroughly cleaning the equipment and transportation carts. ENV now requires and supplies their technicians with clean room coveralls to wear during certification procedures. ENV technicians also thoroughly clean their testing equipment which is properly maintained for clean room entry and transfer all necessary equipment to GE clean room carts prior to certification testing.
3. In 2016 we have also changed our protocols to a more aggressive daily "cleaning and disinfection" of our primary and secondary engineering controls. We now use germicidal cleaning and disinfecting agents daily in addition to using sterile 70% isopropyl alcohol in the primary engineering controls. Prior to this change we used germicidal agents weekly and 70% isopropyl alcohol daily. We have also started a rotation of a sporicidal agent in our cleaning and disinfecting procedures.

If you have any questions, please do not hesitate to contact me at 973-533 9109

Sincerely,

John Marzocca R.Ph

APR 0 4 2017

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated march 9, 2017 concerning the observations identified during an inspection of our Livingston New Jersey Nuclear Pharmacy conducted August 10, 2016. The observations stated in your letter are listed below for ease of reference:

[N.J.A.C.13:39-1124(a)6]- Adequate efforts were not made to ensure the pharmacy's quality assurance program.

Although this regulation does not make any reference to internal sampling to be analyzed for species to the genus to exclude the possibility of the existence of highly pathogenic species, Medi-Physics, Inc. d/b/a/ GE Healthcare Livingston NJ, has added this to our environmental monitoring protocols. Contact plate samples incubated on site which show organism growth will be analyzed by an independent certified third party laboratory for ID'ing to genus level. Additionally, our cleanroom certification company (ENV) shall continue to take environmental samples for air and surface contamination biannually during re-certification procedures. All growth recovered from third party vendor sampling shall also be ID'd to genus level.

[N.J.A.C.13:39-24(a)10]-When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the primary engineering controls or cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

The Livingston Pharmacy did not take action to immediately cease using secondary engineering controls on September 28, 2015, as a result of the environmental monitoring tests, due to the fact the we were unaware of this requirement per 13:39-24(a)10 until the **January 2016** New Jersey Board of Pharmacy newsletter article titled- Regulation Regarding Out-of-Compliance Cleanrooms and Primary Engineering. Our Standard Operating Procedures, at the time required us to immediately deep clean the area of concern, perform an investigation to determine action necessary to eliminate recurrence of the contamination, and retest prior to reuse. After further review of the information in that newsletter, the Livingston Pharmacy is in the process of updated

General Electric Company

protocols to include 13:39-24(a)10. At this time, we are in compliance with this regulation as evidenced by our SOP's as well as Mr. Qi's follow up visit on October 19, 2016 stating that ENV services monitoring found a maximum CFU count exceeded in a BSC hood which was taken out of service until an EVN re-test was performed.

If you any questions or require any additional information, please contact me at (973) 533-9009.

Sincerely,

John Marzocca R.Ph

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

CHRISTOPHER S. PORRINO
Acting Attorney General

STEVE C. LEE
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

March 9 , 2017

Medi-Physics, Inc. dba GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
Attn: Jon Marzocca, RPIC

RE: Inspection Report #8-1066-16X for the period:08/10/2016

Dear Mr. Marzocca:

The New Jersey Board of Pharmacy (the "Board") has received the above mentioned inspection report, a copy of which is included with this letter, and has requested that you respond to the following items within **ten (10) days** of receipt of this letter:

1) Please provide a detailed response to the inspector's observations and any "areas of concern" noted for each citation in the "Report of Inspection" on pages #1 through #5. Your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

2) Please provide a detailed response for each citation and any "areas of concern" noted on page #1 of "Exhibit #15". You do not need to respond to items a second time, if you addressed a citation as part of your response to the "Report of Inspection" section. Again, your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

Feel free to include any additional supporting documentation you feel the Board should consider when reviewing your response. The Board will review this report and your response to this letter at the next available Board meeting.

Failure to respond and provide this information within ten (10) days from receipt of this letter will constitute a failure of a duty to cooperate pursuant to N.J.A.C. 13:45C-1.3 and may result in disciplinary action by the Board, including suspension of your permit to operate a pharmacy and/or to engage in sterile compounding.

Sincerely,

Anthony Rubinaccio, RPh
Executive Director
New Jersey Board of Pharmacy

5620

MEDI physics

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

Please see the enclosed Biological Sampling Report that was requested with regards to inspection report #8-1066-16-X. Should you have any questions please do not hesitate to contact me at 973- 533 9109.

Sincerely

John Marzocca R.Ph

MAY 24 2017

General Electric Company

2880 Bergey Road, Ste. K
Hatfield, PA 19440
www.envservices.com
800 - 345 - 6094

Presents:

Biological Sampling Report

Control ID #: 802-136385-2114V

Prepared for:

GE HEALTHCARE - LIVINGSTON
ONE NAYLON PLACE
LIVINGSTON, NJ 07039

CLEANROOM

Attention:

MIKE AGNELLO
1-973-533-9109
MICHAEL.AGNELLO@GE.COM

Date(s) Tested:

21 MARCH 2017

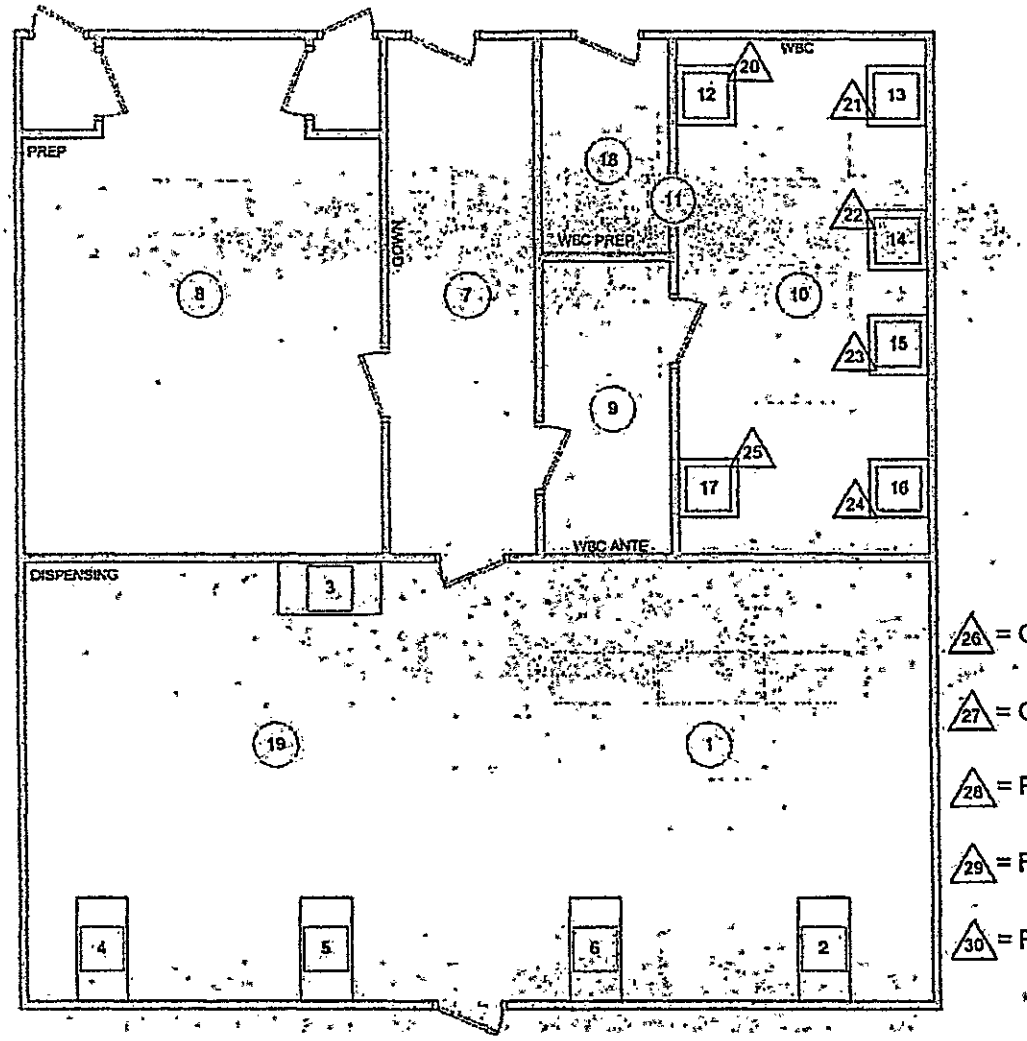
Field Service Technician(s):

JONATHAN STETTLER

BIOLOGICAL SAMPLING LOCATIONS

OPERATIONAL / DYNAMIC

CLEANROOM



Simple Location Key

- Air and Surface, Bacteria and Fungal
- Surface Only, Bacteria and Fungal
- Air Only, Bacteria and Fungal

MAY 24 2017

Test Result
For Reference Only

ENV SERVICES, Inc. PROVIDING NATIONWIDE SOLUTIONS, CERTIFICATION, CALIBRATION, VALIDATION, CLEANROOMS	Project: GE HEALTHCARE - LIVINGSTON ONE NAYLON PLACE LIVINGSTON, NJ 07039
	Control ID #: 802-136385-2114V

TEST EQUIPMENT

GE HEALTHCARE - LIVINGSTON
LIVINGSTON, NJ 07039
CLEANROOM

Equipment Name	Manufacturer	Model	Serial	Calibration Due Date
AIR SAMPLER	PBI	SAS SUPER 360	16-D-11262	21 NOV 17

Test equipment calibration certificates available upon request.
Company ID: NJ0795-024 Unique ID: 350931

RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

USP <797>Viable Sample Report

Client Project ID:

802-136385 NJ0795-024 GE LIVNGSTON

Reported To:

Client Name: ENV Services, Inc.
Client Address: 2880 Bergey Rd, Suite K
City, State, Zip: Hatfield, PA 19940
Attn: REPORTS DEPT
Sample(s) Condition: Acceptable

Sampling Date: 03/21/2017
Date Received: 03/22/2017
Final Analyzation: 03/27/2017
Report Generation: 03/27/2017
Job ID: 17032214

Failed Sample Summary

COC No.	Location of Sample	Test Method	ISO Class	Result (Total CFUs)	Comments

* Microorganisms above the action levels per USP <797> or CAG-009-00 or deemed highly pathogenic.

Overall Comments: Growth Found On Client Samples

USP <797> Recommended Action Levels for Microbial Contamination

ISO Class	Particulate Size ($0.5m/m^3$)	Air (400-1000L) (CFU/m^3/plate)	Surface CFU/Plate	Post Media-Fill Gloved Fingertip (CFU/plate, combined hands, all risk levels)	Gloved Fingertip (CFU/plate, combined hands, all risk levels)	Media-Fill Test
5	3,520	>1	>3	>3	0	+ or -
7	352,000	>10	>5	N/A	N/A	N/A
8 or worse	3,520,000	>100	>100	N/A	N/A	N/A

Approved By:

Jerritt Nunneley, M.S., CNBT
Laboratory Director

Approved Date: 03/27/2017

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

Pass: Less than the limit of detection.

Acceptable: Microorganisms under the action levels per USP <797> or CAG-009-00.

Fail: Microorganisms above the action levels per USP <797> or CAG-009-00 or deemed highly pathogenic.

Unclassified: (non-HEPA filtered area).

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
1	Accept	1 (CFU/m³)	7	DISPENSING ROOM	BACTERIA - AIR USP	1000 (L)	17032214.01	1
				Raw CFU	CFU/m³		Origin	
Micrococcus luteus				1	1		Human	

Comments :

1	[redacted]	No Growth (CFU/m³)	7	DISPENSING ROOM	FUNGAL - AIR USP	1000 (L)	17032214.02	1

Comments :

2	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012084	BACTERIA - AIR USP	1000 (L)	17032214.03	1

Comments :

2	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012084	FUNGAL - AIR USP	1000 (L)	17032214.04	1

Comments :

2	[redacted]	No Growth (25cm²)	5	LFU S/N:20012084	BACTERIA - SURFACE USP	25cm²	17032214.05	1

Comments :

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
3	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012083	BACTERIA - AIR USP	1000 (L)	17032214.06	1

Comments :

3	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012083	FUNGAL - AIR USP	1000 (L)	17032214.07	1

Comments :

3	[redacted]	No Growth (25cm²)	5	LFU S/N:20012083	BACTERIA - SURFACE USP	25cm²	17032214.08	1

Comments :

4	[redacted]	No Growth (CFU/m³)	5	LFU S/N:206000075	BACTERIA - AIR USP	1000 (L)	17032214.09	1

Comments :

4	[redacted]	No Growth (CFU/m³)	5	LFU S/N:206000075	FUNGAL - AIR USP	1000 (L)	17032214.10	1

Comments :

4	[redacted]	No Growth (25cm²)	5	LFU S/N:206000075	BACTERIA - SURFACE USP	25cm²	17032214.11	1

Comments :

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
5	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012082	BACTERIA - AIR USP	1000 (L)	17032214.12	1

Comments :

5	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012082	FUNGAL - AIR USP	1000 (L)	17032214.13	1

Comments :

5	[redacted]	No Growth (25cm²)	5	LFU S/N:20012082	BACTERIA - SURFACE USP	25cm²	17032214.14	1

Comments :

6	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20207024	BACTERIA - AIR USP	1000 (L)	17032214.15	1

Comments :

6	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20207024	FUNGAL - AIR USP	1000 (L)	17032214.16	1

Comments :

6	[redacted]	No Growth (25cm²)	5	LFU S/N:20207024	BACTERIA - SURFACE USP	25cm²	17032214.17	1

Comments :

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
7	[redacted]	No Growth (CFU/m³)	8	GOWN ROOM	BACTERIA - AIR USP	1000 (L)	17032214.18	1

Comments :

8	[redacted]	No Growth (CFU/m³)	8	PREP ROOM	BACTERIA - AIR USP	1000 (L)	17032214.19	1

Comments :

9	Accept	2 (CFU/m³)	7	WBC ANTE ROOM	BACTERIA - AIR USP	1000 (L)	17032214.20	1

	Raw CFU	CFU/m³	Origin
Staphylococcus epidermidis	2	2	Human

Comments :

10	[redacted]	No Growth (CFU/m³)	7	CENTER OF WBC ROOM	BACTERIA - AIR USP	1000 (L)	17032214.21	1

Comments :

10	[redacted]	No Growth (CFU/m³)	7	CENTER OF WBC ROOM	FUNGAL - AIR USP	1000 (L)	17032214.22	1

Comments :

11	[redacted]	No Growth (CFU/m³)	7	HEPA PASS THRU	BACTERIA - AIR USP	1000 (L)	17032214.23	1

Comments :

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
12	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10052	BACTERIA - AIR USP	1000 (L)	17032214.24	1

Comments :

12	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10052	FUNGAL - AIR USP	1000 (L)	17032214.25	1

Comments :

12	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10052	BACTERIA - SURFACE USP	25cm²	17032214.26	1

Comments :

13	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10053	BACTERIA - AIR USP	1000 (L)	17032214.27	1

Comments :

13	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10053	FUNGAL - AIR USP	1000 (L)	17032214.28	1

Comments :

13	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10053	BACTERIA - SURFACE USP	25cm²	17032214.29	1

Comments :

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc.

Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON

Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
14	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10054	BACTERIA - AIR USP	1000 (L)	17032214.30	1

Comments :

14	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10054	FUNGAL - AIR USP	1000 (L)	17032214.31	1

Comments :

14	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10054	BACTERIA - SURFACE USP	25cm²	17032214.32	1

Comments :

15	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10384	BACTERIA - AIR USP	1000 (L)	17032214.33	1

Comments :

15	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10384	FUNGAL - AIR USP	1000 (L)	17032214.34	1

Comments :

15	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10384	BACTERIA - SURFACE USP	25cm²	17032214.35	1

Comments :

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 I Toll: (877) 659-4353 I Fax: (844) 849-5313 I www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
16	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10055	BACTERIA - AIR USP	1000 (L)	17032214.36	1

Comments :

16	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10055	FUNGAL - AIR USP	1000 (L)	17032214.37	1

Comments :

16	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10055	BACTERIA - SURFACE USP	25cm²	17032214.38	1

Comments :

17	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10619	BACTERIA - AIR USP	1000 (L)	17032214.39	1

Comments :

17	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10619	FUNGAL - AIR USP	1000 (L)	17032214.40	1

Comments :

17	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10619	BACTERIA - SURFACE USP	25cm²	17032214.41	1

Comments :

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12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
18	Accept.	1 (CFU/m³)	8	WBC PREP ROOM	BACTERIA - AIR USP	1000 (L)	17032214.42	1

	Raw CFU	CFU/m³	Origin
Staphylococcus epidermidis	1	1	Human

Comments :

19	[redacted]	No Growth (CFU/m³)	7	DISPENSING ROOM #2	BACTERIA - AIR USP	1000 (L)	17032214.43	1

Comments :

20	[redacted]	No Growth (25cm²)	7	2515CH10052 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.44	1

Comments :

21	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10053 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.45	1

Comments :

22	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10054 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.46	1

Comments :

23	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10384 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.47	1

Comments :

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
24	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10055 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.48	1

Comments :

25	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10619 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.49	1

Comments :

26	[redacted]	No Growth (25cm²)	7	GENERATOR LID HANDLE	BACTERIA - SURFACE USP	25cm²	17032214.50	1

Comments :

27	[redacted]	No Growth (25cm²)	7	GENERATOR SUPPORT TABLE	BACTERIA - SURFACE USP	25cm²	17032214.51	1

Comments :

28	[redacted]	No Growth (25cm²)	7	PHARMACISTS COMPOUNDING TABLE	BACTERIA - SURFACE USP	25cm²	17032214.52	1

Comments :

29	Accept.	1 (25cm²)	7	RANDOM CART	BACTERIA - SURFACE USP	25cm²	17032214.53	1

	Raw CFU	CFU/25cm²	Origin
Bacillus infantis	1	1	Environment

Comments :

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RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
30	[redacted]	No Growth (25cm²)	7	RANDOM CART	BACTERIA - SURFACE USP	25cm²	17032214.54	1

Comments :

	[redacted]	Growth (CFU/m³)	N/A	(+) Controls	(+) BACTERIA CNTL- AIR/SURF. USP	0 (L)	17032214.55	1

Comments :

	[redacted]	Growth (CFU/m³)	N/A	(+) Controls	(+) FUNGAL CNTL - AIR/SURF. USP	0 (L)	17032214.56	1

Comments :

	[redacted]	No Growth (CFU/m³)	N/A	(-) Controls	(-) BACTERIA CNTL- AIR/SURF. USP	0 (L)	17032214.57	1

Comments :

	[redacted]	No Growth (CFU/m³)	N/A	(-) Controls	(-) FUNGAL CNTL - AIR/SURF. USP	0 (L)	17032214.58	1

Comments :

Control Media

Test	Type	Media	Manufacturer	Lot#	Exp. Date
(+) BACTERIA CNTL	AIR/SURF.	TSA	Remel	990985	05/08/2017
(-) BACTERIA CNTL	AIR/SURF.	TSA	Remel	990985	05/08/2017
(+) FUNGAL CNTL	AIR/SURF.	SabDex	Remel	993957	04/13/2017
(-) FUNGAL CNTL	AIR/SURF.	SabDex	Remel	993957	04/13/2017

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

GLOSSARY

OrganismName	Description
Bacillus infantis	
Micrococcus luteus	Can be found in many places such as the human skin, water, dust, and soil. Generally thought of as harmless bacterium, but there have been rare cases of Micrococcus infections in people with compromised immune systems.
Staphylococcus epidermidis	A coagulase-negative Staphylococcus that is part of the normal human flora, typically the skin flora, and less commonly the mucosal flora. Although S. epidermidis is not usually pathogenic, patients with compromised immune systems are at risk of developing infection. These infections are generally hospital-acquired. S. epidermidis is a particular concern for people with catheters or other surgical implants because it is known to form biofilms that grow on these devices.

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Client Name: ENV Services, Inc. Job ID: 17032214
Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

USP <797>Supplemental Information

1. Growth Media
   - 1.1. A general microbiological growth medium such as Soybean-Casein Digest Medium (also known as Trypticase Soy Broth (TSB) or agar (TSA) shall be used to support the growth of bacteria.
   - 1.2. Malt Extract Agar (MEA) or suitable substitute shall be used to support the growth of fungi.
   - 1.3. Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with Lethicin and Polysorbate 80).
   - 1.4. Incubate inverted bacterial media for 2-3 days at 33-37°C and fungal for 5-7 days at 26-30°C.

2. Viable Sampling
   - 2.1. Air:
     - 2.1.1. Shall be performed dynamically at least semiannually (i.e. every 6 months) in ALL ISO Class environments.
     - 2.1.2. Impact shall be the preferred method volumetric sampling, settling plates are not sufficient.
     - 2.1.3. 400-1000 litersof air shall be tested at each location and reported as CFU/m³ of air.
   - 2.2. Surface:
     - 2.2.1. Shall be performed dynamically in ALL ISO classified areas on a periodic basis (contact plates and/or swabs) and shall be done at the conclusion of compounding.
     - 2.2.2. Results are reported as CFU per sampled unit area.

3. Gloved Fingertip Testing
   - 3.1. Shall be performed for all CSP risk level compounding.
   - 3.2. Immediately after gowning, the evaluator shall collect a gloved fingertip and thumb sample from both hands on a general microbiological media (TSA).
   - 3.3. Initial gloved fingertip/thumb sampling procedure requires (0 CFU) no less than 3 times before initially being allowed to compound CSPs for human use.
   - 3.4. Re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semiannually for high-risk.
   - 3.5. CFU action level shall be based on the total number of CFU on both gloves and not per hand.
   - 3.6. Should be reported separately as number of CFU per employee per hand (left hand, right hand).

4. Media-Fill Testing
   - 4.1. Shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semiannually for high-risk.
   - 4.2. Shall be evaluated using sterile fluid bacterial (TSA) culture media-fill verification.
   - 4.3. Media-filled vials shall be incubated with a range of 33-37° C for 14 days.

5. Reporting Information
   - 5.1. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, and yeasts) must be immediately remedied, regardless of CFU count. Any CFU count that exceeds its respective action level shall have an investigation into the source of contamination, shall be eliminated, the affected area cleaned, and resampling performed.
   - 5.2. Positive controls are unopened samples submitted for growth promotion testing (inoculation) which eliminates false negatives. Negative controls are unopenedsamples submitted for incubation solely which eliminates false positives.
     - 5.2.1. There should be a positive and negative control for each lot number of every media type used.
   - 5.3. MRL is the minimum reporting limit for a sample.
   - 5.4. Results found in this report are solely tied to the project above and the samples therein.

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California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 14, 2024

DATED MATERIAL ENCLOSED

RLS USA INC
ATTN: WERNER GRUNER, PRS
1283 MOUNTAIN VIEW ALVISO RD STE A-B
SUNNYVALE, CA 94089

RE: CI 2023 103137
RLS USA INC
PHY 57865

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- February 28, 2024: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 15, 2024: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Anne Sodergren
EXECUTIVE OFFICER

By:

Joshua Monforte
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than February 28, 2024 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than March 15, 2024 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any enclosed documents please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number **Name, License No**
CI 2023 103137 **RLS USA INC, PHY 57865**

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1751.3 subd. (a)	**Sterile Compounding Policies and Procedures; Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding...**
CCR, Title 16, § 1751.4(a)	**Facility and Equipment Standards for Sterile Compounding; No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations**

CONDUCT:

Failure to follow policies and procedures: CCR 1751.3(a) states in pertinent part, any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. RLS USA Inc. located at 1283 Mountain View, Alviso Rd Ste A-B, Sunnyvale, CA 94089 was not compliant. Specifically, on at least 12/30/22 and 6/26/23 RLS USA Inc. failed to immediately remove its ISO Class 5 PEC from use following air microbial contamination action level exceedance as required in RLS USA Inc.'s Standard Operating Procedure "6.3.1 Certification of ISO Classified Environments." This was a violation of pharmacy law.

Unsafe compounding of sterile drug preparations: CCR 1751.4(a) states, no sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations. RLS USA Inc. located at 1283 Mountain View, Alviso Rd Ste A-B, Sunnyvale, CA 94089 was not compliant. Between at least 12/30/22 and 1/11/23, and between at least 6/26/23 and 7/14/23, RLS USA Inc. compounded sterile preparations in a laminar flow work bench which was identified as having microbial growth exceeding the action level defined in the pharmacy's written policies and procedures. This was a violation of pharmacy law.

CITATION ISSUED ON: February 14, 2024

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number **Name, License No**
CI 2023 103137 **RLS USA INC, PHY 57865**

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CITATION ISSUED ON: February 14, 2024

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: RLS USA INC

License No: PHY 57865

Citation Number : CI 2023 103137

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check I contest the Citation and request an Office Conference.

Check One:

I contest the entire Citation or

specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name:

Signature: Dated:

Address of Service:

City: State: Zip:

Daytime Number: ( ) Email Address: ( )

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:
RLS USA INC
PHY 57865

Respondent

Citation Case No : CI 2023 103137
NOTICE OF APPEAL
(Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATE

(Respondent)

Mailing Address of Respondent:

(Street Address)

(City (State) (Zip) ( ) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name

(Street Address)

(City (State) (Zip) ( ) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: RLS USA INC, PHY 57865
Citation and Fine CI 2023 103137

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On February 14, 2024, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
RLS USA INC ATTN: WERNER GRUNER, PRS 1283 MOUNTAIN VIEW ALVISO RD STE A-B SUNNYVALE, CA 94089	7019 2970 0002 2051 5965

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 14, 2024, at Sacramento, California.

DECLARANT
Joshua Monforte
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

October 11, 2024

DATED MATERIAL ENCLOSED

RLS USA INC
ATTN: MANNON BANKSON, COO
16259 STAGG ST STE A
VAN NUYS, CA 91406

RE: CI 2024 105586
RLS USA INC
PHY 57866

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

- November 10, 2024: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 25, 2024: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 10, 2024: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 10, 2024.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 25, 2024 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 10, 2024 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2024 105586	RLS USA INC, PHY 57866

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4113(F)	Pharmacist-in-Charge: Notification to Board; if a pharmacy is unable, in the exercise of a reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer or administrator of the pharmacy...	$500.00
Bus. & Prof. Code § 4305 subd. (b)	Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	$1,000.00

CONDUCT:

Business and Professions Code section 4113(f) requires a licensee to, when unable to identify a permanent pharmacist-in-charge within 30 days of the date when a pharmacist-in-charge (PIC) ceases to act, provide the name of a pharmacist, owner, or manager to act as an interim pharmacist-in-charge for a period not to exceed 120 days. Specifically, on March 13, 2024, the Board received an Application for Change of Pharmacist-In-Charge from RLS USA Inc, which had been signed under penalty of perjury by a corporate officer, the disassociated PIC, and the newly designated PIC. The form indicated that the prior interim PIC, Anahita Malekakhlagh (RPH 73484), had disassociated on March 11, 2024 and that Scott Hudek (RPH 49826) took over as the permanent PIC on the same date. However, Anahita Malekakhlagh's (RPH 73484) interim period, which had begun on August 25, 2023, had previously expired on December 22, 2023. Anahita Malekakhlagh (RPH 73484) acted as the interim PIC from August 25, 2023 to March 11, 2024, 199 days.

Business and Professions Code section 4305(b) authorizes the Board to take disciplinary action against a licensee for operation of a pharmacy for more than 30 days without the supervision or management of a pharmacist-in-charge (PIC). Specifically, on March 13, 2024, the Board received an Application for Change of Pharmacist-In-Charge from RLS USA Inc, which had been signed under penalty of perjury by a corporate officer, the disassociated PIC, and the newly designated PIC. The application declared that Scott Hudek (RPH 49826) had taken over as the permanent PIC on March 11, 2024. However, as RLS USA Inc failed to pay their Application for Change of Pharmacist-In-Charge's application fee until July 11, 2024, the Board was unable to approve Scott Hudek (RPH 49826) as the permanent PIC until July 11, 2024. RLS USA Inc operated without a Board approved PIC from March 11, 2024 through July 10, 2024, 121 days.

CITATION ISSUED ON: October 11, 2024	TOTAL AMOUNT OF FINE(S): $1,500.00

PAYMENT OF FINE(S) DUE BY: November 10, 2024

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application
Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Las Vegas Radiopharmacy, Inc.
Pharmacy/Wholesaler License # (if applicable): PH02453
Physical Address: 1771 E Flamingo Rd., #A121
City: Las Vegas State: NV Zip: 89119
Mailing Address (if different from physical address): Same as physical address
City: State: Zip:
Telephone: 702-476-8600 Website: https://rls.bio/
Licensing Company Email: licensing@rls.bio

Section 2: Personal Information

First: Christopher Middle: Glen Last: Southwick
Alias(es, nicknames, name changes, etc.):
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☒ M ☐ F ☐ X
Mailing Address: [redacted]
City: Las Vegas State: [redacted] Zip: [redacted]
Telephone: [redacted] Email: [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name	From - To (MM/YY – MM/YY)
University of Utah college of Pharmacy	9/1990 – 6/1993
Address	**City** / **State** / **Zip**
30 2000 E	Salt Lake City / UT / 84112
Diploma/Degree obtained, if any	
BS Pharmacy	

School Name	From - To (MM/YY – MM/YY)
University of Utah	9/86 – 6/1990
Address	**City** / **State** / **Zip**
201 Presidents Cir	Salt Lake City / UT / 84112
Diploma/Degree obtained, if any	
N/A	

School Name	From - To (MM/YY – MM/YY)
Alta High School	9/82 – 6/86
Address	**City** / **State** / **Zip**
11055 S. 1000 E	Sandy / UT / 84094
Diploma/Degree obtained, if any	

School Name	From - To (MM/YY – MM/YY)
Address	**City** / **State** / **Zip**
Diploma/Degree obtained, if any	

School Name	From - To (MM/YY – MM/YY)
Address	**City** / **State** / **Zip**
Diploma/Degree obtained, if any	

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
8/2016 to 4/25	[redacted]			
6/2001 – 8/2016				
From - To (MM/YY – MM/YY)				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name: Advanced Isotopes of Nevada/Las Vegas Radiopharmacy			From - To (MM/YY – MM/YY): 10/2007 to 4/2025
Business Address: 4771 E Flamingo Rd ste A121	City: Las Vegas	State: NV	Zip: 89119
Phone: 702-476-8600	Title: Pharmacy Manager		Number of Employed Hours: ~34,000
Description of Duties: Order & Compound Radiopharmaceuticals, Manage Employees, Ensure compliance to State & Federal laws, Billing, Customer Service, cleaning ect.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)	X	
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?	X	
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	X	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 1. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1985		UT	Salt Lake City	Salt Lake
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Unknown		Sandy Utah Metro police		
Reason/Charge				
Vandalism				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Chris Southwick (minor)			—	
Name of Business/Industry/Entity				
—				

Provide explanation below:

Arrested for vandalism of a school Bus.

Chris G. Southwick

Original Signature (electronic, copies or stamps not accepted)

4/8/25

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 3. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
1985	—	UT	Salt Lake City	Salt Lake
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
Unknown	Sandy Utah Metro Police			
Reason/Charge				
Vandalism				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
Chris Southwick (minor)			N/A	
Name of Business/Industry/Entity				
N/A .				

Provide explanation below:

Juvenile Record expunged @ 17yo.

Chris G. Southwick

Original Signature (electronic, copies or stamps not accepted)

4/8/25

Date

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
3/2014	7/18/2014	NV	Las Vegas	Clark
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
14-017-RPh-S	Nevada Board of Pharmacy			
Reason/Charge				
Allowed Intern to work without a valid Intern License				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
Christopher G Southwick	—			
Name of Business/Industry/Entity				
Advanced Isotopes of Nevada				

Provide explanation below:

Allowed Intern to work for 21 days without a valid Intern License

Chris G. Southwick

Original Signature (electronic, copies or stamps not accepted)

4/8/25

Date

I, Christopher G Southwick, certify that as the designated representative for Las Vegas Radiopharmacy Inc,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. CGS X I am at least 21 years of age;
3. CGS X I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. CGS I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. CGS I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. CGS I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. CGS I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Christopher Southwick
Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/8/25
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher G Southwick

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

4/8/25

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, _____, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

4/8/25

Date

Subscribed and Sworn to before me this 8 day of April, 2025

Notary Public Signature

KAREN PEIST
Notary Public, State of New Jersey
Comm. # 50222459
My Commission Expires 8/5/2029

(Seal)

RLS (USA), Inc. Nevada Resident Pharmacy Application Change of Ownership Officers and Ownership Information		
Name	**Title**	**Percent Ownership**
Telix Pharmaceuticals (US) Inc.	Owner	100%
Darren Patti	Group Chief Operating Officer	0%
Darren Smith	Group Chief Financial Officer	0%
Sarah Robison	Chief Financial Officer - Americas	0%
Oliver Newman	Company Secretary	0%

Darren Patti
Registered Pharmacist Licenses

License Type	License Number	State	Status
Registered Pharmacist	051290696	IL	Active
Registered Pharmacist	2007031818	MO	Active
Registered Pharmacist	5502043469	MI	Active

SECRETARY OF STATE

STATE OF NEVADA

FOREIGN CORPORATION (80) QUALIFICATION

I, FRANCISCO V. AGUILAR, the duly qualified and elected Nevada Secretary of State, do hereby certify that **LAS VEGAS RADIOPHARMACY, INC.** did on **09/10/2024** file in this office its Qualification to do Business in this State and is now on file and of record in the office of the Nevada Secretary of State, and further, that said corporation is at the date of this Certificate duly qualified to exercise therein all the powers recited in its Articles and to transact business in the State of Nevada in accordance with the laws of said State.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/10/2024.

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202409104949793
You may verify this certificate online at [illegible]

SECRETARY OF STATE

STATE OF NEVADA

NEVADA STATE BUSINESS LICENSE

LAS VEGAS RADIOPHARMACY, INC.

Nevada Business Identification # NV20243197775
Expiration Date: 09/30/2025

In accordance with Title 7 of Nevada Revised Statutes, pursuant to proper application duly filed and payment of appropriate prescribed fees, the above named is hereby granted a Nevada State Business License for business activities conducted within the State of Nevada.
Valid until the expiration date listed unless suspended, revoked or cancelled in accordance with the provisions in Nevada Revised Statutes. License is not transferable and is not in lieu of any local business license, permit or registration.
License must be cancelled on or before its expiration date if business activity ceases. Failure to do so will result in late fees or penalties which, by law, cannot be waived.

IN WITNESS WHEREOF, I have hereunto set my hand and affixed the Great Seal of State, at my office on 09/10/2024.

FVAguilar

FRANCISCO V. AGUILAR
Secretary of State

Certificate Number: B202409104949794
You may verify this certificate online at [redacted]

FOIA CONFIDENTIAL TREATMENT REQUESTED/FOIA EXEMPT PURSUANT TO 5 U.S.C. § 552(b)(4)

Pre-Closing Structure



FOIA CONFIDENTIAL TREATMENT REQUESTED/FOIA EXEMPT PURSUANT TO 5 U.S.C. § 552(b)(4)

Post-Closing Structure



NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RLS (USA) Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): _____

Physical Address: 1771 E Flamingo Rd., #A121

City: Las Vegas State: NV Zip: 89119

Mailing Address (if different from physical address): N/A

City: _____ State: _____ Zip: _____

Telephone: 702-476-8600 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 702-750-1367 Contact Email: licensing@rls.bio

Website: https://rls.bio

Nevada Business License # (if applicable) NV20191644357

Supervising/Managing Pharmacist Name (NRS 639.220): Christopher Southwick, RPh

Supervising/Managing Pharmacist NV Pharmacist Registration #: 11480

Name of Designated Person(s) as defined by revised USP-797 guidelines: Christopher Southwick RPh

Email of Designated Person(s): Chrshandu@cox.net

Telephone of Designated Person(s): 702-466-3997

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   [X] Category 1 [ ] Category 2 [ ] Category 3

If you marked "**Category 3**", you must also complete **section 4**.

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? [ ] Yes [ ] No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? Aseptic [ ] Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? we are a Radiopharmacy we follow USP 825 [ ] Yes [X] No

5. When was the most recent certification for the ISO classified areas? 12/5/24

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? [ ] Yes [X] No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? [ ] Yes [ ] No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? every 6 months

10. Will you be performing sterile hazardous drug compounding? [ ] Yes [X] No

If you marked "**Yes**", you must also complete **section 3**.

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Tc^{99m} Radiopharmaceuticals (Sestamibi, Myoview, DTPA, Mag3, Ceretec, MAA, Choletec, PYP, HDP)

Tc^{99m} White Blood Cell Labeling

Ga^{68} Radiopharmaceuticals (PMSA, Illucix)

In^{111} Radiopharmaceuticals (Prostascint, Octreoscan)

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address:

City: State: Zip:

Telephone:

13. What is your procedure for visual inspection of compounded sterile products?

Look at compounded vials against a Black & White Background. compare for correct color and rule out particulate.

14. How often do you perform glove fingertip and medial fill testing?

Annual per USP 825

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Initial: Observed Aseptic Hand cleaning, observed donning of PPE, observed/tested Disinfecting of PEC. Initial sterile glove Donning requires 3 sequential Trials ≤ Ø CFU growth on Glove Fingertip sampling- Observe/Teach Compounding calculations & negative pressure Techniques. All employees Read USP 825 guidelines & ASHP compounding sterile prep 12th ed. Media Fill Testing.

Ongoing: correct any Deviations to SOP daily/weekly. Pyramyx Glove Fingertip sampling annually w/n ≤ 3CFU growth. Annual media fill testing

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used: USP 825

Daily: Clean Elution & Mixing vials ≤ one step Disinfectant/Cleaner (PreEmpt+)
clean PEC & Everything inside ≤ (PreEmpt)
clean sink ≤ PreEMPt+
SRPA floor mop ≤ PreEmpt+
SRPA work Surfaces ≤ PreEmpt+

Monthly: PEC, Bins, shelves, Floors, walls, Ceiling ≤ PreEmpt+
PEC, Bins, shelves, Floors, walls, ceiling ≤ Peridox (Sporicidal)
Elution & mixing vials shields ≤ Peridox

17. Who performs the sterile compounding process at your facility?

Chris Southwick
Jeff Jorgensen

18. Who is responsible and accountable for the sterile compounding process at your facility?

Chris Southwick

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

All RadioPharmaceuticals are shipped in unit dose shields, inside a DOT TYPE A shipping container (Ammocan) Ammo cans are Blocked & Braced, inside delivery vehicles. All unit dose shields are cleaned ≤ 1/10 mix ~~Bleach~~/H2O & PreEmpt+

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	☐ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☐ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

N/A

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

N/A

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

N/A

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? N/A ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

N/A

5. What is the frequency for completing surface sampling? N/A		
6. What is the frequency for using sporicidal agents? N/A		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component? N/A	Yes	No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method? N/A	Yes	No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Christopher Southwick

Name of Person who Completed the Form

Pharmacy Manager

Title

Chris G. Southwick 2/24/25

Signature (copies or stamps not accepted) Date

Board Use Only	Date Received: 3/5/25 Date Approved: _____ Approved By: _____

11B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☑ Nevada	☐ New Pharmacy	☑ Retail/Community	☑ Retail/Community
☐ Out-of-Nevada	☑ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☑ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: [redacted]
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☐ Other:	☑ Non-sterile Compounding
			☑ Sterile Compounding
			☑ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
			☐ Hospital
	* Current license #: PH 03433		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☑ Monday	☑ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☑ Tuesday	☐ Saturday	☑ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☑ Wednesday	☐ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☑ Thursday	☐ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

Physical Address: 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 W Warm Springs RD, #120

City: Las Vegas State: NV Zip: 89113

Telephone: 702-754-0172 Toll Free # (NAC 639.708, NRS 639.23286): 844-334-1010

Fax: 702-754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) NV20243252567

Supervising/Managing Pharmacist Name (NRS 639.220): Tommy Dinh

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 20256

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name:	Tommy Dinh	NV Pharmacist Registration #:	20256
Name:	Jose Escobedo	NV Pharmacist Registration #:	20782
Name:	Christine Glover	NV Pharmacist Registration #:	18273
Name:	Jenner Sinang	NV Pharmacist Registration #:	18954
Name:	Elise Leonard	NV Pharmacist Registration #:	22906
Name:	Nicole Sy	NV Pharmacist Registration #:	20646
Name:	Maile Olah	NV Pharmacist Registration #:	19841
Name:	Jaymie Padero	NV Pharmacist Registration #:	23846
Name:		NV Pharmacist Registration #:	
Name:		NV Pharmacist Registration #:	

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name:	N/A	Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	
Name:		Credentials:		%:	

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Florida

Parent Company (if any): OGB Meta III, LLC

Corporation/Organization Name: Meta Pharmacy Services, LLC

Mailing Address: 1015 Atlantic Blvd, STE 433

City: Atlantic Beach State: FL Zip: 32233

Telephone: (917) 288-7585 Email: derek@jbncp.com

Contact Person Name: Derek O'Leary

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the President and Treasurer (title) for Meta Pharmacy Services (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Derek O'Leary

Print Name of Authorized Person

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/22/25

Date

Section 11: Managing Pharmacist Acknowledgement, Professional/Personal History – REQUIRED TO BE COMPLETED BY THE MANAGING PHARMACIST FOR NEVADA LOCATED PHARMACY APPLICANTS ONLY

Managing Pharmacist Name: Tommy Dinh Pharmacist Registration #: 20256

Pharmacy Name: Meta Pharmacy Services

Initial each statement below to indicate you have read and agree with the following:

TD I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

TD I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

TD I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

TD I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

TD I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested, or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?		✓
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?		✓

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:

Criminal Action:	State:	Date:	Case #:	County:	Court:

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

[redacted]

Original signature of Managing Pharmacist (copies or stamps not accepted)

4/23/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Derek O'Leary, President and Treasurer

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

[redacted]

Original signature of Authorized Person (copies or stamps not accepted)

4/23/25

Date

Board Use Only	Date Received: 5/5/25	Amount: $500-CC

Section 3: History of Company

Nevada State Board of Pharmacy (Case Numbers: 19-002-RPH-S and 19-002-PH-S)

On April 10, 2019 the Nevada State Board of Pharmacy ("Board of Pharmacy") finalized a Findings of Fact, Conclusions of Law and Order ("Order) between the Board of Pharmacy, Mr. Sean Barclay, current Vice President and Secretary, and Barclay Luke & Pillai Specialty Pharmacy PLLC dba M*eta Pharmacy Services*, 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 (Nevada Resident Pharmacy Permit #: PH03433).

On or about November 27, 2018, the Board of Pharmacy alleged that Mr. Barclay, acting as a licensed Nevada pharmacist and as the managing pharmacist for Barclay Luke & Pillai Specialty Pharmacy PLLC dba *Meta Pharmacy Services*, had operated a pharmacy from approximately November 1, 2017 to November 29, 2018 without a current license or registration with the Board of Pharmacy.

Mr. Barclay and Barclay Luke & Pillai Specialty Pharmacy PLLC dba *Meta Pharmacy Services* did not oppose the citation. Mr. Barclay agreed to pay the $3,500 personal fine and Barclay Luke & Pillai Specialty Pharmacy PLLC dba *Meta Pharmacy Services* agreed to pay the $7,683.99 facility fine issued by the Board of Pharmacy.

Upon receipt of the fines, and signed Order, the Board of Pharmacy considered the matter closed and took no further action.

Nevada Board of Pharmacy (Case Number: 24-125-PH-S and 24-125-RPH-A-S)

On April 16, 2025, the Nevada Board of Pharmacy ("Board of Pharmacy") finalized a Stipulation and Order between the Board of Pharmacy, Mr. Sean Barclay, former Pharmacist-in-Charge, current officer and Barclay Luke & Pillai Specialty Pharmacy PLLC dba Meta Pharmacy Services, 8352 W. Warm Springs Road, Suite 120, Las Vegas, NV 89113 (Nevada Resident Pharmacy Permit #: PH03433).

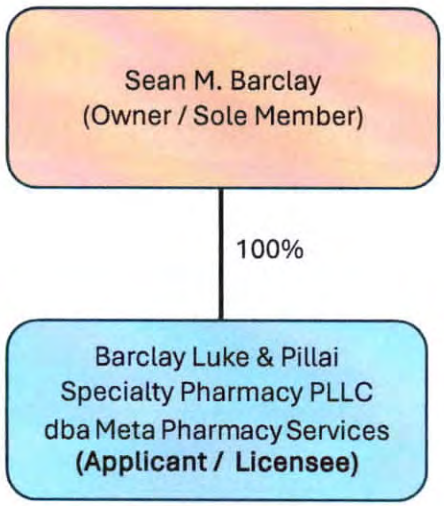
The Board of Pharmacy alleges between 2021 through 2023, Mr. Barclay knowingly filled and dispensed unlawful prescriptions for controlled substances and compounded medications. Further the Board of Pharmacy alleges from October 31, 2024 to November 20, 2024, Mr. Barclay employed a pharmacy technician in training on an expired registration and falsely completed training documentation submitted to the Board of Pharmacy.

Pursuant to the finalized Conditions of the Stipulation and Order, Mr. Barclay's pharmacist license is placed on probation for a period of 10 years and a fine of $10,000 shall be paid by Mr. Barclay.

Additional conditions imposed by the Board of Pharmacy, require Mr. Barclay to complete 12 extra hours of continuing education on pharmacy law and ethics. Mr. Barclay shall divest himself of any ownership intertest in Meta Pharmacy Services, LLC dba Meta Pharmacy Services and immediately cease working as a pharmacist at Meta Pharmacy Services, LLC dba Meta Pharmacy Services.

Meta Pharmacy Services

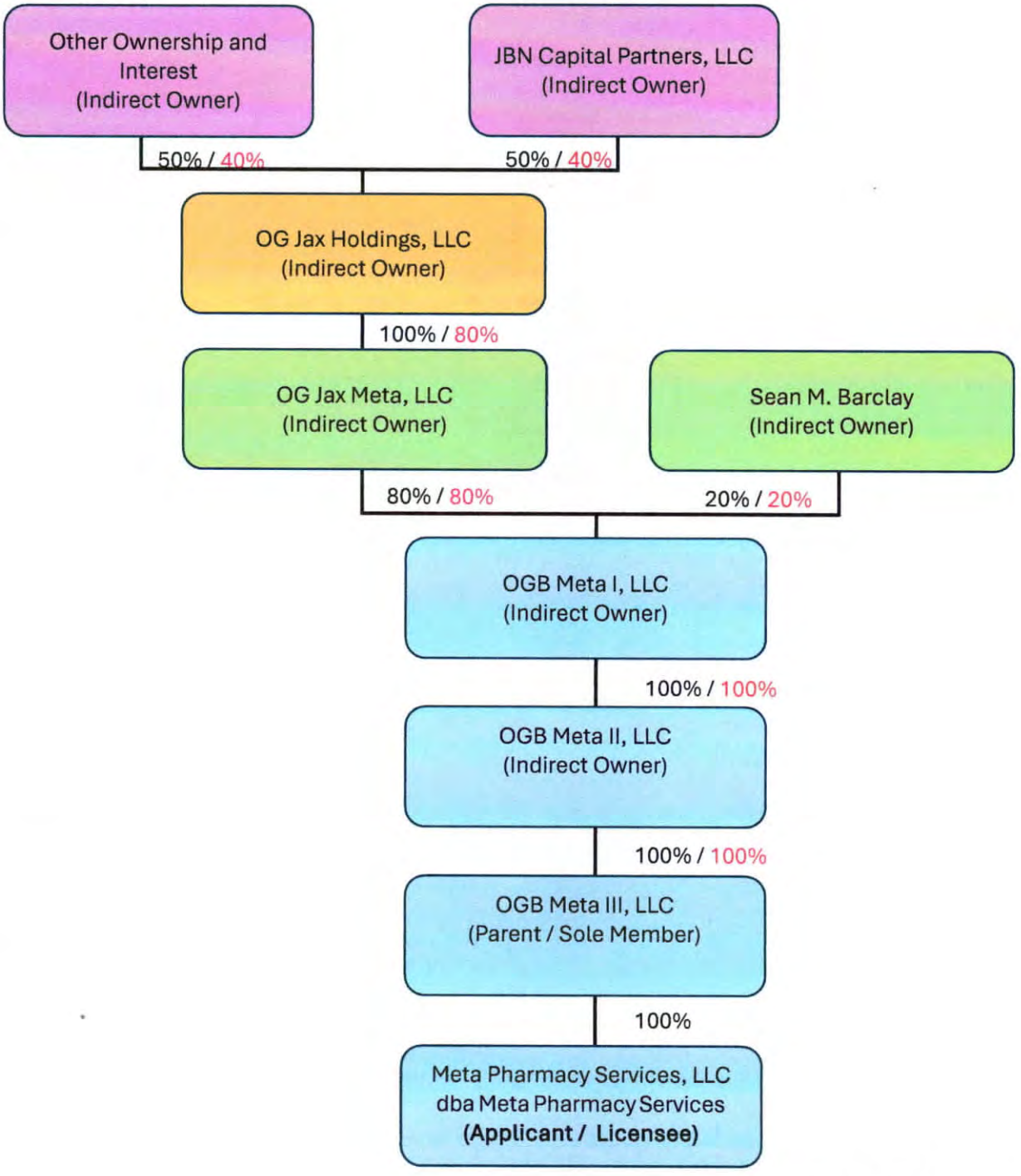
Pre-Close Organizational Chart



December 31, 2024

Meta Pharmacy Services

Post-Close Organizational Chart



Percentage is Direct Ownership in Owned Entity / Percentage is Indirect Ownership of Applicant

January 17, 2025

Meta Pharmacy Services, LLC - Owners and Officers

Name and Title	Business Address and Telephone	Home Address and Telephone	Date of Birth	SSN or FEIN	Ownership %
OGB Meta III, LLC Parent / Sole Member	[redacted]	[redacted]	NA	[redacted]	100%
Derek O'Leary President and Treasurer					0%
Sean M. Barclay* Vice President and Secretary					20% Indirect

*Pharmacist Licenses Held

State	Number	Effective Date	Expiration Date
Alaska	226660	11/08/2024	06/30/2026
Idaho	PR71688	07/13/2023	09/30/2025
Iowa	51930	10/09/2023	12/31/2025
Michigan	5302034202	10/09/2006	10/09/2025
Nevada	17303	01/28/2008	10/31/2025

State of Florida
Department of State

I certify from the records of this office that META PHARMACY SERVICES, LLC. is a limited liability company organized under the laws of the State of Florida, filed on November 22, 2024.

The document number of this limited liability company is L24000492499.

I further certify that said limited liability company has paid all fees due this office through December 31, 2024 and that its status is active.

Given under my hand and the Great Seal of the State of Florida at Tallahassee, the Capital, this the Fifth day of December, 2024

Secretary of State

Tracking Number: 7589678360CU

To authenticate this certificate,visit the following site,enter this number, and then follow the instructions displayed.

https://services.sunbiz.org/Filings/CertificateOfStatus/CertificateAuthentication

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: Meta Pharmacy Services

Pharmacy/Wholesaler License # (if applicable): PH03433

Physical Address: 8352 West Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113-3629

Mailing Address (if different from physical address): 8352 West Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113-3629

Telephone: (702) 754-0172 Website: www.metapharmacyservices.com

Licensing Company Email: admin@metapharmacyservices.com

Section 2: Personal Information

First: Tommy Middle: Last: Dinh

Alias(es, nicknames, name changes, etc.): N/A-Not Applicable

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☑ M ☐ F ☐ X

Mailing Address: [redacted]

City: [redacted] State: [redacted] Zip: [redacted]

Telephone: [redacted] Email: [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N	A

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Roseman University of Health Sciences, College of Pharmacy		08/16-05/19	
Address	City	State	Zip
11 Sunset Way	Henderson	NV	89014
Diploma/Degree obtained, if any			
Doctor of Pharmacy			

School Name		From - To (MM/YY – MM/YY)	
San Diego State University		08/13-05/16	
Address	City	State	Zip
5500 Campanile Drive	San Diego	CA	92182
Diploma/Degree obtained, if any			
Bachelor of Science, Biology			

School Name		From - To (MM/YY – MM/YY)	
San Diego Mesa College		08/09-05/12	
Address	City	State	Zip
7250 Mesa College Drive	San Diego	CA	92111
Diploma/Degree obtained, if any			
Associate of Science, Biology			

School Name		From - To (MM/YY – MM/YY)	
High Tech Institute		2004-2005	
Address	City	State	Zip
1111 Howe Ave Ste 250	Sacramento	CA	95825
Diploma/Degree obtained, if any			
Certificate, Pharmacy Technician			

School Name		From - To (MM/YY – MM/YY	
Bear Creek High School		2000-2003	
Address	City	State	Zip
10555 Thornton Road	Stockton	CA	95209
Diploma/Degree obtained, if any			
High School Dipolma			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
2023-current				
2019-2023				
2018-2019				
2016-2018				
2013-2016				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Meta Pharmacy Services			06/23-present	
Business Address		**City**	**State**	**Zip**
8352 W Warm Springs RD, #120		Las Vegas	NV	89113
Phone	**Title**		**Number of Employed Hours**	
844-334-1010	Pharmacist, Pharmacist-in-Charge		2,000-2,100	

Description of Duties

Practiced pharmacy in compliance with all Federal, state, local laws and regulations as well as company polices.

Business Name			From - To (MM/YY – MM/YY)	
Well Care Compounding Pharmacy			2021-2024	
Business Address		**City**	**State**	**Zip**
3300 W Charleston Blvd,		Las Vegas	NV	89102
Phone	**Title**		**Number of Employed Hours**	
(702) 553-2575	Pharmacy Manager		6,200-6,500	

Description of Duties

Manage and supervise compounding practices, pursuant to USP 795 and 800, Prepare medicine when appropriate using correct dosages and material for each individual patient, Formulate specific compounding medications based on prescriber's order.
Maintains pharmacy operations and records in compliance with federal, 503A, DEA, and Nevada state law.

Business Name			From - To (MM/YY – MM/YY)	
Well Care Pharmacy Long Term Care			2021-2024	
Business Address		**City**	**State**	**Zip**
3312 W Charleston Blvd		Las Vegas	NV	89102
Phone	**Title**		**Number of Employed Hours**	
(702) 553-2577	Pharmacist		6,200-6,500	

Description of Duties: Monitor patients' drug therapies and collaborate with physicians for changes, Make sure all federal and state drug laws are followed. Ensure a safe environment is maintained within the pharmacy.
Ensure orders are filled in a timely manner to meet deadlines with precision and accuracy.
Check and removes outdated medications on a routine basis. Assist with prior authorizations for all Well Care Pharmacy locations

Business Name			From - To (MM/YY – MM/YY)	
Well Care Pharmacy I			2019-2021	
Business Address		**City**	**State**	**Zip**
80 N Pecos Road		Henderson	NV	89074
Phone	**Title**		**Number of Employed Hours**	
(702) 912-1400	Pharmacy Manager		6,200-6,500	

Description of Duties

Review physician orders and prepare medications accordingly.- Assist with prescribers to submit prior authorization request for existing and new therapies. Monitor patients' drug therapies for accuracy and possible interactions.
Participate in meetings with pharmacy staffs to exchange ideas to achieve goals of the department. Collaborate with physicians to discuss potential incompatibility issues with patient prescriptions. Monitor reimbursement rates with different insurances.

Business Name			From - To (MM/YY – MM/YY)	
N/A-Not Applicable				
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	

Description of Duties

Continue on next page if additional space is needed.

Business Name		From - To (MM/YY – MM/YY)	
N/A-Not Applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A-Not Applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A-Not Applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A-Not Applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Business Name		From - To (MM/YY – MM/YY)	
N/A-Not Applicable			
Business Address	City	State	Zip
Phone	Title	Number of Employed Hours	
Description of Duties			

Make copies of this page OR use a separate piece of paper if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✓
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✓
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✓
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✓
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✓
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✓
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✓
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✓
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✓
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # _____. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
Reason/Charge				
			Lawsuit/Arbitration/Bankruptcy	
Name of Business/Industry/Entity				

Provide explanation below:

N/A-Not Applicable

_____ _____

Original Signature (electronic, copies or stamps not accepted) Date

I, Tommy Dinh, **certify that as the designated representative for**

Meta Pharmacy Services,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. TD I am at least 21 years of age;
3. TD I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. TD I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. TD I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. TD I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. TD I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Tommy Dinh

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/23/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tommy Dinh

Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

4/23/2025

Date

Please have this section completed in the presence of a Notary Public.

State of _____, ss. County of _____

I, Tommy Dinh, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

[redacted]

Original Signature

4/23/2025

Date

Subscribed and Sworn to before me this 23 day of April, 2025.

Misty Richardson

Notary Public Signature

MISTY DAWN RICHARDSON
Notary Public, State of Nevada
Appointment No. 24-1238-01
My Appt. Expires Mar 14, 2028

(Seal)

Meta Pharmacy Services
8352 W. Warm Springs Rd Suite 120
Las Vegas, NV 89113

Personal History Record Application

N/A - Not Applicable. Applicant Meta Pharmacy Services, LLC dba Meta Pharmacy Services is a 100% wholly owned subsidiary of OGB Meta III, LLC. There are no individual owners.

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: Meta Pharmacy Services

NV Pharmacy or Outsourcing facility license # (if applicable): PH03433

Physical Address: 8352 W Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Mailing Address (if different from physical address): 8352 W Warm Springs Road, Suite 120

City: Las Vegas State: NV Zip: 89113

Telephone: 844-334-1010 Toll Free # (NAC 639.708, NRS 639.23286): 844-334-1010

Fax: 702-754-6996 Contact Email: admin@metapharmacyservices.com

Website: www.metapharmacyservices.com

Nevada Business License # (if applicable) NV20243252567

Supervising/Managing Pharmacist Name (NRS 639.220): Tommy Dinh

Supervising/Managing Pharmacist NV Pharmacist Registration #: 20256

Name of Designated Person(s) as defined by revised USP-797 guidelines: Tommy Dinh

Email of Designated Person(s): admin@metapharmacyservices.com

Telephone of Designated Person(s): 844-334-1010

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

   ■ Category 1 ■ Category 2 ■ Category 3

If you marked "**Category 3**", you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ■ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 10/29/2024

6. What is the frequency of the recertification for the ISO classified areas? every seven months

7. Were there any follow-up items required from the most recent certification report? ■ Yes ☐ No
   Follow-up to occur at the next annual inspection in October 2025.

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ■ Yes ☐ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Biannually

10. Will you be performing sterile hazardous drug compounding? ■ Yes ☐ No

If you marked "Yes", you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

please see attached

12. What laboratory performs your sterility or endotoxin testing?

Name: ARL Bio Pharma

Address: 840 Research Parkway, Ste. 546

City: Oklahoma City State: OK Zip: 73104

Telephone: (800) 393-1595

13. What is your procedure for visual inspection of compounded sterile products?

Compounded sterile products will be inspected, before dispensing, by supervising pharmacists through a double-check system. (1.) Inspection of CSPs includes: (a.) Visual inspection for particulates and/or cloudiness. The CSP will be examined against a lighted white or black background, or both.; (b.) Verification of prescription orders with the written work order / compounding record (preparation; records). (c.) Verification of ingredients used, including correct amounts and concentrations (d.) Verification of final fill amounts (e.) Verification of aseptic manipulations and sterilization (f.) Package integrity, any leakage observed (g.) Visual inspection of syringes and additive containers used (h.) Correct and complete label: i. Name of patient; ii. Patient location; iii. Correct names, amounts and concentrations of the ingredients; iv. Total volume ; v. Preparation date; vi. Beyond-use date; vii. Route of administration; viii. Storage requirements; ix. Infusion rate when applicable; x. The initials of the final Pharmacist check (i.) Labels for CSPs must be clear, consistent, legible and in compliance with state and federal regulations. (2.) CSPs with visual defects will be immediately discarded. (3.) When the identity and concentrations of ingredients cannot be verified, samples of the CSPs will be assayed. (4.) CSPs that are not immediately dispensed will be stored according to procedure. a. CSPs that are stored, will again be inspected before the CSPs are dispensed.

14. How often do you perform glove fingertip and medial fill testing?

Biannually

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

Aseptic technique training will be ongoing; personnel must pass a media-fill test every 6 months. Compounding personnel who fail media-fill test would be re-evaluated. All compounding personnel must successfully complete 3 (three) Initial Gloved Fingertip sampling prior to compounding CSPs for human use. Ongoing GFS to be performed with the preparation of media fill units which is required initially (before compounding CSPs for human use) and every 6 months for compounding staff of pharmacies performing Category 2 compounding. Personnel who have direct oversight of compounding personnel, but do not compound, must complete training initially and every 12 months. Pharmacy Department shall demonstrate, assess, maintain and improve staff competence on an ongoing basis. Personnel must have didactic and practical training. Staff will receive guided instruction in the theory and practice of compounded sterile preparations, in addition to hands-on training before assuming compounding responsibilities.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

Please see attached policy: 3.020 Cleaning and Maintenance of Non-Sterile Compounding Area

17. Who performs the sterile compounding process at your facility?

Licensed staff members who have documented completion of appropriate competencies.

18. Who is responsible and accountable for the sterile compounding process at your facility?

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

Please see attached policy: 1.090 Delivery of Compounded Preparations

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? Laminar Flow Hood, Powder Hood, Biological Safety Cabinet		
2. Are you complying with all USP 800 guidelines?	■ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	■ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	■ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	■ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	■ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	■ No
9. If yes, list the name of the device: N/A		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

The Applicant provides education to patients upon admission and on an on-going basis while patients are actively on service.
(a.) Patients are to receive an admission packet, including information explaining how to contact the pharmacy for any concerns or questions.
(b.) Patients are to receive individual consultation as well as ongoing communication with the pharmacists.
(c.) Patients have access to the website, which allows them access to patient specific information.
(d.) Patients have access to pharmacists for any concerns or questions about their medications.
(e.) Patients review and sign a consent form explaining the therapy and medications involved (indication for IT drug(s), side effects, and when to call the pharmacy or physician).
(f.) Patients will be given patient drug information leaflets, that are available, the first time a medication is dispensed or when there is serious risk.

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

(1.) On-the-job experiential training from experienced compounding personnel.
(2.) Staff will receive guided instruction in the theory and practice of compounded sterile preparations, in addition to hands-on training before assuming compounding responsibilities. A PATT for the appropriate risk level of CSPs, and a 3-part initial Glove Fingertip Test must be passed before assuming compounding responsibilities.
(3.) Staff will participate in training and assessment (web-based continuing education for USP 797 compliance) upon hire and annually thereafter.
(4.) Staff will have access to the ASHP Sterile Compounding Library in order to complete a 3- course program with interactive lessons and follow-up testing. This program is completed annually and will include: a. Hand hygiene; b. Garbing procedure for ISO classified environments; c. Cleaning and disinfection of the Ante-area, Cleanroom, and PECs; d. Aseptic technique
(5.) Pharmacy Competency Skills Checklist performed annually
(6.) Bi-annual Aseptic Personnel Assessment Form
(7.) Bi-annual PATT requirement
(8.) Bi-annual Glove Fingertip Sampling
(9.) Instruction on safety procedures
(10.) Instruction on CSPs to include: a. Identification; b. Accurate measuring, weighing, dilution and mixing of ingredients; c. Purification, sterilization; d. Packaging; e. Labeling; f. Storage; g. Dispensing; h. Transport; i. Documentation of the compounding process; j. Sterilization for high-risk CSPs
(11.) Proper use and maintenance of all equipment, including an understanding of HEPA Filtered air flow in ISO classified environments
(12.) Transport of materials to and from the Cleanroom
(13.) Only those individuals who are qualified through license, experience and training to assess sterile compounding skills will conduct competency assessments.
(14.) When improvement activities (written test and media-fill tests) lead to a determination that a person with performance problems is unable or unwilling to improve, the staff member's work assignment may be revised. Further education and training will be required or other corrective action(s) may be taken.
(15.) The staff member will not return to compounding duties until performance problems are resolved.
(16.) The competence assessment program is continuous and ongoing, with reports of competency outcomes available to the Pharmacist-in-Charge.

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:

please see attached

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

Biannually

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☒ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

Biannually

5. What is the frequency for completing surface sampling? Monthly
6. What is the frequency for using sporicidal agents? Sporicidal agents are used daily inside PEC's and nonsterile HD room powder hood and table surfaces. All surfaces, including ceilings, walls, and bins undergo monthly terminal cleaning with sporicidal agents.
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component? ☐ Yes ■ No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method? ☐ Yes ■ No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Tommy Dinh

Name of Person who Completed the Form

Pharmacist-in-Charge

Title

[redacted]

Signature (copies or stamps not accepted)

04/23/2025

Date

Board Use Only	Date Received:_____ Date Approved: _____ Approved By: _____

NABP ACCREDITED
COMPOUNDING PHARMACY

Meta Pharmacy Services

located at

8352 W Warm Springs Rd, Ste 120, Las Vegas, NV 89113

This business has met all the compounding pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the compounding pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/compounding.

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/25/2024 - 04/24/2027
Period of Accreditation

Attachment: List of Sterile Compounded Products

Drug Description
ALPHA LIPOIC ACID 25 MG/ML INJECTION
BCAA ISOLEUCINE/LEUCINE/VALINE 15/10/40 MG/ML INJ SOLUTION
BIOTIN 10MG/ML INJECTABLE SOLUTION
CARNITINE 50% INJECTABLE SOLUTION
DEXPANTHENOL 250 MG/ML INJECTABLE SOLUTION
GLUTATHIONE 20% INJECTION
HYDROXOCOBALAMIN (B12) 10 MG/ML INJ
LIPO C 15MG/50MG/50MG/25MG/15MG/5MG (Carnitine, Choline, Inositol, Methionine, Thiamine, Dexpanthenol)
LIPO INJECTION (MIC) (Methionine, Inositol, Choline)
LIPO-B (MIC-B12) STERILE SOLUTION (Methionine, Inositol, Choline, and Methylcobalamin)
METHYLCOBALAMIN 12.5MG/ML INJ
MYERS COCKTAIL IV ADMIXTURE
NAD+ 1,000MG/50ML VIAL INJECTION
NANDROLONE DECANOATE 200 MG/ML GRAPESEED OIL
PYRIDOXINE 100 MG/ML INJECTABLE SOLUTION
QUADMIX STANDARD INJECTION (Atropine, Alprostadil, Papaverine, Phentolamine)
SEMAGLUTIDE/L-CARNITINE 2.5/100MG/ML
SERMORELIN 3MG/3ML SOLUTION INJECTION
STANOZOLOL 50 MG/ML 'IM' INJECTION
SUPER TRIMIX INJ (Alprostadil, Papaverine, Phentolamine)
TAURINE 50 MG/ML INJECTABLE SOLUTION
TIRZEPATIDE/L-CARNITINE 16.7/100MG PER ML
TRIMIX #1 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #3 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #4 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #5 INJ (Alprostadil, Papaverine, Phentolamine)
TRIMIX #6 INJ (Alprostadil, Papaverine, Phentolamine)
TRT CYPIONATE-ZINC SULFATE 200-1 MG/ML IN GRAPESEED OIL
VITAMIN B COMPLEX INJECTION
VITAMIN C 50% FOR INJECTION (Sodium Ascorbate)
VITAMIN D3 50000 UNITS/ML 'IM' INJ
TOBRAMYCIN 1.5% (15 MG/ML) EYE DROP
VANCOMYCIN 2.5% (25 MG/ML) EYE DROPS

Risk Level	Drug Description
High	ALPHA LIPOIC ACID 25 MG/ML INJECTION
High	BCAA ISOLEUCINE/LEUCINE/VALINE 15/10/40 MG/ML INJ SOLUTION
High	BIOTIN 10MG/ML INJECTABLE SOLUTION
High	CARNITINE 50% INJECTABLE SOLUTION
High	DEXPANTHENOL 250 MG/ML INJECTABLE SOLUTION
High	GLUTATHIONE 20% INJECTION
High	HYDROXOCOBALAMIN (B12) 10 MG/ML INJ
High	LIPO C 15MG/50MG/50MG/25MG/15MG/5MG (Carnitine, Choline, Inositol, Methionine, Thiamine, Dexpanthenol)
High	LIPO INJECTION (MIC) (Methionine, Inositol, Choline)
High	LIPO-B (MIC-B12) STERILE SOLUTION (Methionine, Inositol, Choline, and Methylcobalamin)
High	METHYLCOBALAMIN 12.5MG/ML INJ
High	MYERS COCKTAIL IV ADMIXTURE
High	NAD+ 1,000MG/50ML VIAL INJECTION
High	NANDROLONE DECANOATE 200 MG/ML GRAPESEED OIL
High	PYRIDOXINE 100 MG/ML INJECTABLE SOLUTION
High	QUADMIX STANDARD INJECTION (Atropine, Alprostadil, Papaverine, Phentolamine)
High	SEMAGLUTIDE/L-CARNITINE 2.5/100MG/ML
High	SERMORELIN 3MG/3ML SOLUTION INJECTION
High	STANOZOLOL 50 MG/ML 'IM' INJECTION
High	SUPER TRIMIX INJ (Alprostadil, Papaverine, Phentolamine)
High	TAURINE 50 MG/ML INJECTABLE SOLUTION
High	TIRZEPATIDE/L-CARNITINE 16.7/100MG PER ML
High	TRIMIX #1 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #3 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #4 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #5 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRIMIX #6 INJ (Alprostadil, Papaverine, Phentolamine)
High	TRT CYPIONATE-ZINC SULFATE 200-1 MG/ML IN GRAPESEED OIL
High	VITAMIN B COMPLEX INJECTION
High	VITAMIN C 50% FOR INJECTION (Sodium Ascorbate)
High	VITAMIN D3 50000 UNITS/ML 'IM' INJ

TITLE: CLEANING & MAINTENANCE OF NON-STERILE COMPOUNDING AREA	
SOP NUMBER: 3.020	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: Pharmacy Compliance Officer	Date:
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to establish requirements for the cleaning and maintenance of the non-sterile compounding area.

2.0 SCOPE

2.1 This procedure applies to the Meta Pharmacy Services non-sterile compounding area under conditions that meet or exceed state and federal guidelines.

2.2 This procedure must be followed to reduce the amount of particulate matter and airborne contamination and to prevent cross-contamination of chemicals.

3.0 RESPONSIBILITY

3.1 The Pharmacist-in-Charge, or a pharmacist designee, shall supervise this procedure and document that all non-sterile compounding personnel will comply with this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations"

4.2 SOP 1.050 "General Compounding Technique"

4.3 SOP 4.010 "Compounding Equipment"

4.4 SOP 4.020 "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer"

4.5 SOP 8.020 "Good Documentation Practices (GDP)"

4.6 SOP 8.100 "Required Garb for Non-Sterile Compounding Area"

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 Daily (when non-sterile compounding activities are planned)

6.1.1 Clean all horizontal surfaces.

6.1.2 Sweep floors.

6.1.3 Clean all in-use powder hoods.

6.1.4 Wipe down all in-use equipment.

6.1.5 Record room temperature and humidity.

6.1.6 Record temperature of drug product refrigerator/freezer.

6.1.7 Clean all utensils after use.

6.1.8 Remove and discard trash.

6.2 Weekly

6.2.1 Perform daily requirements listed in section 6.1.

6.2.2 Order supplies as necessary.

6.2.3 Mop floors with dry mop followed by a sponge mop and cleaning solution.

6.3 Monthly

6.3.1 Perform daily requirements listed in section 6.1.

6.3.2 Perform weekly requirements listed in section 6.2.

6.3.3 Clean and sanitize the drug product refrigerator/freezer.

6.3.4 Clean and sanitize shelving.

6.3.5 Clean cabinet exteriors.

7.0 EQUIPMENT & SUPPLIES

7.1 Proper gowning protocol placards

7.2 Mop with disposable cleaning pads labeled for use on floors of non-sterile compounding area

7.3 Paper towels

7.4 Bleach concentrate or appropriate cleanser (Acidified Bleach Disinfectant Solution)

7.5 70% isopropyl alcohol (IPA)

7.6 Waste container liners

7.7 Step stool

7.8 Room thermometer

7.9 Room hygrometer (If applicable)

7.10 Equipment manuals (if applicable)

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Prepared By: Pharmacist-In-Charge	Date:
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Date Effective:	

8.0 GENERAL INFORMATION

8.1 Cleaning Solutions

8.1.1 Non-sterile 70% IPA – for use in areas with equipment that may be damaged by the use of bleach.

9.0 PROCEDURE

9.1 Personnel must gown appropriately for the areas to be cleaned following the appropriate gowning procedure.

9.2 Cleaning solutions shall be prepared as needed.

9.2.1 Do not combine disinfectants or use them in concentrations other than those outlined in the SOPs.

9.2.2 Disinfectants with no expiration date should be assigned an expiration date of 30 days after opening.

9.3 Except for sanitization of the workbenches, utensils or equipment, cleaning of the non-sterile compounding area is prohibited during compounding operations.

9.3.1 Ensure all compounded preparations are completed.

9.3.2 The operator must clean and sanitize the exposed work surfaces before and after each batch preparation and immediately should a spill occur.

9.4 The order of cleaning within the non-sterile compounding area is as follows:

9.4.1 Hoods (powder hood)

9.4.2 Non-sterile compounding area: counters, shelves, equipment

9.4.3 Warehouse storage room

9.5 Daily Requirements (when non-sterile compounding has occurred)

9.5.1 At the beginning of the day:

9.5.1.1 Check supplies and straighten up the non-sterile compounding area (if necessary).

9.5.1.2 Calibrate balances.

9.5.1.3 Turn on all necessary equipment and computers.

9.5.1.3.1 Power on all equipment at least 30 minutes prior to compounding.

9.5.1.4 Prepare shipping materials for the day.

9.5.2 Temperature and humidity readings shall be taken in the non-sterile compounding area at the beginning and end of each day and more frequently if needed.

9.5.2.1 The temperature and humidity in the non-sterile compounding area shall be monitored electronically.

9.5.2.2 The humidity should be maintained in the range of 30%–50%.

9.5.2.3 The temperature shall be maintained between 67°F–77°F.

9.5.2.4 Document results on the Temperature and Humidity Monitoring of the Non-Sterile Compounding Area form (Attachment 2).

9.5.3 Record drug product in refrigerator/freezer temperature on Attachment 3 of SOP 4.020, "Use, Calibration and Maintenance of the Drug Product Refrigerator and Freezer."

9.5.4 Clean and sanitize countertops/sinks.

9.5.5 Clean and sanitize equipment as needed. Document equipment cleaning on appropriate cleaning log as per SOP 4.010, "Compounding Equipment."

9.5.6 Allow all rooms and equipment to air dry before non-sterile compounding resumes.

9.5.7 At the end of the day:

9.5.7.1 Turn off all equipment and computers as required.

9.5.7.2 Sweep the floor.

9.5.7.3 Empty all waste receptacles by removing the filled plastic bag.

9.5.8 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.6 Weekly Requirements

9.6.1 Includes all requirements listed in section 8.5.

9.6.2 Mop floors

9.6.3 Order supplies as necessary.

9.6.4 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.7 Monthly Requirements

9.7.1 Includes all requirements listed in section 8.5 an 8.6.

9.7.2 Clean and sanitize the drug product refrigerator/freezer.

9.7.3 Remove all supplies from shelving in the non-sterile compounding area and clean and sanitize the shelves.

9.7.4 Clean and sanitize cabinet exteriors.

9.7.5 Document all activities on the Cleaning and Maintenance of the Non-Sterile Compounding Area form (Attachment 1). If the equipment is not in use, write "N/A" in the appropriate location on the form.

9.8 Cleaning can be performed as often as needed, but the minimum requirement will be at the end of the day after compounding.

9.9 The Pharmacist-in-Charge, or a pharmacist designee, shall ensure the completion of tasks on a daily basis and shall review and sign/date Attachment 1 at the end of each month. The form shall be retained in a cleaning/maintenance binder.

10.0 ATTACHMENTS

10.1 Attachment 1 – Cleaning and Maintenance of the Non-Sterile Compounding Area

10.2 Attachment 2 – Refrigerator Temperature and Humidity Monitoring of the Non-Sterile Compounding Area

10.3 Attachment 3 – PCCA Formula 11186 Acidified Bleach Solution

10.4 Attachment 4 – Daily Cleaning Log

10.5 Attachment 5 – Weekly Cleaning Log

10.6 Attachment 6 – Monthly Cleaning Log

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request

TITLE: CLEANING & MAINTENANCE OF NON-STERILE COMPOUNDING AREA	
SOP NUMBER: 3.020	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: Pharmacy Compliance Officer	Date:
Date Effective:	

			Number
1.0		New SOP	

This policy will be reviewed and updated annually by the Pharmacist-in-Charge and the Pharmacy Compliance Officer.

All pharmacy staff shall comply with this policy. Violations of this policy could result in disciplinary action based on the seriousness of the offense or other factors. Disciplinary action may include written warning, suspension, or termination.

Remainder of this page intentionally left blank.

CLEANING AND MAINTENANCE OF NON-STERILE COMPOUNDING AREA (META PHARMACY SERVICES)

Month/Year: _____ **Cleaning Solution:** _____

Day	Daily							Weekly		Monthly			
	Countertops Cleaned	Floors swept	Hood(s) Cleaned	Equipment Wiped Down	Utensils Cleaned	Trash Discarded	Tacky Mat Refreshed	Supplies Ordered	Floors Mopped	Shelves Cleaned/Sanitized	Drug Product Refrigerator Cleaned/Sanitized	Drug Product Freezer Cleaned/Sanitized	Cabinet Exteriors Cleaned/Sanitized
1													
2													
3													
4													
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31													

Reviewed By: _____ **Date:** _____

REFRIGERATOR TEMPERATURE AND HUMIDITY MONITORING OF THE NON-STERILE COMPOUNDING AREA (META PHARMACY SERVICES)

MONTH/YEAR: _____ Appropriate Refrigerator Temperature: 35°F to 60°F Appropriate Lab Humidity %: 30-50%

Day	Time				Fridge Temp (°F)				Thermostat 1				Thermostat 2			
									Temp (°F)		Humidity (%)		Temp (°F)		Humidity (%)	
	AM	Initial	PM	Initial	AM	Initials	PM	Initial	AM	Initial	PM	Initial	AM	Initials	PM	Initial
1																
2																
3																
4																
5																
6																
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Acidified Bleach Disinfectant Solution

SUGGESTED FORMULA FOR
Acidified Bleach Disinfectant Solution
Version: 1.0
3238.3 mL

Sodium Hypochlorite 8.25% Solution	98 ml
White Vinegar	140 ml
Liquid Dish Soap	0.3 ml
Purified Water, USP	3,000 ml

SUGGESTED COMPOUNDING PROCEDURE

Note: It is recommended that you follow USP <795> recommendations for potency testing which states "... each preparation shall contain not less than 90.0% and not more than 110.0% of the theoretically calculated and labeled quantity of active ingredient ...". In order to provide some guidance in this area, please contact Eagle Analytical Services regarding the use of Skip Lot testing.

Note: Sodium Hypochlorite 8.25% Solution - Pharmacy Stock. Source: Commercial Unscented Laundry Bleach.

Note: White Vinegar - Pharmacy Stock.

Note: Liquid Dish Soap - Pharmacy Stock. Source: Grocery Store.

Note: Use syringe which delivers 20 Drops/mL.

1. In an appropriate size container, add Purified Water. Use an amount of Purified Water that is approximately one-third of the specified amount. For example, if the specified amount is 3000 mL, use 1000 mL of Purified Water.
2. Add Sodium Hypochlorite 8.25% Solution to Step 1 with mixing.
3. Add White Vinegar to Step 2 with mixing. Use an amount of White Vinegar that is approximately 90% of the specified volume. For example, if the specified volume is 140 mL, use 126 mL of White Vinegar.
4. Add Purified Water to Step 3 with mixing. Use an amount of Purified Water that is approximately one-third of the specified amount. For example, if the specified amount is 3000 mL, use 1000 mL of Purified Water.
5. Add Liquid Dish Soap to Step 3 with mixing.
6. Add Purified Water to Step 5 with mixing. Use an amount of Purified Water that is approximately one-third of the specified amount. For example, if the specified amount is 3000 mL, use 1000 mL of Purified Water.
7. Check the pH of Step 6 with a pH meter. If necessary, adjust the pH to 6 (5.8 - 6.2) by adding White Vinegar in small increments with mixing. Check pH after each addition.

Note: The final preparation should contain approximately 2375 ppm of available chlorine.

Note: NOT FOR HUMAN USE!

Note: No claims are made as to the safety or efficacy of this preparation. This formulation is provided solely at the unsolicited request of the pharmacist.

Note: Beyond Use Dates of preparations are conservative estimates by the formulator using reference books, peer reviewed literature, intended duration of therapy, formulation from commercially available products, organoleptic stability observations and current USP guidelines. Compounders may have stability tests performed by a reputable laboratory if they wish to extend the Beyond Use Date.

Note: Beyond Use Date after compounding is estimated to be 5 days.

11186
Revised: Sun Oct 05, 2014

DAILY CLEANING LOG
META PHARMACY SERVICES

Daily cleaning duties are performed and recorded each day at the end of each shift. These duties include; Cleaning and wiping down all compounding surfaces and equipment with 70% isopropyl alcohol. Visually inspecting and cleaning bulk chemical containers. Sweeping and vacuuming the compounding area. Replacing and restocking compounding supplies. Calibrating scales and initial cleaning at the beginning of each shift and cleaning after each compounded order.

Month: _____

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday	Sunday

WEEKLY CLEANING LOG
(META PHARMACY SERVICES)

MONTH	WEEK 1	WEEK 2	WEEK 3	WEEK 4	WEEK 5
January					
February					
March					
April					
May					
June					
July					
August					
September					
October					
November					
December					

MONTHLY CLEANING LOG
META PHARMACY SERVICES

Monthly cleaning activities include the daily and weekly cleaning responsibilities as well as cleaning and sanitize the drug products in refrigerator/freezer, cleaning shelving, and cabinet exteriors.

YEAR: _____

MONTH	COMPLETED BY
JAN	
FEB	
MAR	
APR	
MAY	
JUN	
JULY	
AUG	
SEP	
OCT	
NOV	
DEC	

TITLE: DELIVERY OF COMPOUNDED PREPARATIONS	
SOP NUMBER: 1.090	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: *Pharmacy Compliance Officer*	*Date:*
Date Effective:	

1.0 PURPOSE

1.1 The purpose of this procedure is to ensure that compounded preparations are delivered to the patient or health care facility in a manner such that the product integrity, quality, safety and efficacy are not compromised.

2.0 SCOPE

2.1 This procedure applies to all shipping personnel at Meta Pharmacy Services.

3.0 RESPONSIBILITY

3.1 The Pharmacist-In-Charge, or a pharmacist designee, shall supervise this procedure.

4.0 REFERENCES

4.1 USP Current Version <795> "Pharmaceutical Compounding – Non-Sterile Preparations

5.0 DEFINITIONS

5.1 N/A

6.0 FREQUENCY

6.1 This procedure shall be followed for each compounded preparation that is to be shipped to a patient's home or to another facility.

7.0 EQUIPMENT & SUPPLIES

7.1 Compounded preparation(s) and appropriate equipment/devices if necessary
7.2 Appropriate shipping container
7.3 Affiliated shipping company: i.e. FedEx, USPS (United States Postal Service)
7.4 Detailed shipping instructions

8.0 GENERAL INFORMATION

8.1 N/A

9.0 PROCEDURE

9.1 All pharmacy staff working in Meta Pharmacy Services, shall assure that the compounded preparation is properly shipped to the patient or health care facility without compromising the product integrity, quality, safety and efficacy, which will be verified by the Pharmacist-In-Charge and/or designee.

9.2 All compounded preparations shall be shipped in appropriate containers that will protect the preparation from wide variations in temperatures, structural damage or unapproved light sources.

9.2.1 Handling and shipping of refrigerated products shall follow USP<795 > guidelines

9.2.2 Refrigerated items are shipped in insulated containers with adequate ice packs to ensure product stability.

9.2.3 Refrigerated items are shipped through FedEx.

9.3 Items that are controlled substances or have a value greater than $1,000.00 will be shipped requiring a signature upon delivery (signature required). Once the patient receives the item the signature is documented in the shipping company's system.

9.4 In the case of a shipping error, pharmacy staff will immediately notify the patient and provide a return shipping label via FEDEX, UPS or USPS. The correct item will be resent to the patient without a fee. In addition, in such an error, the Pharmacist-In-Charge or designee will prepare a report and submit same to the Pharmacy Compliance Officer.

9.5 In the case of a lost shipment, Meta Pharmacy Services staff will attempt to track the lost shipment and file a claim with the appropriate shipping company. Pharmacy staff will verify the address with the patient and resend a new product to the patient. The Pharmacist-In-Charge and/or designee will prepare a written report and submit same to the Pharmacy Compliance Officer.

9.5.1 A Tracking Number for each shipment is stored in the system and can be given to patients upon request.

9.6 Instructions for proper inspection of the preparation will be transmitted to the patient or caregiver prior to shipment of the package.

9.7 A material safety data sheet (MSDS) for each product used in the compounded preparation shall be available in Meta Pharmacy Services in case a spill or accident occurs during transit.

9.8 Storage instructions shall be provided to the patient or caregiver to ensure that the product is stored appropriately at the patient's home or at the health care facility.

9.9 Instructions shall be provided to the patient or caregiver on how to contact the pharmacist for patient counseling.

9.10 The patient should be instructed to sign and return the Acknowledgment of Privacy Practice and Shipment Form (Attachment #1)

10.0 ATTACHMENTS

10.1 Attachment 1 – Acknowledgment of Privacy Practice and Shipment Form

11.0 HISTORY

Version Number	Date Effective	Description of Change	Change Request Number
1.0		New SOP	

This policy will be reviewed and updated annually by the Pharmacist-in-Charge and the Pharmacy Compliance Officer.

All pharmacy staff shall comply with this policy. Violations of this policy could result in disciplinary action based on the seriousness of the offense or other factors. Disciplinary action may include written warning, suspension, or termination.

TITLE: DELIVERY OF COMPOUNDED PREPARATIONS	
SOP NUMBER: 1.090	**VERSION NUMBER: 1.0**
Authorized By: Meta Pharmacy Services	Date: 02/01/2022
Prepared By: Pharmacist-In-Charge	Date:
Reviewed By: *Pharmacy Compliance Officer*	Date:
Date Effective:	

Remainder of this page intentionally left blank.

Acknowledgement of Notice of Privacy Practices

The purpose of the form below is to verify that you received the Notice of Privacy Practices. You are not required to sign or return this form; however, we are requesting that you do sign and return, so that we may maintain a record of your receipt of the prescription and privacy notice which will be maintained in your pharmacy records. Your pharmacy services will continue even if you do not return this form.

If you choose to return this form, please complete the information below and mail this page of the notice to the following address:

Meta Pharmacy Services

11717 NE Glisan Street

Portland, OR 97220-2141

All Members of your family who are on your prescription benefits plan may also sign this form acknowledging that they read the notice. Please share this notice with your family members.

Print Name: _____ Date: _____

Signature: _____

In addition, your doctor may have indicated a course of therapy that will require prescription refills. For your convenience we offer an automatic-refill service on certain prescriptions and therapies. Please indicate your interest by placing an "X" in the appropriate box, sign and return to the pharmacy.

☐ Yes, I would like to enroll in your auto-refill service.

☐ No thank you, please call me.

Print Name: _____ Date: _____

Signature: _____

NABP ACCREDITED
COMPOUNDING PHARMACY

Meta Pharmacy Services

located at

[redacted]

This business has met all the compounding pharmacy criteria set in place by the National Association of Boards of Pharmacy® (NABP®). The current status of this business's accreditation may also be verified by visiting the compounding pharmacy section on the NABP website, located at: www.nabp.pharmacy/programs/compounding

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

04/25/2024 - 04/24/2027
Period of Accreditation

5720

Certificate of Compliance

Awarded To:

Meta Pharmacy Services
8352 W. Warm Springs Boulevard, Suite 120
Las Vegas, NV 85705
(702) 250-4406 phone

Testing Completed By:

Controlled Environment Management, LLC
2487 S. Gilbert Rd., Suite 106-610
Gilbert, AZ 85295
(480) 836-4144 phone

This is to certify that the following area(s) have been tested and certified in accordance with ISO 14644 and CETA CAG-003 specifications. The air cleanliness classification designation and testing criteria are listed below.

Area ID: **Pharmacy Compounding Suite**
Date of Testing: October 29, 2024
ISO 14644: Class 7 (Non Haz, Haz, Haz, Ante Rooms)
ISO 14644: Class 8 (Non-Sterile, Gowning Rooms)
Particle Size: ≥ 0.5µm
Area Mode: Dynamic

CEM Project: ATZ241029

CEM

CONTROLLED ENVIRONMENT MANAGEMENT, LLC

PHARMACY POWDER HOOD TEST REPORT

Customer	Meta Pharmacy Services			Report No.	ATZ241029-05 Page 1 of 2
Address	8352 W. Warm Springs Blvd., Suite 120			Manufacturer	AirClean Systems
City, State	Las Vegas, NV	Zip	89113	Model	AC740C
Main Contact	Sean Barclay	Phone	(702) 427-2638	Serial No.	AC740C-1378
Alt. Contact	NA	Phone	NA	Building	Main
Department	Pharmacy			Location	Pharmacy

UNIT TEST RESULTS

- [X] Certified
- [ ] Not Certified
- [ ] Service Only
- [X] See Comments

UNIT TESTED TO STANDARD

- [ ] NSF/ANSI 49
- [X] Manufacturer's Specifications
- [ ] Other

TESTS COMPLETED (See Page 2 For Test Data)

[ ] Downflow Velocity Profile	[ ] Pass	[ ] Fail
[X] Inflow Velocity Test	[X] Pass	[ ] Fail
[X] Airflow Smoke Pattern Test	[X] Pass	[ ] Fail
[X] HEPA Filter Leak Test	[X] Pass	[ ] Fail
[ ] Cabinet Integrity Test	[ ] Pass	[ ] Fail
[ ] Site Installation Assessment	[ ] Pass	[ ] Fail
[X] Fluorescent Lighting (Function Test)	[X] Pass	[ ] Fail
[ ] Vibration Test	[ ] Pass	[ ] Fail
[ ] Noise Level	[ ] Pass	[ ] Fail
[ ] Electrical - Polarity	[ ] Pass	[ ] Fail
[ ] Other Test(s)	[ ] Pass	[ ] Fail

SERVICE COMPLETED

- [ ] Repaired HEPA Filter Leakage
- [ ] Adjusted Airflow/Air Velocities
- [ ] Paraformaldehyde Decontamination (NIH/CDC)
- [ ] Installed New HEPA Filters
- [ ] Installed New Blower Motor
- [ ] Installed New Electrical Component
- [ ] Installed New Fluorescent Bulb(s)
- [ ] Installed New Ultraviolet Bulb
- [ ] Adjusted Pressure Gauge
- [ ] Other Service

EQUIPMENT USED

Equipment	Manufacturer	Model No.	Serial No.
Photometer	TEC Services	PH-5	3543
Generator	TEC Services	AG-E3	3412
Anemometer	TSI	966	P20020001

COPIES OF CALIBRATION CERTIFICATES AVAILABLE UPON REQUEST

COMMENTS:

(1) Airflow smoke pattern test performed over work area. Results of the testing reflected no turbulence or refluxing.

SERVICED BY: James Rawls **DATE:** 10/29/24 **RETEST DATE:** Apr-25

PHARMACY POWDER HOOD TEST REPORT

Customer: Meta Pharmacy Services | Report No.: ATZ241029-05 P2/2 | Technician: JR | Date: 10/29/24

DOWNFLOW VELOCITY PROFILE

Downflow Velocity Measurements

	Non-Zoned	Zoned		
		Front	Center	Rear
Acceptance Criteria	NA	NA	NA	NA fpm
Average Air Velocity	NA	NA	NA	NA fpm

Length	NA	Downflow Air Volume	NA
Width	NA	Air Density Correction	NA
Area	NA	**Final Test Result**	NA

Comments: NA

INFLOW VELOCITY TEST

Exhaust Velocity Measurements

Length	NA	Avg. Velocity	95 fpm	Inflow Velocity	95 fpm
Width	NA	Exhaust Volume	266 cfm	Acceptance Criteria	≥ 75 fpm
Area	NA	Air Density Correction	1.00	**Final Test Result**	**Pass**

Comments: (1) Digital airflow monitor reading 85 fpm during testing.

Workface Opening Velocity Measurements

										92	92	93	98	99	96	94

Workface Dimensions: 8.5" x 47.5"
Workface Area: 2.80 ft²

HEPA FILTER LEAK TEST

Supply HEPA Filter

Exhaust HEPA Filter

Aerosol Type	PAO
Concentration	13 µg/L
Leakage Detected	< 0.005%
Acceptance Criteria	≤ 0.005%
Total Patch Size	NA
Total Patch %	NA
Final Test Result	**Pass**

Comments: (1) No leaks detected in exhaust HEPA filter.

SITE INSTALLATION ASSESSMENT TESTS

Airflow Alarms	NA	Comments	NA
Sash Alarms	NA		
Interlocks	NA		
Exhaust System	NA		
Final Test Result	NA		

AIRFLOW SMOKE PATTERN TEST

Downflow Test	NA
View Screen Retention Test	NA
Work Opening Edge Retention Test	Pass
Sash Wiper Seal Test	NA
Final Test Result	**Pass**

SECONDARY TESTS

Fluorescent Lighting

Background (≤15Fc)		
Operational (Fc)		
Average Light Reading (Fc)	NA	
Acceptance Criteria	NA	
Final Test Result	NA	

Noise Level Test

Noise Level Reading	NA
Ambient Noise Level	NA
Corrected	NA
Acceptance Criteria	NA
Final Test Result	NA

Electrical Tests

Electric#	NA
Ground Resistance (≤0.15 Ohms)	NA
Polarity Test	NA
Ground Fault Interrupter	NA
Final Test Result	NA

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Retail Pharmacy

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Pharmacy DEA#:	FB5538458
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Primary Wholesaler:	McKesson
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	Pharmacy Personnel List complete and accurate. Comments: Completed prior to inspection. Document retained for Inlumon verification.	☒	☐
3.	Controlled Substance Biennial Inventory complete and accurate. Comments: Reviewed document dated 7/25/24. Document contains date and time that inventory was completed. Document signed by pharmacist completing form. C-II products separated from remaining controlled substances.	☒	☐
4.	CSOS receiving documents complete and accurate. Comments: Reviewed documents from September 2024. Date and quantity received completed electronically. CSOS document attached to invoice from wholesaler.	☒	☐
5.	Controlled Substance invoices are complete and accurate. Comments: Pharmacist receiving product are signing and dating all invoices. Pharmacist also placing license number on document.	☒	☐
6.	Records of Pharmacy Personnel on duty complete and accurate. Comments: Manual sign-in log. Log contains date, printed name, staff signature, hours worked, temp, and illness symptoms.	☒	☐
7.	Change in Managing Pharmacist controlled substance inventory complete and accurate (if applicable). Comments: N/A	☐	☐
8.	Security of the pharmacy meets all of Nevada Statutes and Regulations.	☐	☒

	Comments: Location has dead-bolt on front door entry. Safe utilized for C-II products. Barrier between public and pharmacy has a barrier less than 5ft tall. Alarm system in place at location. Cameras located throughout pharmacy.		
9.	In-Service training records for pharmacy technicians complete and accurate. Comments: Will review with 2025 inspection.	☐	☐
10.	Immunization CE (1 hour required annually by 10/31) for immunizing pharmacy technicians complete. Comments: N/A – No immunizations at location.	☐	☐
11.	Activity logs for technicians in training complete and accurate. Comments: Reviewed log for Ronalynn Domingo. Document meets all requirements. Employee has completed 1500 hours of training.	☒	☐
12.	Pharmacy labels on medications being dispensed to patients are labeled with an accurate expiration date. Comments:	☒	☐

Section 3: Controlled Substance Audit Report			
Drug Name	Manual count at time of audit	Balance on hand from software system or manual record at time of audit	Discrepancy
Oxycodone 10mg	350	350	0
Oxy/APAP 10/325mg	504	504	0
Morphine Sulfate 15mg ER	162	162	0
Comments: Location utilizes manual perpetual log.			

Section 4: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
Must meet all security requirements of NAC 639.520.	Completed by October 2025.

Additional Comments:
Well prepared for inspection.
10-20% retail prescriptions vs compounded prescriptions.
Utilizing Infinite Dynamics for delivery service. 50% delivery. Patients are receiving toll-free number and product information as part of delivery service.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – [redacted]
Leo Basch – [redacted]
Joe Dodge [redacted]

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – [redacted]
Jenine Davis – [redacted]

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

☐ Recoverable Signature

X 

Signature of Pharmacist on Duty
Signed by: 1d353de8-32fb-4b00-8ad7-4c1f91c64c65

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Sterile Compounding

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for Inspection f/u:	admin@metapharmacyservices.com
Name of Certification Company:	CEM/TSS
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	List of sterile compounding personnel available for review with associated risk level. Comments: Document retained for Inlumon verification.	☒	☐
3.	Pharmacy compounds high risk sterile products. Comments:	☒	☐
4.	Most recent ISO classified area certification report available for review. Comments: Reviewed document dated March 2024. All pressures passed testing. Meets all air exchanges. Passed all particle testing. Passed all HEPA filter leak tests.	☒	☐
5.	Glove finger-tip results complete and accurate. Comments: Location is using revised guidelines for finger-tip testing. Reviewed document for Maria Vega dated 4/19/24. Document is signed by both employee and person performing assessment.	☒	☐
6.	Media fill results complete and accurate. Comments: Recommend placing employee name on form as opposed to initials. Reviewed document for Maria Vegas dated 4/19/24. Meets all requirements. All hoods passed testing. Location passed all viable testing. Recertification was due in September 2024. CEM/TSS scheduled to come out on 10/29/24 for testing.	☒	☐

7.	Cleaning log completed and available for review for ISO classified areas. Comments: Using manual cleaning log. Document contains initials of person performing compounding. Location is using Pre-empt daily and Peridox monthly.	☒	☐
8.	Compounding record is signed by both technician performing compounding and pharmacist who performs final verification. Comments: Manual document is signed by pharmacist and person completing compounding.	☒	☐
9.	Annual competency documentation complete and accurate. Comments: Reviewed document for Maria Vega dated 4/19/24. Meet all requirements.	☒	☐
10.	Pharmacy assigns beyond use dates in excess of USP-797 guidelines. Comments: Following all revised USP-797 guidelines.	☐	☒
11.	Bubble point testing results complete and accurate if applicable. Comments: Bubble point testing and results are attached to compounding record. List both threshold and actual results on form. Location would discard product with failed bubble point testing.	☒	☐
12.	Biological indicator results complete and accurate if applicable. Comments: BI results documented on compounding record and separate log.	☒	☐
13.	Sterility, Potency, and Endotoxin results available for any products requiring such documentation. Comments: Location is performing sterility and endotoxin testing through ARL. Location plans on following Category 2 with sterility testing.	☒	☐
14.	Pharmacy performs hazardous sterile drug compounding. Comments: Location is compounding hormones and mitomycin	☒	☐
15.	Hazardous compounding is performed in a BSC or CACI. Comments:	☒	☐
16.	Documentation of initial and ongoing training for hazardous compounding staff is available for review. Comments: Specific training for staff members. All employees must sign document regarding risks associated with hazardous compounding.	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of Issue	**Response due date**
No follow-up required.	

Additional Comments:
Confirmed that location is not doing any office use compounding.
Well prepared for inspection.
Location has been through multiple FDA, NAPB, and NVBOP inspections. Location may go through another NABP inspection in 2025.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – [redacted]
Leo Basch – [redacted]
Joe Dodge – [redacted]

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – [redacted]
Jenine Davis – [redacted]

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

Recoverable Signature

X

Signature of Pharmacist on Duty

Signed by: 1d353de8-32fb-4b00-8ad7-4d1f91c64c65

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Inspection Report
Non-Sterile Compounding

Section 1: General Information	
Inspection Date:	10/28/24
Pharmacy Name:	Meta Pharmacy Services
Pharmacy Address:	8352 W. Warm Springs Rd #120
Pharmacy Phone:	702-754-0172
Pharmacy License #:	PH03433
Managing Pharmacist:	Sean Barclay
Managing Pharmacist License #:	17303
E-mail to be utilized for inspection f/u:	admin@metapharmacyservices.com
Name of Certification Company:	CEM/TSS
Name of Pharmacist present for Inspection:	Sean Barclay
Name of NVBOP Inspector:	Joe Dodge

Section 2: Inspector Review		Yes	No
1.	Self-Inspection Form complete and accurate. Comments: Completed prior to inspection. Answers validated during on-site inspection.	☒	☐
2.	List of non-sterile compounding personnel available for review. Comments: Retained for Inlumon verification.	☒	☐
3.	Most recent certification report for powder hoods available for review. Comments: Powder hood certified in March 2024. CEM/TSS will recertify again on 10/29/24.	☒	☐
4.	Annual competency documentation complete and accurate. Comments: Reviewed non-sterile competency assessment for Maria Vega. Last assessment performed on 9/6/23. Competency is past due at this time. See notes below.	☐	☒
5.	Pharmacy assigns beyond use dates in excess of USP-795 guidelines. Comments:	☐	☒
6.	Pharmacy performs potency testing on a sampling of products for validation of compounding process. Comments: Not currently. PIC states that they may this in the near future.	☐	☒
7.	Master formulations meet regulatory requirements. Comments: All master formulations come from Medisca.	☒	☐

8.	Compounding worksheets meet regulatory requirements. Comments: Contains name of the person that performs the compounding and the pharmacist that verified the product. BUD is listed on worksheet.	☒	☐
9.	Pharmacy performs hazardous non-sterile drug compounding. Comments: Hormone compounding only. PIC states that they are ready to implement USP-800.	☒	☐
10.	If performing non-sterile hazardous drug compounding there is documentation of initial and ongoing competency for personnel performing this activity. Comments:	☒	☐
11.	Documentation of cleaning records for non-sterile compounding area. Comments: Manual cleaning record available for review. Location is using Pre-Empt and Peridox for cleaning agents in the area.	☒	☐

Section 3: Required Follow-Up - The following items were identified as issues which require a response from the managing pharmacist.	
Description of issue	**Response due date**
PIC to confirm that all non-sterile compounding employees have completed their competency assessment within the last 12 months.	**ASAP**

Additional Comments:
Separate and complete area for non-sterile compounding.

If you are required to provide documentation to the inspector via fax or e-mail use the contact information listed below.

Please fax required documents to 1-702-486-7903 for Las Vegas inspectors

John Castaldo – [redacted]
Leo Basch –
Joe Dodge –

Please fax required documents to 1-775-850-1444 for Reno inspectors

Mui Lee – [redacted]
Jenine Davis –

Your location has been inspected by an agent of the Nevada Board of Pharmacy. Any noted unsatisfactory conditions that require action are listed above and they must be corrected within the time frames stated to ensure compliance with laws and regulations governing your business.

☐ Recoverable Signature

X _____

Signature of Pharmacist on Duty

Signed by: 1d853de8-32fb-4b00-8ad7-4d1f91c64c65

DEA Certificate

Please be advised, a new DEA certificate application has been submitted and is pending approval. Upon receipt of the new DEA certificate, a copy will be provided to supplement application.

12

12A

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application
Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	☒ New Pharmacy	☒ Retail/Community	☐ Retail/Community
☒ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	☐ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.)	☒ Other:	☐ Non-sterile Compounding
			☐ Sterile Compounding
			☒ Mail-Order Service
			☐ Off-site Cognitive Services
			☒ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: POLARIS PHARMACY SERVICES

Physical Address: 125 TITUS AVENUE

City: WARRINGTON State: PA Zip: 18976

Mailing Address (if different from physical address): SAME AS PHYSICAL ADDRESS

City: _____ State: _____ Zip: _____

Telephone: 267-487-8900 Toll Free # (NAC 639.708, NRS 639.23286): 800-782-4696

Fax: 267-487-8960 Contact Email: GHUNT@POLARISRX.COM

Website: WWW.POLARISRX.COM

Nevada Business License # (if applicable) N/A - NEW APPLICATION

Supervising/Managing Pharmacist Name (NRS 639.220): JONATHAN REIBSTEIN

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24459

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: JONATHAN REIBSTEIN	NV Pharmacist Registration #: 24459
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	Yes	No
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	✔
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: PENNSYLVANIA

Parent Company (if any): POLARIS PHARMACY SERVICES, LLC

Corporation/Organization Name: POLARIS PHARMACY SERVICES OF WARRINGTON LLC

Mailing Address: 2900 NW 60TH STREET

City: FORT LAUDERDALE State: FL Zip: 33309

Telephone: 800-589-9747 Email: GHUNT@POLARISRX.COM

Contact Person Name: GINA HUNT

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the CEO (title) for POLARIS PHARMACY SERVICES (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

DAVID ROMBRO

Print Name of Authorized Person

CEO

Original signature of Authorized Person (copies or stamps not accepted)

1/29/25

Date

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, DAVID ROMBRO hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the CEO (title) for POLARIS PHARMACY SERVICES (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 29 day of Jan, 20 25

Notary Public

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

DAVID ROMBRO

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

CEO

Original signature of Authorized Person (copies or stamps not accepted)

1/29/25

Date

Board Use Only	Date Received: 2/3/25	Amount: $500 ck 2560

Polaris Pharmacy Services of Warrington, LLC
DBA Polaris Pharmacy Services
Officer, Ownership & Manager Detail

125 Titus Avenue
Warrington, PA 18976-2424

Officer Name	DOB	SSN
David Rombro (CEO)	[redacted]	
[redacted]		
Email: drombro@polarisrx.com		
Robert Meyer (CFO)	[redacted]	
[redacted]		
Email: rmeyer@polarisrx.com		
Steven Baker (COO)	[redacted]	
[redacted]		
Email: sbaker@polarisrx.com		

Ownership

Polaris Pharmacy Services of Warrington, LLC DBA Polaris Pharmacy Services

which is owned by: Polaris Pharmacy Services of Philadelphia, LLC (100%)

which is owned by: Polaris Pharmacy Services, LLC (100%)

***all have same officers**

Polaris Pharmacy Services, LLC
2900 NW 60th Street
Ft Lauderdale, FL 33309

FEIN:	47-4098540
Owned by:	Da Pharmacy Guys, LLC (22.03%)
	Enhanced Medical Services (24.30)
	EJJ Pharma, LLC (24.30%)
	PPGRX North Carolina, LLC (29.37%)
Managers:	David W. Rombro, Daniel Galbut, Harold Sussman
Officers:	David W. Rombro (CEO), Robert Meyer (CFO), Steven Baker (COO)

***No one person owns more than 10%**

Managers

David Rombro
[redacted]
Email: drombro@polarisrx.com

Daniel Galbut
[redacted]
Email: dgalbut@gmail.com

Harold Sussman
[redacted]
Email: hsussman@kochingroup.com

Responsible Agent for Board Communication
Gina Hunt
Ghunt@polarisrx.com
[redacted]

Pennsylvania Department of State

Bureau of Corporations and Charitable Organizations
PO Box 8722 | Harrisburg, PA 17105-8722
T:717-787-1057
dos.pa.gov/BusinessCharities

Regarding:	Polaris Pharmacy Services of Warrington, LLC		
Request Type:	Subsistence Certificate	**Issuance Date:**	January 28, 2025
Request No.:	050046917	**File No.:**	0012929110
Receipt No.:	001405158		
Filing Type:	Domestic Limited Liability Company		
Filing Subtype:	Limited Liability Company		
Initial Filing Date:	March 30, 2023		
Status:	Active		

TO ALL WHOM THESE PRESENTS SHALL COME, GREETING:

I DO HEREBY CERTIFY THAT

Polaris Pharmacy Services of Warrington, LLC

is currently subsisting on the records of the Department of State as of the issuance date herein.

I DO FURTHER CERTIFY THAT this Subsistence Certificate shall not imply that all fees, taxes and penalties owed to the Commonwealth of Pennsylvania are paid.



IN TESTIMONY WHEREOF, I have hereunto set my hand and caused the seal of my office to be affixed, the day and year above written

Albert Schmidt
Secretary of the Commonwealth

Verify this certificate online at www.file.dos.pa.gov

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler POLARIS PHARMACY SERVICES

Pharmacy/Wholesaler License # (if applicable) N/A - NEW APPLICATION

Physical Address 125 TITUS AVENUE

City WARRINGTON State PA Zip 18976

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 267-487-8900 Website WWW.POLARISRX.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First JONATHAN Middle MOSS Last REIBSTEIN

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addre[redacted]

City CHALFONT State PA Zi[redacted]

Telephone[redacted] Ema[redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
TEMPLE UNIVERISTY SCHOOL OF PHARMACY		1992-1995	
Address	**City**	**State**	**Zip**
3307 N BROAD ST	PHILADELPHIA	PA	19140
Diploma/Degree obtained, if any			
BS IN PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
TEMPLE UNIVERSITY AMBLER CAMPUS		1990-1992	
Address	**City**	**State**	**Zip**
580 MEETINGHOUSE RD	AMBLER	PA	19002
Diploma/Degree obtained, if any			
UNDERGRAD			

School Name		From - To (MM/YY – MM/YY)	
GEORGE WASHINGTON HIGH SCHOOL		1986-1990	
Address	**City**	**State**	**Zip**
10175 BUSTLETON AVE	PHILADELPHIA	PA	19116
Diploma/Degree obtained, if any			
HIGH DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
04/2003-CURRENT	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
POLARIS PHARMACY SERVICES (FORMERLY CONTRACT PHARMACY SERVICES)			05/2017 TO CURRENT	
Business Address		**City**	**State**	**Zip**
125 TITUS AVENUE		WARRINGTON	PA	18976
Phone	**Title**		**Number of Employed Hours**	
267-487-8900	PHARMACIST IN CHARGE		15,600	
Description of Duties				
OVERSEE COMPLIANCE AND OPERATIONS OF THE PHARMACY				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, JONATHAN REIBSTEIN, **certify that as the designated representative for**

POLARIS PHARMACY SERVICES,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. JR I am at least 21 years of age;
3. JR I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. JR I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. JR I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. JR I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. JR I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

JONATHAN REIBSTEIN

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/22/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Jonathan Reibstein

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/22/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Pennsylvania, ss. County of Bucks

I, Jonathan Reibstein, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/22/2025

Date

Subscribed and Sworn to before me this 22 day of January 2025

Carole A. Janssens

Notary Public Signature

Commonwealth of Pennsylvania - Notary Seal
Carole A. Janssens, Notary Public
Bucks County
My commission expires June 10, 2026
Commission number 1219185
Member, Pennsylvania Association of Notaries

(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site POLARIS PHARMACY SERVICES

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 125 TITUS AVENUE

City WARRINGTON State PA Zip 18976

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 267-487-8900 Website WWW.POLARISRX.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First DAVID Middle _____ Last ROMBRO

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City FORT LAUDERDALE State FL Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF MARYLAND, BALTIMORE		05/81	
Address	**City**	**State**	**Zip**
620 W LEXINGTON ST	BALTIMORE	MD	21201
Diploma/Degree obtained, if any			
B.S. OF PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
BALTIMORE POLYTECHNIC INSTITUTE			
Address	**City**	**State**	**Zip**
1400 COLD SPRINGS LN	BALTIMORE	MD	21209
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
09/20 - CURRENT	[redacted]			
06/16 - 09/20				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)
POLARIS PHARMACY SERVICES			07/15 - CURRENT
Business Address	**City**	**State**	**Zip**
2900 NW 60TH STREET	FORT LAUDERDALE	FL	33309
Phone	**Title**		
954-919-1818	CEO		
Description of Duties			
PLEASE SEE ATTACHED RESUME			

Business Name			From - To (MM/YY – MM/YY)
OMNICARE			06/08 - 04/14
Business Address	**City**	**State**	**Zip**
2955 W CORPORATE LAKES BLVD #600	WESTON	FL	33331
Phone	**Title**		
954-660-5555	GM		
Description of Duties			
PLEASE SEE ATTACHED RESUME			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	**City**	**State**	**Zip**
Phone	**Title**		
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
02/06/2023	PENDING	CA	LOS ANGELES	LOS ANGELES COUNTY
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
23STCV02582		STANLEY MOSK COURTHOUSE		
Reason/Charge				
BREACH OF CONTRACT				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
MED-PLUS PHARMACY, INC VS ANAHEIM HEALTHCARE			LAWSUIT	
Name of Business/Industry/Entity				
MED-PLUS PHARMACY, INC				

Provide explanation below:

PLEASE SEE ATTACHED

CEO

Original Signature (electronic, copies or stamps not accepted)

1/29/25

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Rombro

Print Name (First, Last)

CEO

Original Signature (electronic, copies or stamps not accepted)

1/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Brevard

I, DAVID ROMBRO, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

CEO

Original Signature

1/24/25

Date

Subscribed and Sworn to before me this 29 day of Jan 2025.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

David Rombro

[redacted]

C-Level Senior Executive

Results-driven, highly accomplished senior level operational professional with the demonstrated ability to streamline business operations, execute solid decision-making that drives growth and increases efficiency while developing talent that improves customer relations that increases the bottom line within multi-billion dollar and small business organizations.

Professional Experience

Polaris Pharmacy Services, LLC.

Chief Executive Officer and Member, (2015 - present)

Overall leadership and vision for of the business.

Selected Achievements:

- Successfully led a startup in 2015 to an $800 million dollar company in 2023.
- Leveraged experience and team members to become the 6th largest long term care pharmacy in the US.

Omnicare, Inc., Cincinnati, OH
General Manager – Weston, Florida (2009-2014)

Selected Achievements:

- Led the largest pharmacy in Florida with over 21,000 licensed beds.

First Choice Pharmacy, Hollywood, Florida
Chief Executive Officer and Owner (2005-2009)

Selected Achievements:

- Led the pharmacy from start up to 7500 licensed beds and eventually sold to Omnicare.

Education

Bachelor of Science, Pharmacy, University of Maryland

CASE INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Case Number: 23STCV02582

MED-PLUS PHARMACY, INC. VS ANAHEIM HEALTHCARE CENTER, LLC, ET AL.

Filing Courthouse: Stanley Mosk Courthouse

Filing Date: 02/06/2023
Case Type: Contract/Warranty Breach - Seller Plaintiff (no fraud/negligence) (General Jurisdiction)
Status: Request for Dismissal - Before Trial not following ADR or more than 60 days since ADR 05/14/2024

Click here to access document images for this case

If this link fails, you may go to the Case Document Images site and search using the case number displayed on this page

FUTURE HEARINGS

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

None

PARTY INFORMATION

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:

A - P R - W

ANAHEIM HEALTHCARE CENTER LLC DBA ANAHEIM HEALTHCARE CENTER - Defendant

BARTLETT CARE CENTER LLC DBA FRENCH PARK CARE CENTER - Defendant

BERGMAN ROBERT DAVID - Attorney for Plaintiff

BRUCKER GARY KEITH - Attorney for Defendant

CITRUS NURSING CENTER DBA CITRUS NURSING CENTER - Defendant

COLLEGE VISTA LLC DBA COLLEGE VISTA CARE CENTER - Defendant

COMMUNITY CARE REHAB CENTER LLC DBA COMMUNITY CARE REHABILITATION CENTER - Defendant

COUNTRY OAKS PARTNERS LLC DBA COUNTRY OAKS CARE CENTER - Defendant

DOES 1-20 - Defendant

F. & B. HEALTHCARE DBA EXTENDED CARE HOSPITAL OF RIVERSIDE - Defendant

GARDEN PARK CARE CENTER LLC DBA GARDEN PARK CARE CENTER - Defendant

GIBRALTAR CONVALESCENT HOSPITAL INC. DBA DEL MAR CONVALESCENT HOSPITAL DBA SUNSET MANOR CONVALESCENT HOSPITAL - Defendant

GORDON LANE HEALTHCARE LLC DBA GORDON LANE CARE CENTER - Defendant

HERITAGE MANOR HEALTHCARE LLC DBA HERITAGE MANOR HEALTHCARE - Defendant

INLAND MEDICAL ENTERPRISES INC. DBA ALCOTT REHABILITATION HOSPITAL - Defendant

MED-PLUS PHARMACY LLC DBA MED-PLUS PHARMACY LTC - Plaintiff

MJB PARTNERS LLC DBA POMONA VISTA CARE CENTER - Defendant

MONTERREY PARK CONVALESCENT HOSPITAL INC. DBA MONTERREY PARK CONVALESCENT HOSPITAL - Defendant

PARAMOUNT CONVALESCENT GROUP INC. DBA PARAMOUNT CONVALESCENT HOSPITAL - Defendant

PARK REGENCY CARE LLC DBA PARK REGENCY CARE CENTER - Defendant

PC CARE LLC DBA PACIFIC CONVALESCENT CENTER - Defendant

PUENTE PARTNERS LLC DBA VICTORIA CARE CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

RIVERSIDE EQUITIES LLC DBA MISSION CARE CENTER - Defendant

SIERRA VIEW CARE HOLDINGS LLC DBA SIERRA VIEW CARE CENTER - Defendant

SUN MAR HEALTHCARE INC. DBA SUN-MAR NURSING CENTER - Defendant

VILLA RANCHO BERNARDO HEALTH CARE LLC DBA VILLA RANCHO BERNARDO CARE CENTER - Defendant

WYNGATE NURSING CENTER DBA NORTH VALLEY NURSING CENTER - Defendant

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP A - P R - W

DOCUMENTS FILED

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

Documents Filed (Filing dates listed in descending order)

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
05/18/2023

05/15/2024 Notice of Case Reassignment and Order for Plaintiff to Give Notice
Filed by Clerk

05/14/2024 Request for Dismissal
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

04/05/2024 Stipulation and Order (TO VACATE TRIAL DATES; [PROPOSED] ORDER)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/16/2024 Stipulation and Order (Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Undertaking (bond)

01/12/2024 Undertaking (bond)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Order Appointing Court Approved Reporter as Official Reporter Pro Tempore
Filed by COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Decision on applications for right to attach orders: granted in part
Filed by Clerk

01/11/2024 Objection (Evidentiary)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Objection (Evidentiary)
Filed by COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Minute Order ((Hearing on Application for Writ of Attachment Against Defenda...))
Filed by Clerk

01/08/2024 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Objection (Plaintiff's Evidentiary Objections to Declarations and Evidence Filed in Support of Defendant's Opposition to Its Applications for Right to Attach Orders Against Defendants Community Care Rehab Ctr, LLC and Villa Rancho Bernardo Health Care)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Reply (Plaintiff's Reply Brief in Support of Applications for Right to Attach Orders Against Defendants Community Care Rehab Center, LLC and Villa Rancho Bernardo Health Care, LLC)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TOPLAINTIFF'S APPLICATION__ FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC__)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Objection (DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC's JOINT EVIDENTIARY OBJECTIONS TO DECLARATIONS OF NEIL FARAGE IN SUPPORT OF PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDER AGAINST DEFENDANTS)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF GARY K. BRUCKER, JR. IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT COMMUNITY CARE REHAB CENTER, LLC'S NOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT VILLA RANCHO BERNARDO HEALTH CARE, LLC'SNOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Proof of Service (not Summons and Complaint)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF MICAH RHEAD IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration (DECLARATION OF JORDAN MADER IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATION FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Opposition (DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Stipulation and Order (Stipulation and Proposed Order Amending the Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

01/03/2024 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Proof of Service by Mail
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Proof of Service by Mail
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

07/27/2023 Notice of Ruling
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

07/14/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 07/14/2023)
Filed by Clerk

07/14/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

06/29/2023 Decision on Applications for Right to Attach Orders
Filed by Clerk

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/29/2023 Minute Order ((Hearing on Application for Writ of Attachment against (1) Def...))
Filed by Clerk

06/27/2023 Objection (to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/27/2023 Reply (Brief ISO Application for Right to Attach Order)

Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/22/2023 Declaration (Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration (Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Objection (Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against Defendants)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption
Filed by BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Opposition (To Plaintiffs Application For Right To Attach Orders Against Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc.
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Memorandum of Points & Authorities
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/31/2023 Certificate of Mailing for ((Non-Appearance Case Review) of 05/31/2023)
Filed by Clerk

05/31/2023 Minute Order ((Non-Appearance Case Review))
Filed by Clerk

05/24/2023 Case Management Statement
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/23/2023 Case Management Statement
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/19/2023 Minute Order ((Hearing on Ex Parte Application of Plaintiff for Temporary Pr...))
Filed by Clerk

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:

TOP 05/18/2023

05/18/2023 Opposition (Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr.)
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/18/2023 Declaration (of Richard Fond re Ex Parte for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/18/2023 Declaration (In support of Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

05/18/2023 Ex Parte Application (for Temporary Protective Order)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

03/30/2023 Answer
Filed by ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

03/01/2023 Proof of Service (not Summons and Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/15/2023 Notice (of Case Management Conference)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/10/2023 Notice of Case Management Conference
Filed by Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case
Filed by Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet
Filed by Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing
Filed by Clerk

02/06/2023 Alternate Dispute Resolution Packet
Filed by Clerk

02/06/2023 Summons (on Complaint)
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/06/2023 Civil Case Cover Sheet
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

02/06/2023 Complaint
Filed by MED-PLUS PHARMACY, LLC (Plaintiff)

Click on any of the below link(s) to see Register of Action Items on or before the date indicated:
TOP 05/18/2023

PROCEEDINGS HELD

Proceedings Held (Proceeding dates listed in descending order)

10/29/2024 at 09:30 AM in Department 39
Jury Trial - **Not Held - Vacated by Court**

10/18/2024 at 09:30 AM in Department 39
Final Status Conference - **Not Held - Vacated by Court**

06/25/2024 at 08:30 AM in Department 39
Trial Setting Conference - **Not Held - Vacated by Court**

06/24/2024 at 08:30 AM in Department 39
Post-Mediation Status Conference - **Not Held - Vacated by Court**

01/11/2024 at 09:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Granted**

01/11/2024 at 09:30 AM in Department 85
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Granted**

07/26/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Vacated**

07/14/2023 at 3:41 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

06/29/2023 at 09:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Application for Writ of Attachment (CCP 484.040) - **Held - Motion Denied**

06/08/2023 at 08:30 AM in Department 39
Case Management Conference - **Not Held - Advanced and Continued - by Court**

05/31/2023 at 2:34 PM in Department 39, Stephen I. Goorvitch, Presiding
Non-Appearance Case Review

05/19/2023 at 08:30 AM in Department 85, James C. Chalfant, Presiding
Hearing on Ex Parte Application (In support of Temporary Protective Order) - **Held - Motion Denied**

REGISTER OF ACTIONS

Case Information | Register Of Actions | FUTURE HEARINGS | PARTY INFORMATION | Documents Filed | Proceedings Held

05/20/2024 Case reassigned to Stanley Mosk Courthouse in Department 39 - Hon. Tony L. Richardsoneffective 05/20/2024; Reason: Inventory Transfer

05/15/2024 Notice of Case Reassignment and Order for Plaintiff to Give Notice; Filed by: Clerk

05/14/2024 On the Complaint filed by MED-PLUS PHARMACY, INC. on 02/06/2023, entered Request for Dismissal with prejudice filed by MED-PLUS PHARMACY, LLC as to the entire action

05/14/2024 Request for Dismissal; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

05/14/2024 Order to Show Cause re: Payment of Waived Fees; by:

05/14/2024 Trial Setting Conference scheduled for 06/25/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 05/14/2024

04/05/2024 Trial Setting Conference scheduled for 06/25/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39

04/05/2024 Stipulation and Order TO VACATE TRIAL DATES; [PROPOSED] ORDER; Signed and Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC

(Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER

04/05/2024 Updated -- Stipulation and Order TO VACATE TRIAL DATES; [PROPOSED] ORDER: Filed By: COLLEGE VISTA, LLC (Defendant),CITRUS NURSING CENTER (Defendant),BARTLETT CARE CENTER, LLC (Defendant),ANAHEIM HEALTHCARE CENTER, LLC (Defendant),GARDEN PARK CARE CENTER, LLC (Defendant),F. & B. HEALTHCARE (Defendant),COMMUNITY CARE REHAB CENTER, LLC (Defendant),COUNTRY OAKS PARTNERS, LLC (Defendant),SIERRA VIEW CARE HOLDINGS, LLC (Defendant),RIVERSIDE EQUITIES, LLC (Defendant),PUENTE PARTNERS, LLC (Defendant),PC CARE, LLC (Defendant),WYNGATE NURSING CENTER (Defendant),VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant),SUN MAR HEALTHCARE, INC. (Defendant),INLAND MEDICAL ENTERPRISES, INC. (Defendant),HERITAGE MANOR HEALTHCARE, LLC (Defendant),GORDON LANE HEALTHCARE, LLC (Defendant),GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant),PARK REGENCY CARE, LLC (Defendant),PARAMOUNT CONVALESCENT GROUP, INC. (Defendant),MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant),MJB PARTNERS, LLC (Defendant);

04/05/2024 Post-Mediation Status Conference scheduled for 06/24/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

04/05/2024 Final Status Conference scheduled for 10/18/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

04/05/2024 Jury Trial scheduled for 10/29/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Vacated by Court on 04/05/2024

01/16/2024 Stipulation and Order Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/16/2024 Updated -- Stipulation and Order Stipulation and Proposed Order RE Precedential Effect of Plaintiff's Contemplated Initial Motions to Compel Further Discovery Responses: Filed By: MED-PLUS PHARMACY, LLC (Plaintiff); Result: Granted ; Result Date: 01/16/2024

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/12/2024 Updated -- Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment: As To Parties: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant)

01/12/2024 Right to Attach Order After Hearing and Order for Issuance of Writ of Attachment; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/12/2024 Undertaking bond; Filed by:

01/12/2024 Undertaking bond; Filed by:

01/11/2024 Objection Evidentiary; Filed by: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Objection Evidentiary; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/11/2024 Decision on applications for right to attach orders: granted in part; Filed by: Clerk

01/11/2024 Order Appointing Court Approved Reporter as Official Reporter Pro Tempore; Filed by: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

01/11/2024 Minute Order (Hearing on Application for Writ of Attachment Against Defenda...)

01/11/2024 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 01/11/2024; Result Type to Held - Motion Granted

01/11/2024 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 01/11/2024; Result Type to Held - Motion Granted

01/08/2024 Reply Plaintiff's Reply Brief in Support of Applications for Right to Attach Orders Against Defendants Community Care Rehab Center, LLC and Villa Rancho Bernardo Health Care, LLC; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Objection Plaintiff's Evidentiary Objections to Declarations and Evidence Filed in Support of Defendant's Opposition to Its Applications for Right to Attach Orders Against Defendants Community Care Rehab Ctr, LLC and Villa Rancho Bernardo Health Care; Filed by: MED-PLUS PHARMACY, LLC (Plaintiff)

01/08/2024 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: MED-PLUS PHARMACY, LLC (Plaintiff); ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant) et al.

01/05/2024 Updated -- MED-PLUS PHARMACY, LLC (Plaintiff): Organization Name changed from MED-PLUS PHARMACY, INC. to MED-PLUS PHARMACY, LLC

01/04/2024 Opposition DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Declaration DECLARATION OF JORDAN MADER IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATION FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF MICAH RHEAD IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Proof of Service (not Summons and Complaint); Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT VILLA RANCHO BERNARDO HEALTH CARE, LLC'SNOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANT COMMUNITY CARE REHAB CENTER, LLC'S NOTICE OF OPPOSITION TO RIGHT TO ATTACH ORDER AND CLAIM OF EXEMPTION; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF GARY K. BRUCKER, JR. IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TO PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Objection DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC's JOINT EVIDENTIARY OBJECTIONS TO DECLARATIONS OF NEIL FARAGE IN SUPPORT OF PLAINTIFF'S APPLICATIONS FOR RIGHT TO ATTACH ORDER AGAINST DEFENDANTS; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Declaration DECLARATION OF ADRIAN DEHGHANMANESH IN SUPPORT OF DEFENDANTS' JOINT OPPOSITION TOPLAINTIFF'S APPLICATION__ FOR RIGHT TO ATTACH ORDERS AGAINST DEFENDANTS COMMUNITY CARE REHAB CENTER, LLC AND VILLA RANCHO BERNARDO HEALTHCARE, LLC__; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

01/04/2024 Stipulation and Order Stipulation and Proposed Order Amending the Complaint; Signed and Filed by: MED-PLUS PHARMACY, LLC (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

01/04/2024 Updated -- Stipulation and Order Stipulation and Proposed Order Amending the Complaint: Filed By: MED-PLUS PHARMACY, INC. (Plaintiff); Result: Granted ; Result Date: 01/04/2024

01/03/2024 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: COMMUNITY CARE REHAB CENTER, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

11/07/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

11/07/2023 Proof of Service by Mail; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); After Substituted Service of Summons and Complaint ?: No

11/07/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant)

11/07/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 01/11/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 85

07/27/2023 Notice of Ruling; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

07/14/2023 Final Status Conference scheduled for 10/18/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Jury Trial scheduled for 10/29/2024 at 09:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Post-Mediation Status Conference scheduled for 06/24/2024 at 08:30 AM in Stanley Mosk Courthouse at Department 39

07/14/2023 Minute Order (Non-Appearance Case Review)

07/14/2023 Certificate of Mailing for (Non-Appearance Case Review) of 07/14/2023; Filed by: Clerk

07/14/2023 On the Court's own motion, Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Vacated on 07/14/2023

06/29/2023 Objections to Declaration of Adrian Dehghanmanesh Submitted in Opposition to Applications for Right to Attach Orders; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/29/2023 Decision on Applications for Right to Attach Orders; Filed by: Clerk

06/29/2023 Minute Order (Hearing on Application for Writ of Attachment against (1) Def...)

06/29/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 06/29/2023; Result Type to Held - Motion Denied

06/27/2023 Reply Brief ISO Application for Right to Attach Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/27/2023 Objection to Decl. of A. Dehghanmanesh Submitted in Opp to Appl. for Right to Attach Order; Filed by: MED-

PLUS PHARMACY, INC. (Plaintiff)

06/22/2023 Opposition To Plaintiffs Application For Right To Attach Orders Against Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Notice of Opposition to Right to Attach Order and Claim of Exemption; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/22/2023 Objection Defendants Anaheim Healthcare Center, LLC And Bartlett Care Center, LLC Joint Evidentiary Objections To Declarations Of Neil Farage In Support Of Plaintiffs Applications For Right To Attach Order Against Defendants; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Adrian Dehghanmanesh In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of Channon Balana Yin Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/22/2023 Declaration Declaration Of John Kimball In Support Of Defendants Joint Opposition To Plaintiffs Application For Right To Attach Order; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

06/06/2023 Notice of Application and Hearing for Writ of Attachment (CCP 484.040); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Memorandum of Points & Authorities; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

06/06/2023 Application for Right to Attach Order, Temporary Protective Order, etc. Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: BARTLETT CARE CENTER, LLC (Defendant)

06/06/2023 Hearing on Application for Writ of Attachment (CCP 484.040) scheduled for 06/29/2023 at 09:30 AM in Stanley Mosk Courthouse at Department 85

05/31/2023 Minute Order (Non-Appearance Case Review)

05/31/2023 Certificate of Mailing for (Non-Appearance Case Review) of 05/31/2023; Filed by: Clerk

05/31/2023 Updated -- Gary Keith Brucker (Attorney): Organization Name: Lewis Brisbois Bisgaard & Smith LLP; Middle Name changed from K. to Keith

05/31/2023 Address for Gary Keith Brucker (Attorney) null

05/31/2023 On the Court's own motion, Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39 Not Held - Advanced and Continued - by Court was rescheduled to 07/26/2023 08:30 AM

05/24/2023 Case Management Statement; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC

(Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant)

05/23/2023 Case Management Statement; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Name Extension changed from In support of Temporary Protective Order to for Temporary Protective Order ; As To Parties changed from ANAHEIM HEALTHCARE CENTER, LLC (Defendant) to ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/19/2023 Updated -- Ex Parte Application for Temporary Protective Order: Filed By: MED-PLUS PHARMACY, INC. (Plaintiff); Result: Denied ; Result Date: 05/19/2023

05/19/2023 Minute Order (Hearing on Ex Parte Application of Plaintiff for Temporary Pr...)

05/19/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85 updated: Result Date to 05/19/2023; Result Type to Held - Motion Denied

05/18/2023 Ex Parte Application In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

05/18/2023 Declaration In support of Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Declaration of Richard Fond re Ex Parte for Temporary Protective Order; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff)

05/18/2023 Hearing on Ex Parte Application In support of Temporary Protective Order scheduled for 05/19/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 85

05/18/2023 Opposition Opposition To Plaintiffs Ex Parte Applications For Temporary Protective Orders Against Defendants Anaheim Healthcare Center And Bartlett Care Center; Declaration Of Gary K. Brucker, Jr. Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LL

03/30/2023 Answer; Filed by: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant); COLLEGE VISTA, LLC (Defendant); COUNTRY OAKS PARTNERS, LLC (Defendant); COMMUNITY CARE REHAB CENTER, LLC (Defendant); F. & B. HEALTHCARE (Defendant); GARDEN PARK CARE CENTER, LLC (Defendant); GIBRALTAR CONVALESCENT HOSPITAL, INC. (Defendant); GORDON LANE HEALTHCARE, LLC (Defendant); HERITAGE MANOR HEALTHCARE, LLC (Defendant); INLAND MEDICAL ENTERPRISES, INC. (Defendant); MJB PARTNERS, LLC (Defendant); MONTERREY PARK CONVALESCENT HOSPITAL, INC. (Defendant); PARAMOUNT CONVALESCENT GROUP, INC. (Defendant); PARK REGENCY CARE, LLC (Defendant); PC CARE, LLC (Defendant); PUENTE PARTNERS, LLC (Defendant); RIVERSIDE EQUITIES, LLC (Defendant); SIERRA VIEW CARE HOLDINGS, LLC (Defendant); SUN MAR HEALTHCARE, INC. (Defendant); VILLA RANCHO BERNARDO HEALTH CARE, LLC (Defendant); WYNGATE NURSING CENTER (Defendant); As to: MED-PLUS PHARMACY, INC. (Plaintiff)

03/01/2023 Notice and Acknowledgment of Receipt; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant)

03/01/2023 Proof of Service (not Summons and Complaint); Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/15/2023 Notice of Case Management Conference; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/10/2023 Case Management Conference scheduled for 06/08/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Case Management Conference scheduled for 07/26/2023 at 08:30 AM in Stanley Mosk Courthouse at Department 39

02/10/2023 Address for Robert David Bergman (Attorney) updated

02/10/2023 Notice of Case Management Conference; Filed by: Clerk

02/07/2023 Case assigned to Hon. Stephen I. Goorvitch in Department 39 Stanley Mosk Courthouse

02/06/2023 Complaint; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Civil Case Cover Sheet; Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Summons on Complaint; Issued and Filed by: MED-PLUS PHARMACY, INC. (Plaintiff); As to: ANAHEIM HEALTHCARE CENTER, LLC (Defendant); BARTLETT CARE CENTER, LLC (Defendant); CITRUS NURSING CENTER (Defendant) et al.

02/06/2023 Alternate Dispute Resolution Packet; Filed by: Clerk

02/06/2023 First Amended General Order re: Mandatory Electronic Filing; Filed by: Clerk

02/06/2023 Voluntary Efficient Litigation Stipulation Packet; Filed by: Clerk

02/06/2023 Notice of Case Assignment - Unlimited Civil Case; Filed by: Clerk

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"); followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site POLARIS PHARMACY SERVICES

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (if applicable) _____

Physical Address 125 TITUS AVENUE

City WARRINGTON State PA Zip 18976

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 267-487-8900 Website WWW.POLARISRX.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First ROBERT Middle _____ Last MEYER

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Address [redacted]

City FORT LAUDERDALE State FL Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
UNIVERSITY OF CINCINNATI		1988-1993	
Address	**City**	**State**	**Zip**
2600 CLIFTON AVE	CINCINNATI	OH	45221
Diploma/Degree obtained, if any			
B.S. IN ACCOUNTING, B.S. IN REAL ESTATE			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
POLARIS PHARMACY SERVICES			2019 - CURRENT	
Business Address		**City**	**State**	**Zip**
2900 NW 60TH STREET		FORT LAUDERDALE	FL	33309
Phone	**Title**			
800-589-9747	CFO			
Description of Duties				
OVERSEE FINANCIAL REPORTING, PLANNING (BUDGETING), TREASURY AND CAPITAL STRUCTURE.				

Business Name			From - To (MM/YY – MM/YY)	
WELLFOUNT PHARMACY			2015 - 2019	
Business Address		**City**	**State**	**Zip**
5751 W 73RD ST		INDIANAPOLIS	IN	46278
Phone	**Title**			
	CFO AND PRESIDENT, LTC DIVISION			
Description of Duties				
DIRECT A TEAM ENCOMPASSING CONTROLLERSHIP, BUSINESS OPERATIONS, DECISON SUPPORT, FINANCIAL PLANNING AND ANALYSIS, SALES REPORTING, REAL ESTATE, BUSINESS SYSTEMS, AND HR.				

Business Name			From - To (MM/YY – MM/YY)	
ORIONRX, LLC			2014 - 2015	
Business Address		**City**	**State**	**Zip**
13100 MAGISTERIAL DRIVE, SUITE 102		PRESIDENT & CFO	KY	
Phone	**Title**			
502-213-8444	PRESIDENT & CFO			
Description of Duties				
EVALUATED AREA OPERATIONS TO IDENTIFY OPPORTUNITIES FOR DECREASED EXPENSES, IMPLEMENT PLANS FOR OPERATIONAL INFRASTRUCTURE OF SYSTEMS, PROCESSES, AND PERSONNEL.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	MINNEAPOLIS	RAMSEY

Case #	Governing, licensing, Arresting Presiding Body/Agency/Court
265679	MINNESOTA BOARD OF PHARMACY

Reason/Charge
PHARMACY WAS ALLOWING REMOTE ORDER ENTRY.

Plaintiff/Defendant/Claimant/Respondent	Lawsuit/Arbitration/Bankruptcy
PLEASE SEE ATTACHED.	HEARING

Name of Business/Industry/Entity
POLARIS SPECIALTY SERVICES OF MINNESOTA, LLC

Provide explanation below:

PLEASE SEE ATTACHED.

Original Signature (electronic copies or stamps not accepted)

1/29/24
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Robert Meyer

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

1/29/25

Date

Please have this section completed in the presence of a Notary Public.

State of FLORIDA, ss. County of BROWARD

I, Robert Meyer, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

1/29/25

Date

Subscribed and Sworn to before me this 29 day of Jan 2025.

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Personal History Application

Rev (05/18/2023)

Section 1: Pharmacy/ MDEG/Wholesaler Information

Name of Pharmacy/MDEG/Wholesaler/Dispensing Site POLARIS PHARMACY SERVICES

Pharmacy/MDEG/Wholesaler/Dispensing Practitioner License # (If applicable) _____

Physical Address 125 TITUS AVENUE

City WARRINGTON State PA Zip 18976

Mailing Address (if different from physical address) SAME AS PHYSICAL ADDRESS

City _____ State _____ Zip _____

Telephone 267-487-8900 Website WWW.POLARISRX.COM

Licensing Company Email GHUNT@POLARISRX.COM

Section 2: Personal Information

First STEVEN Middle _____ Last BAKER

Alias(es, nicknames, name changes, etc.) _____

Date of Birt[redacted] SSN or ITIN[redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]

City FORT LAUDERDALE State FL Zip[redacted]

Telephone[redacted] Email[redacted]

Are you a citizen of the United States? ☐ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
VCU SCHOOL OF PHARMACY		08/89 - 06/92	
Address	**City**	**State**	**Zip**
410 NORTH 12TH STREET	RICHMOND	VA	23298
Diploma/Degree obtained, if any			
BS PHARMACY			

School Name		From - To (MM/YY – MM/YY)	
SOUTHWEST VIRGINIA COMMUNITY COLLEGE		08/87 - 06/89	
Address	**City**	**State**	**Zip**
635 COMMUNITY COLLEGE ROAD	CEDAR BLUFF	VA	24609
Diploma/Degree obtained, if any			
ASSOCIATES DEGREE			

School Name		From - To (MM/YY – MM/YY)	
RICHLANDS HIGH SCHOOL		08/83 - 06/87	
Address	**City**	**State**	**Zip**
138 TORNADO ALLEY	RICHLANDS	VA	28574
Diploma/Degree obtained, if any			
HIGH SCHOOL DIPLOMA			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
02/22 - CURRENT	[redacted]			
02/20 - 02/22				
02/19 - 02/20				
02/18 - 02/19				
02/16 - 02/18				
02/14 - 02/16				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: Beginning with the most current employment, list your work history and corporations, partnerships or any other business ventures with which you have been associated as an officer, director, shareholder, stockholder, partner, owner, or related capacity within the last 10 years.

Business Name			From - To (MM/YY – MM/YY)	
POLARIS PHARMACY SERVICES			11/15 - CURRENT	
Business Address		**City**	**State**	**Zip**
2900 NW 60TH STREET		FORT LAUDERDALE	FL	33309
Phone	**Title**			
954-919-1818	COO			
Description of Duties				
OVER SEE DAY-TO-DAY OPERATIONS OF PHARMACIES AND CUSTOMER RETENTION.				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**			
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)	✔	
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?	✔	
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?	✔	
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-10, you have marked "YES" to in section 8 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 4, 5, 6. **Provide all the following *where applicable*:**

Date of Event/Arrest	Disposition Date	State	City	County
03/19/2019	12/08/2021	MN	MINNEAPOLIS	RAMSEY
Case #	**Governing, licensing, Arresting Presiding Body/Agency/Court**			
265279	MINNESOTA BOARD OF PHARMACY			
Reason/Charge				
PHARMACY WAS ALLOWING REMOTE ORDER ENTRY				
Plaintiff/Defendant/Claimant/Respondent	**Lawsuit/Arbitration/Bankruptcy**			
PLEASE SEE ATTACHED	HEARING			
Name of Business/Industry/Entity				
POLARIS PHARMACY SERVICES OF MINNESOTA, LLC				

Provide explanation below:

PLEASE SEE ATTACHED

Original Signature (electronic, copies or stamps not accepted)

01/29/2025
Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

STEVEN BAKER

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

01/29/2025

Date

Please have this section completed in the presence of a Notary Public.

State of Florida, ss. County of Broward

I, Steven Baker, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

01/29/2025

Date

Subscribed and Sworn to before me this 29 day of Jan 2025

Notary Public Signature

IVOR STEWART
Notary Public - State of Florida
Commission # HH 339460
My Comm. Expires Apr 2, 2027
Bonded through National Notary Assn.

(Seal)

Challenges Polaris Faced in Minnesota

Polaris entered the Minnesota market in November 2018. The company operates only one pharmacy in Minnesota, which is located at 5220 Park Glen Road, St. Louis Park. Polaris' early experience in Minnesota was not without its challenges, but the company has made a good faith effort to address its challenges and is constantly looking to improve.

When Polaris entered the Minnesota market, it was surprised to find a labor market (particularly for pharmacy technicians) that was much tighter than other markets in which Polaris operates and experienced more staff turnover in Minnesota than it is accustomed to in other markets. The Covid-19 pandemic obviously put an incredible amount of stress on every stakeholder in the pharmacy industry, and Polaris was no exception. The pandemic made it even more difficult for Polaris to recruit, hire, and retain talented staff.

Polaris continues to believe it did not engage in central services by having Minnesota-licensed technicians located in Florida perform remote order entry tasks in connection with prescription orders filled in Minnesota. In letters to the Board dated July 19, 2019, Polaris explained why it began using Minnesota-licensed technicians based in Florida to assist Polaris Minnesota with order entry tasks.

In sum, during its initial months of operation, Polaris faced an unanticipated and unacceptable backlog of prescription orders that needed to be filled in Minnesota. The backlog resulted largely from Polaris' inability to recruit and retain enough capable pharmacy technicians in Minnesota during the early months of operation. To address the backlog and ensure the timely delivery of prescriptions to Minnesota patients, Polaris initially had Minnesota-licensed technicians based in Florida perform order entry services on behalf of Polaris Minnesota. These technicians were experienced technicians who were licensed in Minnesota before they performed order entry work for Polaris Minnesota. Further, while performing remote order entry work from a Polaris Florida location, these technicians were connected virtually to Polaris Minnesota's physical workspace through Polaris' FrameworkLTC software platform, which is commonly used across the long-term care pharmacy industry. At all times, the work of these technicians was overseen by a licensed pharmacist at the Florida pharmacy (where the data was entered into FrameworkLTC), as well as a Minnesota-licensed pharmacist in the Minnesota pharmacy, who ultimately controlled and was responsible for the technicians' work and any prescriptions filled in connection with data they entered into the system. Additionally, until May 2019, Polaris had IND Consulting and its "Team X" do some remote order entry work for Polaris Minnesota. Aside from the order entry function, Polaris Minnesota's prescription processing and filling functions have always taken place entirely in the Minnesota pharmacy. Polaris has at times relied on similar remote order entry processes in other states without triggering central service pharmacy requirements.

Accordingly, when Polaris started using this process to help deal with the Minnesota backlog, it did not anticipate that it might be triggering central services pharmacy requirements. For this reason, Polaris initially did not submit or seek approval from the Board for a central prescription drug processing policy or procedure. In March 2019, after Board staff expressed a

view that Polaris' use of Minnesota-licensed technicians based in Florida to perform remote entry work constituted an unauthorized central service arrangement, Polaris took immediate steps to address the issue. Polaris initially flew Minnesota-licensed technicians from Florida to Minnesota, so they could be physically present in the Polaris Minnesota pharmacy while performing the same order entry functions they had been performing in Florida.

Finally, Polaris sought Board approval of several remote order entry variances, with the goal of being authorized to resume using Minnesota-licensed technicians based in Florida to perform remote order entry for Polaris Minnesota, and particularly to deal with emergencies or backlogs. When Board staff initially raised this issue in March 2019, Polaris did not believe it could immediately shift all order entry functions to its limited staff in Minnesota without compromising patient safety and welfare. At the time, Polaris was still working through the backlog, onboarding new care facilities, and working hard to locate, hire, train, and retain technicians and other staff in Minnesota in a challenging labor market. Under the circumstances, Polaris determined it was necessary to continue using Minnesota licensed, Florida-based technicians for a period of time in order to deal with the backlog and continue filling prescriptions in a timely manner for patients who needed them, while simultaneously building up its Minnesota workforce and making the changes necessary to meet the expectations of Board staff. As soon as Polaris was staffed and equipped to perform all order entry functions in Minnesota, it stopped utilizing technicians who were not physically located in Minnesota altogether. Accordingly, from June 2019 to the present, Polaris has only used Minnesota-licensed technicians physically located in the Polaris Minnesota pharmacy to perform order entry work on prescription orders filled in Minnesota. Polaris took concerns raised by Board staff over remote order entry issues seriously, and it believes it acted reasonably under the circumstances to address those concerns, while also maintaining high levels of patient care.

Polaris remained committed to working cooperatively with the Board to better understand what it must do in order to utilize remote order entry processes in the future. Polaris would always attempt to rely on technicians physically located in its Minnesota pharmacy to perform data entry and other prescription filling functions. The Board acknowledged granting variance requests to many pharmacy chains and health-systems that authorize the use of remote order entry processes. In March 2020, the Board also issued Covid-19 related guidance acknowledging that pharmacists and technicians could perform various prescription drug filling functions while working remotely—including data entry of prescriptions and orders; verifying prescriptions; certifying data entry and the finished prescriptions (i.e., the product check); conducting profile and prospective drug utilization reviews; and stage-checking for compounding—so long as affiliated pharmacies were using adequate computer software and hardware for the tasks being performed. While the Board's Covid-19 guidance evolved after Governor Walz's Peacetime Emergency declaration was rescinded, Polaris continues to believe remote order entry processes like those implemented during the first few months of Polaris' operations in Minnesota were safe, effective, and should have a place in the delivery of modern pharmacy services.

The Board approved the central services variance #265679-010 on July 13, 2022 between Polaris Pharmacy Services of Minnesota, LLC and both the Polaris Pharmacies located in Tampa and Ft. Lauderdale Florida for urgent or emergent needs.

BEFORE THE MINNESOTA

BOARD OF PHARMACY

In the Matter of
Polaris Pharmacy Services of Minnesota, LLC
License No. 265679

STIPULATION AND CONSENT ORDER

STIPULATION

Polaris Pharmacy Services of Minnesota, LLC ("Licensee") and the Minnesota Board of Pharmacy Committee on Professional Standards ("Committee") agree the above-referenced matter may be resolved without trial of any issue or fact as follows:

I.

JURISDICTION

1. The Minnesota Board of Pharmacy ("Board") is authorized pursuant to Minnesota Statutes chapter 151 to license and regulate pharmacies and to take disciplinary action as appropriate.

2. Licensee holds a pharmacy license from the Board and is subject to the jurisdiction of the Board with respect to the matters referred to in this Stipulation and Consent Order.

II.

CONFERENCE

3. On August 18, 2021, Licensee met with the Committee to discuss the allegations described in a Notice of Conference. Board members Kendra Metz and Stuart Williams comprised the Committee. The Board's Executive Director, Cody Wiberg; Deputy Director, Jennell Bilek; and staff attorney, Brian Park, were also present. Alex Mountain, Assistant Attorney General, represented the Committee. Brian A. Dillon, of Lathrop GPM LLP, represented licensee and was

accompanied by Licensee's Pharmacist-in-Charge, Neil Uitto; Polaris' Chief Operating Officer, Steven Baker; and Polaris' Executive Vice President of Operations, Todd Zisek.

III.

FACTS

4. On or about November 1, 2018, the Board licensed Licensee as a pharmacy in Minnesota.

5. Licensee is a closed door, long-term care ("LTC") pharmacy that prepares sterile and non-sterile compounded drug products for dispensing.

6. Licensee has two affiliated pharmacy locations in Florida, both licensed by the Board as follows:

a. On or about July 8, 2016, the Board issued Polaris Rx, located in Fort Lauderdale, Florida ("Pharmacy 1"), non-resident pharmacy license #265101.

b. On or about December 5, 2018, the Board issued Polaris Pharmacy Services of Tampa, located in Tampa, Florida ("Pharmacy 2"), non-resident pharmacy license #265721.

7. On or about March 19, 2019, two Board Surveyors visited Licensee for the purpose of completing a routine inspection, met with the pharmacist-in-charge, and identified the following:

a. Seven pharmacy technicians registered by the Board and employed by Pharmacy 1 and Pharmacy 2, were living in Florida but listed their current physical address as Licensee's address in Minnesota.

b. During the inspection, the Board Surveyors cited Licensee for engaging in central services with Pharmacy 1 and Pharmacy 2, by allowing pharmacy technicians working in Florida to remotely perform data entry of prescription drug information for Minnesota patients into

Licensee's Frameworks LTC prescription processing and dispensing software system ("FW-LTC"), followed by verification of the data entry by Licensee's pharmacist staff members working in Minnesota ("Central Service").

c. Prior to beginning Central Service, Licensee failed to submit a copy of its policy and procedure manual and failed to obtain Board approval to participate in a Central Service arrangement with Pharmacy 1 and Pharmacy 2.

d. Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the March 2019 citation.

e. Licensee's nonsterile compounding records failed to include an assigned beyond use date ("BUD") for the final compounded drug product, or included a BUD exceeding those recommended within United States Pharmacopeia, General Chapter 795 for Pharmaceutical Compounding - Nonsterile Preparations ("USP 795"), without documentation of a reference for literature or a stability study applicable to the specific drug product allowing for extension of the BUD. Licensee avers that it responded to these findings by providing education to its staff to ensure compounded components included lot numbers, expiration dates, and BUDs, along with noting the supporting reference sources. Licensee states that it is not aware of any other issues regarding its compliance with BUD requirements since 2019.

8. On or about March 20, 2019, the Board received a complaint alleging that Licensee was utilizing pharmacy technicians from outside of Minnesota to enter prescription data. On or about April 9, 2019, a Board Surveyor reminded Licensee, after expanding its operations to 24-

hours, that pharmacy technicians working outside of its Minnesota location could not be used to help with covering the additional hours that the pharmacy is open, due to the lack of Board approved policies for Central Services with Pharmacy 1 and Pharmacy 2. As noted above, Licensee disputes that it was operating a "central services arrangement" as it understands that term to be commonly used within the industry. Licensee maintains that its use of remote order entry processes was necessary under the circumstances, due to a backlog of prescription orders that had accumulated due in large part to Licensee's inability to recruit and retain sufficient staff in Minnesota during its early months of operating in the State. Nonetheless, for purposes of this stipulation, Licensee acknowledges and understands the Board's concern regarding the use of out-of-state technicians to enter prescription data.

9. On June 11, 2019, two Board Surveyors visited Licensee for the purpose of an investigation, met with representatives of the Licensee, and identified the following:

a. The pharmacist-in-charge stated that, as far as she was aware, Pharmacy 1 and Pharmacy 2, both located in Florida, were the only two locations providing Central Services for Licensee.

b. Licensee utilized a company named IND Consulting ("IND") for emergency kit ("E-kit") billing and entry of patient information when pharmacy services are initiated in a new LTC facility. IND's website states its staff are able to provide services including, but not limited to, billing services, medical record entry, and data entry solutions, with guaranteed staffing in fully operational data centers that are open 24 hours a day and 365 days a year, located within or outside of the United States across the globe in Mexico, India, the Philippines, and Florida. During the conference with the Committee, Licensee admitted that IND consulting had been used to enter prescription data for prescription drug orders ultimately dispensed by its

Minnesota pharmacy. Licensee cannot definitively state where individuals affiliated with IND were licensed or physically located when entering such data.

c. At the end of the visit, the Board Surveyor's provided an Investigative Report requesting additional information and reminding Licensee again that it cannot engage in Central Services without Board approval.

10. On February 12, 2020, two Board Surveyors visited Licensee for the purposes of an investigation, met with representatives of Licensee, and identified the following:

a. After arriving at 4:36 a.m., one of the Board Surveyors observed two of Licensee's pharmacy technicians were allowed badge access to the pharmacy entrance prior to the arrival of RPh 3 at around 5:55 a.m. One technician was found to be working in the sterile compounding area and another was logged into Licensee's computer. A representative of Licensee later stated that three pharmacy technicians had been given keys and passcodes to access Licensee's pharmacy. During its conference with the Committee, Licensee admitted that this allegation is true, but stated that senior management took corrective action upon learning of the situation, including immediately revoking the access code of all non-pharmacists and physically rekeying all doors within the pharmacy. Licensees avers that periodic security assessments confirm that no unauthorized persons have had access to the pharmacy since February 2020.

b. Six pharmacy technicians, including the IV pharmacy technician, were present in the "filling area" with only one pharmacist, who was the second pharmacist to arrive. Another pharmacist was in an "order entry" area, a distinctly different area separated by a wall and door. The Board Surveyors were told that additional pharmacy technicians were scheduled that morning to perform non-technician "staging or stocking" duties. However, the Board Surveyors observed that the additional pharmacy technicians that were supposedly scheduled to perform non-technician duties, were filling orders in the "filling area" to be checked by the one pharmacist.

Licensee avers that is does not have sufficient information to admit or deny the Board surveyors' observations, but that company policy requires compliance with required technician-to-pharmacist ratios.

IV.

LAWS

11. Licensee acknowledges the conduct described in section III above constitutes a violation of Minn. Stat. § 151.071, subd. 2(7), and warrants the disciplinary action described below.

V.

DISCIPLINARY ACTION

The parties agree the Board may take the following disciplinary action and require compliance with the following terms:

12. The Board **REPRIMANDS** Licensee and imposes a **CIVIL PENALTY** in the amount of $50,000 for the conduct described in section III above. The civil penalty shall be paid by cashier's check or money order made payable to the Minnesota Board of Pharmacy, c/o Cody Wiberg, Executive Director, 2829 University Avenue S.E., Suite 530, Minneapolis, Minnesota 55414, within 60 days of the date of entry of this Order.

13. The Board places the following **CONDITION** on Licensee's License: every six months, for a period of three years, Licensee's CEO must certify to the Board's Executive Director that Licensee's licensed pharmacies that provide services to Minnesota residents are in full compliance with all applicable Minnesota statutes and rules.

VI.

CONSEQUENCES FOR NONCOMPLIANCE OR ADDITIONAL VIOLATIONS

14. If Licensee fails to comply with or violates this Stipulation and Consent Order, the Committee may, in its discretion, seek additional discipline either by initiating a contested case proceeding pursuant to Minnesota Statutes chapter 14 or by bringing the matter directly to the Board pursuant to the following procedure:

a. The Committee shall schedule a hearing before the Board. At least 20 days before the hearing, the Committee must mail Licensee a notice of the violation(s) alleged by the Committee. In addition, the notice must designate the time and place of the hearing. Within ten days after the notice is mailed, Licensee shall submit a written response to the allegations. If Licensee does not submit a timely response to the Board, the allegations may be deemed admitted.

b. The Committee, in its discretion, may schedule a conference with Licensee prior to the hearing before the Board to discuss the allegations and to attempt to resolve the allegations through agreement.

c. Prior to the hearing before the Board, the Committee and Licensee may submit affidavits and written argument in support of their positions. At the hearing, the Committee and Licensee may present oral argument. Argument may not refer to matters outside the record. The evidentiary record must be limited to the affidavits submitted prior to the hearing and this Stipulation and Consent Order. The Committee will have the burden of proving by a preponderance of the evidence that a violation has occurred. If Licensee has failed to submit a timely response to the allegations, Licensee may not contest the allegations, but may present argument concerning the appropriateness of additional discipline. Pursuant to this process, Licensee waives a hearing before an administrative law judge, discovery, cross-examination of

adverse witnesses, and other procedures governing hearings pursuant to Minnesota Statutes chapter 14.

d. Licensee's correction of a violation before the conference, hearing, or meeting of the Board may be taken into account by the Board but does not limit the Board's authority to impose discipline for the violation. A decision by the Committee not to seek discipline when it first learns of a violation does not waive the Committee's right to later seek discipline for that violation, either alone or in combination with other violations, at any time while Licensee's license is in a suspended status.

e. Following the hearing, the Board will deliberate confidentially. If the allegations are not proved, the Board must dismiss the allegations. If a violation is proved, the Board may impose additional discipline, including conditions or limitations on Licensee's license, a period of suspension, conditions of reinstatement, or revocation of Licensee's license.

f. Nothing herein limits the Committee's or the Board's right to temporarily suspend Licensee's license as provided in Minnesota Statutes chapters 151 and 214, based on a violation of this Stipulation and Consent Order or based on conduct of Licensee not specifically referred to herein.

VII. ADDITIONAL INFORMATION

15. Licensee waives the contested case hearing and all other procedures before the Board to which Licensee may be entitled under the Minnesota and United States constitutions, statutes, or rules.

16. Licensee waives any claims against the Board, the Minnesota Attorney General, the State of Minnesota, and their agents, employees, and representatives related to the

investigation of the conduct herein, or the negotiation or execution of this Stipulation and Consent Order, which may otherwise be available to Licensee.

17. This Stipulation and Consent Order, the files, records, and proceedings associated with this matter shall constitute the entire record and may be reviewed by the Board in its consideration of this matter.

18. Either party may seek enforcement of this Stipulation and Consent Order in any appropriate civil court.

19. Licensee has read, understands, and agrees to this Stipulation and Consent Order and has voluntarily signed the Stipulation and Consent Order. Licensee is aware this Stipulation and Consent Order must be approved by the Board before it goes into effect. The Board may either approve the Stipulation and Consent Order as proposed, approve it subject to specified change, or reject it. If the changes are acceptable to Licensee, the Stipulation and Consent Order will take effect and the order as modified will be issued. If the changes are unacceptable to Licensee or the Board rejects the Stipulation and Consent Order, it will be of no effect except as specified in the following paragraph.

20. Licensee agrees that if the Board rejects this Stipulation and Consent Order or a lesser remedy than indicated in this settlement, and this case comes again before the Board, Licensee will assert no claim that the Board was prejudiced by its review and discussion of this Stipulation and Consent Order or of any records relating to it. If the Board rejects this Stipulation and Consent Order, the parties agree that this Stipulation and Consent Order will not be admissible in any proceedings.

21. This Stipulation and Consent Order does not limit the Board's authority to proceed against Licensee by initiating a contested case hearing or by other appropriate means on the basis

of any act, conduct, or admission of Licensee which constitutes grounds for disciplinary action, and which is not directly related to the specific facts and circumstances set forth in this document.

VIII.

DATA PRACTICES NOTICES

22. This Stipulation and Consent Order constitutes disciplinary action by the Board and is classified as public data pursuant to Minnesota Statutes section 13.41, subdivision 5. Data regarding this action will be provided to data banks as required by Federal law or consistent with Board policy. While this Stipulation and Consent Order is in effect, information obtained by the Board pursuant to this Order is considered active investigative data on a licensed health professional, and as such, is classified as confidential data pursuant to Minnesota Statutes section 13.41, subdivision 4.

23. This Stipulation contains the entire agreement between the parties, there being no other agreement of any kind, verbal or otherwise, which varies this Stipulation.

CONSENT:

POLARIS PHARMACY SERVICES OF MINNESOTA, LLC (LICENSEE)

Dated: 12-3-2021

MINNESOTA BOARD OF PHARMACY
COMMITTEE ON PROFESSIONAL STANDARDS

BOARD MEMBER

Dated: 12/8/21

ORDER

Upon consideration of the Stipulation, the Board **REPRIMANDS** Licensee, imposes a **CIVIL PENALTY**, and **CONDITIONS** Licensee's license and adopts all of the terms described above on this 8TH day of December, 2021.

MINNESOTA BOARD OF PHARMACY

CODY WIBERG
Executive Director

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

POLARIS PHARMACY SERVICES OF WARRINGTON, LLC
DBA CONTRACT PHARMACY SERVICES
125 TITUS AVENUE
WARRINGTON, PA, 18976

Phone: 267-487-8900
Owner:

LICENSE

License No: AA0005405462 (PP481213)
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 06/27/2024
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	YES
Is the automated medication systems properly validated?	YES
Are there policies and procedures for the operation of the automated medication systems?	YES
Is there a program for quality assurance for the automated medication systems?	YES
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

POLARIS PHARMACY SERVICES OF WARRINGTON, LLC
DBA CONTRACT PHARMACY SERVICES
125 TITUS AVENUE
Warrington, Pennsylvania, 18976

Phone: 267-487-8900
Owner: CONTRACT PHARMACY SERVICES

LICENSE

License No: PP481213
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 06/27/2024
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

ROBERT MONTGOMERY	6/27/2024 11:51:55 AM	Jonathan Reibstein - RP042085L
Signature of Inspector	Date/Time	Signature of Owner/Representative

PA State Board of Pharmacy
PO Box 2649
Harrisburg, PA, 17105-2649
Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

POLARIS PHARMACY SERVICES OF WARRINGTON, LLC
DBA CONTRACT PHARMACY SERVICES
125 TITUS AVENUE
Warrington, Pennsylvania, 18976

Phone: 267-487-8900
Owner: CONTRACT PHARMACY SERVICES

LICENSE

License No: PP481213
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: Non-Directed Routine

Inspection Date: 06/27/2024
Inspection Result: Passed

Remarks:

Question	Answer
Are all licenses current and posted?	YES
Is a "No Smoking" sign prominently posted?	YES
Is the generic equivalent sign and list of commonly used equivalents properly posted?	YES
Is there a refrigerator with temperature monitoring for drug storage only?	YES
Is hot and cold water available in the prescription area?	YES
Are current copies of all Federal, State, and Board statues and regulations pertaining to pharmacy practice available? (Internet access is acceptable)	YES
Are outdated drugs appropriately removed from active stock?	YES
Does the pharmacy meet all security requirements?	YES
Does the pharmacy have adequate equipment and supplies to enable it to properly prepare and dispense consistent with the pharmacy's scope of practice?	YES
Is the pharmacy in compliance with all sanitation, cleanliness, maintenance, and construction requirements?	YES
Do labels have all the required information and match the license record?	YES
Are all prescriptions verified by registered pharmacists?	YES
Is the name or initials of the dispensing pharmacist noted on the prescriptions?	YES
Are prescription files properly maintained? (electronic files are acceptable)	YES
Are transferred prescriptions properly recorded?	YES
Are Schedule II drugs securely locked in a substantially constructed cabinet or dispersed throughout the stock?	YES
Are there signed and dated protocols for each pharmacy technician?	YES
Does the pharmacy have an automated medication system?	YES
Is the automated medication systems properly validated?	YES
Are there policies and procedures for the operation of the automated medication systems?	YES
Is there a program for quality assurance for the automated medication systems?	YES
Does the pharmacy administer injectable medications, biologicals, or immunizations?	NO

PA State Board of Pharmacy
PO Box 2649
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Phone: 717-783-7156 Fax: 717-787-7769

FACILITY

POLARIS PHARMACY SERVICES OF WARRINGTON, LLC
DBA CONTRACT PHARMACY SERVICES
125 TITUS AVENUE
WARRINGTON, PA, 18976

Phone: 267-487-8900
Owner:

LICENSE

License No: AA0005405462 (PP481213)
Profession: Pharmacy
License Type: Pharmacy

Inspection Type: New Business

Inspection Date: 06/27/2024
Inspection Result: Passed

Remarks:

The undersigned licensee, designee, or other authorized representative of the licensee acknowledges the completion of this inspection and the results as indicated on the summary and checklist reports.

If this is a New Business Inspection, this PASS inspection form will serve as a temporary authority to operate pending final review and approval by the State Board. The temporary authority must be prominently displayed and will expire upon receipt of a properly issued license or six months from the date of inspection.

ROBERT MONTGOMERY	6/27/2024 11:39:31 AM	Jonathan Reibstein - RP042085L
Signature of Inspector	Date/Time	Signature of Owner/Representative

BUREAU OF PROFESSIONAL AND OCCUPATIONAL AFFAIRS

P. O. Box 2649

Harrisburg, PA 17105-2649

02/18/2025

License Information

POLARIS PHARMACY SERVICES

125 TITUS AVENUE
WARRINGTON, Pennsylvania 18976

Board/Commission:	State Board of Pharmacy	Status Effective Date:	02/04/2003
LicenseType:	Pharmacy	Issue Date:	02/04/2003
Specialty Type:	Inspected by Board	Expiration Date:	08/31/2025
License Number:	PP481213	Last Renewal:	07/13/2023
Status:	Active		

Prerequisite Information

Licensee	Relationship	License Type	License Number	License Status	Associated Date	License Expiration Date
ERIC JASON BORELL	Pharmacist Manager	Pharmacist	RP036529L	Active		09/30/2026
CHERYL LASTOWKA	Pharmacist Manager	Pharmacist	RP036827L	Active	02/04/2003	09/30/2026
JONATHAN REIBSTEIN	Pharmacist Manager	Pharmacist	RP042085L	Active	02/11/2023	09/30/2026

Disciplinary Action Details

No disciplinary actions were found for this license.

This site is considered a primary source for verification of license credentials provided by the Pennsylvania Department of State.

COMPLETED

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP2984690	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-15-2023

POLARIS PHARMACY SERVICES
125 TITUS AVE
WARRINGTON, PA 189762424

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

CONTROLLED SUBSTANCE REGISTRATION CERTIFICATE
UNITED STATES DEPARTMENT OF JUSTICE
DRUG ENFORCEMENT ADMINISTRATION
WASHINGTON D.C. 20537

DEA REGISTRATION NUMBER	THIS REGISTRATION EXPIRES	FEE PAID
FP2984690	03-31-2026	$888

SCHEDULES	BUSINESS ACTIVITY	ISSUE DATE
2,2N,3, 3N,4,5	RETAIL PHARMACY	06-15-2023

POLARIS PHARMACY SERVICES
125 TITUS AVE
WARRINGTON, PA 189762424

Sections 304 and 1008 (21 USC 824 and 958) of the Controlled Substances Act of 1970, as amended, provide that the Attorney General may revoke or suspend a registration to manufacture, distribute, dispense, import or export a controlled substance.

THIS CERTIFICATE IS NOT TRANSFERABLE ON CHANGE OF OWNERSHIP, CONTROL, LOCATION, OR BUSINESS ACTIVITY, AND IT IS NOT VALID AFTER THE EXPIRATION DATE.

Form DEA-223 (9/2016)

12B

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada	■ New Pharmacy	☐ Retail/Community	☐ Retail/Community
■ Out-of-Nevada	☐ Ownership Change*	☐ Hospital (# beds _____)	☐ Dangerous drugs
	☐ Location Change *	☐ Internet	☐ Controlled substances
	☐ Service Modification*	■ Nuclear	DEA #: _____
	☐ Name Change* (if only a Name Change occurred, submit a **$50.00** fee with the application.)	☐ Other:	■ Non-sterile Compounding
			■ Sterile Compounding
			☐ Mail-Order Service
			☐ Off-site Cognitive Services
			☐ Long Term Care
	* Current license #:		☐ Hospital
	PH_____		☐ Other:

Days of Operation		Ownership Type (check applicable box)
■ Monday	■ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
■ Tuesday	■ Saturday	■ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
■ Wednesday	■ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
■ Thursday	■ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RLS (USA) Inc

Physical Address: 1 Naylon Place

City: Livingston State: NJ Zip: 07039

Mailing Address (if different from physical address): same as above

City: _____ State: _____ Zip: _____

Telephone: 973-533-9109 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 973-533-1116 Contact Email: licensing@rls.bio

Website: www.rls.bio

Nevada Business License # (if applicable) _____

Supervising/Managing Pharmacist Name (NRS 639.220): Hussam Abbassi

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24404

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Hussam Abbassi	NV Pharmacist Registration #: 24404
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✓
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✓
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✓	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✓
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✓

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: N/A	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: _____

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Telix Pharmaceuticals (US) Inc (100% owner)

Corporation/Organization Name: RLS (USA) Inc

Mailing Address: 255 Primera Boulevard

City: Lake Mary State: FL Zip: 32746

Telephone: 813-425-5905 Email: licensing@rls.bio

Contact Person Name: David Miller, R.Ph.

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☒ No

Section 7: Partnership

Partnership Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: _____

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Manager, Licensing and Com (title) for RLS (USA) Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NR5 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

David Miller, R.Ph.

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/6/25

Date

KAREN PEIST
Notary Public, State of New Jersey
Comm. # 50222459
My Commission Expires 8/8/2029

Section 10: Affidavit for Pharmacies- MUST BE COMPLETED by pharmacies NOT CURRENTLY PERFORMING Sterile Compounding

Affidavit for Pharmacy License

I, David Miller hereby certify that the assertions in this Affidavit are true and correct to the best of my knowledge and belief, and state as follows:

1. I am the Manager, Licensing and Complian (title) for RLS (USA) Inc (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I certify that upon licensure, the Pharmacy will not perform sterile compounding or ship sterile compounds into Nevada.
3. I understand and acknowledge that the Pharmacy and any of its staff members may be subject to discipline by the Board if the Pharmacy performs sterile compounding or ships any sterile compounds into Nevada without first obtaining written authorization from the Board to do so.
4. I certify that if the Pharmacy makes the decision to perform sterile compounding or to ship any sterile compounds into Nevada, the Pharmacy, through an authorized representative, will first notify the Board via a written request, and obtain written approval to perform sterile compounding or to ship any sterile compounds into Nevada.
5. I understand that if the Pharmacy seeks approval to perform sterile compounding or to ship any sterile compounds into Nevada, an authorized representative of the Pharmacy may be required to appear before the Board to answer questions before such approval is granted.

FURTHER YOUR AFFIANT SAYETH NAUGHT.

Signature

SUBSCRIBED AND SWORN TO
Before me, a notary public this 6 day of February, 2025

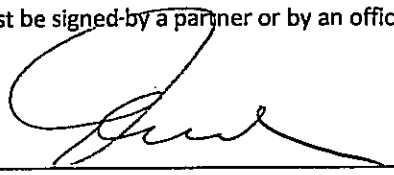
Notary Public

KAREN PEIST
Notary Public, State of New Jersey
Comm. # 50222459
My Commission Expires 6/5/2029

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Miller, R.Ph. Manager, Licensing and Compliance

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215



Original signature of Authorized Person (copies or stamps not accepted)

2/6/2025

Date

Board Use Only	Date Received: _____	Amount: _____

To the Nevada Board of Pharmacy:

There have been two actions by our home state Board and none by any other state since 2003. I have enclosed a description of these two actions and steps taken to remediate the conditions as provided by the Pharmacist in Charge (PIC) at the time. I have also enclosed copies of the Inspection Reports and the plan of action from the PIC for the 2016 finding.

Since 2016 any excursions have been addressed per regulation. The NJ Board of Pharmacy was notified timely, the affected areas closed, triple cleanings done, and the sterile areas reopened after successful environmental testing. There have been no Disciplinary Actions since 2016.

It is important to note that RLS does only low risk, sterile to sterile, compounding.

Inspection Report #8-1066.6 dated 12/19/2003

N.J.A.C. 13:39-12.2.e – Label missing information
N.J.A.C. 13:39.12.4.c – Missing Reference textbook
Actions taken – paid fine corrected deficiencies.

Inspection Report #8-1066-16-X dated 8/10/2016

N.J.A.C. 13:39-24.a.6 – Adequate efforts were not made to ensure the pharmacy's quality assurance program.
N.J.A.C. 13:39-11.24.a.10 – When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards
Actions taken – see the plan of action submitted by the Pharmacist in Charge and accepted by the NJBOP.

Please contact me if you need any further information at david.miller@RLS.bio.

Sincerely,

David Miller, R.Ph.

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. McGREEVEY
Governor

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 8, 2004

John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Re: Inspection Report #8-1066.6
Inspection Date: 12/19/03

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated:

N.J.A.C. 13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.
$25.00

N.J.A.C. 13:39-12.4(c)
Missing a current text in the category of "General Practice of Pharmacy".
$200.00

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the attached acknowledgment and agree to the following:

1. Pay a penalty in the amount of $225.00 and provide to the Board a Letter of Corrective Action. (To be paid immediately upon your signing of the attached Acknowledgment.)

Alternatively, you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed certification should be completed and returned to the Board **within fifteen (15) days following your receipt of this letter.** In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: Joanne Boyer
Joanne Boyer
Executive Director

JB/mw

cc: Marianne Greenwald, Deputy Attorney General
Daniel L. Peters, 1068 S. Kimbles Road, Yardley, PA 19067

Amersham Health
1 Naylon Place
Livingston New Jersey 07039

Ph. # 200
8/18/04
#72267

August 17, 2004
Joanne Boyer
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark NJ 07101

RE: Inspection Report #8-1066.6

Dear Ms. Boyer

Please find enclosed check for $200.00 for the deficiency of N.J.A.C. 13:39-12.4(c), missing a current edition of a text in the category of "General Practice of Pharmacy".

As a corrective action, Amersham Health has purchased a current edition of Remington's "The Science and Practice of Pharmacy" on 11 March 2004.

If you have any questions or require any additional information, please contact me at [redacted].

Sincerely,

John Marzocca R.Ph
Pharmacist in charge

Date: 8/10/2016
Time entered: 11:15 Am
Time departed: 3:00 Pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: GE Healthcare (Nuclear) Pharmacy.
Address: 1 Naylon Place, Livingston, NJ 07039.
Name and registration number of pharmacist-in-charge:
John Marzocca, 28RI0474700
(If pharmacist-in-charge not present, give name and # of R.P. on duty)

The following deficiencies have been noted:

[ ] 13:39- 11.04 (a)10]- During the environmental monitoring test on 9/28 - 9/29/2015, ISO class Dispensing room and WBC room had 0.0 C results. Reports were released in the time period of 10/9/2015 - 10/12/2015 Pharmacy did an internal retest on 10/30/2015. Results indicated no growth after 7 day incubation period. Rooms were cleaned but there was no indication that equipments were ceased using during the time period.

- Pharmacy since then updated its P&P (see attached)

[ ] 13:39- 11.04 (a) 6]- Internal semi-annual Surface sampling indicated a below actia level cfu results. They need to be analyzed to the genius level to exclude any possibilities of highly pathogenic species. Internal action plan needs to be detailed along with cleaning process.

[ ] ~~13:39- 11.10(b)12.]~~ ~~pharmacy will obtain sterile admixture references per NJ Regulations~~ Ttk

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS:

File # E-1066-16-X
Exhibit # 1
Page 1 of 1 Pages

(Signature of pharmacist identified above)

EB-33

3/07

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
ENFORCEMENT BUREAU

REPORT OF INSPECTION

TO:	ASSIGNMENT#	DATE:	PERIOD:
BOARD OF PHARMACY	8-1066-16-X	JAN 0 9 2017	8/10/2016

SUBJECT(S): **BY: Tony H. Qi, RP**

Medi-Physics, Inc dba GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
John Marzocca, RPIC

REFERENCE:

Board of Pharmacy inspection conducted per N.J.S.A. 45:1-18 and N.J.S.A. 45:14-48(a) 11&12 and a request from the Board to inspect all pharmacies that engage in compounding sterile preparations.

DETAILS:

A. On August 10, 2016, I, Bureau Investigator Tony Qi, visited the Subject Pharmacy for the purpose of engaging in a Board of Pharmacy inspection activity.

B. Present and at practice in the pharmacy was John Marzocca (R.P. #RI01474700). For identification purposes, all pharmacy personnel who were present and involved in the prescription filling/dispensing activities, completed respective "Pharmacy Personnel Identification" forms (**Exhibit #1**).

A. On the occasion of my visit, the following Board of Pharmacy inspection activities were conducted: an active drug stock inventory review(**Exhibit#2**), an EB-02 General Requirements form (**Exhibit#3**), a pharmacy library required texts review (**Exhibit #4**) and a prescription file records review. This inspection activity included the completion of a sterile compounding compliance survey per N. J.A.C Subchapter 13:39-11, Et Seq.

Reviewed By Robert Lee R. Ph.

B. Inspection of the pharmacy's "active" drug stock inventory revealed the following:

A total of Zero (0) containers of medication was discovered to be out-of-date, misbranded, or improperly stored.

C. The pharmacy compliance inspection activity identified the following deficiencies:

[13:39-11.24(a) 6]-Adequate efforts were not made to ensure the pharmacy's quality assurance program.

Specifically, on June 17, 2015, the Subject pharmacy's internal surface sampling detected a total of twenty-two (22) Colony Forming Units (CFU) from various locations, including support tables used in sterile compounding, the prep room and the pass through (see **Exhibit #5**).

On January 11, 2016, internal surface sampling detected one (1) CFU from the ISO 5 hood, one (1) CFU from Tech Hood 2, and one (1) CFU from Biologic Safety Cabinet (BSC) 6. Sixty-nine (69) CFUs were detected at various testing sites, including support tables, support carts and the dispensing room (see **Exhibit#6**).

on June 27, 2016, according to the Subject pharmacy's internal surface sampling (see **Exhibit #7**), four(4) CFUs were detected at BSC support table 1, four(4) CFUs were detected at BSC support table 6, one(1) CFU at cart 2, and three (3) CFUs at a general support table. Additionally, a total of twenty-one (21) CFUs were found in the gowning room.

On all of these occasions, the Subject pharmacy failed to analyze the species to the genus level in order to exclude the possibility of the existence of highly pathogenic species. By reviewing the cleaning log for the month of June, 2016, the Subject pharmacy failed to specify the details of cleaning in the event of CFU detection.

[13:39-11.24(a)10]-When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

Specifically, on September 28, 2015, during the environmental monitoring tests conducted by ENV Services, a laboratory equipment certification company, air sampling detected multiple CFUs in the dispensing room, the gowning room, the prep room, the White Blood Cell (WBC) anteroom, and the WBC prep room. The nature of CFUs detected in these areas was deemed non-highly pathogenic. The quantities of CFUs were below action level (see **Exhibit#8**).

Air Sample number 10 (see the Biologic Sampling Location map **Exhibit #9**) detected one (1) CFU in the center of the WBC Room and the species was identified as fungal in nature (see **Exhibit #10**). This finding was deemed as Out-Of-Compliance (O.O.C).

On the following day, September 29, 2015, ENV Services detected one (1) CFU in the Dispensing Room, classified as ISO Class 7. The species was identified as fungal in nature. This finding was again deemed as O.O.C (see **Exhibit #11**).

John Marzocca, PIC, acknowledged that, upon learning the test results on October 9, 2015, the Subject pharmacy failed to cease using the affected equipment. The cleaning log for the month of October, 2015, failed to indicate that the Subject pharmacy performed a triple cleaning in order to address these findings.

On October 19, 2016, during a follow-up visit by Inv. Qi to the Subject pharmacy, Mr. Marzocca stated that, during the most recent environmental monitoring test performed by ENV Services, the maximum CFU count for two ISO Classified areas was exceeded. Air sampling detected one (1) CFU of genus in fungi nature from one of the BSC units, ISO Class 5, as well as thirteen (13) CFUs from one of the support tables. The CFUs detected were a highly pathogenic species (see **Exhibit #12**).

Mr. Marzocca stated that the Subject pharmacy followed the N.J.A.C regulation this time and ceased using this affected equipment (see **Photograph Exhibit #13**).

Daily and weekly cleaning procedures were reviewed in detail. Upon review, it appeared that the Subject pharmacy updated the cleaning frequency, cleaning methods and cleaning materials since my August 2016 visit.

D. In connection with the sterile compounding inspection, I reviewed additional documents pertaining to temperature log, humidity log, training records and sterility testing reports.

USP 797 Employee Aseptic Techique Compounding/Dispensing Assessment was last completed on April 13, 2016. The training was in compliance.

In addition, the Subject pharmacy performs a WBC dual verification training. The verification training is to ensure the hospital and patient name match on the tracking form, prescription label, and leukocyte labeling tracking stickers and delivery case. This training is conducted as a discussion and a demonstration.

A sample copy of the labeling procedure demonstration is attached as **Exhibit #14**.

The Subject pharmacy compounds a variety of radiopharmaceuticals and does not engage in any high risk level of sterile compounding involving Active Pharmaceutical Ingredients (API).

The Subject pharmacy validates its aseptic processing procedure by applying regular sterility checks on the residual material from the compounding process. The Subject pharmacy uses the most aseptically challenging products in annual sterility testing.

Myoview, an intravenous injection kit preparation of a technetium Tc99m, is the largest batch produced sterile product on site. Sulfur Colloid is the component primarily used in preparing technetium Tc99m radio imaging at the Subject pharmacy. The Subject pharmacy tests one vial of Myoview and one vial of Sulfur Colloid annually, with at least 2ml of residual product, in two separate media for incubation and visual inspection.

Complete clarity of solution is negative for microbial contamination. Turbid solution is a conditional failure and an investigation follow-up would be conducted.

The process of this sterility method and results were reviewed and they were deemed to be in compliance.

E. Prior to departing from the Subject pharmacy, I conducted an exit briefing with Registered Pharmacist John Marzocca. In connection with the exit briefing, I completed forms EB-33 (**Exhibit#15**) and explained to the pharmacist each deficiency noted. The pharmacist was given the opportunity to make any comments, corrections, or explanations, to the deficiencies noted in the reports.

   After the pharmacist was satisfied and understood the deficiencies noted, the pharmacist signed off on the previously mentioned forms. I left the pharmacist with copies of each form that was listed above, and then departed from the Subject pharmacy.

CERTIFICATION:

I, the undersigned, of full age, employed by the State of New Jersey, Division of Consumer Affairs, Enforcement Bureau, certify that all of the information which is contained in this report and which is based upon my personal knowledge is true. I am aware that if any of the information reported by me which the context discloses is not based on my personal knowledge, I certify that I have reported in good faith and to the best of my recollection, an accurate account of the information reported to me.

Investigator

-END OF REPORT-

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated march 9, 2017 concerning the observations identified during an inspection of our Livingston New Jersey Nuclear Pharmacy conducted August 10, 2016. The observations stated in your letter are listed below for ease of reference:

[N.J.A.C.13:39-1124(a)6]- Adequate efforts were not made to ensure the pharmacy's quality assurance program.

Although this regulation does not make any reference to internal sampling to be analyzed for species to the genus to exclude the possibility of the existence of highly pathogenic species, Medi-Physics, Inc. d/b/a/ GE Healthcare Livingston NJ, has added this to our environmental monitoring protocols. Contact plate samples incubated on site which show organism growth will be analyzed by an independent certified third party laboratory for ID'ing to genus level. Additionally, our cleanroom certification company (ENV) shall continue to take environmental samples for air and surface contamination biannually during re-certification procedures. All growth recovered from third party vendor sampling shall also be ID'd to genus level.

[N.J.A.C.13:39-24(a)10]-When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the primary engineering controls or cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

The Livingston Pharmacy did not take action to immediately cease using secondary engineering controls on September 28, 2015, as a result of the environmental monitoring tests, due to the fact the we were unaware of this requirement per 13:39-24(a)10 until the **January 2016** New Jersey Board of Pharmacy newsletter article titled- Regulation Regarding Out-of-Compliance Cleanrooms and Primary Engineering. Our Standard Operating Procedures, at the time required us to immediately deep clean the area of concern, perform an investigation to determine action necessary to eliminate recurrence of the contamination, and retest prior to reuse. After further review of the information in that newsletter, the Livingston Pharmacy is in the process of updated

protocols to include 13:39-24(a)10. At this time, we are in compliance with this regulation as evidenced by our SOP's as well as Mr. Qi's follow up visit on October 19, 2016 stating that ENV services monitoring found a maximum CFU count exceeded in a BSC hood which was taken out of service until an EVN re-test was performed.

If you any questions or require any additional information, please contact me at (973) 533-9009.

Sincerely

John Marzocca R.Ph

RLS
RADIOISOTOPE LIFE SCIENCES

Corporate Officer List

Name and Title	Business Address and Phone Number	Home Address and Phone Number		
Stephen Belcher Chief Executive Officer	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065	[redacted]		
Mannon George Bankson III (Trey) Chief Operating Officer	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065			
Glenn Sullivan Director of Regulatory Assurance	255 Primera Blvd, Suite 440, Lake Mary, FL 32746 Phone: 813-285-3065			

STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

RLS USA INC.
0450416230

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign For-Profit Corporation was registered by this office on September 10, 2019.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATE CREATIONS NETWORK INC.
181 New Rd 304
PARSIPPANY, NJ 07054

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 17th day of April, 2024

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6152762700

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (08/02/2022)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RLS (USA) INC

NV Pharmacy or Outsourcing facility license # (if applicable): n/a

Physical Address: 1 Naylon Place

City: Livingston State: NJ Zip: 07039

Mailing Address (if different from physical address):

City: State: Zip:

Telephone: 973-533-9109 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 973-533-1116 Contact Email: newjersey@rls.bio

Website: www.rls.bio

Nevada Business License # (if applicable) n/a

Supervising/Managing Pharmacist Name (NRS 639.220): Hussam Abbassi

Supervising/Managing Pharmacist NV Pharmacist Registration #: n/a

Name of Person with direct knowledge of compounding procedures: Hussam Abbassi

Email of Person with direct knowledge of compounding procedures: hussam.Abbassi@rls.bio

Telephone of Person with direct knowledge of compounding procedures: 973-533-9109

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)? ☒ Low ☐ Medium ☐ High
If you marked "High", you must also complete section 4.

2. Will you be performing sterile hazardous drug compounding? ☐ Yes ☒ No
If you marked "Yes", you must also complete section 3.

3. List the sterile compounded products that you will be compounding for Nevada patients or consumers:
Radiopharmaceuticals only prepared or compounded in compliance with USP<825>.

4. Will you be utilizing beyond use dates in excess of USP-797? ☐ Yes ☒ No

5. If yes, describe the additional testing performed on your products to validate the extended BUD:
NA

6. What laboratory performs this additional testing?
Name: NA
Address: _____
City: _____ State: _____ Zip: _____
Telephone: _____

7. What is your procedure for visual inspection of compounded sterile products?
Visual inspection of Radiopharmaceuticals in compliance with radiation safety ALARA principals.

8. How often do you perform glove fingertip and medial fill testing?

Every 12 months

9. What is your policy if an employee fails a glove fingertip or media-fill test?

Immediate notification of the PIC, investigation for cause, corrective action(s) identified and taken as needed to prevent re-occurrence, retraining as required, retesting performed and passing results obtained prior to initiating or resuming product preparation or dose drawing duties.

10. Describe your initial and annual training program for all personnel performing sterile compounding:

All new hire personnel performing sterile compounding must be licensed or registered in compliance with local regulations. Initial training is assigned based on job title/duties performed through an electronic platform. Personnel are trained on all policies and procedures associated with their job duties prior to performing those duties. Annual retraining is tracked, completed, and maintained using the electronic platform.

11. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached SOPs 6.4.1, 6.4.1.1, and 6.4.1.2.

12. Who performs the sterile compounding process at your facility?

All products are prepared by or under the direct supervision of the licensed, authorized nuclear pharmacist on duty.

13. Who is responsible and accountable for the sterile compounding process at your facility?

The PIC is responsible and accountable for the sterile compounding process.

14. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

RLS (USA) Inc. is a Nuclear Pharmacy dispensing radiopharmaceuticals in compliance with USP<825>. All transportation of prepared radiopharmaceuticals are completed by trained staff or contracted courier services in climate controlled vehicles in DOT-7A, Type A certified packaging designed and tested to maintain the quality and integrity of the product. Where temperature monitoring is required, RLS (USA) Inc. utilizes appropriate ColdMark Indicators to ensure proper temperature is maintained during shipping.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? NA		
2. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
3. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
4. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
5. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
6. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
7. If yes, list the name of the device:		
8. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?		
9. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?		

Section 4: Sterile High Risk Compounding Questions (Complete this section ONLY if you will be performing High Risk Compounding.)

1. List the specific high risk sterile products that your facility compounds:

NA

2. What sterilization methods are utilized at your facility?

3. Does your facility utilize biological indicators? ☐ Yes ☐ No

4. If yes, describe how they are utilized:

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Hussam Abbassi, RPh

Name of Person who Completed the Form

Business Unit Manager/PIC

Title

Signature (copies or stamps not accepted)

5/31/2024

Date

Board Use Only	Date Received: 6/24/24 Date Approved: _____ Approved By: _____

NABP
National Association of Boards of Pharmacy

1600 Feehanville Dr
Mount Prospect, IL 60056

1.847.391.4406
help@nabp.pharmacy

June 7, 2024

VIA EMAIL

Hussam Abbassi
RLS USA INC
1 Naylon Pl
Livingston, NJ 07039

Dear Hussam Abbassi:

Thank you for participating in the National Association of Boards of Pharmacy® (NABP®) Verified Pharmacy Program® (VPP®). Attached please find a copy of your pharmacy's VPP inspection report for your review.

Summary next steps in the VPP process are:

1. The facility reviews the attached inspection report. Though it is considered final, and no changes can be made, your facility may provide a written response to any of NABP's observations listed in this report on the response template described below. A response is optional. For your convenience, we have listed some salient observations, questions, and/or sections the facility may want to review in the Focused Information section of the inspection report. These are areas where additional information or clarification may be needed and can be provided by your facility in a written response if you so choose. For example, the facility may have made an improvement, changed a process, updated a form, completed staff training, found a missing document since the inspection, or have other pertinent information to share. Please see the following requirements if you wish to provide a written response to NABP:

    a. Responses must be submitted **within 30 calendar days from the date of this letter.** Responses received after that time will not be reviewed and no extensions will be granted.
    b. Responses should be submitted on the **Response Template** available on the NABP website for download in the VPP FAQs section. For your convenience, a copy of the template has also been included with this cover letter.
    c. If including attachments, each page must be clearly identified, whether it is by attachment number or by name at the top of the page. Please include a description(s) of pertinent Policies and Procedures if it is necessary to reference them.
    d. Upon receipt of the response documentation, NABP will make this information available to the boards of pharmacy.
    e. All documents should be submitted at one time rather than individually and must be provided **electronically** using **one** of the following methods:
        i. Email the documents to inspections@nabp.pharmacy; or
        ii. Mail a flash drive of the documents to NABP at the following address:
            National Association of Boards of Pharmacy
            ATTN: Verified Pharmacy Program
            1600 Feehanville Drive

Mount Prospect, IL 60056
Please include the following with your documentation: Facility Name, City, State, and e-Profile ID. **No hard copies of documentation will be accepted.**

2. As a courtesy, NABP notifies the state boards of pharmacy that an inspection has been completed. If requested by a state board of pharmacy, the VPP Inspection report is provided to them via a secure interface with the following supplemental information:
    a. License verifications
    b. Public disciplinary board orders/actions and other public information from the boards of pharmacy

    State boards of pharmacy and/or applicable state regulators may request your written response to the inspection report (if any) and/or other documents directly from you.

Other Items to Note:

- Many state boards of pharmacy may use your responses to the findings of this report when making licensure determinations.
- Although one of the primary purposes of VPP is to support uniform requirements and inspections among the states, the nonresident state may have additional requirements over and above what is required by your resident state.
- Although changes to this report cannot be made, any response your facility provides will serve as a supplement to your facility's original report.
- Any issues relating to your facility's licensure must be addressed directly with the applicable board of pharmacy.
- NABP does not provide a "seal of approval" related to this inspection, the inspection is not an accreditation and does not make the facility a member of NABP.

Do not hesitate to contact us should you have any additional questions via email at inspections@nabp.pharmacy or via phone at 847/391-4539.

Sincerely,

NATIONAL ASSOCIATION OF
BOARDS OF PHARMACY

Lemrey "Al" Carter, PharmD, MS, RPh
Executive Director/Secretary

Attachment

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler RLS (USA) Inc

Pharmacy/Wholesaler License # (if applicable) N/A

Physical Address 1 Naylon Place

City Livingston State NJ Zip 07039

Mailing Address (if different from physical address) same as above

City _____ State _____ Zip _____

Telephone 973-533-9109 Website rls.bio

Licensing Company Email licensing@rls.bio

Section 2: Personal Information

First David Middle Marten Last Miller

Alias(es, nicknames, name changes, etc.) _____

Date of Birth [redacted] SSN or ITIN [redacted] Sex ☑ M ☐ F ☐ X

Mailing Addres[redacted]

City Waldwick State NJ Zip [redacted]

Telephone [redacted] Email [redacted]

Are you a citizen of the United States? ☑ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✔

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✔
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name		From - To (MM/YY – MM/YY)	
Ramapo High School		1968-1972	
Address	**City**	**State**	**Zip**
George St	Franklin Lakes	NJ	07417
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Cornell University		1972-1976	
Address	**City**	**State**	**Zip**
	Ithaca	NY	14853
Diploma/Degree obtained, if any			
AB			

School Name		From - To (MM/YY – MM/YY)	
Albany College of Pharmacy		1976-1980	
Address	**City**	**State**	**Zip**
New Scotland Ave	Albany	NY	12203
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY)	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

School Name		From - To (MM/YY – MM/YY	
Address	**City**	**State**	**Zip**
Diploma/Degree obtained, if any			

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	[redacted]			
5/2022-present				
From - To (MM/YY – MM/YY)				
6/2010-5/22				
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip
From - To (MM/YY – MM/YY)	Address	City	State	Zip

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above.

Business Name			From - To (MM/YY – MM/YY)	
Millers of Wyckoff, Inc			6/80-7/23	
Business Address		**City**	**State**	**Zip**
678 Wyckoff Ave		Wyckoff	NJ	07481
Phone	**Title**		**Number of Employed Hours**	
2018913333	President, PIC		83,200	
Description of Duties				
Owner, Pharmacist in Charge				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Business Name			From - To (MM/YY – MM/YY)	
Business Address		**City**	**State**	**Zip**
Phone	**Title**		**Number of Employed Hours**	
Description of Duties				

Continue on next page if additional space is needed.

Section 8: Arrests, Detentions, Litigations, Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		✔
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		✔
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		✔
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		✔
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		✔
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		✔
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		✔
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		✔
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		✔
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✔

I, David Miller, R.Ph. **, certify that as the designated representative for**

RLS (USA) Inc, 1 Naylon Place, Livngston,NJ 07039 ,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. x I am at least 21 years of age;
3. x I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. x I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. x I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. x I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. x I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

David Miller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/18/2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

David Miller

Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

2/18/2025

Date

Please have this section completed in the presence of a Notary Public.

State of New Jersey, ss. County of Essex

I, David Miller, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Original Signature

2/18/25

Date

Subscribed and Sworn to before me this 18 day of February.

Notary Public Signature

KAREN PEIST
Notary Public, State of New Jersey
Comm. # 50222459
My Commission Expires 6/5/2029

(Seal)

RLS (USA), Inc.		
Change of Ownership		
Ownership Information		
Name	**Title**	**Business Address**
Telix Pharmaceuticals (US) Inc.	Owner, 100%	11700 Exit 5 Pkwy Suite 200, Fishers, IN 46037
Darren Patti	Group Chief Operating Officer	255 Primera Boulevard, Suite 440, Lake Mary, FL 32746
Darren Smith	Group Chief Financial Officer	255 Primera Boulevard, Suite 440, Lake Mary, FL 32746
Sarah Robison	Chief Financial Officer - Americas	255 Primera Boulevard, Suite 440, Lake Mary, FL 32746
Oliver Newman	Company Secretary	255 Primera Boulevard, Suite 440, Lake Mary, FL 32746

ORGANIZATIONAL CHART FOR RLS (USA) Inc

Officers and Directors are listed next to the Triangle

Legend:

△ **Officers:** Darren Patti: Group COO
Darren Smith: Group CFO
Sarah Robison: CFO - Americas
Oliver Newman: Company Secretary

Directors: Darren Patti
Darren Smith

▩ **Officers:** Darren Patti: Officer
Sarah Robison: Officer
Genevieve Ryan: Secretary

Directors: Kevin Richardson
Darren Smith

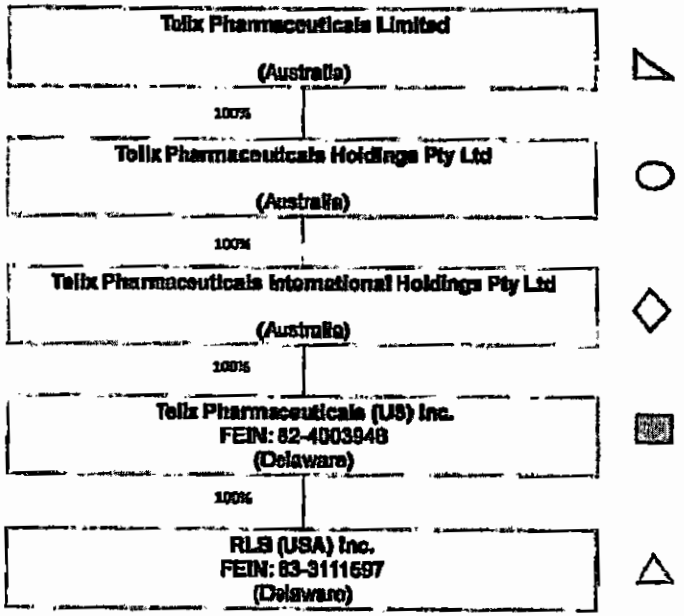
◇ **Officers:** Darren Smith: Public Officer
Genevieve Ryan: Secretary

Directors: Darren Smith
Christian Behrenbruch

⬭ **Officers:** Darren Smith: Public Officer
Genevieve Ryan: Secretary

Directors: Darren Smith
Christian Behrenbruch

◺ **Officers:** Christian Behrenbruch: Group CEO, Managing Director
Darren Patti: Group COO
Darren Smith: Group CFO
David Cade: Group CMO
Genevieve Ryan: Company Secretary



STATE OF NEW JERSEY
DEPARTMENT OF THE TREASURY
DIVISION OF REVENUE AND ENTERPRISE SERVICES
SHORT FORM STANDING

RLS USA INC.
0450416230

I, the Treasurer of the State of New Jersey, do hereby certify that the above-named Delaware Foreign For-Profit Corporation was registered by this office on September 10, 2019.

As of the date of this certificate, said business continues as an active business in good standing in the State of New Jersey, and its Annual Reports are current.

I further certify that the registered agent and office are:

CORPORATE CREATIONS NETWORK INC.
111 TOWN SQUARE PLACE
SUITE 1510
JERSEY CITY, NJ 07310

IN TESTIMONY WHEREOF, I have hereunto set my hand and affixed my Official Seal at Trenton, this 10th day of February, 2025

Elizabeth Maher Muoio
State Treasurer

Certificate Number : 6161482355

Verify this certificate online at

https://www1.state.nj.us/TYTR_StandingCert/JSP/Verify_Cert.jsp

RLS

Historical Disciplinary Actions

There have been two actions by our home state board and none by any other state since 2003. I have enclosed a description of these two actions and steps taken to remediate the conditions as provided by the Pharmacist-in-charge at the time. I have also enclosed copies of the inspection report and plan of action for the 2016 findings.

It is important to note that RLS does only low risk, sterile to sterile nuclear compounding.

Inspection Report #8-1066.6 dated 12/19/2003

N.J.A.C. 13:39-12.2e – Label missing information

N.J.A.C. 13:39-12.4c – Missing Reference text

Actions taken – corrected deficiencies and paid fine.

Inspection Report #8-1066.16-X dated 8/10/2016

N.J.A.C. 13:39-24.a.6 – Adequate efforts were not made to ensure the pharmacy's quality assurance program.

N.J.A.C. 13:39-11.24.a.10 – When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

Actions taken – see the plan submitted by the Pharmacist-in-charge and accepted by the NJBOP.

Please contact me if you need any further information at newjersey@rls.bio.

Sincerely,

David Miller, R.Ph.

255 Primera Blvd.
Lake Mary, FL 32746

RLS.BIO
813-285-3065

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. McGREEVEY
Governor

PETER C. HARVEY
Attorney General
KENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 8, 2004

John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Re: Inspection Report #8-1066.6
Inspection Date: 12/19/03

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated:

N.J.A.C. 13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.
$25.00

N.J.A.C. 13:39-12.4(c)
Missing a current text in the category of "General Practice of Pharmacy".
$200.00

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the attached acknowledgment and agree to the following:

1. Pay a penalty in the amount of $225.00 and provide to the Board a Letter of Corrective Action. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively, you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed certification should be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained here in shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: Joanne Boyer
Joanne Boyer
Executive Director

JB/mw

cc: Marianne Greenwald, Deputy Attorney General
Daniel L. Peters, 1068 S. Kimbles Road, Yardley, PA 19067

Amersham Health
1 Naylon Place
Livingston New Jersey 07039

Ph. # 200
8/18/04
7926

August 17, 2004
Joanne Boyer
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark NJ 07101

RE: Inspection Report #8-1066.6

Dear Ms. Boyer

Please find enclosed check for $200.00 for the deficiency of N.J.A.C. 13:39-12.4(c), missing a current edition of a text in the category of "General Practice of Pharmacy".

As a corrective action, Amersham Health has purchased a current edition of Remington's "The Science and Practice of Pharmacy" on 11 March 2004.

If you have any questions or require any additional information, please contact me at [redacted].

Sincerely,

John Marzocca R.Ph
Pharmacist in charge

Date: 8/10/2016
Time entered: 11:15 Am
Time departed: 3:00 Pm

New Jersey Office of the Attorney General
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY

Report of Inspection

Name of Pharmacy: GE Healthcare (Nuclear) Pharmacy.
Address: 1 Naylon Place, Livingston, NJ 07039.
Name and registration number of pharmacist-in-charge:
John Marzocca, 28RI0477703
(If pharmacist-in-charge not present, give name and # of R.P. on duty)

The following deficiencies have been noted:

I [13:39-11.04(a)10]- During the environmental monitoring test on 9/28-9/29/2015, ISO class Dispensing room and WBC room had 0.0 C results. Reports were released in the time period of 10/9/2015-10/14/2015 Pharmacy did an internal retest on 10/30/2015. Results indicated no growth after 7 day incubation period. Rooms were cleaned but there was no indication that equipments were ceased using during the time period.

- Pharmacy since then updated its P&P (see attached)

I [13:39-11.04(a)6]- Internal semi-annual Surface sampling indicated a below actin level cfu results. They need to be analyzed to the genius level to exclude any possibilities of highly pathogenic species. Internal action plan needs to be detailed also with cleaning process.

I ~~[13:39-11.04(a)12]- Pharmacy will obtain sterile admixture references per NJ Regulations~~ (Title)

This is to acknowledge that I have been present during this inspection and concur with the findings, as so noted, with the following exceptions; if any.

COMMENTS:

File # 8-1066-16-X
Exhibit # 1
Page 1 of 1 Pages

(Signature of pharmacist identified above)

EB-33 3/07

5871

STATE OF NEW JERSEY
DEPARTMENT OF LAW & PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
ENFORCEMENT BUREAU

REPORT OF INSPECTION

TO:	ASSIGNMENT#	DATE:	PERIOD:
BOARD OF PHARMACY	8-1066-16-X	JAN 0 0 2017	8/10/2016

SUBJECT(S): **BY: Tony H. Qi, RP**

Medi-Physics, Inc dba GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
John Marzocca, RPIC

REFERENCE:

Board of Pharmacy inspection conducted per N.J.S.A. 45:1-18 and N.J.S.A. 45:14-48(a) 11&12 and a request from the Board to inspect all pharmacies that engage in compounding sterile preparations.

DETAILS:

A. On August 10, 2016, I, Bureau Investigator Tony Qi, visited the Subject Pharmacy for the purpose of engaging in a Board of Pharmacy inspection activity.

B. Present and at practice in the pharmacy was John Marzocca (R.P. #RI01474700). For identification purposes, all pharmacy personnel who were present and involved in the prescription filling/dispensing activities, completed respective "Pharmacy Personnel Identification" forms (**Exhibit #1**).

A. On the occasion of my visit, the following Board of Pharmacy inspection activities were conducted: an active drug stock inventory review(**Exhibit#2**), an EB-02 General Requirements form (**Exhibit#3**), a pharmacy library required texts review (**Exhibit #4**) and a prescription file records review. This inspection activity included the completion of a sterile compounding compliance survey per N. J.A.C Subchapter 13:39-11, Et Seq.

Reviewed By Robert Lee R. Ph.

B. Inspection of the pharmacy's "active" drug stock inventory revealed the following:

A total of Zero (0) containers of medication was discovered to be out-of-date, misbranded, or improperly stored.

C. The pharmacy compliance inspection activity identified the following deficiencies:

[13:39-11.24(a) 6]-Adequate efforts were not made to ensure the pharmacy's quality assurance program.

Specifically, on June 17, 2015, the Subject pharmacy's internal surface sampling detected a total of twenty-two (22) Colony Forming Units (CFU) from various locations, including support tables used in sterile compounding, the prep room and the pass through (see **Exbibit #5**).

On January 11, 2016, internal surface sampling detected one (1) CFU from the ISO 5 hood, one (1) CFU from Tech Hood 2, and one (1) CFU from Biologic Safety Cabinet (BSC) 6. Sixty-nine (69) CFUs were detected at various testing sites, including support tables, support carts and the dispensing room (see **Exbibit#6**).

on June 27, 2016, according to the Subject pharmacy's internal surface sampling (see **Exhibit #7**), four(4) CFUs were detected at BSC support table 1, four(4) CFUs were detected at BSC support table 6, one(1) CFU at cart 2, and three (3) CFUs at a general support table. Additionally, a total of twenty-one (21) CFUs were found in the gowning room.

On all of these occasions, the Subject pharmacy failed to analyze the species to the genus level in order to exclude the possibility of the existence of highly pathogenic species. By reviewing the cleaning log for the month of June, 2016, the Subject pharmacy failed to specify the details of cleaning in the event of CFU detection.

[13:39-11.24(a)10]-When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

Specifically, on September 28, 2015, during the environmental monitoring tests conducted by ENV Services, a laboratory equipment certification company, air sampling detected multiple CFUs in the dispensing room, the gowning room, the prep room, the White Blood Cell (WBC) anteroom, and the WBC prep room. The nature of CFUs detected in these areas was deemed non-highly pathogenic. The quantities of CFUs were below action level (see **Exhibit#8**).

Air Sample number 10 (see the Biologic Sampling Location map **Exhibit #9**) detected one (1) CFU in the center of the WBC Room and the species was identified as fungal in nature (see **Exhibit #10**). This finding was deemed as Out-Of-Compliance (O.O.C).

On the following day, September 29, 2015, ENV Services detected one (1) CFU in the Dispensing Room, classified as ISO Class 7. The species was identified as fungal in nature. This finding was again deemed as O.O.C (see **Exhibit #11**).

John Marzocca, PIC, acknowledged that, upon learning the test results on October 9, 2015, the Subject pharmacy failed to cease using the affected equipment. The cleaning log for the month of October, 2015, failed to indicate that the Subject pharmacy performed a triple cleaning in order to address these findings.

On October 19, 2016, during a follow-up visit by Inv. Qi to the Subject pharmacy, Mr. Marzocca stated that, during the most recent environmental monitoring test performed by ENV Services, the maximum CFU count for two ISO Classified areas was exceeded. Air sampling detected one (1) CFU of genus in fungi nature from one of the BSC units, ISO Class 5, as well as thirteen (13) CFUs from one of the support tables. The CFUs detected were a highly pathogenic species (see **Exhibit #12**).

Mr. Marzocca stated that the Subject pharmacy followed the N.J.A.C regulation this time and ceased using this affected equipment (see **Photograph Exhibit #13**).

Daily and weekly cleaning procedures were reviewed in detail. Upon review, it appeared that the Subject pharmacy updated the cleaning frequency, cleaning methods and cleaning materials since my August 2016 visit.

D. In connection with the sterile compounding inspection, I reviewed additional documents pertaining to temperature log, humidity log, training records and sterility testing reports.

USP 797 Employee Aseptic Techique Compounding/Dispensing Assessment was last completed on April 13, 2016. The training was in compliance.

In addition, the Subject pharmacy performs a WBC dual verification training. The verification training is to ensure the hospital and patient name match on the tracking form, prescription label, and leukocyte labeling tracking stickers and delivery case. This training is conducted as a discussion and a demonstration.

A sample copy of the labeling procedure demonstration is attached as **Exhibit #14**.

The Subject pharmacy compounds a variety of radiopharmaceuticals and does not engage in any high risk level of sterile compounding involving Active Pharmaceutical Ingredients (API).

The Subject pharmacy validates its aseptic processing procedure by applying regular sterility checks on the residual material from the compounding process. The Subject pharmacy uses the most aseptically challenging products in annual sterility testing.

Myoview, an intravenous injection kit preparation of a technetium Tc99m, is the largest batch produced sterile product on site. Sulfur Colloid is the component primarily used in preparing technetium Tc99m radio imaging at the Subject pharmacy. The Subject pharmacy tests one vial of Myoview and one vial of Sulfur Colloid annually, with at least 2ml of residual product, in two separate media for incubation and visual inspection.

Complete clarity of solution is negative for microbial contamination. Turbid solution is a conditional failure and an investigation follow-up would be conducted.

The process of this sterility method and results were reviewed and they were deemed to be in compliance.

E. Prior to departing from the Subject pharmacy, I conducted an exit briefing with Registered Pharmacist John Marzocca. In connection with the exit briefing, I completed forms EB-33 (**Exhibit#15**) and explained to the pharmacist each deficiency noted. The pharmacist was given the opportunity to make any comments, corrections, or explanations, to the deficiencies noted in the reports.

   After the pharmacist was satisfied and understood the deficiencies noted, the pharmacist signed off on the previously mentioned forms. I left the pharmacist with copies of each form that was listed above, and then departed from the Subject pharmacy.

CERTIFICATION:

I, the undersigned, of full age, employed by the State of New Jersey, Division of Consumer Affairs, Enforcement Bureau, certify that all of the information which is contained in this report and which is based upon my personal knowledge is true. I am aware that if any of the information reported by me which the context discloses is not based on my personal knowledge, I certify that I have reported in good faith and to the best of my recollection, an accurate account of the information reported to me.

Investigator

-END OF REPORT-

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated march 9, 2017 concerning the observations identified during an inspection of our Livingston New Jersey Nuclear Pharmacy conducted August 10, 2016. The observations stated in your letter are listed below for ease of reference:

[N.J.A.C.13:39-1124(a)6]- Adequate efforts were not made to ensure the pharmacy's quality assurance program.

Although this regulation does not make any reference to internal sampling to be analyzed for species to the genus to exclude the possibility of the existence of highly pathogenic species, Medi-Physics, Inc. d/b/a/ GE Healthcare Livingston NJ, has added this to our environmental monitoring protocols. Contact plate samples incubated on site which show organism growth will be analyzed by an independent certified third party laboratory for ID'ing to genus level. Additionally, our cleanroom certification company (ENV) shall continue to take environmental samples for air and surface contamination biannually during re-certification procedures. All growth recovered from third party vendor sampling shall also be ID'd to genus level.

[N.J.A.C.13:39-24(a)10]-When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the primary engineering controls or cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

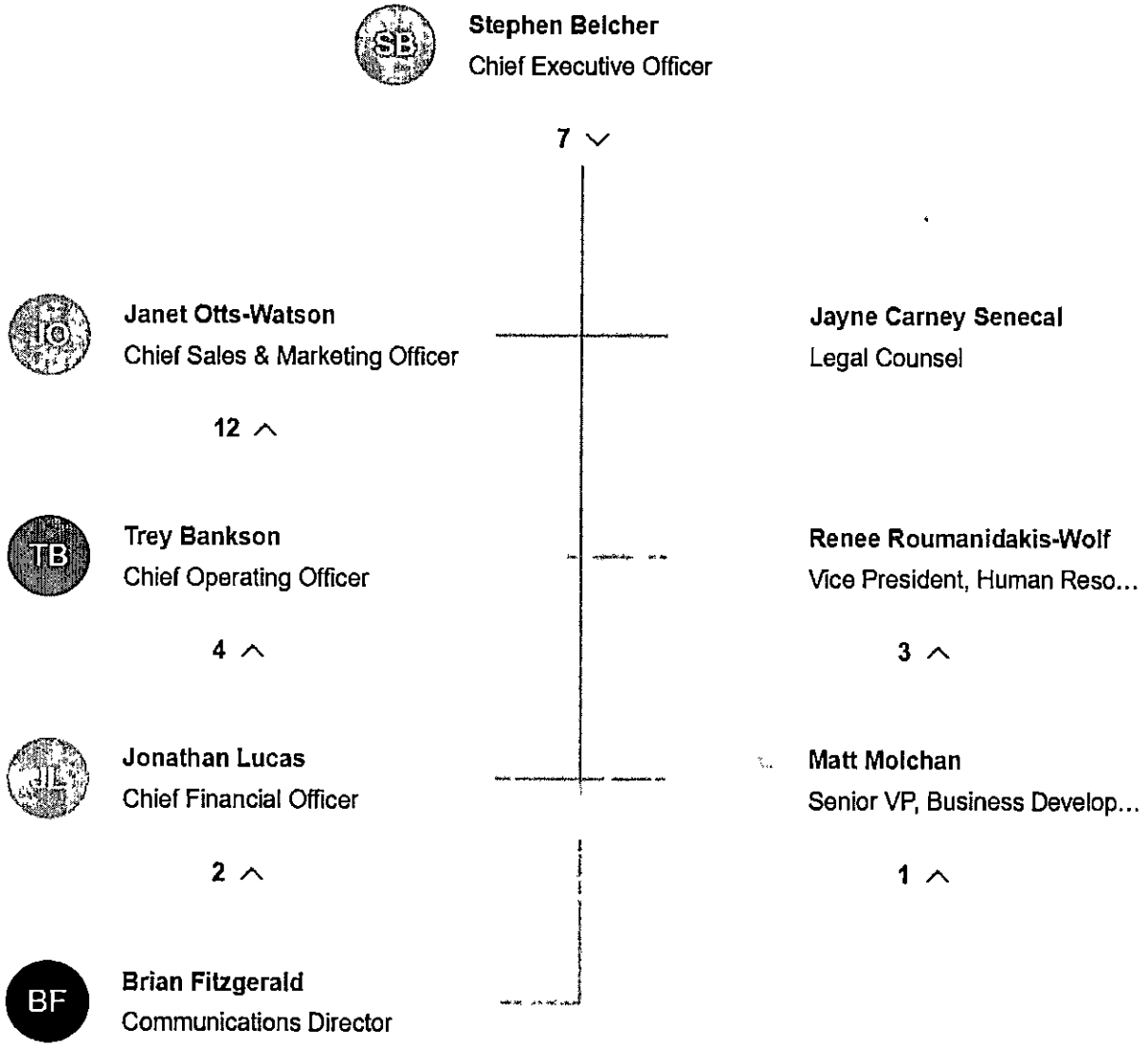
The Livingston Pharmacy did not take action to immediately cease using secondary engineering controls on September 28, 2015, as a result of the environmental monitoring tests, due to the fact the we were unaware of this requirement per 13:39-24(a)10 until the **January 2016** New Jersey Board of Pharmacy newsletter article titled- Regulation Regarding Out-of-Compliance Cleanrooms and Primary Engineering. Our Standard Operating Procedures, at the time required us to immediately deep clean the area of concern, perform an investigation to determine action necessary to eliminate recurrence of the contamination, and retest prior to reuse. After further review of the information in that newsletter, the Livingston Pharmacy is in the process of updated

protocols to include 13:39-24(a)10. At this time, we are in compliance with this regulation as evidenced by our SOP's as well as Mr. Qi's follow up visit on October 19, 2016 stating that ENV services monitoring found a maximum CFU count exceeded in a BSC hood which was taken out of service until an EVN re-test was performed.

If you any questions or require any additional information, please contact me at (973) 533-9009.

Sincerely

John Marzocca R.Ph



RLS Leadership Org Chart

4/19/2024

THIS DOCUMENT IS PRINTED ON WATERMARKED PAPER WITH A MULTI-COLORED BACKGROUND AND MULTIPLE SECURITY FEATURES. PLEASE VERIFY AUTHENTICITY.

State Of New Jersey
New Jersey Office of the Attorney General
Division of Consumer Affairs

THIS IS TO CERTIFY THAT THE
Board of Pharmacy

HAS LICENSED

RLS (USA) INC.
HUSSAM M ABBASSI
1 Naylon Place
Livingston NJ 07039

FOR PRACTICE IN NEW JERSEY AS A(N): Pharmacy

Nuclear Pharmacy
Radio Nuclear

04/23/2024 TO 08/30/2025
VALID

28RS00446300
LICENSE/REGISTRATION/CERTIFICATION #

Signature of Licensee/Registrant/Certificate Holder

Cari Fais
ACTING DIRECTOR

New Jersey Office of the Attorney General
Division of Consumer Affairs
THIS IS TO CERTIFY THAT THE
Board of Pharmacy
HAS LICENSED
RLS (USA) INC.
Pharmacy

Nuclear Pharmacy
Radio Nuclear

04/23/2024 TO 08/30/2025
VALID

SIGNATURE Cari Fais
ACTING DIRECTOR

28RS00446300
License/Registration/Certificate #

PLEASE DETACH HERE

IF YOUR LICENSE/REGISTRATION/
CERTIFICATE ID CARD IS LOST
PLEASE NOTIFY:
Board of Pharmacy
P.O. Box 45013
Newark, NJ 07101

PLEASE DETACH HERE

6

NEW JERSEY DIVISION OF
CONSUMER AFFAIRS

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Direct
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License Information

Accurate as of March 04, 2025 1:08 PM

Return to Search Results

Name: RLS (USA) INC.

Address: Livingston,NJ

Profession/License Type: Pharmacy,Pharmacy

License No: 28RS00446300

License Status: Active

Status Change Reason:

Issue Date: 9/12/1990

Expiration Date: 6/30/2025

SPL:

Board Action: YES*

Please visit DCA's website to see the final disposition documents.

* A "YES" in the "Board Action" field indicates that the licensee has a public record of some form of action on file with the Board/Committee. Board actions may come in the form o and Desist Order, Interim Order, Reprimand, a finalized Uniform Penalty Letter, agreed upon Settlement Letter or Final Order. In some instances, "Yes" will represent that a public such as an Administrative Complaint or a Provisional Order of Discipline may have been filed with the Board/Committee. Such documents represent the filing of allegations by the not represent a finding of misconduct until the matter is adjudicated by the Board. Contact the Board/Committee directly to obtain a copy of such documents.

To obtain copies of such documents not readily available on the "Actions (Disciplinary and Other)" page of the Board's website, or if no documents are displayed below, please c NJBOPVerifications@dca.lps.state.nj.us.

Documents

28RS00446300 - ALEXANDER'S TWIN PHARMACY - 03202024 - RE	Pages: 102
28RS00446300 - RLS (USA) INC. - 03082004 - RE	Pages: 7
28RS00446300 - RLS (USA) Inc. - 05192017 - RE	Pages: 27

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Nuclear USP <825> Inspection Form

Nuclear Pharmacy Inspection

Business e-Profile ID:	1285742		**Inspection Information**
Legal Business Name:	RLS USA INC	**Conference Call Date:**	5/22/2024
Doing Business As (DBA):	N/A	**Start Time: 24-hour format (13:00)**	14:00
Address:	1 Naylon Place	**End Time: 24-hour format (13:00)**	14:45
City:	Livingston	**Onsite Inspection Date(s):**	5/24/2024
State:	New Jersey	**Start Time(s): 24-hour format (13:00)**	7:00
Zip Code:	07039	**End Time(s): 24-hour format (13:00)**	15:30
Telephone number:	973/53-39109	**Inspector Name:**	Rita Weiss, PharmD, JD, BCGP
Toll free number:	800/242-8004	**Inspection Performed by (NABP, State, etc):**	NABP
Fax number:	973/533-1116	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.rls.bio	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all-inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.
General Nuclear Pharmacy- 21.00,58.00, 61.00
Nuclear- 15.02, 159.00, 160.00, 165.00, 217.02, 219.02

Additional information on NABP's Inspection website.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday	12:00	15:30	
Monday	12:00	15:30	
Tuesday	12:00	15:30	
Wednesday	12:00	15:30	
Thursday	12:00	15:30	
Friday	12:00	15:30	
Saturday	12:00	15:30	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Designated Person	Hussam M Abbassi	hussam.abbassi@rls.bio	170568
Designated Person	Hussam M Abbassi	hussam.abbassi@rls.bio	170568
Pharmacist in Charge	Hussam M Abbassi	hussam.abbassi@rls.bio	170568
Radiation Safety Officer (RSO)	Hussam M Abbassi	hussam.abbassi@rls.bio	170568
HIPAA privacy officer	Corporate	N/A	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current
1	Hussam M Abbassi	PIC	Y
2	Karen Peist	Administrative Assistant	N/A
3	Erik Diaz	Pharmacy Technician	Y
4	James Smith	Pharmacy Technician	Y
5	Damian Jacobs	Pharmacy Technician	Y
6	Stephen Shields	Courier	N/A
7	Taniasha Jenkins	Courier	N/A
8	Norman Leftwich	Courier	N/A
9	Sylvanus Toweh	Pharmacy Technician	Y
10	Martin Simboli	Courier	N/A

If more than 10, list the first 10 below, then list the title and number (eg: 2 designated persons, 4 pharmacists, 6 technicians, 2 technicians-in-training, 1 intern, 4 clerks, etc) for the additional personnel present.

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Business Licensure Information for State of Residence and Federal (Board of Pharmacy, State Controlled Substance, State Radiation Control Agency, Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), Nuclear Regulatory Commission (NRC))

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number / Expiration Date
New Jersey State Board of Pharmacy	RLS (USA) INC.	Pharmacy	28RS00446300 Exp: 6/30/2024
State of New Jersey Department of Environmental Protection	RLS HOLDINGS, LLC	RAM	456318-RAD220001 Exp: 11/20/2032
N/A	N/A	N/A	N/A

Inspector Notes: The pharmacy is in the process of obtaining out-of-state pharmacy licenses for all states that require licensing.
List states in which Non-Resident licenses are held. CO, NY, WI, WY, IA, ME, SD, MT

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
N/A	N/A

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	Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT		Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT
Ship/Deliver (in state)	X	Manufacturer	
Ship/Deliver (out-of-state, list below)	X	Wholesale Distributor (WD)	
Central Fill/Processing/Shared Services		Handles Positron Emission Tomography (PET) Preparations	
Institutional		Handles Nonsterile Preparations	X
Free Standing	X	Handles Sterile Preparations (eg including minor deviations)	X
Telepharmacy		Handles Investigational New Drugs (IND)	
Provide radiopharmaceuticals for 'Office Use'	X	Handles Blood Preparations	X
Provide radiopharmaceuticals for 'Physician Use'	X	Handles Volatile Isotopes (Xe-133 gas, liquid I-131 NaI)	
Outsourcing Facility		Provide radiopharmaceuticals for Immediate Use	
Handles Sterile dispensing and repackaging	X		

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Facility Size (in Square Feet) and Number of PECs		Personnel	
Total Nuclear Pharmacy size:	10,000	Total Nuclear Pharmacists:	3
Nonsterile Processing area size:	0	Total Nuclear Pharmacy Technicians:	6
Sterile Processing Anteroom size:	123	Total Interns or Students:	0
Sterile Processing Clean/Buffer Room size:	631	Total Other Personnel:	5
Blood Preparations Processing Room size:	205	Total Nuclear Pharmacist Hours Per Week:	120
Size of the decay storage area:	450	Total Nuclear Pharmacy Technician Hours Per Week:	240
Sterile number of PECs:	5	Board Certified Nuclear Pharmacist (BCNP):	0
Nonsterile number of PECs:	0		
Blood Preparations - number of PECs (eg BSC):	5		
Segregated Radiopharmaceutical processing area (SRPA) size:	0		
Number of Hot Cells:	0		

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	350	Total Orders Distributed/day:	10
% Veterinary	0%	% Veterinary	0%
% Controlled Substances	0%	% Controlled Substances	0%
% Nonsterile Compounded	0%	% Nonsterile Compounded	0%
% Sterile Compounded	15%	% Sterile Compounded	15%
% of Sterile preparations	85%	% of Sterile preparations	85%
% of Nonsterile preparations	0%	% of Nonsterile preparations	0%

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription.
DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific - is not labeled with the patient name at the pharmacy. HD means drugs on the National Institute for Occupational Safety and Health (NIOSH) list of HD such as hormones, chemotherapy, etc. There are currently no radiopharmaceuticals which are considered NIOSH HDs.

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States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)			
California (CA)			
Colorado (CO)	0	0	5/23/2024
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)			
Indiana (IN)			
Iowa (IA)	0	0	5/23/2024
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)	0	0	5/23/2024
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)	0	0	5/23/2024

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States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)	390	0	5/23/2024
New Mexico (NM)			
New York (NY)	1	0	5/23/2024
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)	0	0	5/23/2024
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)	0	0	5/23/2024
Wyoming (WY)	0	0	5/23/2024
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection - General

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes
	General Pharmacy		
1.00	Is the Designated Person present for the inspection?	Yes	
2.00	Is the PIC (or nuclear pharmacy manager/director) present for the inspection? *If no, list the nuclear pharmacist on duty.*	Yes	
3.00	Are photographs allowed during the inspection (no Protected Health Information (PHI))?	Yes	
	General Operations and Licensure		
4.00	Are pharmacy licenses, permits and registrations (state, controlled substance, DEA, etc.) posted?	Yes	
5.00	Is the RSO the same as is listed on the radioactive materials (RAM) license?	Yes	
6.00	Is the PIC an Authorized Nuclear Pharmacist (ANP) on the RAM license or other retrievable documentation as confirmed by the NRC or agreement state?	Yes	
7.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	Yes	The last board of pharmacy inspection occurred on June 30, 2022, and the pharmacy is routinely inspected every few years.
7.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	No deficiencies were noted.
8.00	Is the most recent NRC (and/or state radiation control agency) inspection report available for review? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	Yes	The pharmacy was inspected by New Jersey state radiation control agency on January 9, 2024. The pharmacy has never been inspected by another state.
8.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	No	

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection - General

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes
9.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
10.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
11.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
12.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	No	
13.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
14.00	Has the pharmacy been inspected by the Environmental Protection Agency (EPA), Department of Transportation (DOT) or any other outside agency? *If yes, indicate the inspection date and note any deficiencies related to pharmacy practice.*	No	
15.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	The pharmacy holds a JCAHO Home Care Accreditation and was last visited for a survey in 2019.
16.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold?	No	
17.00	Were any deficiencies detected on the last internal audit? *List date of last audit and note any deficiencies found and action plan to correct.*	No	The last internal audit occurred in October 2023 and no deficiencies were found.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection - General

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes
	Policy and Management		
18.00	Are policies and procedures for the program maintained in the pharmacy in an immediately retrievable form? *Indicate if hard copy, electronic, or both.*	Yes	Electronic
19.00	Are the P&Ps reviewed and updated regularly? *Indicate the review frequency and who performs the reviews.*	Yes	The corporate regulatory department provides the updates and the review is performed annually.
20.00	Are systems in place for the ongoing monitoring of state and federal laws/regulations for changes? *Give details of the system and resources, or indicate if it is a corporate process and who is responsible overall as well as at the site.*	Yes	The monitoring is handled by the corporate office and implementation of changes is the responsibility of the PIC.
21.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	No	
22.00	Does the pharmacy maintain all required records, including but not limited to prescription files, on site? *Record how long records are kept. If not on site, where?*	Yes	Five years
23.00	Does the pharmacy have access to appropriate law references including state and federal regulations (including state regulations for all states in which the facility is licensed and NRC)? *Indicate if they are hard copies or are accessed online (demonstrate access) or both.*	Yes	Online access
24.00	Does the pharmacy have access to other references as required by state law? (eg appropriate dosage and toxicology references). *Indicate if they are hard copies or are accessed online or both.*	Yes	Both
25.00	Does the pharmacy have access to appropriate practice specific references? Nuclear, geriatric, pediatric, etc. List and indicate if hard copy or online or both.	Yes	Fundamentals of Nuclear Pharmacy is accessible both hard copy and online.

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		Observations	Notes
26.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] up to date and available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
27.00	Does the pharmacy have a hazardous waste handling and collection system? *Indicate how often waste is collected and the vendor(s) used.*	Yes	Blood is disposed of as medical waste by Stericycle.
	Product Ordering, Receipt and Inventory		
28.00	Is the pharmacy restricted to buying prescription drugs from certain WDs or manufacturers?	Yes	
28.01	If restricted, does the PIC approve the vendors? *If not, who does approve (corporate)?*	No	The corporate office approves of vendors.
29.00	Are all orders received when the pharmacy is open or placed in a secure area if the pharmacy is closed?	Yes	
30.00	Does the pharmacy purchase any compounded radiopharmaceuticals from other entities for dispensing to patients? *If so, describe which compounded radiopharmaceuticals and from where they are purchase (collect name and license of other entity).*	No	
31.00	Does the pharmacy make any sterile or nonsterile compounded radiopharmaceuticals using bulk powder or liquid (APIs)? *Indicate bulk products and vendors used.*	No	
32.00	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*	No	
33.00	Does the computer system track on-hand quantities of products? *Who can adjust the on-hand quantities, and are adjustments tracked?*	Yes	Only pharmacists can make an adjustment to on-hand quantities. Adjustments are tracked based on log-in of the person who makes the change.

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		Observations	Notes
34.00	Are orders generated and sent by the computer for prescription products, including controlled substances? *Who can alter the orders before they are sent?*	Yes	The pharmacies standing orders are generated by the computers. All the pharmacists, one pharmacy technician and one courier have been trained to alter the orders before they are sent.
35.00	Does the pharmacy maintain required inventories (such as change in PIC, theft/loss, etc)? *Indicate which.*	Yes	The pharmacy is required to perform an end-of-month inventory.
36.00	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	Incidents would be reported to the board of pharmacy.
37.00	Does the pharmacy have a complete physical inventory of products performed at least once yearly? *If cycle counting, indicate the process.*	Yes	The pharmacy is required to perform an end-of-month inventory for the corporate office.
38.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe process (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	Perpetual inventory in the computer
39.00	Are all products inspected upon receipt to detect any packaging issues, damage, etc.? *Describe what happens if products are damaged.*	Yes	The pharmacy calls the manufacturer if an item arrives damaged.
40.00	How are outdated, damaged, or recalled products segregated? *Indicate how often the pharmacy checks for out-of-date products.*	Yes	The pharmacy checks for out-of-dates every month.
41.00	Are non-RAM expired or damaged products destroyed on site? *View documentation. If "no", note the name of the reverse distributor.*	No	Stericycle

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		Observations	Notes
	Prescription/Order Processing		
42.00	Are any portions of the prescription processing performed at a different location? *If so, explain. Indicate whether there is a central fill/central processing agreement in place.*	No	
43.00	Does the pharmacy obtain a copy or verify of the RAM license (of the facility to which the radiopharmaceutical will be delivered) issued by the State Radiation Control Agency or the NRC?	Yes	
44.00	Is there a procedure to obtain a RAM license for the facility when a license cannot be obtained or verified?	Yes	If the license is expiring, the pharmacy contacts the facility and asks for either the new license or a timely renewal letter. If the location does not have either, then the pharmacy calls the state and documents the phone call, including if state authorities give permission to deliver to the facility.
45.00	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	The pharmacy does not handle CS.
46.00	Is the pharmacy computer system provided routine maintenance and is the information backed up? *Indicate the frequency of backup and if the backup data is stored off site .*	Yes	The company has a central server that backs up data in real time.
47.00	Is there a continuity plan should the system become inoperable? *Describe how data will be retrieved.*	Yes	The pharmacy has a template that allows it to create manual records and when the system is live, the orders are re-entered.

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		Observations	Notes
	Patient Profiles and Communication		
48.00	Does the patient information gathered include patient contact information, age or date of birth, and gender, as required by the State Board of Pharmacy?	Yes	
49.00	For therapy doses, does the pharmacy receive appropriate information to assess correct dosage, such as geriatric or pediatric weight-based doses, as required by the State Board of Pharmacy and/or Radioactive Materials Regulatory Agency?	N/A	The pharmacy does not dispense therapy doses.
50.00	Does the pharmacist perform an evaluation of the dose, safety, and intended use of the preparation to be compounded?	Yes	
51.00	Does the pharmacy take back prescription drugs from customers (eg clinic, prescriber, etc.)? If so, describe.	Yes	The pharmacy allows 10% of unused doses to be returned, e.g if a patient doesn't show up. And, it takes back "used" doses to store for decay.
52.00	Are providers instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Yes	

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		Observations	Notes
	Patient Confidentiality		
53.00	Is there a HIPAA policy in place for employees, vendors, and contractors?	Yes	
54.00	Do employees deemed nonessential to patient care have access to confidential patient information, such as delivery personnel, etc.?	No	
55.00	Is access to the pharmacy system limited to appropriate personnel? *Password protected, access limited by job type, access revoked as appropriate such as upon termination, access to patient information in the computer is tracked.*	Yes	
56.00	Are confidential documents shredded? *Indicate if In-house or by a service and list service in notes if applicable.*	Yes	Shred-It is used to destroy confidential documents.
57.00	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	
58.00	Does the crisis plan include security of paper and electronic patient information?	No	

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		Observations	Notes
	Prescription Packing and Transporting		
59.00	Does the pharmacy utilize employee drivers to deliver prescriptions to patients and/or facilities?	Yes	
60.00	Does the pharmacy utilize other services/carriers to deliver prescriptions to patients and/or facilities? *Indicate carriers used.*	No	
61.00	Is there is a tracking system in place to verify delivery of prescription products? *Indicate if signatures obtained or how tracked.*	No	The pharmacy uses a DOT bill of lading with each package that discloses the isotopes and amount of activity in the package. One copy of the documents stays at the pharmacy and the other copy is with the package. The pharmacy does not have a signature process. The PIC advised that the new software will have a tracking system.
62.00	Are deliveries of RAM directly to a secure location at a health care facility?	Yes	
63.00	Is only authorized packaging used?	Yes	
64.00	Is the packaging tamper-evident?	Yes	

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		Observations	Notes
	Personnel Qualifications		
65.00	Is there a process for periodic verification of validity of personnel licenses (registrations)? *Describe the process.*	Yes	On an annual basis, the PIC performs a primary source verification and prints a copy of the verification for his files.
66.00	Are all personnel wearing name tags that clearly identify if they are a pharmacist or a technician? *What about other positions?*	Yes	
67.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, the training and certifications are verified. *View documentation.*	N/A	
68.00	Does the pharmacy have a technician policy that specifies what a technician is allowed and not allowed to do?	Yes	
69.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	The pharmacy is allowed a 3:1 ratio and the maximum number of staff who work at the same time is 8 people.
70.00	Do employees undergo background checks upon hire? *Indicate if performed periodically for existing employees.*	Yes	The corporate office completes regular background checks for the courier staff.
71.00	Do employees undergo drug testing upon hire? *Indicate if performed periodically for existing employees and if it is random, for cause, or both.*	Yes	The pharmacy may perform for cause drug testing.
72.00	Is there a performance review process and is it documented? *If yes, how often?*	Yes	There is a documented annual performance review.
73.00	Is a procedure for corrective or disciplinary action in place and documented?	Yes	

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		Observations	Notes
	Facility and Security		
74.00	Is entry to prescription product storage and processing areas limited to task-critical employees?	Yes	
75.00	Is entry into the handling areas limited to task-critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?	Yes	
76.00	Are drugs secured to prevent unauthorized removal or access?	Yes	
77.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	The security system includes motion detectors, cameras, and third-party remote monitoring of the alarm.
78.00	Does the pharmacy have cameras? *If yes, record how long images are retained.*	Yes	The images are retained for at least 30 days.
79.00	Does anyone have access to the pharmacy after hours in the absence of the pharmacist? *Explain.*	No	
80.00	Do pharmacy staff remain in the pharmacy if the pharmacist is absent on a meal break?	N/A	A pharmacist stays in the licensed pharmacy space during meal breaks.
80.01	If so, is there a policy regarding what activities may or may not be allowed during the pharmacist's absence?	N/A	

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Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes	USP Reference(s)
	Nonsterile Radiopharmaceuticals			1.1
1.00	Does the pharmacy compound nonsterile radiopharmaceuticals? *If so, list which of the following do they compound (eg Oral Capsules, oral solutions, other (if other, list those products in the notes)).*	No		1.1
2.00	Does the pharmacy obtain conventionally manufactured nonsterile drug products for dispensing? *If so, list those products in the notes.*	No		1.1
3.00	Does the pharmacy obtain compounded nonsterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	No	The pharmacy transfers prescriptions for nonsterile preparations, specifically iodine capsules, from a "sister" RLS location in Trevose, PA. This pharmacy sends the RAM license for the customer to the Pennsylvania location and it dispenses the dose. This pharmacy sends a courier to deliver the dose to the customer.	1.1
	Sterile Radiopharmaceuticals			1.2
4.00	Does the pharmacy compound sterile radiopharmaceuticals? *If so, list which of the following do they compound in the notes. (eg, intravenous, intrathecal, intraperitoneal, subcutaneous, intradermal, inhalations, ophthalmics, intra-organ instillations)*	Yes	Intravenous and aerosolized for lung imaging.	1.2
5.00	Does the pharmacy obtain conventionally manufactured sterile drug products for dispensing? *If so, list those products in the notes.*	No		1.2
6.00	Does the pharmacy obtain compounded sterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	No		1.2
7.00	Does the pharmacy compound sterile preparations involving one or more nonsterile components?	No		1.2
8.00	If the pharmacy compounds sterile preparations requiring a sterilization procedure, is testing (eg filtration with bubble point testing) performed prior to dispensing?	N/A		1.2
9.00	If the pharmacy compounds injectable sterile preparations involving one or more components that are not certified to be pyrogen-free, is pyrogen testing performed prior to dispensing?	N/A		1.2

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		Observations	Notes	USP Reference(s)
	Immediate Use of Sterile Radiopharmaceuticals			3
10.00	Does the pharmacy prepare and dispense sterile radiopharmaceuticals in a patient care setting as immediate use?	No		3
11.00	Does the pharmacy prepare immediate use sterile radiopharmaceuticals in an ambient environment without primary or secondary engineering controls?	N/A		3
12.00	Does handling for immediate use sterile radiopharmaceuticals in an ambient environment lacking primary and secondary engineering controls when intended for a single patient meet the following requirements? as applicable:	N/A		3
12.01	Are preparations (including minor deviations) and/or dispensing limited to use for a single patient?	N/A		3
12.02	Are preparation (including preparations with minor deviations) components sterile, conventionally manufactured drug products (eg, NDA, ANDA)?	N/A		3
12.03	Are dispensing of drug products produced under an approved IND or RDRC protocol?	N/A		3
12.04	Are manipulations for any unit doses (eg, decreasing the dosage, needle changes) or dispensing for one patient (eg, withdrawing a dose) ?	N/A		3
12.05	Are preparations labeled for administration within 1 hour of the first container puncture or exposure of any critical site involved (eg, syringe tip, needle hub or needle) to ambient air, whichever is first?	N/A		3
12.06	Are all components involved (eg, Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first?	N/A		3

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		Observations	Notes	USP Reference(s)
12.07	Does the pharmacy indicate that dose pooling (combining doses from two or more syringes to meet one patient's need) is performed as immediate use? Is any residual activity that remains is immediately discarded and not utilized for any other patient?	N/A		3
12.08	Does pharmacy staff follow proper hand hygiene and garbing?	N/A		3
12.09	Does the pharmacy follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling?	N/A		10.4
12.10	Does the pharmacy follow 12.2 Labeling for labeling?	N/A		12.2
12.11	Is area for sterile preparation and/or dispensing functionally separate from nonsterile compounding area (eg, radiolabeling food) during the time of use?	N/A		
12.12	Does the pharmacy require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC?	N/A		
12.13	Are the number of steps or punctures limited?	N/A		
12.14	Does the pharmacy require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications (eg, aseptic technique training with documented assessment, media fill challenge, gloved fingertip testing)?	N/A		4.1
12.15	Is adding non-radioactive, sterile and commercially manufactured pharmaceutical(s) only applicable if performing immediate use. *While adding a non-radioactive, sterile and commercially manufactured pharmaceutical (eg, lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes as long as all of the above are adhered to.*	N/A		
12.16	Is dose splitting (splitting a unit dose for administration to more than one patient) performed as immediate use?	N/A		
12.17	If performed, is dose splitting done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area? *Note where this is performed.*	N/A		

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		Observations	Notes	USP Reference(s)
	Personnel Qualifications, Training, and Hygiene			4
13.00	Are personnel trained to work with radiopharmaceuticals per policies and standard operating procedures (SOPs) authorized by an ANP or AU (eg physician)?	Yes		4
14.00	Do personnel follow these policies or SOPs of the ANP or AU (eg physician) and work under their supervision?	Yes		4
14.01	Are personnel trained in blood-borne pathogens (as appropriate)?	Yes		4
15.00	Are individuals entering a handling area properly garbed and maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals?	Yes		4
15.01	Are individuals who have a condition that may pose a higher potential of contaminating the radiopharmaceutical and the environment with microorganisms (eg, rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) reported to their supervisor?	Yes		4
15.02	Is the designated person responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved?	No	The PIC stated there is no formal process for the designated person to evaluate these individuals.	4
16.00	Have all personnel of reproductive capability who handle, or compound radiopharmaceuticals/radioactive materials confirmed in writing they understand the risks of handling radiopharmaceuticals/radioactive materials?	Yes		4
17.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, administrative, clerks, etc.) who may have contact with radiopharmaceuticals/radioactive materials on handling the spills associated with these?	Yes		4
18.00	Can personnel demonstrate knowledge and can verbalize the principles of the safe use of RAM – time (working quickly/efficiently), distance (not handling RAM directly, using tongs), and shielding (using lead containers and shields in work areas)?	Yes		4
19.00	Can personnel demonstrate a knowledge of emergency procedures and are able to point out the locations of the eyewash station, emergency spill kit, and can verbalize how to handle contamination including reporting?	Yes		4

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		Observations	Notes	USP Reference(s)
	Aseptic Qualifications		***Note to Inspector:*** *Check two (2) employee personnel files for documentation (1 RPh and 1 Tech), as appropriate*	4.1
20.00	Do personnel prove competency under the observation of a designated person, as applicable to their jobs, prior to performing radiopharmaceutical aseptic tasks (that are beyond immediate use). *Note– these can be completed at a different site if all SOPs are identical for the applicable job function.*	Yes	The inspector reviewed records for all nine employees who are trained in aseptic techniques.	4.1
21.00	Do the minimum qualifications include the following?	Yes		4.1
21.01	Aseptic technique with a documented assessment (written or electronic)	Yes		4.1
21.02	Garbing and hand hygiene, as defined by policies and SOPs	Yes		4.1
21.03	PEC cleaning and disinfecting	Yes		4.1
21.04	Gloved fingertip and thumb sampling	Yes		4.1
21.05	Media-fill testing (not required for non-compounding personnel)	Yes		4.1
	Gloved Fingertip and Thumb Sampling			4.1
22.00	Is gloved fingertip and thumb sampling required for all personnel who enter and perform tasks in an ISO Class 5 PEC (eg, aseptic manipulations, cleaning the PEC)?	Yes		4.1
23.00	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?	Yes		4.1
23.01	Is successful completion of initial gloved fingertip and thumb sampling defined as zero colony- forming units (cfu)?	Yes		4.1

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Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes	USP Reference(s)
24.00	Is subsequent gloved fingertip and thumb sampling after media-fill testing defined as ≤3 cfu (total for both hands)?	Yes		4.1
25.00	Is the gloved fingertip and thumb sampling performed with touch plates or other devices (eg, plates, paddles, or slides) that contain a general microbial growth agar [eg, trypticase soy agar (TSA) soybean–casein digest media] supplemented with neutralizing additives (eg, lecithin and polysorbate 80) which support both bacterial and fungal growth?	Yes		4.1
26.00	Per P&P review, gloves are not disinfected immediately before touching the sampling device.	Yes		4.1
27.00	Is a gloved fingertip and thumb sample from both hands collected by rolling finger pads and thumb pad over the agar surface, using a separate sampling device for each hand?	Yes		4.1
28.00	Are the plates incubated in an incubator at 30°–35° C for no less than 48 h, and then at 20°–25° C for no less than 5 additional days?	Yes		4.1
	Media-Fill Testing			4.1
29.00	Is media-fill testing done for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals?	Yes		4.1
30.00	Is testing reflective of the actual manipulations to be carried out by the individual and simulate the most challenging and stressful conditions to be encountered in the worker's duties?	Yes		4.1
31.00	Are media-fill tests documented as defined by the facility's policies and SOPs?	Yes		4.1
32.00	*Recommendation: Are media-fill tests be performed at the end of a work session in the PEC.*	Yes		4.1

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		Observations	Notes	USP Reference(s)
33.00	Are media-fill tests performed with a commercial source of soybean–casein digest medium?	Yes		4.1
34.00	Do those performing sterile-to-sterile processing activities start with sterile media?	Yes		4.1
35.00	Do those performing nonsterile-to-sterile compounding use a nonsterile soybean–casein digest powder to make a solution?	N/A		4.1
35.01	Is dissolved nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution?	N/A		4.1
35.02	Is the final media manipulated in a manner that simulates nonsterile-to-sterile compounding activities?	N/A		4.1
35.03	Is the final media prepared with at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation?	N/A		4.1
36.00	Does the certificate of analysis (CoA) include documentation of growth promotion testing for each lot of media used?	Yes		4.1
37.00	Once the media-fill simulation is completed and the final containers are filled with the test medium, are the media filled containers incubated for 7 days at 20°–25° C followed by 7 days at 30°–35° C to detect a broad spectrum of microorganisms? Note: Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in 1 or more container–closure unit(s) on or before 14 days.	Yes		4.1
38.00	In the event of failure, are results of the evaluation and corrective actions documented and the documentation maintained to provide a record and long-term assessment of personnel competency?	Yes		4.1
39.00	Do media and components used include the following?	Yes		4.1
39.01	manufacturer	Yes		4.1
39.02	expiration date	Yes		4.1

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39.03	lot number	Yes		4.1
40.00	Does the documentation include at a minimum the following?	Yes		4.1
40.01	starting temperature for each interval of incubation	Yes		4.1
40.02	dates of incubation	Yes		4.1
40.03	results	Yes		4.1
40.04	name of the person evaluated	Yes		4.1
40.05	evaluation date	Yes		4.1
40.06	evaluation time	Yes		4.1
	Reevaluation, Retraining, and Requalification			4.2
41.00	Do personnel who fail visual observation of hand hygiene, garbing, and aseptic technique, gloved fingertip and thumb sampling, or media-fill testing successfully pass reevaluations in the deficient area(s) before they can resume processing of sterile radiopharmaceuticals?	Yes		4.2
42.00	Are all failures, retraining, and re-evaluations documented?	Yes		4.2
43.00	Do personnel successfully complete requalification in the core competencies via demonstrated through observation, written testing, and hands-on demonstration of skills?	Yes		4.2

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		Observations	Notes	USP Reference(s)
	Timing of Reevaluation and Requalification			4.2
44.00	**Visual observation**: Are personnel visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures both initially, and then at least once every 12 months?	No	Based on the records reviewed, the pharmacy missed visual observation of some personnel in 2022 and 2023. All of the personnel have been visually observed in 2024.	4.2
45.00	**Gloved fingertip and thumb sampling:** Do personnel perform fingertip and thumb sampling 3 times initially, and then every 12 months (in conjunction with media-fill testing).	Yes		4.2
46.00	**Media-fill testing:** After initial qualification, is a media-fill test of all personnel engaged in sterile radiopharmaceutical processing performed at least every 12 months (in conjunction with gloved fingertip and thumb sampling)?	Yes		4.2
47.00	**Cleaning and disinfecting:** Does the pharmacy retrain and requalify personnel in the cleaning and disinfecting of sterile processing areas every 12 months or in conjunction with any change(s) in cleaning and disinfecting SOPs, whichever is sooner?	Yes		4.2
48.00	**After a pause in sterile radiopharmaceutical processing:** Are personnel that have not performed radiopharmaceutical processing in more than 6 months requalified in all core competencies before resuming duties?	Yes		4.2
49.00	**Sterile compounding using a nonsterile drug substance or components:** Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies every 6 months?	N/A		4.2
	Ancillary Personnel			4.3
50.00	Are personnel who are authorized to be within the sterile processing area and do not handle sterile preparations required to complete all training and testing other than training on media-fill testing ?	N/A		4.3
51.00	Do other personnel or visitors (eg, auditors, regulators, student observers) comply with garbing and gloving SOPs without the need to prove competency?	Yes		4.3

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		Observations	Notes	USP Reference(s)
	Hand Hygiene and Garbing for Immediate Use Preparations			4.4
52.00	**Hand hygiene:** Do personnel wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub with a time based on institution policies to reduce bioburden on the hands?	N/A		4.4
53.00	**Garbing:** Immediately after hand hygiene, do personnel don a clean coat/gown that has not been exposed to a patient or patient care area, and either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with sterile 70% IPA?	N/A		4.4
54.00	Is a different lab coat worn to care for a patient than the coat/gown used for radiopharmaceutical preparation?	N/A		4.4
	Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area			4.5
55.00	Before entering the SRPA or buffer area, do personnel remove all the following (as applicable)? *(Radiation dosimetry devices are allowed, as required by the RAM license).*	Yes		4.5
55.01	Outer garments (eg, bandanas, coats, hats, jackets, sweaters, vests)	Yes		4.5
55.02	All cosmetics	Yes		4.5
55.03	All hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing	Yes		4.5
55.04	Nail products (eg, artificial nails, polish, extenders). {Natural nails kept neat and trimmed.}	Yes		4.5
55.05	Ear buds	Yes		4.5

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		Observations	Notes	USP Reference(s)
55.06	Headphones	Yes		4.5
56.00	Are electronic devices that are not necessary for compounding or other required tasks banned from the SRPA?	N/A	The pharmacy does not have a SRPA.	4.5
57.00	Do personnel don shoe covers, head/hair/facial hair cover(s) and face masks? Note – these items are donned in an order that eliminates the greatest risk of contamination, as defined in facility SOPs.	Yes		4.5
58.00	Does the process before entering the buffer area or SRPA include the following?	Yes		4.5
58.01	Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner	Yes		4.5
58.02	Wash hands and arms up the elbows with soap and water for at least 30 seconds and then dry using low-lint towels	Yes		4.5
58.03	Electronic hand dryers are not permitted	Yes		4.5
58.04	Hand antisepsis cleansing is performed using a suitable alcohol-based hand rub	Yes		4.5
58.05	Don a low-lint gown with sleeves that fit snugly around the wrist and enclosed at the neck. Note: Disposable gowns are preferred.	Yes		4.5
58.06	If reusable gowns are used, a clean gown is donned daily.	Yes		4.5
58.07	Aseptically don sterile, powder-free gloves. Gloves completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped.	Yes		4.5
59.00	Does the routine process include the following?	Yes		4.5

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		Observations	Notes	USP Reference(s)
59.01	Do personnel periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination; due to touching or handling potentially nonsterile materials?	Yes		4.5
59.02	Do personnel inspect the gloves they are wearing for holes, punctures, radioactivity contamination, or tears?	Yes		4.5
59.03	If a defect, radioactivity contamination, or malfunction is detected, do personnel immediately do the following?	Yes		4.5
59.04	Remove the gloves	Yes		4.5
59.05	Repeat antiseptic hand cleansing using an alcohol-based hand rub	Yes		4.5
59.06	Don new sterile gloves	Yes		4.5
59.07	Personnel avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites	Yes		4.5
60.00	Do exiting processes for buffer area or SRPA include the following?	Yes		4.5
60.01	Shoe covers, head/hair/facial hair cover(s), face masks and gloves are properly disposed of	Yes		4.5
60.02	New PPE is used for each re-entry	Yes		4.5
60.03	Gowns may be re-used within the same shift if maintained to minimize contamination (eg away from sinks)	Yes		4.5
60.04	Gowns are in a classified area or,	Yes		4.5
60.05	Gown are kept in (or immediately outside of) the SRPA	N/A		4.5

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		Observations	Notes	USP Reference(s)
	Facility Design and Environmental Controls			5.1
61.00	Is the facility is designed to minimize airborne contamination (for sterile radiopharmaceutical facilities)?	Yes		5.1
62.00	Is the facility is well-lighted?	Yes		5.1
63.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes		5.1
64.00	Are the temperatures in classified areas and SRPA continuously maintained at 25 degrees C or cooler?	Yes		5.1
65.00	Are the temperatures monitored in the classified areas and SRPA each day that they are used, either manually or by a continuous recording device?	Yes		5.1
66.00	Are the temperature readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Yes		5.1
67.00	Are the temperature readings reviewed as described in the facility's SOPs?	Yes		5.1
68.00	Are free-standing air conditioners used within the classified area or SRPA?	No		5.1
69.00	Are temperature monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Yes		5.1
70.00	*Recommendation: The humidity in classified areas and SRPA are continuously maintained at a relative humidity (RH) below 60%.*	Yes		5.1
71.00	Is the humidity monitored in the classified areas and SRPA each day that it is used, either manually or by a continuous recording device?	Yes		5.1

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		Observations	Notes	USP Reference(s)
72.00	Are the humidity readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Yes		5.1
73.00	Are the humidity readings reviewed as described in the facility's SOPs?	Yes		5.1
74.00	Are free-standing humidifiers/dehumidifier used within the classified area or SRPA?	No		5.1
75.00	Are humidity monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Yes		5.1
76.00	Is the designated person responsible to ensure the following?	Yes		5.1
76.01	Does each area related to sterile radiopharmaceutical processes meet the classified air quality standard appropriate for the activities to be conducted in that area?	Yes		5.1
76.02	Are ISO Class 5 PECs located, operated, maintained, monitored, and certified to have appropriate air quality?	Yes		5.1
	Types of Secondary Engineering Controls and Design:			5.1
77.00	Were placement of doors, door surfaces, and movement of the door, all of which can affect airflow, considered when designing doors for a sterile radiopharmaceutical processing facility?	Yes		5.1
78.00	Are tacky surfaces not used in ISO-classified areas?	Yes		5.1
79.00	Are the PEC located in a SEC?	Yes		5.1
80.00	When the PEC is located in an SEC which is an ISO-classified buffer room with an ante room, does all of the following apply?	Yes		5.1

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80.01	Is the ISO-classified ante-room and buffer area separated from the surrounding unclassified areas of the facility with fixed walls and doors?	Yes		5.1
80.02	Are facility design and controls in place to minimize the flow of lower-quality air into the more controlled areas?	Yes		5.1
80.03	Is the air supplied to the classified areas introduced through HEPA filters that are located in the ceiling?	Yes		5.1
80.04	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?	Yes		5.1
80.05	Is a smoke study of the PEC repeated whenever a change to the placement of the PEC within the area is made?	Yes		5.1
80.06	Is the classified areas equipped with a pressure-differential monitoring system?	Yes		5.1
80.07	Does the ante-room have a line of demarcation to separate the clean side from the less clean side?	Yes		5.1
80.08	Is the ante-room entered through the less clean side, and the clean side is the area closest to the buffer area?	Yes		5.1
80.09	Is required garb worn prior to crossing the line of demarcation?	Yes		5.1
81.00	When the PEC is located in an SEC, which is an unclassified area, without an ante room or buffer area (aka SRPA), the following apply:	N/A		5.1
81.01	Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA	N/A		5.1
81.02	The SRPA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC.	N/A		5.1

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81.03	A visible perimeter establishes the boundaries of the SRPA.	N/A		5.1
81.04	Access to the SRPA is restricted to authorized personnel and required materials.	N/A		5.1
81.05	An SRPA is not located adjacent to environmental control challenges	N/A		5.1
81.06	If the SRPA meets ISO Class 8 total airborne particle count specifications, it can also be used for storage and elution of non-direct infusion radionuclide generators (eg, Tc-99m)	N/A		5.1
82.00	If a pass-through is used to prevent influx of contaminants, both doors are never opened at the same time.	Yes		5.1
83.00	*Recommendation: Interlocking mechanisms are used in the pass-through(s).*	Yes		5.1
	The Radiopharmaceutical Processing Environment:			5.1
84.00	Is the PEC certified to meet ISO Class 5 or better conditions (3520 particle count (with limit ≥0.5 µm) per cubic meter) under dynamic operating conditions?	Yes		5.1
85.00	Is the airflow in the PEC unidirectional (laminar flow)?	Yes		5.1
86.00	Is "first air" at the face of the filter free from airborne particulate contamination?	Yes		5.1
87.00	Is the HEPA-filtered air supplied in the direct processing area (DPA) at a velocity sufficient to sweep particles away from aseptic processing areas and maintain unidirectional airflow as much as possible during operations, given the limitations added from the radiation shielding in the DPA?	Yes		5.1
88.00	Are in situ air pattern analyses via smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?	Yes		5.1

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	Types of PECs and Placement:			5.1
89.00	Does the placement of the PEC allow for cleaning around the PEC?	Yes		5.1
90.00	**Laminar airflow workbench (LAFW):** Does a LAFW used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow?	Yes		5.1
91.00	In cases where the LAFW is located within the segregated containment area of a hot-cell, it is acceptable for a horizontal unidirectional HEPA-filtered airflow pattern to be utilized.	N/A		5.1
92.00	**Placement of PEC:** Is the PEC located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC?	Yes		5.1
92.01	If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA.	N/A		5.1
92.02	If used to compound sterile radiopharmaceuticals, the PEC is located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom.	Yes		5.1
93.00	Is a dynamic airflow smoke pattern test performed initially and at least every 6 months to ensure that the PEC is properly placed into the facility and that workers understand how to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA?	Yes		5.1

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		Observations	Notes	USP Reference(s)
	Air-Exchange Requirements		***Note to Inspector:*** *Airflow is measured in terms of the number of HEPA-filtered air changes per hour (ACPH). SRPA do not have an ACPH requirement.*	
94.00	For ISO-classified rooms, does the total ACPH maintain the ISO class under dynamic operating conditions?	Yes		
95.00	Are at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?	Yes		
96.00	Is there a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?	Yes		
96.01	Does HEPA-filtered air from the PEC, added to the HVAC-supplied HEPA-filtered air, increase the total HEPA-filtered ACPH to at least 30 ACPH?	Yes		
96.02	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?	N/A		
96.03	Are both the ACPH from HVAC contributed from the PEC, and the total ACPH documented on certification reports?	Yes		
97.00	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?	Yes		
97.01	Are ante-rooms where activity levels are high, required more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions?	N/A		
97.02	Are the total ACPH documented on certification reports?	Yes		

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Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes	USP Reference(s)
	Creating Areas to Achieve Easily Cleanable Conditions			5.2
	Classified Areas:			5.2
98.00	Are the surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area smooth, impervious, free from cracks and crevices, and non-shedding, so they can be cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate?	Yes		5.2
99.00	*Recommendation: Surfaces are resistant to damage by cleaning agents, disinfectants, and tools used to clean.*	Yes		5.2
100.00	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices where dirt can accumulate?	Yes		5.2
101.00	If ceilings consist of inlaid panels, are each panel caulked or otherwise sealed and secured to seal them to the support frame?	Yes		5.2
102.00	Are walls constructed of or covered with a durable material (eg, epoxy-painted walls or heavy-gauge polymer) and the integrity of the surface maintained?	Yes		5.2
103.00	Are panels joined together and sealed to each other and the support structure?	Yes		5.2
104.00	Do floors include coving to the sidewall or the juncture between the floor and wall are caulked?	Yes		5.2
105.00	*Recommendation: Classified areas minimize dust-collecting overhangs such as utility pipes, ledges, and windowsills.*	Yes		5.2
106.00	If overhangs or ledges are present, are they easily cleanable?	Yes		5.2
107.00	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?	Yes		5.2
108.00	Are any other penetrations through the ceiling or walls sealed?	Yes		5.2

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		Observations	Notes	USP Reference(s)
	SRPA:			5.2
109.00	Is the SRPA and all surfaces (eg, walls, floors, counters, equipment) within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?	N/A		5.2
110.00	*Recommendation: Surfaces in the SRPA are smooth, impervious, free from cracks and crevices, and non-shedding, so they can be easily cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate.*	N/A		5.2
111.00	*Recommendation: Surfaces are be resistant to damage by cleaning agents, disinfectants, and tools used to clean.*	N/A		5.2
112.00	*Recommendation: Dust-collecting overhangs such as utility pipes, ledges, and windowsills are minimized.*	N/A		5.2
113.00	If overhangs or ledges are present, are they easily cleanable?	N/A		5.2
	Water Sources:			5.3
114.00	*Recommendation: Sinks are hands-free use with a closed system of soap (ie, non-refillable).*	Yes		5.3
115.00	In facilities with an ante room and buffer room, is the sink placed inside or outside of the ante room? *Note placement, inside or outside.*	Yes	Outside the anteroom.	5.3
115.01	If the sink is located outside of the ante-room, it is located in a clean space to minimize the risk of bringing in contaminants into the anteroom.	Yes		5.3
115.02	If the sink is located inside the ante-room, describe where it is located.	Yes	The sink is located in the hallway outside the anteroom, around a corner from the anteroom door.	5.3

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		Observations	Notes	USP Reference(s)
115.03	The buffer area does not contain plumbed water sources [eg, sink(s), eyewash(es), shower(s), or floor drain(s)].	Yes		5.3
115.04	The ante room does not contain floor drain(s).	Yes		5.3
116.00	*Recommendation: If installed, sprinkler systems in classified areas are recessed & covered and are easily cleanable.*	N/A		5.3
117.00	In facilities with a SRPA design:			5.3
117.01	Is the sink accessible but located at least 1 m from the PEC and generators, if present?	N/A		5.3
117.02	Is the sink not located inside the perimeter of the SRPA?	N/A		5.3
	Placement and Movement of Materials:			5.4
118.00	Are only furniture, equipment, and other materials necessary permitted in the classified area or SRPA?	Yes		5.4
118.01	*Recommendation: Are furniture, equipment and materials low-shedding and easily cleaned & disinfected.*	Yes		5.4
118.02	Does the number, design, location, and manner of furniture, equipment and material installation not adversely impact environmental air quality and promote effective cleaning and disinfecting?	Yes		5.4
119.00	Are shipping carton(s) or other corrugated or uncoated cardboard not allowed in the classified area or SRPA?	Yes		5.4
120.00	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?	Yes		5.4

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		Observations	Notes	USP Reference(s)
121.00	In a classified area, are carts not moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected?	Yes	Carts are not moved from the dirty side to the clean side.	5.4
122.00	Are all items wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-room(s), pass-through(s), into an SRPA or into an ISO 5 PEC?	Yes		5.4
	Classified Areas:			5.5
123.00	Are activities and tasks carried out within the buffer area limited to only those necessary?	Yes		5.5
124.00	Are food and drinks exposed in patient care and treatment areas not in the ante-rooms or buffer areas?	Yes		5.5
125.00	When processing activities require the manipulation of blood-derived or other biological material (eg, radiolabeling patient's or donor's blood cells) do the following occur?	Yes		5.5
125.01	Are the manipulations clearly separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities?	Yes		5.5
125.02	Are manipulations controlled by specific SOPs to avoid any cross-contamination?	Yes		5.5

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		Observations	Notes	USP Reference(s)
	Remote Aseptic Processing Involving a Hot-Cell:		*Note to Inspector: In settings where tasks are carried out within the hot-cell enclosure not within an ISO-classified space by remote means (ie, no direct intervention by personnel into the ISO Class 5 space), it is not necessary for personnel to don the garbing described in this chapter for that environment to carry out these aseptic manipulations or to perform other routine tasks in the general area where the hot-cell is located.*	5.6
126.00	Does a hot-cell device provide an inherent physical segregation for the ISO Class 5 aseptic processing area?	N/A		5.6
127.00	If the hot-cell is located in an ISO-classified space, do personnel garb according to requirements of <825> for that environment?	N/A		5.6
128.00	If hand and arm incursions into the interior of the hot-cell occur causing personnel to stage the required materials and supplies, do personnel garb in relation to the contamination risk associated with the individual hot-cell/ISO Class 5 relationship?	N/A		5.6
129.00	For situations where a PEC device is located within a hot-cell, all the following apply:	N/A		5.6
129.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials in the demarcated PEC area does not allow the influx of unclassified air into the PEC?	N/A		5.6
129.02	For interventions that are outside of the PEC, do personnel garb in nonsterile gloves and a low-particulate lab coat?	N/A		5.6
129.03	If the hot-cell has failed the airflow smoke pattern test, are personnel required to garb differently?	N/A		5.6

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		Observations	Notes	USP Reference(s)
130.00	For situations where the hot-cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, the following apply:	N/A		5.6
130.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials into the demarcated PEC area does not allow the influx of less than ISO Class 5 quality air into the PEC?	N/A		5.6
130.02	If a failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the PEC.	N/A		5.6
131.00	For other hot-cell/PEC configurations and technologies that may exist, the following apply:	N/A		5.6
131.01	Does verification (either by airflow smoke pattern tests or other manufacturer specified methods) ensure, upon each certification, that the staging of materials and supplies does not allow for the intrusion of less than ISO Class 5 air into the designated ISO Class 5 space?	N/A		5.6
131.02	Does failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the hot-cell?	N/A		5.6
	Environmental Controls:			5.7
132.00	Do all RAM users comply with the conditions specified in their approved RAM license application and regulations, and RAM license conditions may supersede the following requirements for environmental controls? Refer to the RAM license for pressure requirements, as applicable.	Yes		5.7
133.00	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area (eg, between the buffer area and ante-room)?	Yes		5.7

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		Observations	Notes	USP Reference(s)
134.00	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?	Yes		5.7
134.01	Is the buffer area, if present, positive pressure compared to the ante-room?	Yes		5.7
134.02	Is the ante-room, if present, positive pressure compared to unclassified portions of the restricted area?	Yes		5.7
135.00	Is the restricted area, in the presence of volatile or airborne radiopharmaceuticals, negative pressure compared to the unrestricted area?	N/A		5.7
136.00	Is the SRPA negative pressure compared to unrestricted areas in the presence of volatile or airborne radiopharmaceuticals (eg, I-131 sodium iodide and Xe-133 gas)?	N/A		5.7
	Establishing and Maintaining Pressure Differentials:			5.7
137.00	Any time a pressure differential is required, is there a pressure monitoring device?	Yes		5.7
138.00	In a classified area, is a pressure differential monitoring system used to continuously monitor the pressure differential between the ante-room(s) and buffer area(s) and between the ante-room and the general environment outside the classified area(s) or area(s)?	Yes		5.7
139.00	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?	Yes		5.7
140.00	All pressure monitoring devices are tested for accuracy and required performance at least every 6 months.	Yes		5.7

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		Observations	Notes	USP Reference(s)
	Ambient Atmosphere for Immediate Use Preparations:			5.7
141.00	All of the following requirements met in ambient atmosphere environments:	N/A		5.7
141.01	Is non-patient care space, functionally separate (not necessarily a different area) from the patient care area, such as a radiopharmaceutical handling space, or hot lab, in a hospital, clinic, or mobile coach?	N/A		5.7
141.02	Is there a designated area for medication preparation that is clean and free from clutter?	N/A		5.7
141.03	Is it a low traffic area (ie, limited number of people going in and out or moving around the area during times that radiopharmaceutical processing is being carried out)?	N/A		5.7
	SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations:			5.7
142.00	Does the SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations meet the following requirements?	N/A		5.7
142.01	Area surrounding the PEC may be ambient (unclassified) atmosphere.	N/A		5.7
142.02	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals.	N/A		5.7
142.03	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals.	N/A		5.7
142.04	An area that is used to store and elute non-direct infusion radionuclide generators (eg, Tc-99m) must meet ISO Class 8 total airborne particle-count specifications.	N/A		5.7

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		Observations	Notes	USP Reference(s)
	An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector**: Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
143.00	ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	N/A		5.7
	An ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector**: Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
144.00	ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room and sterile compounding.	Yes		5.7
	Hot-Cell:		***Note to Inspector**: Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
145.00	Hot-Cell environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	N/A		5.7
	Certification of PEC and Environment in which the PEC is located:			5.7
146.00	Certification of the classified areas, including the PEC, is performed initially.	Yes		5.7
147.00	Recertification is performed at least every 6 months.	Yes		5.7

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148.00	Procedures outlined in the current CETA certification guide for Sterile Compounding Facilities, or an equivalent guideline, are followed.	Yes		5.7
149.00	Airflow testing is performed to determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions.	Yes		5.7
150.00	HEPA filter integrity testing is performed (HEPA filters are leak tested after installation and as part of recertification).	Yes		5.7
151.00	Total Particle Counts testing is performed and conducted under dynamic operating conditions using calibrated electronic equipment.	Yes		5.7
152.00	Smoke Visualization Studies are performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).	Yes		5.7
153.00	Are other equivalents for certifying the PEC performed and documented per facility SOPs, in cases where technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards?	N/A		5.7
154.00	In this case, the PEC maintains the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air.	N/A		5.7

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		Observations	Notes	USP Reference(s)
	Daily Monitoring of Environment:			5.7
155.00	The temperature and humidity is monitored in the SRPA or area containing a hot-cell, and if in a classified area the pressure is monitored, each day that radiopharmaceutical handling occurs, either manually or by a continuous recording device.	Yes		5.7
156.00	Does Monitoring include the following?	Yes		5.7
156.01	*Recommendation: Relative humidity is kept at 60% or lower*	Yes		5.7
156.02	Are temperature continuous readings confirmed daily to have remained within the acceptable range?	Yes		5.7
156.03	Are relative humidity continuous readings confirmed daily to have remained within the acceptable range?	Yes		5.7
156.04	Are excursion documented and, if applicable, appropriate corrective actions taken?	Yes		5.7
156.05	Are temperature monitoring devices verified for accuracy every 12 months or as required by the manufacturer?	Yes		5.7
156.06	Are monitoring of pressure differentials performed?	Yes		5.7

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		Observations	Notes	USP Reference(s)
	Microbial Air and Surface Monitoring:			6
157.00	Has the pharmacy developed and implemented written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?	Yes		6
158.00	Are air and surface monitoring results and the corrective actions documented, and records readily retrievable as required by jurisdictional laws and regulations?	Yes		6
	General Monitoring Requirements:			6.1
159.00	Is the air and surface monitoring program clearly described in the established SOPs of the facility and include a diagram of the sampling locations, SOPs for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the classified areas, and action levels that will trigger corrective action?	No	The SOP does not include a diagram, but it has a description of locations where personnel should collect a surface sample.	6.1
159.01	Are samples obtained from locations that pose the highest possible contamination risk to the sterile radiopharmaceuticals involved with the operation's processes and are likely to be representative of the conditions throughout the area?	Yes		6.1
160.00	Are personnel who operate the equipment trained in the proper operation of the air and surface sampling equipment to ensure accurate and reproducible sampling?	No	The PIC has been trained in air sampling. The equipment is only used if the pharmacy has a failure when air sampling is conducted by the third-party vendor every 6 months. The internal personnel have not been trained in surface sampling.	6.1

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161.00	Are all air sampling devices serviced and calibrated as recommended by the manufacturer?	Yes	The pharmacy does not conduct its own air sampling. The third party vendor provides documentation of calibration with its report.	6.1
162.00	Does the microbiological air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?	Yes		6.1
163.00	Are air and surface sampling performed initially for PECs & classified areas in a facility to establish a baseline level of environmental quality?	Yes		6.1
164.00	After initial sampling, are the PECs & classified area(s) monitored according to the minimum frequencies?	Yes		6.1
165.00	Are air and surface sampling conducted during actual or simulated dynamic operating conditions to confirm that the required environmental quality in classified areas is maintained?	No	Monthly surface sampling is conducted after production and not under simulated dynamic conditions. When the third-party vendors provides sampling, it occurs during dynamic conditions.	6.1
166.00	Is sampling carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area?	Yes		6.1
167.00	Is sampling performed in all of the following circumstances?	Yes		6.1
167.01	In conjunction with the certification of new facilities and equipment?	Yes		6.1
167.02	After any modification of facilities or equipment	Yes		6.1
167.03	In response to identified problems (eg, positive growth in sterility tests of compounded radiopharmaceuticals)?	Yes		6.1

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		Observations	Notes	USP Reference(s)
167.04	In response to identified trends (eg, repeated positive gloved fingertip sampling results or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination)?	Yes		6.1
167.05	In response to changes that could impact the controlled area environments (eg, significant change in cleaning process or the agents involved)?	Yes		6.1
168.00	Is regular review of the sampling data performed to detect trends such as elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment?	Yes		6.1
169.00	Are results reviewed in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination?	Yes		6.1
170.00	Is Prompt corrective action in response to any adverse findings taken to maintain the necessary environmental quality for handling sterile radiopharmaceutical?	Yes		6.1
171.00	Is data also reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface quality levels?	Yes		6.1
	Monitoring Air Quality for Viable Airborne Particles:			6.2
	Viable Air Sampling: Timing and Locations			6.2
172.00	Volumetric active air sampling of all classified areas (eg, ISO Class 5 PEC and ISO Class 7 and 8 areas) using an impaction device are conducted during dynamic operating or simulated operating conditions at least every 6 months.	Yes		6.2
173.00	Does viable air sampling include the following?	Unknown		6.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes	USP Reference(s)
173.01	Following the manufacturer's instructions for operation of the air sampling device, including placement of media?	Unknown	The pharmacy contracts with a third-party for viable air sampling every six months during the recertification. It is unknown if the personnel from the third-party vendor follow the manufacturer's instructions.	6.2
173.02	Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled?	Yes		6.2
173.03	At the end of the sampling, retrieve the media plates/devices and cover?	Unknown	It is unknown if the third-party vendor covers the media plates/devices.	6.2
173.04	Inverting the media and incubate at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (ie, viable air). Include sample location and date?	Unknown	The pharmacy contracts with a third-party for viable air sampling every six months during the recertification. It is unknown if the personnel from the third-party vendor incubate as described.	6.2
173.05	Incubates the inverted media at 20°–25° C for no less than 5 additional days? Examines the media plates for growth? Records the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (ie, viable air)? Includes sample location and date?	Unknown	The pharmacy contracts with a third-party for viable air sampling every six months during the recertification. It is unknown if the personnel from the third-party vendor incubate as described.	6.2
174.00	To shorten the overall incubation period, can two samples be collected for each sample location and incubated concurrently?	Unknown		6.2
175.00	Both samples could be TSA, or one sample could be TSA and the other fungal media [eg, malt extract agar (MEA) or sabouraud dextrose agar (SDA)]. Describe samples in notes.	Unknown		6.2

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		Observations	Notes	USP Reference(s)
176.00	Each sample is incubated in a separate incubator.	Unknown		6.2
177.00	One sample is incubated at 30°–35°C for no less than 48 hours and the other sample is incubated at 20°–25° C for no less than 5 days.	Unknown		6.2
178.00	Fungal media samples are incubated at 20°–25° C for no less than 5 days.	Unknown		6.2
179.00	The count of the total number of discrete colonies of microorganisms are done on each sample and these results are recorded as cfu per sample.	Unknown		6.2
180.00	Are the results of the sampling recorded on an environmental sampling form based on sample type (ie, viable air) and include the sample location, and sample date?	Unknown		6.2
181.00	Are general microbiological growth medium that supports the growth of bacteria and fungi used (eg, TSA medium)?	Unknown		6.2
182.00	Do CoA(s) from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?	Unknown		6.2
183.00	Are samples incubated in a temperature monitored incubator with a calibrated measuring device?	Unknown		6.2
184.00	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device, and the results reviewed and documented?	Unknown		6.2
185.00	Are the incubators used for microbiological testing placed in a location outside of any classified area or SRPA and kept away from areas where compounding or sterile processing activities are carried out?	Unknown		6.2

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		Observations	Notes	USP Reference(s)
	Data Evaluation and Action Levels:			6.2
186.00	Air Sampling Action Levels (cfu/cubic meter (1000L) of air per plate) are within the appropriate range: *ISO Class 5 - >1* *ISO Class 7 - >10* *ISO Class 8 - >100*	Yes		6.2
187.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Yes		6.2
187.01	If two pieces of media were collected at a single location, are all recovered growth documented and action levels are applied individually to each plate/device (ie, results from each cubic meter of air sampled are compared to the action level for that area)?	N/A		6.2
188.00	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?	Yes		6.2
188.01	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Yes	New Jersey requires reporting to board of pharmacy within 48 hours, decommissioning the PEC until retesting is complete and passed and board of pharmacy is notified of the passing results.	6.2
188.02	If levels measured during viable air sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?	Yes		6.2
188.03	Is the corrective action plan documented?	Yes		6.2
188.04	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Yes		6.2

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		Observations	Notes	USP Reference(s)
	Monitoring Surfaces for Viable Particles:			6.3
189.00	Are all sampling sites and procedures described in the facility's SOP?	Yes		6.3
	Surface Sampling: Timing and Locations			6.3
190.00	Is surface sampling of all classified areas and all PECs conducted at least monthly for the detection of microbial contamination?	Yes		6.3
191.00	Is each classified area sampled?	Yes		6.3
192.00	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?	Yes		6.3
193.00	Are work surfaces in classified areas near the PEC, frequently touched surfaces in classified areas, and pass-through enclosure(s) for all classified areas evaluated to determine the locations that pose the greatest risk of harboring microbial contamination?	Yes		6.3
194.00	Is surface sampling performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?	Yes		6.3
195.00	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?	Yes		6.3
196.00	If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk (eg, implementation of appropriate shielding, performing the sampling at a later time or alternate day)?	Yes		6.3

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		Observations	Notes	USP Reference(s)
	Sampling Procedures:			6.3
197.00	Are surface sampling devices (eg, plates, paddles, or slides) containing microbial growth media used for sampling flat surfaces?	Yes		6.3
198.00	Are CoAs from the manufacturer verified that the media meet the expected growth promotion, pH, and sterilization requirements?	Yes		6.3
199.00	Do surface sampling devices contain general microbial growth media (eg, TSA) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents?	Yes		6.3
200.00	If used, do contact plates have a raised convex surface?	Yes		6.3
201.00	Are sterile swabs wetted with sterile water or a sterile neutralizing buffer used when sampling irregular surfaces and difficult-to-reach locations, such as crevices, corners, and spaces between surfaces?	N/A		6.3
202.00	After sampling, is the sampled area thoroughly cleaned and disinfected?	Yes		6.3
203.00	Are the following procedures for surface sampling on flat surfaces used?	Yes		6.3
203.01	Remove the cover from the surface sampling device. Firmly press, using a rolling motion, if possible, the media surface onto the surface to be sampled. The surface sampling device will leave a residue of growth medium on the sample site. After sampling, use sterile 70% IPA to remove residue. Cover each surface sampling device.	Yes		6.3
203.02	If using plates, invert the plates.	Yes		6.3

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		Observations	Notes	USP Reference(s)
203.03	Incubate the surface sampling devices at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu/sample on an environmental sampling form based on sample type (ie, surface). Include sample location and date.	Yes		6.3
203.04	Incubate the sampling device at 20°–25° C for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms (cfu/sample) on the environmental sampling record based on sample type (ie, surface). Include sample location and date.	Yes		6.3
204.00	Does the facility use two samples for each sampling location?	No		6.3
204.01	Are both TSA?	N/A		6.3
204.02	Is one TSA and one Fungal?	N/A		6.3
204.03	Is each sample incubated in a separate incubator?	N/A		6.3
204.04	Is one sample media incubated at 30°–35° C for no less than 48 hours?	N/A		6.3
204.05	If fungal media are used as one of the samples, is it fungal media sample incubated the at 20°–25° C or no less than 5 days?	N/A		6.3
204.06	Are the total number of discrete colonies of microorganisms on each sample counted as cfu per sample?	N/A		6.3
204.07	Are the results of the sampling recorded?	N/A		6.3

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		Observations	Notes	USP Reference(s)
	Data Evaluation and Action Levels:			6.3
205.00	Surface Sampling Action Levels (cfu/device or swab) are within the appropriate range: *ISO Class 5 - >3* *ISO Class 7 - >5* *ISO Class 8 - >50*	Yes		6.3
206.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Yes		6.3
206.01	If two pieces of media were collected at a single location, is all recovered growth on each documented and action levels are applied to each piece of media individually (ie, results from each sampling device are compared to the action level for that area)?	N/A		6.3
207.00	If levels measured during the viable surface monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?	Yes		6.3
207.01	Is data collected in response to corrective actions reviewed to confirm that the actions taken have been effective?	Yes		6.3
207.02	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Yes		6.3
207.03	If levels measured during surface sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?	Yes		6.3
207.04	Is the corrective action plan documented?	Yes		6.3
207.05	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Yes		6.3

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		Observations	Notes	USP Reference(s)
	Cleaning and Disinfecting			7
208.00	Are all cleaning and disinfecting activities performed by trained and appropriately garbed personnel using facility approved agents and procedures described in written SOPs?	Yes		7
209.00	Is cleaning performed in the direction of most to least clean areas?	Yes		7
210.00	Are the frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable, and followed by all cleaning personnel?	Yes		7
210.01	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?	Yes		7
210.02	When sterile 70% IPA is used, is it allowed to dry?	Yes		7
211.00	Are all cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?	Yes		7
212.00	Are surfaces cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step?	Yes		7
212.01	After cleaning and disinfecting or the application of a one-step disinfectant cleaner in a PEC, is sterile 70% IPA applied to remove any residue?	Yes		7

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		Observations	Notes	USP Reference(s)
213.00	Does cleaning and disinfecting surfaces occur at the minimum frequencies in Table 5 or if activities are not performed daily, cleaning and disinfecting completed before initiating activities?	Yes		7
214.00	Is the act of reducing or removing radioactivity (radioactive decontamination) from an object or surface balanced with the risk of spreading radioactive contamination?	Yes		7
214.01	*Recommendation: Areas shielded until radiation exposure levels lowered.*	Yes		7
214.02	Is this balance specified in SOPs (eg, trigger levels for safe cleaning)?	Yes		7
214.03	*Recommendation: The PEC is checked for radioactive contamination prior to cleaning and disinfecting to prevent spreading radioactive contamination in the PEC.*	Yes		7
	Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified Areas and within the perimeter of the SRPA:			7
215.00	Does Cleaning of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occurs in the following situations?	Yes		7
215.01	Prior to performing sterile processing of radiopharmaceuticals on each day that activities are carried out, are the walls, bars, torso shield and any exposed surface of equipment inside the PEC cleaned to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (eg, microbiologist or industrial hygienist)?	Yes		7
215.02	Is radioactive contamination shielded with appropriate temporary material, providing the material is covered with low-lint absorbent pads or has equivalent low shedding properties?	Yes		7

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		Observations	Notes	USP Reference(s)
216.00	Does disinfecting of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occur in the following situations?	Yes		7
216.01	Following cleaning on each day that activities are carried out, are exposed surfaces of the equipment disinfected to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (eg, microbiologist or industrial hygienist)?	Yes		7
216.02	When used, are low-lint absorbent pads removed and the PEC surveyed for radioactive contamination prior to disinfecting?	Yes		7
216.03	Are new pads replaced after disinfecting or as required after spills?	Yes		7
217.00	Does Cleaning and Disinfecting occurs **DAILY** for the following?	No		7
217.01	PEC(s) and equipment inside the PEC(s)	Yes		7
217.02	Surface of sink(s)	No		7
217.03	PEC and equipment inside the PEC(s) located in a hot cell.	Yes		7
217.04	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	N/A		7
217.05	Work surface(s) outside the PEC	Yes		7
217.06	Floor(s)	Yes		7
218.00	Does Cleaning and Disinfecting occurs **MONTHLY** for the following?	Yes		7
218.01	Ceiling(s)	Yes		7

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		Observations	Notes	USP Reference(s)
218.02	Wall(s), door(s), door frame(s), and other fixtures	Yes		7
218.03	Storage shelving and storage bins	Yes		7
219.00	Does Sporicidal application occurs **MONTHLY** for the following?	No		7
219.01	PEC(s) and equipment inside the PEC(s)	Yes		7
219.02	Surface of sink(s)	No		7
219.03	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	N/A		7
219.04	PEC and the equipment inside the PEC(s) located in a hot-cell	N/A		7
219.05	Work surface(s) outside the PEC	Yes		7
219.06	Ceiling(s)	Yes		7
219.07	Wall(s), door(s), door frame(s), and other fixtures	Yes		7
219.08	Floor(s)	Yes		7
219.09	Storage shelving and storage bins	Yes		7

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		Observations	Notes	USP Reference(s)
	Cleaning, Disinfecting and Sporicidal Agents:		***Note to Inspector**: Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties.*	7.1
220.00	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?	Yes		7.1
221.00	Are considerations when selecting and using disinfectants include their anti-microbial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected?	Yes		7.1
221.01	After the disinfectant is applied on the surface to be disinfected, is the disinfectant allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed?	Yes		7.1
222.00	Is only sterile 70% IPA used in the ISO Class 5 PEC?	Yes		7.1
223.00	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?	Yes		7.1
	Cleaning Supplies:			7.2
224.00	Are all cleaning supplies (eg, wipers and mop heads), with the exception of tool handles and holders, low-lint?	Yes		7.2
225.00	*Recommendation: All cleaning supplies (eg, wipers and mop heads), with the exception of tool handles and holders are disposable.*	Yes		7.2
225.01	If disposable cleaning supplies are used, are they discarded after each cleaning activity?	Yes		7.2
226.00	Are reusable cleaning tools made of cleanable materials (eg, no wooden handles) and are cleaned and disinfected before and after each use?	Yes		7.2

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227.00	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal?	Yes		7.2
228.00	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?	Yes		7.2
229.00	*Recommendation: Cleaning supplies and solutions used in the classified areas and SRPAs are be monitored for radioactive contamination after use and prior to disposal, as per facility SOPs.*	Yes		7.2
230.00	Are cleaning supplies used in the classified areas and SRPAs disposed in a manner that minimizes the potential for dispersing particulates into the air (eg, with minimal agitation, away from work surfaces)?	Yes		7.2
	Cleaning and Disinfecting the PEC:			7.3
231.00	Is the PEC cleaned and disinfected at the minimum frequencies specified in Table 5?	Yes		7.3
232.00	If the PEC contains a removable work tray, are all sides of the work tray and the area underneath the work tray cleaned and disinfected at least monthly?	Yes		7.3
233.00	If necessary are all surfaces of the PEC surveyed for radioactive contamination and follow facility SOPs to decontaminate?	Yes		7.3
234.00	If necessary, any particles, debris, or residue removed with an appropriate solution (eg, Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers?	Yes		7.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes	USP Reference(s)
235.00	Is a cleaning agent applied followed by a disinfecting agent or an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved?	Yes		7.3
236.00	Is sterile 70% IPA applied?	Yes		7.3
237.00	Are the surfaces allowed to dry completely before beginning activities?	Yes		7.3
238.00	Is the PEC wiped with a sporicidal agent at least monthly?	Yes		7.3
	Disinfecting Supplies for Classified Areas and SRPAs:			7.4
239.00	Are shipping carton(s) or other corrugated or uncoated cardboard prohibited in the classified area (eg, clean side of ante-room) or within the perimeter of the SRPA?	Yes		7.4
240.00	Before items are introduced into a classified area or SRPA, are they wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers?	Yes		7.4
241.00	After the sporicidal or sterile disinfectant is applied onto the surface, is the agent allowed to dwell on the surface for the minimum contact time specified by the manufacturer?	Yes		7.4
241.01	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?	Yes		7.4

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242.00	Are any items to be transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant (eg, sterile 70% IPA)?	Yes		7.4
243.00	If radiopharmaceuticals are being processed by remote means in a hot-cell, the opening of sterile packages (eg, syringes, luer lock caps) may not be possible by remote means within the ISO Class 5 area.			7.4
243.01	In this case, are the syringes opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle?	N/A		7.4
	Disinfecting Critical Sites:			7.5
244.00	Are critical sites (eg, vial stoppers) wiped with sterile 70% IPA? Note: If the vial shield top is then closed, the septum is disinfected again with sterile 70% IPA prior to another needle puncture.	Yes		7.5
245.00	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?	Yes		7.5
246.00	Is the sterile 70% IPA allowed to dry before piercing critical sites?	Yes		7.5
247.00	Is the septum wiped with sterile 70% IPA frequently whenever multiple punctures are occurring (eg, removing several individual doses from a multiple-dose container)?	Yes		7.5

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		Observations	Notes	USP Reference(s)
	Cleaning and Disinfecting Items from Patient Care Area:			7.6
248.00	Is radiation shielding and equipment used in the classified area/SRPA or PEC that is exposed to patient care areas during the process of administration cleaned and disinfected before returning to any classified area (eg, buffer or ante-room) or SRPA in accordance with the Centers for Disease Control and Prevention Guidelines 1 classified as noncritical equipment requiring low-risk disinfection?	Yes		7.6
249.00	Are syringes that have been used in a patient care area not brought back into the classified area (eg, buffer or ante-room) or SRPA for re-assaying or disposal unless the syringe is sealed inside an impervious container (eg, sealed plastic bag) that is disinfected prior to entry into the classified area or SRPA?	Yes		7.6
250.00	Is equipment that has been exposed to needles and syringes contaminated with blood-borne pathogens and RAMs considered mixed waste (eg, syringe shields and syringe carrying containers)?	Yes		7.6
250.01	Is this equipment cleaned and disinfected through actions regulated by the facility's SOPs?	Yes		7.6
250.02	Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?	Yes		7.6
	Assigning BUDs:			8
251.00	Does the pharmacy have policies and SOPs appropriate to the assignment of BUD and maintain documentation of applicable study results and calculations?	Yes		8
252.00	*Recommendation: Studies of radiolabeling efficiency and radiochemical stability employ quality control (QC) testing methods described in the manufacturer's package insert, USP monographs and general chapters, or other equivalent testing methods and are sufficiently rigorous to allow statistical confidence in the results.*	Yes		8

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253.00	Does the pharmacy have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs?	Yes		8
254.00	*Recommendation: Policies and SOPs are also in place to reevaluate the assigned BUD based on complaints, which may include repeating studies and/or performing additional studies on radiolabeling efficiency and/or radiochemical stability.*	Yes		8
255.00	Does the individual responsible for the manipulation assign the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature?	Yes		8
256.00	Preparation Conditions for Sterile Radiopharmaceuticals: *Describe condition used at the pharmacy in notes section (Table 7).*		PEC with ISO Class 5 and SEC with ISO Class 7 with ISO Class 8 anteroom.	8
257.00	For compounded preparations (sterile and nonsterile) plus preparations with minor deviations, is BUD dependent on maintenance of quality and purity including radiochemical purity, radionuclidic purity and other applicable parameters as specified in individual monographs or as clinically appropriate?	Yes		8
258.00	Assignment of BUD for a radiopharmaceutical considers several factors, as appropriate. Issues of concern include all but are not limited to the following:	Yes	The assigned BUD is based on a 90% tag.	8
259.00	*Recommendation: The assigned BUD does not exceed the sterility-related times listed in Table 7 unless a longer time is justified by Sterility tests per <71>.*	Yes	The pharmacy performs sterility testing once a year for the items with the most manipulations and the most dispensed, by compounding, allowing the isotope to decay and then completing a sterility test.	8
260.00	Radiochemical Purity - Is the assigned BUD based on stability studies in which these variables are controlled and are representative of the conditions of actual use?	Yes		8

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		Observations	Notes	USP Reference(s)
261.00	*Recommendation: For factors that allow a range of values (eg, storage temperature, quantity of radioactivity, radioactivity concentration), studies are conducted at the extreme of the ranges.*	Yes		8
262.00	Radionuclidic purity - USP monographs for Tc-99m radiopharmaceuticals require that the radionuclidic impurity Mo-99 not exceed 0.15 µCi Mo-99 per mCi Tc-99m at the time of administration.	Yes		8
263.00	Are calculations of radionuclidic purity at future times necessary to ensure compliance throughout the assigned BUD?	Yes		8
264.00	Age of the generator eluate - Extension of the BUD for Tc-99m pertechnetate intended for radiolabeling of kits take into account the build-up of Tc-99 and peroxides over time.	Yes		8
265.00	Number of particles - For radiolabeled particulates, the number of particles per unit radioactivity increases over time as the radionuclide decays. Calculation of the number of MAA particles in the patient dose is conducted to ensure compliance with the prescribed particle range throughout the assigned BUD.	Yes		8
266.00	Specific Activity - For some receptor-based radiopharmaceuticals, the mass quantity may influence uptake. In such situations, the assigned BUD ensures that the patient dose contains no more than the specified mass.	N/A		8
267.00	Container Type – The assigned BUD is determined in the proper storage container.	Yes		8
268.00	*Cell Viability – Recommendation: The assigned BUD is as short as circumstances reasonably allow so as to maximize cell viability.*	Yes		8

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		Observations	Notes	USP Reference(s)
269.00	In the case of manufactured radiopharmaceuticals that are distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing, the assigned BUD of the dispensed dose cannot exceed the expiration date/time of the manufactured radiopharmaceutical(s).	Yes		8
270.00	In the case of radiopharmaceuticals prepared from kits, the BUD of a dispensed dose cannot exceed the assigned BUD of the finished kit preparation.	Yes		8
271.00	A radiopharmaceutical may not exceed the shortest BUD of any of its components.	Yes		8
	Documentation:			9
272.00	Are applicable records (hard-copy or electronic), including policies and SOPs, maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals?	Yes		9
273.00	Do such records include all but are not limited to the following?	Yes		9
273.01	Personnel training and testing including visual assessment of aseptic technique competency	Yes		9
273.02	Validation	Yes		9
273.03	Garbing	Yes		9
273.04	Hand hygiene	Yes		9
273.05	Equipment/environment cleaning and disinfecting	Yes		9
273.06	Gloved fingertip and thumb sampling	Yes		9
273.07	Media fill evaluation initially	Yes		9
273.08	Media fill follow up testing at specified intervals	Yes		9

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		Observations	Notes	USP Reference(s)
273.09	Equipment maintenance and cleaning/disinfecting	Yes		9
273.10	End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations	Yes		9
273.11	Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding	Yes		9
273.12	Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature	Yes		9
273.13	Investigations and corrective actions and tracking of events to closure.	Yes		9
274.00	Do Testing and Monitoring of environmental controls include the following?	Yes		9
274.01	ISO classification	Yes		9
274.02	ACPH	Yes		9
274.03	Pressure differentials	Yes		9
274.04	Temperature	Yes		9
274.05	*Recommendation: Humidity*	Yes		9
274.06	Viable air	Yes		9
274.07	Viable surface	Yes		9
274.08	Total particle test results	Yes		9

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		Observations	Notes	USP Reference(s)
	Master Formulation Record:			9.1
275.00	Preparations with minor deviations or compounding have a MFR. *Note: A MFR is not required for a preparation following the manufacturer's instructions.*	Yes		9.1
276.00	Do the elements of the MFR include at a minimum the following?	Yes		9.1
276.01	Name of the radiopharmaceutical	Yes		9.1
276.02	Name or ID number, pharmacy, strength, purity, quality, and quantity of ingredients with validated documentation (eg, CoA)	Yes		9.1
276.03	Detailed procedure (eg, heating, components, incubation time)	Yes		9.1
276.04	Range of radioactivity	Yes		9.1
276.05	Range of volume	Yes		9.1
276.06	Equipment to be used	Yes		9.1
276.07	PEC and SEC to be used, if applicable	Yes		9.1
276.08	Quality control tests to be performed for final release of the radiopharmaceutical (eg, radiochemical purity, pH)	Yes		9.1
276.09	Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits	N/A		9.1
276.10	Trained Personnel	Yes		9.1
276.11	Garbing procedure, if different than standard procedure	N/A		9.1
276.12	Container(s)	Yes		9.1
276.13	Reference source of the BUD assignment and storage conditions	Yes		9.1

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		Observations	Notes	USP Reference(s)
	Records for Preparation with Minor Deviations/Compounding:			9.2
277.00	Does the record for preparation with minor deviation or compounding includes at a minimum, as applicable, the following?	Yes		9.2
277.01	Name of the radiopharmaceutical	Yes		9.2
277.02	Physical form (eg capsule or solution)	Yes		9.2
277.03	Name and quantity of ingredients including calibration time for radioactive ingredients (eg, 100 mCi Tc 99m sodium pertechnetate @ 1300)	Yes		9.2
277.04	Total volume	Yes		9.2
277.05	Reference to the MFR	Yes		9.2
277.06	Any deviation from the MFR, if applicable	N/A		9.2
277.07	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components	Yes		9.2
277.08	Name of the person who prepared and name of the supervising personnel (eg, ANP)	Yes		9.2
277.09	Date and time of preparation	Yes		9.2
277.10	Assigned internal identification number (eg, lot number)	Yes		9.2
277.11	Unique reference [eg, prescription, order number(s)]	Yes		9.2
277.12	Assigned BUD and storage requirements	Yes		9.2
277.13	Documentation of QC results	Yes		9.2

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		Observations	Notes	USP Reference(s)
	Preparation			10
278.00	The individual responsible for preparing the radiopharmaceutical(s) ensures that the final preparation complies with quality and purity specifications throughout the assigned BUD.	Yes		10
279.00	Do the quality and purity specifications include, as appropriate for the preparation, the following?	Yes		10
279.01	Radionuclidic purity	Yes		10
279.02	Radiochemical purity	Yes		10
279.03	Chemical purity	Yes		10
279.04	Physical and chemical properties	Yes		10
	Preparation Following Manufacturer Instructions			10.1
	Nonsterile Preparations			10.1
280.00	For nonsterile preparations, manufacturer preparation instructions are followed (eg, I-131 NaI capsules or solution), taking into account appropriate radiation safety considerations and environmental controls, if applicable (eg, negative air pressure area, chemical fume hood, activated charcoal filters when handling a potentially volatile radionuclide).	N/A		10.1
281.00	*Recommendation: The area is cleaned and uncluttered to ensure the overall integrity and quality of the prepared radiopharmaceutical(s).*	N/A		10.1
282.00	*Recommendation: There is a documented process for activities (eg, cleaning) between the preparation cycles of different nonsterile products, to decrease the likelihood of contamination from other prepared products.*	N/A		10.1

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		Observations	Notes	USP Reference(s)
	Sterile Preparations			10.1
283.00	For sterile preparations (including intravascular devices), manufacturer preparation instructions are followed, taking into account appropriate radiation safety considerations, appropriate environmental controls, and aseptic handling practices to maintain sterility.	Yes		10.1
284.00	The minimum environmental standard for the preparation of sterile radiopharmaceuticals beyond immediate-use is within an ISO Classified area or device.	Yes		10.1
	Preparation with Minor Deviations			10.2
285.00	In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that are necessary to accommodate circumstances not contemplated in the FDA-approved labeling.	Yes		10.2
285.01	Deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions.	Yes		10.2
286.00	The minor deviations utilized require appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or are supported by appropriate peer-reviewed publications.	Yes	The pharmacy uses in-house QC testing.	10.2
287.00	Do the pharmacy radiopharmaceutical preparations with minor deviations include all of the following when applicable?	Yes		10.2
287.01	Altering the quantity of radioactivity or volume added to the vial	Yes		10.2
287.02	Changes in step-by-step operations (eg, dilute Tc-99m sodium pertechnetate after rather than before addition to the vial)	N/A		10.2
287.03	Using alternative devices or equipment (eg, a heating block rather than a hot water bath, using a different sized needle, different shielding materials)	Yes		10.2
287.04	Using QC test methods other than those described in the product labeling (eg, radiochemical purity)	N/A		10.2
287.05	Filtering Tc-99m sulfur colloid	Yes		10.2
287.06	Other, (if so, describe in the notes)	N/A		10.2

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		Observations	Notes	USP Reference(s)
	Preparation of Radiolabeled Blood Components		***Note to Inspector:*** *Handling blood and radiolabeling of blood components requires special attention to biological risks and need to be handled with standard precautions using aseptic technique to prevent the introduction of new microorganisms into the preparation that will be administered.*	10.3
288.00	The preparation BUD does not exceed 6 hours after the blood sample is obtained from the patient or blood bank.	Yes		10.3
289.00	Equipment and supplies are never shared with other activities unless they are first thoroughly cleaned and disinfected.	Yes		10.3
290.00	Do special precautions when radiolabeling of blood components for non-immediate use include the following?	Yes		10.3
290.01	There is complete physical separation (either fixed or non-fixed wall) of areas where blood products are handled from areas where non-blood products are handled. An ISO Class 5 BSC located in an ISO Class 7 buffer area is required for blood-labeling processes. If more than one ISO Class 5 PEC is located within the ISO Class 7 buffer area, policies and SOPs are in place to include certification that the SEC meets conditions of air quality at maximum occupancy under dynamic operating conditions.	Yes		10.3
290.02	One radiolabeling procedure per PEC at a time. Blood products from more than one patient are never manipulated at the same workstation at the same time. Each area has dedicated supplies, equipment, and waste disposal to eliminate sharing of these items or overlap in pathways.	Yes		10.3
290.03	Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, occurs prior to starting another blood component radiolabeling procedure.	Yes		10.3
290.04	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator is used or the dose calibrator dipper and liner is cleaned and disinfected following the radio assay.	N/A		10.3

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		Observations	Notes	USP Reference(s)
290.05	Centrifuge is located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes.	Yes	Each BSC has an individual centrifuge.	10.3
290.06	Dedicated (per each radiolabeling procedure) consumable products (eg, 0.9% sodium chloride injection, diluent, tubes, syringes, and other supplies) necessary for each individual patient radiolabeling procedure.	Yes		10.3
290.07	All tubes and syringes in contact with the patient's blood components are clearly labeled with the patient's name and at least one additional identifier (eg, date of birth, medical record number, barcode).	Yes	The labels include the patient's name and a "tracking" number that is a barcode.	10.3
290.08	Dedicated syringe shields and vial shields.	Yes		10.3
290.09	Any garb that enters the ISO Class 5 BSC is removed and replaced before handling anything else not related to performing this procedure.	Yes		10.3
290.10	Removal of all disposable items from the ISO Class 5 BSC is utilized in each radiolabeling procedure.	Yes		10.3
290.11	Cleaning and disinfection of all reusable equipment and components (eg, BSC, centrifuge, dose calibrator, syringe shields, vial shields, syringe transport shields and delivery cases) is done after each radiolabeling procedure prior to any further use. Policies and SOPs address cleaning and disinfection processes including the use of an EPA-registered (or equivalent) one-step disinfectant cleaner with activity against blood-borne pathogens followed by sterile 70% IPA. Sterile 70% IPA alone is not sufficient.	Yes		10.3
290.12	After the completion of blood radiolabeling procedures, 4.5 Hand Hygiene and Garbing requirements for Buffer Areas and segregated Radiopharmaceutical Processing Area are followed.	Yes		10.3

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e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes	USP Reference(s)
	Preparation of Radiolabeled Red Blood Cells for Immediate Use			10.4
291.00	Is In vitro red blood cell labeling prepared with the following conditions?	N/A		10.4
291.01	A dedicated space for blood handling is designated through the entirety of the blood radiolabeling process. This area is free from clutter and not used for any other radiopharmaceutical preparation or handling until the completion of cleaning and disinfection.	N/A		10.4
291.02	Only one radiolabeling procedure is performed at a time or there are documented processes that maintain the integrity of samples and environment.	N/A		10.4
291.03	Dedicated equipment is used for blood radiolabeling procedure (eg, L-block, syringe shield, vial shield, forceps, needle recapper).	N/A		10.4
291.04	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator or a cleaning and disinfecting procedure with an appropriate product is used to decontaminate the dipper and liner of the dose calibrator following the radio assay	N/A		10.4
291.05	A cleaning and disinfecting procedure with an appropriate agent(s) is used to decontaminate the area and equipment prior to and after the radiolabeling is complete and all disposable components have been discarded	N/A		10.4
291.06	All requirements in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations are followed.	N/A		10.4
291.07	The start time of the preparation begins with the initial container puncture or the exposure of a critical site (eg, syringe tip, needle hub or needle) to ambient air, whichever is first.	N/A		10.4
291.08	The compounded product has a BUD of 1 hour	N/A		10.4

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Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

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		Observations	Notes	USP Reference(s)
	Compounding		***Note to Inspector:*** *The combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides.*	11
292.00	Each compounding activity is based on a pre-established written procedure and includes maintenance of compounding records.	Yes		11
292.01	The compounding record provides traceability for components and person(s) involved.	Yes		11
293.00	All sterile compounding, using aseptic technique, is performed in an ISO 5 PEC. Compounding employees are using appropriate aseptic technique. May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). ***When applicable, Compounding MUST be observed***, *if compounding is not being performed at the time of survey mark item as "No".*	Yes		11
293.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "**Denial of Authorization**" form. List individual who signs the Denial of Authorization.*			11
294.00	Compounding is not be performed for any radiopharmaceutical(s) that has been withdrawn from the market because of safety or lack of effectiveness, unless part of an institutional review board approved investigational study.	Yes		11
295.00	Radiopharmaceuticals that are essentially copies of marketed FDA-approved radiopharmaceuticals are not be compounded unless there is a change that produces a clinical difference for an identified individual patient, as determined by a prescriber.	N/A	The pharmacy does not compound any essential copies.	11

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		Observations	Notes	USP Reference(s)
	Compounding Nonsterile Radiopharmaceuticals		***Note to Inspector:*** *Compounding nonsterile radiopharmaceuticals is the combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical.*	11.1
296.00	Areas designated for nonsterile compounding are cleaned, uncluttered and separated from areas designated for sterile radiopharmaceuticals.	N/A		11.1
297.00	*Recommendation: Compounding takes into account RAM licensing requirements for appropriate radiation safety considerations and utilize appropriate environmental controls, if applicable.*	N/A		11.1
298.00	The placement of equipment and materials are designed to prevent cross-contamination.	N/A		11.1
299.00	When feasible, disposable material is used to reduce the chance of cross-contamination.	N/A		11.1
300.00	Each compound has a unique MFR.	N/A		11.1
301.00	The preparation information is documented on a compounding record.	N/A		11.1
302.00	The MFR details the selection of all components.	N/A		11.1
303.00	**The ingredients obtained from sources in this preferential order:** FDA-approved product; FDA-registered facility; and lastly, if the ingredients for the compound are not available from either of these two sources, the MFR details the selection of a material that is suitable for the intended use.	N/A		11.1

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304.00	The MFR establishes the identity, strength, purity, and quality of the ingredients by validated means (eg, CoA).	N/A		11.1
305.00	Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means.	N/A		11.1
306.00	A BUD for the compounded radiopharmaceutical is validated, taking into account the stability of the ingredients, any intermediate containers, the final container, and the storage conditions.	N/A		11.1
306.01	A BUD cannot be extended past the labeled expiration date of any component in the compound.	N/A		11.1
306.02	If the compounded radiopharmaceutical(s) includes components from other preparations or preparations with minor deviations, the BUD of the final compounded radiopharmaceutical does not exceed the shortest remaining BUD of any of those components.	N/A		11.1
	Sterile Compounding		***Note to Inspector**: Kit-splitting (also referred to as "fractionation") may be used to meet patient need.*	11.2
307.00	Do personnel responsible for compounding consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (eg, osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD?	N/A		11.2
308.00	Do the compounding activities involve the addition of a conventionally manufactured drug product (eg, Ascorbic Acid Injection, Lidocaine Hydrochloride Injection, Sodium Bicarbonate Injection) approved by the appropriate regulatory agency to a radiopharmaceutical?	N/A		11.2
309.00	Does the pharmacy split conventionally marketed kits?	N/A		11.2

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		Observations	Notes	USP Reference(s)
310.00	Do personnel responsible consider all possible interactions of kit components with these other containers (eg, container walls, closures), as well as possible alterations in stability (eg, physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD?	N/A		11.2
310.01	Systematic QC testing is performed to validate the appropriateness of a particular BUD.	N/A		11.2
	Sterile Compounding Using Nonsterile Drug Substance or Components			11.3
311.00	Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides.	N/A		11.3
311.01	If one or more materials or components are not certified to be sterile and pyrogen-free, a sterilization procedure (eg, filtration with bubble point testing) and testing described in <85> is performed. Record calibration date of the bubble test pressure gauge, as applicable.	N/A		11.3
312.00	The designated person for compounding is responsible for ensuring that the final preparation complies with pre-established standards or acceptance criteria for identity, quality, and purity.	N/A		11.3
313.00	The designated person considers all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (eg, osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD.	N/A		11.3
313.01	Testing to validate the appropriateness of a particular BUD may be required.	N/A		11.3
314.00	If compounding involves a bulk drug substance, the radiopharmaceutical complies with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product.	N/A		11.3

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314.01	A bulk drug substance includes a radionuclide, a ligand, or other substance, such as a precursor that becomes an active ingredient in the final radiopharmaceutical.	N/A		11.3
315.00	Each bulk drug substance is manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures.	N/A		11.3
316.00	If compounding involves excipients or other inactive ingredients, the excipients or other inactive ingredients comply with standards of an applicable USP or NF monograph, if one exists.	N/A		11.3
317.00	It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.	N/A		11.3
	Dispensing and Radio assay		*Note to Inspector: Dispensing refers to the manipulations necessary to transfer the prescribed or ordered amount of radiopharmaceutical into the final container (eg, syringe or vial).*	12.1
318.00	Labeling of the final patient-ready dose or ordered amount of a radiopharmaceutical is also a component of the dispensing process.	Yes		12.1
319.00	Except for an unopened manufacturer container, the final dose or ordered amount is radio assayed (ie, in a dose calibrator).	Yes		12.1
320.00	*Recommendation: The measured activity is mathematically corrected for radioactive decay to the time of scheduled administration (calibration time).*	Yes		12.1
321.00	The activity at calibration time is always be within federal, state, and local variance limits.	Yes		12.1

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		Observations	Notes	USP Reference(s)
	Labeling			12.2
322.00	*Recommendation: All personnel distributing and/or dispensing radiopharmaceuticals verify that any labeling is in compliance with regulatory agencies.*	Yes		12.2
323.00	Is the inner container (eg syringe, vial) labeled with all of the following?	Yes		12.2
323.01	Standard radiation symbol	Yes		12.2
323.02	The words "Caution—Radioactive Material"	Yes		12.2
323.03	For all therapeutic and blood-products, the patient name/identifier	Yes		12.2
323.04	Radionuclide and chemical form (generic name)	Yes		12.2
323.05	Radioactivity at the date and time of calibration	Yes		12.2
324.00	Is the outer shielding (eg, syringe or vial shielding) labeled with all the following?	Yes		12.2
324.01	Standard radiation symbol	Yes		12.2
324.02	The words "Caution—Radioactive Material"	Yes		12.2
324.03	For all therapeutic and blood-products, the patient name/identifier	Yes		12.2
324.04	The radionuclide and chemical form (generic name)	Yes		12.2

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324.05	Radioactivity with units at time of calibration and the calibration time	Yes		12.2
324.06	Volume or number of units (eg, 2 capsules), as applicable	Yes		12.2
324.07	Product expiration or BUD, as applicable, and any special storage and handling requirements for non-immediate use (eg, refrigeration, resuspension)	Yes		12.2
324.08	Route of administration	Yes		12.2
	Direct Infusion Systems			12.3
325.00	Do the operations of the direct infusion systems follow the "Instructions for Use" in the device labeling?	N/A		12.3
326.00	Are each of the following parameters considered by the operator of the system?	N/A		12.3
326.01	Setup attachment or needle-puncture should be performed in a defined environment	N/A		12.3
326.02	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems	N/A		12.3
326.03	The 0.9% sodium chloride bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag is labeled with the date and time of puncture and the BUD	N/A		12.3
326.04	Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial is disinfected with sterile 70% IPA prior to puncturing the vial with the needle	N/A		12.3

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326.05	The septum of any vial and the ports of any diluent bag is wiped with sterile 70% IPA prior to puncturing	N/A		12.3
326.06	When puncturing the vial in ambient air, it is only punctured once	N/A		12.3
326.07	If there are problems with the infusion device, no sterile container(s) associated with the system is repunctured or transferred to a PEC for further manipulations and the container, with contents, is discarded	N/A		12.3
	Transporting Generators Between Facilities			12.4
327.00	Are the following standards followed if transporting generators between facilities?	N/A		12.4
327.01	The generator needle and/or ports are capped in ISO Class 8 air or better with sterile protectors	N/A		12.4
327.02	The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system	N/A		12.4
	Repackaging			13
328.00	If the facility repackages, are the following applicable?	Yes		13
328.01	Removes conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product.	Yes		13

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328.02	Places the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients	Yes		13
329.00	Does the facility repackage nonsterile radiopharmaceuticals (eg, I-131 sodium iodide oral capsules)?	N/A		13
330.00	Does the facility repackage sterile radiopharmaceuticals (eg, thallous chloride Tl 201 injection)?	Yes		13
331.00	Unopened manufacturer dosage units (eg, capsules, Xe-133 vials) are not radioassayed.	Yes		13
332.00	The repackaged radiopharmaceutical is radioassayed (ie, in a dose calibrator), if it is not an unopened manufacturer dosage unit.	Yes		13
333.00	*Recommendation: The inner container is labeled with all of the following:*	Yes		13
333.01	*Standard radiation symbol*	Yes		13
333.02	*The words "Caution—Radioactive Material"*	Yes		13
333.03	*The radionuclide and chemical form (generic name)*	Yes		13
333.04	*Radioactivity with units at time of calibration and the calibration time*	Yes		13
334.00	*Recommendation: The outer container is labeled with all of the following:*	Yes		13
334.01	*Standard radiation symbol*	Yes		13
334.02	*The words "Caution—Radioactive Material"*	Yes		13
334.03	*The radionuclide and chemical form (generic name)*	Yes		13
334.04	*Radioactivity with units at time of calibration and the calibration time*	Yes		13

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334.05	*Volume, or number of units (eg, capsules), as applicable*	Yes		13
334.06	*Product expiration or BUD, as applicable*	Yes		13
334.07	*Special storage and handling instructions*	N/A		13
	Quality Assurance and Quality Control			14
335.00	QA and QC programs are formally established and documented in SOPs that ensure that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable federal, state, and local laws and regulations.	Yes		14
336.00	A designated person ensures that the facility has formal, written QA and QC programs. List this person in the notes.	Yes	Kristin Anson, Quality Manager (Corporate).	14
337.00	Do QA and QC programs establish a system which include of all of the following?	Yes		14
337.01	Adherence to procedures	Yes		14
337.02	Prevention and detection of errors and other quality problems	Yes		14
337.03	Evaluation of complaints and adverse events	Yes		14
337.05	Appropriate investigations and corrective actions	Yes		14
338.00	The SOPs describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.	Yes		14

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339.00	The overall QA and QC program is reviewed at least once every 12 months by the designated person. List last date of review in notes.	Yes	The PIC is performing a review at this time, therefore the last review is ongoing in May of 2024.	14
340.00	The results of the review are documented, and appropriate corrective action taken, if needed.	Yes		14
	Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals			14.1
341.00	If a radiopharmaceutical is dispensed or administered before the results of release testing are known, does the facility have all of the following SOPs in place?	N/A	All quality control testing is complete before doses are released.	14.1
341.01	Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes)	N/A		14.1
341.02	Determine whether a recall is necessary	N/A		14.1
342.00	Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain all of the following procedures?	N/A		14.1
342.01	Determine the severity of the problem and the urgency for the implementation and completion of the recall	N/A		14.1
342.02	Determine the distribution of any affected radiopharmaceutical, including the date and quantity	N/A		14.1
342.03	Identify patients who have received the radiopharmaceutical	N/A		14.1

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342.04	Outline the disposition and reconciliation of the recalled radiopharmaceutical	N/A		14.1
343.00	Does the facility document the implementation of the recall procedures?	N/A		14.1
344.00	Is the recall is reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (eg, state board of pharmacy, state health department)?	N/A		14.1
	Complaint Handling			14.2
345.00	Has the nuclear pharmacy developed and implemented SOPs for handling complaints? Note: Complaints may include concerns or reports on the quality and container labeling of, or possible adverse reactions to, a specific radiopharmaceutical.	Yes		14.2
346.00	Does the designated person review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical?	Yes		14.2
346.01	If a complaint indicates potential quality issues with radiopharmaceuticals, is an investigation into the potential cause of the issue completed?	Yes		14.2
346.02	Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?	Yes		14.2
346.03	Is corrective action, if necessary, implemented for all potentially affected radiopharmaceuticals?	Yes		14.2
346.04	Does the investigation consider whether to initiate a recall of potentially affected radiopharmaceuticals and whether to cease sterile compounding until all underlying problems have been identified and corrected?	Yes		14.2

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347.00	Is a readily retrievable record (written or electronic) of each complaint kept by the facility, regardless of the source of the complaint (eg, e-mail, telephone, mail)?	Yes		14.2
348.00	Does the record contain all of the following?	Yes		14.2
348.01	The name of the complainant	Yes		14.2
348.02	The date the complaint was received	Yes		14.2
348.03	The nature of the complaint	Yes		14.2
348.04	The response to the complaint	Yes		14.2
348.05	If known, the name and strength of the radiopharmaceutical and the assigned internal identification number (eg, prescription, order, or lot number).	Yes		14.2
349.00	Does the record also include the findings of any investigation and any follow-up?	Yes		14.2
350.00	Are records of complaints easily retrievable for review and evaluation for possible trends?	Yes	Records of complaints are not maintained onsite, the PIC would need to reach out to corporate quality team for review of previous complaints to evaluate for possible trends.	14.2
351.00	Are records retained in accordance with the record keeping requirements?	Yes		14.2
352.00	Is a radiopharmaceutical that is returned in connection with a complaint quarantined until it is destroyed after completion of the investigation and in accordance with applicable jurisdictional laws and regulations?	Yes		14.2

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS USA INC
e-Profile ID: 1285742
Inspection Date: 5/22/2024 & 5/24/2024

		Observations	Notes	USP Reference(s)
	Adverse Event Reporting			14.3
353.00	Are adverse events potentially associated with the quality of radiopharmaceuticals reported in accordance with the facility's SOPs and all applicable jurisdictional laws and regulations?	Yes		14.3
354.00	*Recommendation: Adverse events potentially associated with the quality of the radiopharmaceutical preparation are reported to the applicable jurisdictional regulatory body (eg, state boards of pharmacy, state health departments, FDA's MedWatch program for human drugs).*	Yes	The PIC stated it would be reported to the manufacturer and would report to FDA MedWatch if all customers who received doses from the vial had a similar complaint.	14.3

The information and comments obtained are based on USP General Chapter <825> Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging
An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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Acronym	Definition
ACPH	Air changes per hour
ALARA	As low as reasonably achievable
ANDA	Abbreviated new drug application
ANP	Authorized nuclear pharmacist
AU	Authorized user
BLA	Biologics license application
BSC	Biological safety cabinet
BUD	Beyond-use date
CETA	Controlled Environment Testing Association
cfu	Colony-forming unit
CoA	Certificate of analysis
DPA	Direct processing area
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation, and air conditioning
IND	Investigational new drug
IPA	Isopropyl alcohol
ISO	International Organization for Standardization
LAFW	Laminar airflow workbench
MAA	Macroaggregated albumin
MEA	Malt extract agar
MFR	Master Formulation Record
NDA	New drug application
NRC	Nuclear Regulatory Commission
PEC	Primary engineering control
PET	Positron emission tomography
RAM	Radioactive material
RDRC	Radioactive drug research committee
RH	Relative humidity
SDA	Sabouraud dextrose agar
SEC	Secondary engineering control
SOP	Standard operating procedure
SRPA	Segregated radiopharmaceutical processing area
TSA	Trypticase soy agar

Term	Definition
Dispense/dispensing	Pursuant to a patient specific prescription, labeled with patient name at the pharmacy
Distribute/distributing	Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy.
Type of Practice: Central Fill/Processing/ Shared Services	Where part of the prescription processing and dispensing process occurs at another location
Type of Practice: Closed Door	Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent
Type of Practice: HMO/PBM only	Limited to only the beneficiaries of the specific insurance program - no cash patients
Type of Practice: Institutional	Such as a hospital or jail
Type of Practice: Internet Pharmacy	Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line.
Type of Practice: Investigational Drugs, Clinical Trials or Research	Approved to handle investigational drugs
Type of Practice: Long Term Care	Nursing Home pharmacy
Type of Practice: Manufacturer	Registered with the FDA as a manufacturer
Type of Practice: Open to the Public	Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist

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Type of Practice: Outsourcing Facility	Registered with the FDA as an Outsourcing Facility
Type of Practice: Provides Office Use	Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy.
Type of Practice: Specialty Pharmacy	Business is primarily with specialty drugs and works with specific disease states
Type of Practice: Telepharmacy	Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility.
Type of Practice: Traditional retail	Also known as Community Pharmacy.
Type of Practice: Veterinary Pharmacy	Pharmacy business is primarily or exclusively for animals.
Type of Practice: Wholesale Distributor	Pharmacy is licensed or registered as a wholesale distributor
Glossary	
Administration:	The direct and immediate application of a radiopharmaceutical to a patient by injecting, infusing, ingesting, or otherwise providing a radiopharmaceutical in its final form.
Airlock:	A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas.
Ante-room:	An ISO Class 8 or cleaner area with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels are performed. The ante-room is the transition area between the unclassified area in a facility and the classified buffer area.
Aseptic processing or preparation:	A process by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility.
Aseptic technique:	Methods utilized during the processing of radiopharmaceuticals to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at a nearly irreducible number.
As low as (is) reasonably achievable (ALARA):	The effort to maintain exposures to ionizing radiation as far below the dose limits as practical. These efforts should be consistent with the purpose for which the licensed activity is undertaken, in relation to utilization of licensed materials in the public interest. Limiting exposure time, using adequate shielding, and maintaining the most distance possible from all radioactive sources (i.e., time, distance, shielding) are the basic principles for successfully following ALARA guidelines.
Authorized nuclear pharmacist (ANP):	A pharmacist recognized by the U.S. Nuclear Regulatory Commission or an Agreement State agency as having met training and experience requirements for the practice of nuclear pharmacy.
Authorized user (AU):	A physician recognized by the U.S. Nuclear Regulatory Commission or an Agreement State agency as meeting training and experience requirements for specified medical uses of radioactive material.
Beyond-use date (BUD):	The assigned date and time beyond which the radiopharmaceutical must not be administered.
Biological safety cabinet (BSC) Class II:	A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. The BSC is designed to provide worker protection from exposure to biohazardous material and to provide an ISO Class 5 or better environment for preparing sterile radiopharmaceuticals.
Blood components:	Any constituent of blood that is separated by physical or mechanical means (eg, red cells, white cells, platelets)
Buffer area:	An ISO Class 8 or cleaner area with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer area may only be accessed through the ante-room.
Chemical purity:	The fraction of the total chemical species present in the radiopharmaceutical as the specified chemical component(s). A chemical impurity is the presence of an unwanted non-radioactive chemical.
Classified area:	An area that maintains an air quality classification based on the ISO guidelines (i.e., ante-room, buffer area). See ISO class.
Cleaning agent:	A material for the removal of residues (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Compounding:	The combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides. See Preparation with minor deviations.
Container–closure system:	The packaging components that contain or come in contact with the radiopharmaceutical and maintain the integrity of the radiopharmaceutical contained within. Examples include (but are not limited to) vials, tubes and syringes.
Critical site:	A location that includes any component or fluid pathway surface (eg, vial septa, injection ports) or openings (eg, needle hubs) that, when exposed is at risk for contamination by direct contact with air (eg, ambient area or HEPA-filtered), moisture (eg, oral and mucosal secretions), or touch.
Designated person:	One or more individuals assigned to be responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.
Direct infusion system:	An FDA-cleared medical device used to dispense and/or administer radiopharmaceuticals to multiple patients. The standards of this chapter pertain to devices with ambient air that lack and ISO Class 5 environment.
Direct processing area (DPA):	An area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant:	A chemical or physical agent used on inanimate surfaces and objects to destroy microbiological contamination (eg, fungi, viruses, and bacteria) when used in the appropriate concentrations and for the appropriate contact times. Sporicidal disinfectant agents are considered a special class of disinfectants that also are effective against bacterial endospores and fungal spores.

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Dispensing:	The manipulation or labeling of a radiopharmaceutical to render it in its final form for administration, typically obtained from a single-dose or multiple-dose container (eg, withdrawing a volume of finished product or preparation from a vial into a syringe). Dispensing is performed under the supervision of a physician or pharmacist and for radiopharmaceuticals includes dilution with an appropriate diluent or adjusting the activity in an individual dosage.
Dose pooling:	The combining of doses from two or more syringes to meet one patient's need, also see "repackaging".
Dose splitting:	The splitting of a patient-ready unit dose for use with more than one patient.
Dynamic operating conditions:	Conditions in the SRPA or classified area in which operating personnel are present and performing actual or simulated activities. The PEC should contain equipment and materials regularly used for radiopharmaceutical processing (eg, low-lint absorbent pads, dose calibrator, syringe shields).
Expiration date:	For conventionally manufactured radiopharmaceuticals, the specified date (and time) beyond which the product must not be administered. The expiration date is determined by the manufacturer.
First air:	The air exiting the HEPA filter in a unidirectional air stream.
Garb:	Gloves, gowns, shoe covers, head (covers ears and all hair) and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of microbiological contamination to radiopharmaceuticals.
High efficiency particulate air (HEPA) filtration:	Using a tested and certified air filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter from the air passing through it.
Hot-cell:	A device used for the shielding and containment of radioactive materials. The shielding material(s) (eg, lead) is generally incorporated into the structure of the unit itself. Radiopharmaceutical personnel carry out the majority of the tasks within the hot-cell from the exterior of the unit. This is accomplished by the use of remote manipulation systems (eg, manipulator arms, automated dispensing system) of various designs. Numerous air quality configurations of the hot-cell may exist, including integrated HEPA filtration systems to render all or a specified portion (DPA) of the device capable of certifying to a controlled ISO Class 5 environment. In other situations, the hot-cell offers only radiation protection and a laminar flow PEC, capable of achieving an ISO Class 5 environment, is placed within the enclosure to allow for safe aseptic manipulations. A hot-cell may also be referred to by other designations (eg, shielded isolator with laminar flow, PET dispensing station, manipulator hot-cell, shielded isolators for dispensing, radiopharmaceutical dispensing isolator).
Hot lab:	Unclassified radiopharmaceutical processing area located within a hospital or clinical site that is only appropriate for immediate use radiopharmaceuticals if there is not an ISO 5 PEC within SRPA located within the area.
Immediate use:	A preparation (including preparations with minor deviations) and/or dispensing of a sterile radiopharmaceutical that is limited for a single patient. Only sterile conventionally manufactured drug products (eg, NDA, ANDA) or drugs produced under an approved IND or RDRC protocol may be used. Administration must begin within 1 hour of the first container puncture or exposure of any critical site involved (eg, syringe tip, needle hub or needle) to ambient air, whichever is first.
Individual dose (unit dose):	A radiopharmaceutical in its final form ready for administration (eg, capsule, sterile solution in a syringe) consisting of the amount (dose) prescribed, ordered, or other intended for an individual patient or research subject.
Inverse square law:	The specified physical quantity or intensity of a radiation emission is inversely proportional to the square of the distance from the source of the emission.
ISO class:	A quality classification from the International Organization for Standardization based on quantity and size of particles per volume of air.
Kit:	Conventionally manufactured package containing all ingredients required to prepare a radiopharmaceutical with the exception of the radionuclide.
Kit-splitting (fractionation):	The act of dividing the contents of a kit vial and transferring aliquots into other containers for storage and subsequent radiolabeling.
Ligand:	An ion or molecule that incorporates a metal atom to form a coordination complex.
Line of demarcation:	A visible line on the floor that separates the clean and less clean sides of the ante-room.
Low-lint wiper:	A wiper exhibiting few, if any, fibers or other particulates, visible without magnification, which are separate from, or easily removed from, the wiper material in a dry condition.
Master Formulation Record (MFR):	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished preparations as well as the processing instructions, including the in-process controls.
Media-fill test:	A simulation used to qualify processes and personnel engaged in sterile radiopharmaceutical processing to ensure that the processes and personnel are able to prepare radiopharmaceuticals without microbiological contamination. Molar mass: The measured mass that is attained from a molar amount of a given substance (eg, element, compound).
Molar mass:	The measured mass that is attained from a molar amount of a given substance (eg, element, compound). It is generally expressed with units such as g/mol and kg/mol.
Multiple-dose container:	A container of a radiopharmaceutical for administration that is designed to contain more than one patient dose of the radiopharmaceutical.

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Negative-pressure area:	An area that is maintained at lower pressure than the adjacent spaces, and therefore the net airflow is into the area. This area is appropriate for volatile or gaseous radionuclides and radiopharmaceuticals (eg, I-131 NaI, N-13 ammonia) and intended to lend a measure of protection for the radiation workers and the general public.
One-step disinfectant cleaner:	A product with an EPA-registered claim (or equivalent) that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Pass-through:	An enclosure with sealed doors on both sides to ensure that both doors are not opened at the same time. The pass-through is positioned between two spaces creating an airlock for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter:	A visible demarcation on the floor that defines the boundaries of the SRPA.
Positive-pressure area:	An area that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the area.
Preparation:	The act of combining a conventionally manufactured kit with a conventionally manufactured radionuclide following manufacturer's recommended instructions. Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.
Preparation with minor deviations:	The act of preparing a conventionally manufactured kit with a conventionally manufactured radionuclide with volume, and/or radioactivity, and/or step-by-step deviations from the manufacturers recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the BUD. Examples of minor deviations include, but are not limited to, altering the amount of activity or volume added to the vial, changes in step-by-step operations (eg, dilute Tc-99m solution after, rather than before, addition to the vial, use of a venting needle or filter), using alternative devices or equipment (eg, a heating block rather than a hot water bath), and using alternative radiochemical purity testing methods.
Primary engineering control (PEC):	A device or zone that provides an ISO Class 5 air quality environment for sterile processing.
Pyrogen:	A substance that induces a febrile reaction in a patient.
Quality assurance (QA):	The system of procedures, activities, and oversight that ensures that radiopharmaceutical processing consistently meets quality standards.
Quality control (QC):	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the radiopharmaceutical.
Radioactive materials (RAM) license:	A document(s) issued by the US NRC or an Agreement State agency that authorizes various activities involving the use of radioactive materials. These uses can include possession, research and development, distribution, medical use, and other purposes not included in this list. Only those activities specifically authorized are allowed.
Radioassay:	Measurement of the quantity of radioactivity present in a container using a suitable and calibrated instrument, such as a well-type ionization chamber (i.e., dose calibrator).
Radiochemical purity:	The ratio, expressed as a percentage, of the radioactivity of the intended active radiopharmaceutical ingredient to the total radioactivity of all radioactive ingredients and impurities present in the radiopharmaceutical preparation (see Radioactivity <821>).
Radionuclidic purity:	The ratio, expressed as a percentage, of the radioactivity of the intended radionuclide to the total radioactivity of all radionuclides in the radiopharmaceutical preparation (see <821>).
Radiopharmaceutical (radiopharmaceutical preparation/radioactive drug):	(See <821>.) A finished dosage form that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The terms "radiopharmaceutical" and "radioactive drug" are commonly used interchangeably.
Repackaging:	The act of removing a conventionally manufactured radiopharmaceutical from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. Repackaging also includes the act of placing the contents of multiple containers (eg, vials) of the same finished drug product into one container, as long as the container does not include other ingredients. Radiopharmaceutical manipulation in any other way, including reconstitution, dilution, mixing, or combination with another ingredient, is not considered repackaging.
Restricted area:	Any area to which access is controlled for the protection of individuals from exposures to radiation and radioactive materials.
Secondary engineering control (SEC):	The area where the PEC is placed (eg, a classified area or an SRPA). It incorporates specific design and operational parameters required to minimize the risk of microbial contamination.
Segregated radiopharmaceutical processing area (SRPA):	A designated, unclassified space, area, or room with a defined (by facility procedures) perimeter that contains a PEC. An SRPA is only suitable for radiopharmaceutical preparation (with and without minor deviations), dispensing, and repackaging. If the SRPA is used to elute radionuclide generators it must have ISO Class 8 particle count non-viable particle count air quality.
Shielding:	Barriers of appropriate radiation attenuating material, used for radiopharmaceuticals, to protect the personnel. These barriers can be general in nature (eg, L-block, hot-cell), as to afford protection from a radiation field, or specific to a container used to hold a particular radiopharmaceutical (eg, syringe shield, vial shields, "pigs").
Single-dose container:	A container of a radiopharmaceutical for administration that is designed for use with a single patient as a single administration.
Specific activity:	The radioactivity of a radionuclide per unit mass of the compound involved with the radionuclide (see Radioactivity—Theory and Practice <821>). The units of specific activity involve those for the activity (eg, mCi, MBq, Ci, GBq)and those for the unit of mass (eg, µg, mmol)

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Sporicidal agent:	A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Start of preparation:	Time at which a vial septum is punctured or a component container is opened (eg, removal of cap on a pre-filled syringe), whichever comes first.
Sterility:	The absence of viable microorganisms.
Strength:	The radioactivity concentration of the radiopharmaceutical at the calibration time (see <821>). Strength is expressed as the quantity of radioactivity on a volume basis (eg, mCi/mL or MBq/mL).
Unclassified space:	A space not required to meet any ISO air cleanliness classification.
Unrestricted area:	An area in which a person should not be exposed to radiation levels in excess of 2 millirems in any 1 h from external sources.
Use-by time:	For radiopharmaceuticals prepared from kits, the time period after preparation during which the radiopharmaceutical should be used or administered, as suggested or stated in the manufacturer's prescribing information.

SUMMARY OF UNSATISFACTORY CONDITIONS

	DEFICIENCY	CHECK IF *
1)	The PIC stated there is no formal process for the designated person to evaluate individuals who have a condition that may interfere with their ability to safely compound.	
2)	Based on the records reviewed, the pharmacy missed visual observation of some personnel in 2022 and 2023. All of the personnel have been visually observed in 2024.	
3)	The SOP for the air and surface monitoring program does not include a diagram, but it has a description of locations where personnel should collect a surface sample.	
4)	The PIC has been trained in air sampling. The equipment is only used if the pharmacy has a failure when air sampling is conducted by the third-party vendor every 6 months. The internal personnel have not been trained in surface sampling.	
5)	Monthly surface sampling is conducted after production is completed and not during dynamic conditions. When the third-party vendors provides sampling, it occurs during dynamic conditions.	
6)	The pharmacy contracts with a third-party for viable air sampling every six months during the recertification. It is unknown if the personnel from the third-party vendor follow the manufacturer's instructions. Also, it is unknown if the personnel from the third-party vendor incubate as described in the USP chapter.	
7)	The pharmacy does not have a process to clean the sink, either daily or monthly.	
8)		
9)		
10)		

IMMEDIATE CORRECTIVE ACTION IS REQUIRED (I.E., CONTINUING OPERATION WOULD CONSTITUTE A THREAT TO PUBLIC HEALTH AND WELFARE)

Pharmacy Name:	RLS (USA) Inc.
Pharmacy Address:	1 Naylon Place, Livingston NJ 07039
NABP Business e-Profile ID:	1285742
VPP Inspection Date(s):	5/24/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	Pg 22 of 96	15.02	Policy 6.2 Personnel Hygiene, Qualifications and Training indicates the State Licensed RPh on duty is the designated responsible person for evaluation of personnel who pose a higher risk of contamination to the products and environment and if the individual should be excluded from working in sterile processing areas until their conditions are resolved. SOP 6.2.1 Clean Room Entry indicates that persons with rash, sunburn, weeping sores, conjunctivitis, or an active repiratory infection shall not enter the clean room. These established procedures were not communicated at the time of the inspection.	06/14/2024	Y	Policy 6.2 Personnel Hygiene, Qualifications, and Training; SOP 6.2.1 Clean Room Entry
Clarification or Further Explanation	Pg 27 of 96	44.00	At the end of calendar year 2023, the PIC self-identified the missed visual observations of some personnel during 2022 and 2023. A corrective action was implemented to complete all missed observational assessments as soon as possible. To prevent reoccurance, the PIC implemented a calendar notification system of pending due dates in order to complete these tasks in a timely and compliant manner.	06/14/2024	N	
Updates/New SOPs or P&Ps	Pg 48 of 96	159.00	RLS internal Form 31 EM Sampling Log has been updated to include a keyed diagram to all routine air and surface sample locations.	06/14/2024	Y	Form 31A Livingston In-House Air Monitoring Record; Form 31S Livingston IN-House Surface Monitoring Record
Clarification or Further Explanation	Pg 48 of 96	160.00	For clarification, RLS (USA) does not perform its own routine air sampling. Air sampling is only conducted by RLS staff if out of compliance samples are recovered by the third party provider and after investigation, corrective actions and remediation are complete. The PIC is trained on using the air sampler and has been the only person who has operated the air sampler as a result of an excursion event. At no time has anyone operated an air sampler for environmental monitoring without being trained on proper use. In the event of a future air sample excursion and to ensure retest sampling is conducted in a timely manner, training on SOP 6.3.6 SAS Air Sampler Operations has been assigned to all of staff pharmacists.	6/14/2024	N	

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Pharmacy Name:	RLS (USA) Inc.
Pharmacy Address:	1 Naylon Place, Livingston NJ 07039
NABP Business e-Profile ID:	1285742
VPP Inspection Date(s):	5/24/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	Pg 49 of 96	165.00	Per USP standards, surface samples are required to be taken at the end of aseptic operations, prior to cleaning and disinfection. In comliance with current USP<797> and <825>, RLS SOP 6.3.3 Environmental Monitoring: In-House Sampling, requires surface samples to be taken at the end of aseptic operations but before cleaning and disinfection have been completed. The third-party vendor is provided and follows RLS SOP 6.3.3. The third-party vendor does not take surface samples during dynamic conditions. Confusing language in the third-party vendor report has been removed and language has been added regarding proper timing of surface samples in relationship to aseptic processing. Further, USP<825> and RLS SOP 6.3.3 require radiation surveys prior to surface sampling to ensure personnel exposures are as low as reasonably achievable (ALARA). Requirements for radiation surveys to ensure ALARA principles prior to surface samples is further rationale why surface samples are not taken during dynamic conditions. Interviews with staff confirm that all surface samples taken by staff and third-party vendors are in compliance with USP standards and RLS standard operating procedures.	6/14/2024	Y	SOP 6.3.3 Environmental Monitoring: In-House Sampling; Microbial Test Results
Clarification or Further Explanation	Pg 51 of 96	173.01	The contracted third party vendor has amended their microbial test reports to include the requirement of using testing equipment per the manufacturers' instructions.	6/14/2024	Y	Microbial Test Results
Clarification or Further Explanation	Pg 51 of 96	173.04	Certification reports do indicate incubation conditions and duration on the page(s) titled Final Report: Microbiological Analysis, of 30-35°C for at least 48 hours and an additional 120-168 hours at 20-25°C. These incubation times and temperatures are compliant with USP chapters and RLS standard operating procedures. The location of the incubation time and temperatures were present but not identified on the documentation at the time of the inspection.	6/14/2024	Y	Microbial Test Results
Clarification or Further Explanation	Pg 60 of 96	217.02	SOP 6.4.1.2 ISO 7 & 8 Cleaning and Disinfecting requires daily cleaning and disinfecting of hand hygiene sinks located both inside and outside of the ISO environments and documented on Form 76 Cleaning/Disinfection Log: Hand Hygiene Sink. Monthly cleaning and disinfecting with a sporicidal agent is requried per this SOP and documented on Form 76 Cleaning/Disinfection Log: Monthly General Dispensing Areas.	6/14/2024	Y	SOP 6.4.1.2 ISO 7 & 8 Cleaning and Disinfecting Form 76 Cleaning/Disinfection Log: Monthly General Dispensing Areas; Form 76 Cleaning/Disinfection Log: Hand Hygiene Sink

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

SOP 6.2.1 Clean Room Entry

I. Purpose

To describe the hand hygiene and garbing technique for clean room entry.

II. Scope

This applies to all Nuclear Pharmacy sites.

III. Responsibilities

It is the responsibility of the Pharmacy Manager or designee to oversee policy compliance for personnel under his/her supervision. All Nuclear Pharmacy employees and contractors will adhere to this procedure.

IV. Definitions

A. Buffer Area- The area where a primary engineering control (PEC) is physically located.
B. Clean Room Apparel- Apparel that is simply constructed, easily cleaned, with no nap or pile, full-length pants and socks. Clean room apparel must be freshly laundered and donned at the beginning of each work shift. Clean room apparel may be worn throughout the facility during the employee's work shift. Scrubs are preferred.
C. **Clean Room Dedicated Shoes- Shoes that are donned inside the ante room and only worn inside the clean room environment.**
D. Facility Dedicated Shoes – Shoes donned at the pharmacy worn during the work shift, only worn inside the facility. Shoes shall be constructed of low particulate materials such as leather, plastic or rubber that contain minimal exposed organic content. Facility dedicated shoes are not worn outside of the facility.
E. Street Clothes/Street Shoes – Refers to clothing and shoes that have been worn outside the facility.
F. Overalls- A one-piece clean room garment that fully encases clothing

V. Related Documents

Form 77: Weekly Shoe Cleaning Log

VI. Equipment and Materials

A. Shoe covers or dedicated clean room shoes with sinks inside ante rooms
B. Hair Net/Bouffant
C. Face masks
D. Beard covers to be worn when necessary to assure all facial hair is covered.
E. Approved disposable clean room or low particulate laboratory coats or overalls
F. Sterile - Powder free gloves
G. Disposable clean room/low particulate over sleeves (blood processing)

VII. Procedure

A. General Guidelines for Employee and Visitor Clean Room Entry
   1. Persons with rash, sunburn, weeping sores, conjunctivitis, or an active respiratory infection shall not enter the clean room.
   2. Eating, drinking, chewing gum, combing hair, smoking, use of personal electronic devices, or personal cell phones, is strictly prohibited. Company approved headsets may be donned for business calls only.
   3. Artificial nails are prohibited. Natural unpainted nails shall be kept neat and trimmed.
   4. Remove all cosmetics and visible jewelry including lanyards, necklaces, watches, earrings, and rings.

5. Remove personal outer garments (e.g., coats, hats, scarves, sweaters, vests).
6. Clean room apparel shall be freshly laundered and donned at the facility each work shift.
7. Clean room apparel is not required if overalls are donned per this procedure.
8. Clean room apparel shall only be worn for one work shift and shall not be worn outside of the facility prior to clean room entry.
9. If apparel is worn outside the facility, it must be replaced with freshly laundered attire for clean room entry or completely covered with clean room overalls.
10. Clean room pants shall fully cover lower limbs without dragging on the floor.
11. Socks must be worn to ensure no exposed skin on the lower extremities.
12. Clean room shirts must allow for washing to the elbows without being touched or adjusted after hand hygiene is performed.
13. If employees or visitors leave the facility, clean room apparel may be removed and re-donned during a single work shift.
14. **Street shoes are not to be worn into the clean room environments. The only exception to this is in the case of a visitor or those who don overalls. In these cases, shoe covers may be donned over street shoes immediately outside the clean room environment before hand hygiene is completed. When crossing the gown room line of demarcation, street shoes covered with shoe covers shall be treated as facility dedicated shoes and covered with a second pair of shoe covers.**
15. Facility **and clean room** dedicated shoes shall be:
    a. Cleaned by the employee wearing the shoes once per work week.
    b. Cleaned after each visitor use.
    c. Cleaning of facility dedicated shoes shall consist of spraying the outer surfaces with a list A agent for the required contact time and wiping down with a low lint towel.
    d. Record weekly cleaning of facility **and clean room** dedicated shoes on Form 77: Weekly Shoe Cleaning Log.
16. Shoe covers shall be placed over facility dedicated shoes without touching shoes, as the gown room line of demarcation is crossed. Shoe covers which contact the dirty side shall be replaced.
17. **If clean room dedicated shoes are worn, they shall be donned as the gown room line of demarcation is crossed in such a manner as to minimize touching of shoes with freshly washed hands, and to prevent stocking feet from coming in contact with clean room floor.**
18. Clean room lab coats and overalls will have elastic cuffs and may be reused during one work shift if not contaminated.
    a. Coats and overalls for reuse shall be turned inside out and hung up on the clean side of the line of demarcation.
    b. Overalls shall not be allowed to touch the floor when donning, doffing or hanging for later use during the shift.
19. Clean room garb shall be inspected while donning. No garb shall be used if it is found defective or torn. If garb becomes damaged while wearing, it shall be replaced.
20. No clean room garb other than **dedicated clean room shoes and** shoe covers shall touch the floor on the clean side of the gown room line of demarcation. If garb contacts the floor, it shall be discarded and replaced.
21. Clean room garb shall be worn appropriately and completely.
    a. Hair nets and beard covers shall cover all hair
    b. Face masks shall always cover the nostrils and mouth

c. Face masks shall be pinched across the bridge of the nose and the top edge smoothed to the cheeks to prevent slipping
d. Gloves shall cover the cuff of the clean room coat
e. Clean room coats shall be completely closed to the neck.

22. Access to clean rooms shall be performed hands free by using your arm or elbow to engage the lever type door handle or push plate.
23. Personnel entering the WBC Prep room shall perform hand hygiene prior to entry. No other clean room garb is required in this area.

B. Apparel for All Persons Entering the Clean Room

1. Follow all general hygiene and garbing guidelines for employee and visitor clean room entry.
2. Remove street clothes (pants, shirts, shoes) in the area designated by the facility and don freshly laundered clean room apparel and facility dedicated shoes (if used). Note: If overalls are to be donned, street clothes do not need to be removed.
3. Secure long hair as needed to eliminate manipulation during hand hygiene or clean room garbing.
4. Restricted area lab coats **must** be worn while in the facility's restricted area.

C. Hand Hygiene and Garbing When Sinks are Outside the Ante Room

1. Remove restricted area lab coat and hang up near the hand hygiene sink.
2. Ensure personal dosimeters are worn. Note: ring badges should be removed for hand washing and immediately put back on after drying. Employees shall avoid touch contact with surfaces.
3. Remove debris from under fingernails with a nail cleaner and warm running water.
4. Wash hands and forearms for at least 30 seconds with unscented soap.
   a. Scrub brushes should not be used as they can damage the skin.
   b. Carefully wash all surfaces of hands and forearms including around each finger and thumb.
   c. Rinse with clean water.
5. Dry hands and forearms thoroughly with low lint towels.
   a. Do not allow freshly washed hands to touch surfaces, clothing, or unwashed skin surfaces prior to entering the ante room. Note: allowance for touching of ring badges.
6. Walk across the entry door tacky mat to remove surface dirt from shoes.
7. Enter the clean room with hands free entry.
8. Don dedicated clean room shoes or shoe covers over facility shoes as the line of demarcation is crossed. Do not allow dedicated shoes or shoe covers to touch the dirty side of the line of demarcation
9. Don the following garb in this order: hair bouffant, face mask, and beard cover as needed to ensure all head and facial hair is covered. Use mirrors provided.
10. Perform hand antisepsis cleansing using an alcohol-based hand rub and following manufacturer's directions for use.
11. Don an appropriate clean room lab coat ensuring it is fully closed to the neckline or a disposable overall consistent with site procedures.
    a. Don a disposable lab coat if entering the WBC area to perform a leukocyte labeling procedure.
    b. Don a laundered or disposable lab coat consistent with site procedure if entering the Dispensing or Prep areas.

c. Donning of an overall must be completed without allowing the overall to touch the floor. Overalls must completely cover all street clothes.

12. Don sterile gloves using aseptic technique described in this procedure.
13. Enter room using hands free entry.

D. Hand Hygiene and Garbing When Sinks are Inside the Ante Room

1. Remove general laboratory coat and hang on the coat hooks provided outside the Gown room.
2. Ensure personal dosimeters are worn.
3. Walk across the clean room entry door tacky mat to remove surface dirt from shoes.
4. Enter the clean room with hands free entry.
5. Don shoe covers or dedicated clean room shoes as line of demarcation is crossed to the clean side of the ante room. Do not allow dedicated shoes or shoe covers to touch the dirty side of the line of demarcation.
6. Don the following garb in this order: hair bouffant, face mask, and beard cover as needed to ensure all head and facial hair is covered. Use mirrors provided.
7. Remove debris from under the fingernails with a nail cleaner under warm running water. Note: ring badges should be removed for hand washing and immediately put back on after drying. Employees shall avoid touch contact with any surfaces.
8. Wash hands and forearms for at least 30 seconds with unscented soap.
   a. Scrub brushes should not be used as they can damage the skin.
   b. Carefully wash all surfaces of hands and forearms including around each finger and thumb.
   c. Rinse with clean water.
9. Dry hands and forearms thoroughly with low lint towels.
   a. Do not allow freshly washed hands to touch surfaces, clothing or unwashed skin.
10. Perform hand antisepsis cleansing using an alcohol based hand rub and following manufacturer's directions for use.
11. Don an appropriate clean room lab coat ensuring it is fully closed to the neckline or a disposable overall consistent with site procedures.
    a. Don a disposable lab coat if entering the WBC area to perform a cell labeling procedure.
    b. Don a laundered or disposable lab coat consistent with our site procedure if entering the Dispensing or Prep areas.
    c. Donning of an overall must be completed without allowing the overall to touch the floor. Overalls must completely cover all street clothes.
12. Don sterile gloves using aseptic technique described in this procedure.
13. Enter rooms using hands free entry.

E. Donning Sterile Gloves

1. Employees and visitors shall aseptically don sterile gloves according to the following:
   a. Choose the proper glove size for your hands.
   b. Open the outer wrapper of the glove package and place the inner paper wrapper containing the sterile gloves on a clean surface.
   c. Without touching the inside of the package, expose the sterile gloves by unfolding the flaps away from the gloves. Turn the paper so the L and R symbols are facing you.
   d. Using the opposite hand, grasp the folded edge of the glove cuff for the dominant hand, touching only the inside surface of the glove.
   e. Moving slightly back from the sterile opened glove package, carefully pull the glove over the

dominant hand. Avoid skin contact with the outside surface of the glove. Allow the cuff to stay turned down on itself.

f. Using the sterile gloved hand, slide the fingers under the cuff of the second glove. Do not touch the inside of the cuff with your gloved hand.
g. Gently lift and insert your ungloved hand into the glove. Ease the glove on by pushing on the inside fold of the cuff. Turn back the cuff when the glove is on and fully cover the cuff of the clean room coat.
h. Turn back the cuff of the first glove without touching the inside of the first glove to fully cover the cuff of the clean room coat. Adjust gloves for comfort.
i. Check gloves for rips or tears. If no defects are visible, aseptically dispose of packaging and spray all newly donned glove surfaces with sterile 70% IPA.

2. Sterile gloves shall be donned as part of the garbing procedure performed in the Gown room.
3. If gloves are removed, care must be taken not to touch surfaces in the cleanroom with bare hands, including handles on hot waste cans and door levers.
4. Perform hand antisepsis cleansing using an alcohol based hand rub and following the manufacturer's directions of use, prior to donning each pair of sterile gloves.
   Note: **Double gloving is not required** but if double gloving, the initial layer of sterile gloves will be sprayed with sterile IPA whenever donning the top layer of sterile gloves.

F. Garbing Requirements for WBC Room Entry

Employees entering the WBC areas of the clean room shall follow the garbing procedure outlined in the WBC garbing procedure.

G. Exiting the Clean Room

1. Gloves and shoe covers shall be surveyed prior to exiting and properly disposed if contaminated.
   a. Follow site procedures to prevent spread of contamination.
2. If another operator is in the process of donning garb for clean room entry, do not de-garb. Wait until the other operator is fully garbed before initiating de-garbing procedure.
3. If the employee is going to re-enter during a single work shift, they may remove the lab coat or overall on the clean side of the line of demarcation and hang up on hooks provided so the inside of the coat is facing outward.
4. If the employee is not re-entering during the work shift, do not remove the lab coat or overall.
5. **If dedicated clean room shoes are worn, remove them and don facility dedicated shoes as the line of demarcation is crossed. Stocking feet must not touch clean room floors.**
6. If shoes covers are worn, cross over the line of demarcation to the dirty side wearing the remaining garb. Once shoe covers touch the dirty side, you cannot re-cross the line of demarcation, new shoe covers need to be donned for re-entry.
7. Disinfect hands or gloved hands with alcohol-based hand sanitizer to avoid spreading skin contamination on doorknobs or other touch surfaces and exit the clean room.
8. Remove remaining garb and dispose. Hair covers, shoe covers, face masks, and lab coats/overalls removed from the clean room cannot be reused.
9. Remove facility dedicated shoes and store in the designated area before exiting the facility.

VIII. Training

Personnel performing these tasks shall be trained on this procedure.

List of Attachments

None

Document History		
Version	**Date**	**Brief Description of Change**
1	01 June 2020	New Document
2	01 Dec 2020	Update for compliance to USP<825>, change to garbing sequence: hand rub use prior to donning frock, remove air dryer use- require low lint towels for hand drying.
2.1	1 Nov 2021	Administrative
2.2	1 Apr 2023	Added definition for clean room dedicated shoes. Added clarifying language regarding clean room dedicated shoes as garbing option. Removed references to required face shields during WBC labeling. Clarified double gloving as optional.

Form 31S: Livingston In-House Surface Monitoring Record

Record Retention: CY + 5 years

Incubate samples 30-35°C for no less than 48 hours, count CFUs and indicate as "CFU Count #1. Then immediately incubate samples 20-25°C for no less than 5 additional days, count CFUs and indicate as "CFU Count #2. Total of count 1 + count 2 must be less than the action limit or the sample fails. Operator shall verify correct incubator temp at initial time of incubation. Daily incubation temps are recorded on local Form 28. See SOP 6.3.3 for full procedure and actions to be taken upon failures.

Sampling Date:_____ **Sampling *Time:**_____ **Performed By:**_____

Plate Lot#:_____ **Plate Expiration:**_____ **Air Sampler Serial #:**_____

Action	Date	Time	Performed By
Initial Placement in Incubator 30-35C			
Date/Time of #1 CFU Count post 30-35C Incubation			
Date/Time of #2 CFU Count post 20-25C Incubation			

Plate ID	Location Name	CFU Count #1	CFU Count #2	**Total CFU Count: #1 + #2	ISO Class	*CFU Action Limit	Comments: Pass or Fail
NA	Negative Control				NA	0	
S1	LFH 1 Deck				5	>3	
S2	LFH 1 Keyboard				5	>3	
S3	LFH 2 Deck				5	>3	
S4	LFH 2 Keyboard				5	>3	
S5	LFH 3 Deck				5	>3	
S6	LFH 3 Keyboard				5	>3	
S7	LFH 4 Deck				5	>3	
S8	LFH 4 Keyboard				5	>3	
S10	BSC 2 Deck				5	>3	
S11	BSC 3 Deck				5	>3	
S12	BSC 4 Deck				5	>3	
S13	BSC 5 Deck				5	>3	
S14	BSC 6 Deck				5	>3	
S15	LFH 5 Deck				5	>3	
S16	LFH 5 Keyboard				5	>3	
S17	Random Cart				7	>5	

Form 31S: Livingston In-House Surface Monitoring Record

Record Retention: CY + 5 years

** See 6.3.3 Plate ID	Location Name	CFU Count #1	CFU Count #2	**Total CFU Count: #1 + #2	ISO Class	*CFU Action Limit	Comments: Pass or Fail
S18	RPh Cart				7	>5	
S19	Generator Table				7	>5	
S20	Generator Lid Handle				7	>5	
S21	PT to LFH 1				NA	NA	
S22	PT to LFH 2				NA	NA	
S23	PT to LFH 3				NA	NA	
S24	PT to LFH 4				NA	NA	
S25	PT Disp. Room To WBC Room				7	>5	
S26	HEPA PT into WBC Room				7	>5	
S27	WBC Room Table				7	>5	
S28	BSC 2 Table				7	>5	
S29	BSC 3 Table				7	>5	
S30	BSC 4 Table				7	>5	
S31	BSC 5 Table				7	>5	
S32	BSC 6 Table				7	>5	
S33	Doorknob- WBC Ante into WBC				7	>5	
S34	Doorknob- Gown into Dispensing				8	>50	
S35	Doorknob- Prep into Gown				8	>50	
S36	Prep Room PT to outside CR				NA	NA	
S37							
S38							

SOP

Surface samples are to be taken at the end of aseptic activities, but before the area has been cleaned and disinfected. Radiation safety considerations must be considered. See SOP 6.3.3. for full details.

PIC/Reviewer's Signature: _____ **Date:** _____

Form 31S: Livingston In-House Surface Monitoring Record

Record Retention: CY + 5 years

Livingston Facility Surface Sample Map



Policy 6.2: Personnel Hygiene, Qualifications and Training

I. Purpose

To ensure all pharmacy personnel are properly trained, qualified, and to support infection prevention and control measures and to maintain the ISO classified environments.

II. Scope

This policy applies to all Nuclear Pharmacy sites.

III. Responsibilities

The Pharmacy Manager or Pharmacist-on-Duty will oversee policy compliance for personnel under his/her supervision. All Pharmacy employees and contractors will adhere to this policy.

IV. Definitions

A. PEC- Primary Engineering Control

B. Designated person (DP)- One or more individuals assigned to be responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.

V. Related Documents

Form 165 Designated Persons List

VI. Policy

A. Personnel Hygiene/Infection Control

1. All who enter an ISO classified environment shall follow SOP 6.2.1 Clean Room Entry.
2. All who prepare sterile drug products shall follow SOP 6.2.2 Aseptic Technique & Preparation.
3. All who perform deliveries shall follow SOP 8.1.5 Customer RAM Deliveries & Returns.
4. All shall follow SOP 6.2.6 Infection Prevention and Control & Influenza Vaccine Program.
5. All required garb and supplies shall be provided.

B. Training Scope and Responsibilities

1. Employees and vendors will receive training on policies and procedures in this manual that pertain to their assigned job duties prior to performing those duties.
    a. Training materials are the written policies and procedures in this manual.
2. Employees and vendors shall receive training on policy and procedure changes that pertain to their assigned job duties when changes are implemented.
    a. Training material shall be the updated policies and procedures.
3. Pharmacy employees will receive initial and annual retraining pertaining to their assigned job duties in order to support and maintain ISO classified areas which cover the following topics:
    a. Quality Assurance program overview
    b. Hand hygiene and garbing
    c. Proper clean room behavior
    d. Key practices to maintaining the classified environment
    e. Proper cleaning and disinfection of secondary engineering controls
    f. Understanding of primary and secondary engineering controls
    g. Proper documentation practices

4. Compounding and dispensing personnel shall receive initial and annual retraining pertaining to their assigned job duties in order to support and maintain ISO classified areas. This training shall cover the following topics:
    a. Proper donning and maintenance of sterile gloves
    b. Understanding the primary engineering control and first air
    c. Proper cleaning and disinfection of a primary engineering controls
    d. Aseptic manipulations and key practices to maintain an ISO 5 environment
5. Quality program responsibilities and Designated Person required training are outlined in Attachment B: Responsibility/Training List.
6. Designated Persons assigned responsibilities by the Pharmacist in Charge (PIC) shall be documented on Form 165.
    a. Form 165 shall be updated by the PIC and maintained on file.

C. Core Competency Assessments
1. Personnel or vendors must prove core competency, as applicable to their duties prior to performing aseptic tasks beyond immediate use.
2. These qualifications must be completed initially, then successfully repeated at intervals as described in SOPs.
3. Core competency qualifications must be repeated prior to resuming duties if the person has not performed the process in more than 6 months.
    a. Form 107 Non-Sterile Compounding observational assessment
    b. Form 114 Cleaning Vendor Assessment
    c. Form 116 (appropriate version depending on environment or local regulation)- Garbing and Hand Hygiene observational assessment
    d. Form 117- Aseptic Technique observational assessment
    e. Form 118- Cleaning and Disinfecting PEC observational assessment
    f. Initial gloved fingertip sampling as outlined in SOP 6.2.4
    g. Media-fill testing as outlined in SOPs 6.2.3 and 7.1.3.
4. Core competency qualifications may be completed at a different facility if all SOPs, environments, and equipment used for product preparation are identical.
    a. PICs are responsible for confirming their local regulations allow core competency qualifications to be shared from another facility.
5. Upon request, site personnel core competencies shall be uploaded into Teams Facility Folders for remote monitoring purposes by the Quality Assurance Department.

D. Observational Assessments
1. **Observational assessments of other processes not identified as a core competency, shall be performed at the frequencies indicated in Attachment A: Observational Assessment List.**
2. **PICs are responsible for confirming their local regulations and completing observational assessments as required.**

Policy 6.2: Personnel Hygiene, Qualifications and Training

LIST OF ATTACHMENTS

Attachment A: Observational Assessment List
Attachment B: Responsibility/Training List

DOCUMENT HISTORY		
Version	**Date**	**Brief Description of Change**
1	1 June 2020	New Document
2	1 Dec 2020	Update for 825 revisions, requirement for core competency training and retraining for 6-month lapse in performing aseptic duties. Added Attachment A: Observational Assessment List to clarify and maintain complete list of observational assessment. Added assessments for Hand Hygiene Tracker, QC, Product Receipt, Production Run/Product Setup, and non-sterile compounding. Added Attachment B: Responsibilities/Training List.
2.1	1 Nov 2021	Administrative
2.2	1 Nov 2022	JC Finding- Require core competencies are uploaded into Teams Facility Folder for review upon QA request. Require review of local regulations before sharing core competencies across facilities. Update Attachment B to remove QA Lead from list and clarify designated person training requirements. Add Form 165 to document Designated Person(s).
2.3	1 Apr 2023	Clarified core competency qualifications and required observational assessments to align with USP<795> and <825>. Identified observational assessments of non-core competencies as "per local regulation".

Policy 6.2: Personnel Hygiene, Qualifications and Training

Attachment A: Observational Assessment List- Below is a list of tasks and duties critical to the quality program. For each task/duty an employee performs, they shall be trained on the policies and procedures associated with that task/duty and their performance assessed using the forms listed.

Task/Duty	Associated Policies and Procedures (State/site specific versions if applicable)	Assessment Form	Frequency
***Core Competency:** Non-sterile Compounding	SOP 3.3.5 Dispensing & Distributing I-131 SOP 3.3.10 Compounding I-123 Capsules	Form 107 Non-Sterile Compounding Assessment	Initial and Annual Reassessment
***Core Competency:** Monthly Cleanroom Cleaning by Vendor	SOP 6.2.1 (listed to ensure training on entry for vendor) SOP 6.4.1 Cleaning and Disinfecting the Clean Room	Form 114 Cleaning Vendor Assessment	Initial and Annual *Reassessment
***Core Competency:** Cleanroom Entry	SOP 6.2.1 Clean Room Entry	Form 116 Hand Hygiene and Garbing Assessment	Initial and Annual *Reassessment
***Core Competency:** Aseptic Product Preparation	SOP 6.2.2 Aseptic Technique & Preparation	Form 117 Aseptic Technique Assessment	Initial and Annual *Reassessment
***Core Competency:** Cleaning and Disinfecting	SOP 6.4.1 Cleaning and Disinfecting the Clean Room	Form 118 Cleaning and Disinfecting Assessment	Initial and Annual *Reassessment
Cleanroom Certification by Vendor	*SOP 6.2.1 *SOP 6.3.1 *Vendor may be responsible nationally for vendor employee training requirements. Records available upon request.	Form 115 Certification Vendor Assessment	Initial and Annual Reassessment
Driving Company Vehicle	SOP 5.1.5 Motor Vehicle Safety SOP 8.1.5 Customer RAM Deliveries and Returns	Form 68 Driving and Delivery Assessment and License Validation	Initial and Annual Retraining
Aseptic Operations/Customer Deliveries	SOP 6.2.1 Clean Room Entry SOP 6.2.2 Aseptic Technique & Preparation SOP 8.1.5	Form 141 Hand Hygiene Tracker	Biannual- January and July
Quality Control (QC)	TM Module: Quality Control Testing Procedures QC procedures in each Master Formula performed	Form 100 QC Assessment	Per Local Regulation
Product Receipt and Storage	Policy 3.2 Ordering, Receiving, and Tracing SOP 3.2.2 Receiving RAM and Cold Kits SOP 3.2.3 Medication & Component Storage SOP 3.2.4 High Alert Medication	Form 103 Product Receipt and Storage Assessment	Per Local Regulation
Production Run and Product Setup	Policy 3.3 Order Processing, Preparation, Dispensing and Distribution SOP 3.3.2 Product Preparation SOP 3.3.3 Dispensing and Distribution	Form 106 Production Run and Product Setup Assessment	Per Local Regulation

*Core Competency: Observational Assessment must be repeated prior to resuming duties if employee has not performed aseptic processing in more than 6 months. See Policy for additional requalification requirements.

Policy 6.2: Personnel Hygiene, Qualifications and Training

Attachment B: Responsibility/Training List- Below is a list of responsibilities critical to the quality program and identified in USP<825>. Personnel designated as responsible shall be trained as listed here:

Responsibility:	**Designated Role/Training Requirements:**
The QA Program Manager is responsible for ensuring each facility has a formal, written QA and QC programs that establish a system of:	
o Adherence to procedures	QA Manager- No additional training requirements
o Prevention and detection of errors and other quality problems	QA Manager- No additional training requirements
o Evaluation of complaints and adverse events	QA Manager- No additional training requirements
o Appropriate investigations and corrective actions	QA Manager- No additional training requirements
The PIC of each facility is responsible for the following:	
Training, qualifications, and evaluations of the QA Lead	PIC- No additional training requirements
Ensuring radiopharmaceutical processing areas, SEC and PECs are located, operated, maintained, monitored, and certified to have appropriate air quality.	PIC- No additional training requirements
Ensuring manufactured sterile products are used when available for the compounded sterile product or active pharmaceutical ingredient. If an active pharmaceutical ingredient cannot be obtained from a FDA-registered facility, the designated person(s) must select an acceptable and reliable source as described in USP<797>.	PIC- No additional training requirements
Ensuring final preparations comply with pre-established standards or acceptance criteria for identity, quality, and purity, and must consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (e.g., osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD.	PIC- No additional training requirements
Ensuring that standard operating procedures (SOPs) are appropriate and are implemented, which includes ensuring that personnel demonstrate competency in performing every procedure that relates to their job function.	PIC- No additional training requirements
Reviewing the QA and QC program at least once every 12 months. The results of the review must be documented, and appropriate corrective action taken, if needed to ensure SOPs reflect current practices and regulatory requirements.	PIC- No additional training requirements
Ensuring any changes or alterations to a QA or QC program SOPs are approved, documented, and fully implemented.	PIC- No additional training requirements
Ensuring literature or analytical testing is consulted to determine if compounded sterile products (CSP) exposed to temperatures above or below the storage temperature limits, are expected to retain their integrity or quality. If this cannot be determined, the CSP must be discarded.	PIC- No further training requirements.
Review all customer complaints to determine if they indicate potential quality problems with the radiopharmaceutical.	PIC- No further training requirements.
The Staff RPh on duty is responsible for the following:	
Adhering to all aspects of the quality assurance program and supervising staff to ensure aseptic procedures are followed.	State Licensed RPh on duty- No further training requirements.
Evaluation of personnel who may pose a higher risk of contamination to the products and environment and will determine if the individual should be excluded from working in sterile processing areas until their conditions are resolved.	State Licensed RPh on duty- No further training requirements.

Notifying the PIC of any deviations in the quality program during their work shift that may affect the identity, quality, or purity of prepared products prior to dispensing.	State Licensed RPh on duty- No further training requirements.
The facility PIC may retain the following responsibilities or may assign to a Designated Person (DP) who has been trained on applicable SOPs and as indicated:	
Review of quality program logs and documents for completion, compliance to internal procedure and accuracy.	DP shall be trained on each SOP in the Aseptic and Quality Assurance Program that has been assigned to their responsibilities under the supervision and to the satisfaction of the PIC.
Review all certification and recertification records. The number of personnel present in each PEC and SEC during total particle count tests and dynamic smoke pattern tests must be documented and maintained.	DP shall be trained on SOPs 6.3.1 Certification & Performance of ISO Environments, and 6.3.3 Environmental Monitoring, under the supervision and to the satisfaction of the PIC.
Perform garbing and hand hygiene training to current SOP Perform garbing and hand hygiene observational assessments Perform employee initial garbing gloved fingertip testing	DP shall be a state licensed RPh, or Technician who has passed initial gloved fingertip testing and passed an observational assessment Form 116 completed by the PIC within 12 months.
Perform PEC cleaning and disinfecting training to current SOP Perform cleaning and disinfecting observational assessment	DP shall be a state licensed RPh, or Technician who has passed an observational assessment Form 118 completed by the PIC within 12 months
Perform aseptic technique training to current SOP Perform aseptic observational assessments	DP shall be a state-licensed RPh, or Technician who has passed media-fill/gloved fingertip tests, and an observational assessment on Form 117 completed by the PIC within 12 months.
Aid and assist employees performing media-fill testing/gloved fingertip testing	DP shall be a state-licensed RPh, or Technician with previously passed media-fill(s) and gloved fingertip tests within 12 months.
Perform follow up to ensure corrective actions are taken if problems, deviations, failures, or errors are identified. Corrective actions and follow up must be documented.	DP shall be a state licensed RPh, or Technician trained on Policy 4.3 and all associated SOPs.

12C

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Pharmacy Application

Non-Refundable $500.00 Fee

Rev (6/11/2024)

Facility Location	Application Type (check all applicable)	Pharmacy Type (check all applicable)	Services the Pharmacy will Provide (check all applicable)
☐ Nevada ☒ Out-of-Nevada	☐ New Pharmacy ☒ Ownership Change* ☐ Location Change * ☐ Service Modification* ☐ Name Change* (if only a Name Change occurred, submit a $50.00 fee with the application.) * Current license #: PH 04663	☐ Retail/Community ☐ Hospital (# beds _____) ☐ Internet ☒ Nuclear ☐ Other:	☐ Retail/Community ☐ Dangerous drugs ☐ Controlled substances DEA #: _____ ☒ Non-sterile Compounding ☒ Sterile Compounding ☐ Mail-Order Service ☐ Off-site Cognitive Services ☐ Long Term Care ☐ Hospital ☐ Other:

Days of Operation		Ownership Type (check applicable box)
☒ Monday	☒ Friday	☐ Publicly Traded (complete sections 1, 2, 3, 4, 5, 9, 10, 11, 12)
☒ Tuesday	☒ Saturday	☒ Non-Publicly Traded (complete sections 1, 2, 3, 4, 6, 9, 10, 11, 12)
☒ Wednesday	☒ Sunday	☐ Partnership (complete sections 1, 2, 3, 4, 7, 9, 10, 11, 12)
☒ Thursday	☒ Holidays	☐ Sole Owner (complete sections 1, 2, 3, 4, 8, 9, 10, 11, 12)

Section 1: General Information

Pharmacy Name: RLS (USA) Inc.

Physical Address: 945 N. Edgewood Ave., Suite A-1

City: Wood Dale State: IL Zip: 60191

Mailing Address (if different from physical address): Same as physical Address

City: N/A State: N/A Zip: N/A

Telephone: 603-595-6642 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 603-595-8583 Contact Email: licensing@rls.bio

Website: https://rls.bio/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Arasally Rodriguez

Supervising/Managing Pharmacist NV Pharmacist Registration # (if applicable): 24298

Section 2: List the name(s) of at least one NEVADA registered pharmacist who practices at the pharmacy, who may be the managing pharmacist or another pharmacist, who will be responsible for any prescriptions dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. NRS 639.2328. (Use a separate piece of paper if additional space is needed.)

Name: Arasally Rodriguez	NV Pharmacist Registration #: 24298
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:
Name:	NV Pharmacist Registration #:

Section 3: History of Company	**Yes**	**No**
1. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been charged, or convicted of a felony or gross misdemeanor (including by way of a guilty plea or no contest plea)?		✔
2. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been denied a license, permit or certificate of registration from any jurisdiction?		✔
3. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been subject of an administrative action, board citation, cite fine, or proceeding relating to the pharmaceutical industry?	✔	
4. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever been found guilty, pled guilty or entered a plea of nolo contendere to any offense federal or state, related to controlled substances?		✔
5. Has the corporation, any owner(s), shareholder(s) or partner(s) with any interest, ever surrendered a license, permit or certificate of registration voluntarily or otherwise (other than upon voluntary close of a facility)?		✔

If you marked YES to any of the number questions (1-5) above, a signed statement of explanation must be attached. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Section 4: Are any of the owners a health professional (i.e. Practitioner as defined by NRS 639.0125, Advanced Practice Registered Nurse, Physician's Assistant, Physical Therapist, Occupational Therapist, Registered Nurse, Respiratory Therapist, etc.)? If yes, please provide the name(s) of the owner(s), their credentials and their percent ownership. Write NA if not applicable. NRS 639.232. (Use a separate piece of paper if additional space is needed.)

Name: Darren Patti	Credentials: See attached list	%: 0
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:
Name:	Credentials:	%:

1. The Board shall not issue a license to conduct a pharmacy:
   a) To any practitioner; or
   b) To any partnership, corporation, or association in which a practitioner has a controlling interest or owns more than 10 percent of the available stock.
2. This section does not:
   a) Apply to a hospital pharmacy or a health maintenance organization which holds a certificate of authority under chapter 695C of NRS.
   b) Prohibit ownership by a practitioner of a building in which a pharmacy is located, if space for the pharmacy is rented at the prevailing rate.

Section 5: Publicly Traded Corporation

State of Incorporation: N/A

Parent Company (if any): _____

Corporation Name: _____

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Date of SEC Registration:	SEC Registration Number:	Stock Exchange Symbol:

Does the number of stockholders/shareholders of the corporation exceed four? NRS 639.231 ☐ Yes ☐ No

Section 6: Non-Publicly Traded Corporation or Company

State of Incorporation/Organization: Delaware

Parent Company (if any): Telix Pharmaceuticals (US) Inc.

Corporation/Organization Name: RLS (USA) Inc.

Mailing Address: 255 Primera Boulevard, Suite 440

City: Lake Mary State: FL Zip: 32746

Telephone: 813-285-3065 Email: licensing@rls.bio

Contact Person Name: David Miller

Does the number of stockholders/shareholders of the corporation or members exceed four? NRS 639.231 ☐ Yes ☑ No

Section 7: Partnership

Partnership Name: N/A

Mailing Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Contact Person Name: _____

Please check type of partnership (NAC 639.214) ☐ General ☐ Limited

Does the number of partners or members of the partnership exceed four? NRS 639.231 ☐ Yes ☐ No

Section 8: Sole Owner

Owner's Name: N/A

Business Name: _____

Business Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____ Email: _____

Section 9: Statement of Responsibility - MUST BE COMPLETED by an Authorized Person (NAC 639.945)

Statement of Responsibility

1. I am the Group Chief Operating Officer (title) for RLS (USA) Inc. (name of Pharmacy) and in that capacity, I am authorized to speak on the Pharmacy's behalf.
2. I understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be responsible for any violations of pharmacy law that may occur in the Pharmacy owned by such owner(s), shareholder(s), member(s), or partner(s).
3. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) may be named in any action taken by the Nevada State Board of Pharmacy against the Pharmacy.
4. I further understand and acknowledge that any owner(s), shareholder(s), member(s), or partner(s) cannot require or permit the pharmacist(s) in said Pharmacy to violate any provision of local, state, or federal laws or regulations pertaining to the practice of pharmacy.
5. I further understand and acknowledge that Nevada law requires that each pharmacy located inside the State of Nevada employ only pharmacists, intern pharmacists, pharmaceutical technicians, and technicians in training that are licensed by the Nevada State Board of Pharmacy. (NRS 639.100).
6. I further understand and acknowledge that Nevada law requires that each pharmacy located outside the State of Nevada engaged in providing pharmacy services into Nevada employs at least one pharmacist licensed by the Nevada State Board of Pharmacy who will be responsible for any prescription dispensed to a patient located in Nevada and responsible for any acts or omissions of pharmacy personnel who are not registered with the Board. (NRS 639.2328).

Darren Patti

Print Name of Authorized Person

Original signature of Authorized Person (copies or stamps not accepted)

2/14/21

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Darren Patti

Print Name of Authorized Person Submitting Application (If the applicant is a partnership or corporation, the application must be signed by a partner or by an officer of the corporation). NAC 639.215

Original signature of Authorized Person (copies or stamps not accepted)

2/14/25

Date

Board Use Only	Date Received: 3/3/25	Amount: $500-CK1000002080

Disciplinary Summary
RLS (USA) Inc. Pharmacies

RLS (USA) Inc., f/k/a Amersham Health Nuclear, Medical Pharmacy, 1 Naylon Place, Livingston, NJ 07039

March 8, 2004: New Jersey Board of Pharmacy issued a $225.00 penalty and requested a letter of corrective action as a result of violations of N.J.A.C 13:39-12.2(e) (Prescription label does not have the chemical form of the radioactive drug) and N.J.A.C 13:39-12.4(c) (Missing a current text in the category of "General Practice of Pharmacy") found during an inspection conducted on 12/19/2003. RLS (USA) Inc. satisfied all requirements of the corrective action, paid the fine, and remains in good standing with the New Jersey Board of Pharmacy.

RLS (USA) Inc., f/k/a/ Med-Physics, Inc., d/b/a/ GE Healthcare, 1 Naylon Place, Livingston, NJ 07039

May 19, 2017: New Jersey Board of Pharmacy issued a $5,500.00 penalty and requested a letter of corrective action as a result of violations of N.J.A.C 13:39-11.24(a)6 (Adequate efforts were not made to ensure the pharmacy's quality assurance program) and N.J.A.C 13:39-11.24(a)10 (When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards) found during an inspection conducted on 8/10/2016. The pharmacy paid the fine and met all requirements of the corrective action, and remains in good standing with the New Jersey Board of Pharmacy.

RLS (USA) Inc., 1283 Mountain View Alviso Road Ste. A - B, Sunnyvale, CA 94089

February 14, 2024: RLS (USA) Inc. failed to follow its written policies and procedures when, on dates ranging from 12/30/2022 to 6/26/2023, it failed to remove pharmacy equipment from use following microbial contamination. This resulted in a violation of California pharmacy law for which the Board issued a Citation. No fine was assessed and the pharmacy took corrective action to address the violations. The pharmacy remains in good standing with the California Board of Pharmacy.

RLS (USA) Inc., 16259 Stagg Street, Ste A, Van Nuys, CA 91406

October 11, 2024: RLS (USA) Inc. failed to timely notify the California Board of Pharmacy upon a change in the Pharmacist-in-Charge. RLS (USA) Inc. operated without an approved PIC for the pharmacy and was fined a total of $1500. RLS complied with all requirements of the citation and the pharmacy remains in good standing with the California Board of Pharmacy.

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. MCGREEVEY
Governor

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

March 8, 2004

John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Re: Inspection Report #8-1066.6
Inspection Date: 12/19/03

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated:

N.J.A.C. 13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.
$25.00

N.J.A.C. 13:39-12.4(c)
Missing a current text in the category of "General Practice of Pharmacy".
$200.00

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you should sign the attached acknowledgment and agree to the following:

1. Pay a penalty in the amount of **$225.00** and provide to the Board a Letter of Corrective Action. (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively, you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, directing you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973).504-6450.

The enclosed certification should be completed and returned to the Board **within fifteen (15) days following your receipt of this letter.** In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained here in shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: Joanne Boyer
Joanne Boyer
Executive Director

JB/mw

cc: Marianne Greenwald, Deputy Attorney General
[redacted]

5/26/04 Exhibit 10E (6)

CERTIFICATION

I, JOHN MARZOCCA, hereby acknowledge that I have read and reviewed the Board's letter dated March 8, 2004 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

☐ I acknowledge the conduct which has been charged and agree to:

1. Cease and desist in engaging in the conduct alleged and pay a penalty in the amount of **$225.00** (to be paid upon signing of this certification).

2. Send a **Letter of Corrective Action**, as requested by the Board, with this certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this certification are public documents.

☑ I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before the rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the certifications are public documents.

☐ I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this certification are public documents.

(Signature)

Dated: 3/31/04

JOHN MARZOCCA
(Print Name)

Ref: John Marzocca, RPIC
Amersham Health Nuclear
Medical Pharmacy
1 Naylon Place
Livingston, NJ 07039

Amersham Health
1 Naylpn Place
Livingston New Jersey 07039

March 31, 2004

Joanne Boyer
Executive Director
Division of Consumer Affairs
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Ms. Boyer:

We are in receipt of your letter dated 8 March 2004 concerning the alleged deficiencies sited during an inspection of our Livingston, New Jersey facility conducted 19 December 2003. The alleged deficiencies as stated in your letter are listed below for ease of reference:

N.J.A.C.13:39-12.4(c)
Missing a current edition of a text in the category of "General Practice of Pharmacy".

We at Amersham Health believe that in the spirit of, and pursuant to, New Jersey State Board of Pharmacy Regulations, current texts via computer access, pertaining to the General Practice of Pharmacy meet these requirements of N.J.A.C.13:39-12.4(c). The two texts are USP/NF via internet access, and Pass Assured, a computer text used by our pharmacy technicians to prepare for the PTCB certification test. This computer text covers the following items in the general practice of pharmacy:

Pharmacy Law
Terminology
Calculations
Metric Conversions
Dosage Forms
Aseptic Techniques
Pharmacy Operations
Third Party Reimbursements.

The above notwithstanding, Amersham Health has also purchased a current edition of Remington's "The Science and Practice of Pharmacy" on 11 March 2004.

N.J.A.C.13:39-12.2(e)
Prescription label does not have the chemical form of the radioactive drug.

Amersham Health was unable to locate the definition of chemical form within New Jersey Board of Pharmacy Regulations so we reverted to the DOT interpretation. The Chemical form of a radioactive drug is required on all DOT Bills-of-Lading for radioactive deliveries and is addressed by the U.S D.O.T. under 49 CFR 172.203, and is defined as "a generic chemical description is acceptable for chemical form". Under these conditions Amersham Health can only interpret "chemical form" in NJAC 13:39-12.2(e) to be the name of the radiopharmaceutical drug. Attachment 1 contains an actual prescription label listing the name of the radionuclide (i.e., Tc-99m, In-111, etc...) along with the actual generic chemical (radiopharmaceutical/brand) name of the drug (i.e., Myoview, MAA, MDP, etc...). Amersham Health believes that if one interpreted "chemical form", as "inorganic salt", then all radioactive prescriptions have the potential of being "mislabeled". For example, Tc99mMyoview, Tc99mMDP, Tc99mMag 3, and Tc99mDTPA are "different" radiopharmaceutical drugs used to diagnose different organs within the body. Following the current board of pharmacy labeling

guidelines, and interpreting chemical form as inorganic salt, then all five prescription labels would read "Tc99m Inorganic Salt". The actual drug(brand) name would not have to appear on the label pursuant to regulation, which would cause all five prescriptions to be identical which in turn could be described as "mislabeled". Therefore the only way to assure that a radioactive prescription is not "mislabeled" is to interpret chemical form to be the name of the radiopharmaceutical. The name of the radiopharmaceutical currently appears on all Amersham Health prescriptions.

Based on this understanding Amersham Health respectfully requests that the both "deficiencies" be rescinded, and would like to request an informal meeting to discuss the matter with the board.

If you have any questions or require any additional information, please contact me at (973) 533-9109, or Richard Hughes, Corporate Radiation Safety Officer at (609) 514-6647.

Sincerely,

John Marzocca R.Ph
Pharmacist in charge

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-011
[redacted]
Nuclear Medicine

Order #2450929 Date 03/31/04

Tc-99m MAA
4.0000 mCi
0.5234 ml
9:30 On 03/31/04 Calibration Time

ACT DISP: 4.0000 mCi 148.0000 MBq (+/- 10%)
LOT NO. 35-03/31/04 RX-2416608
ASSAY: 7.6423 mCi/ml MFGR: In-House Prep
EXP TIME: 15:05 EXP DATE: 03/31/04
LIC. NO. 29-14017-01 P.O. NO.: SO3000184
PIC: John Marzocca, R.Ph.

ADDRESS: 600 RIVER AVE., LAKEWOOD, NJ, 087
DOCTOR: Patel, Bharat
PATIENT: Per Physician's Order
PROCEDURE: Pulmonary Perfusion

SPECIAL INSTRUCTIONS:
Mo-99 content < 0.15 uCi/mCi at expiration time Agitate Syringe Prior to Injection – Don't Use If Particles Visible.

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

CAUTION RADIOACTIVE MATERIAL

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-015
[redacted]
Nuclear Medicine

Order #2447823 Date 03/31/04

Tc-99m MDP
25.0000 mCi
5.8235 ml
10:00 On 03/31/04 Calibration Time

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 18-03/31/04 RX-2413566
ASSAY: 30.3545 mCi/ml MFGR: In-House Prep
EXP TIME: 13:35 EXP DATE: 03/31/04
LIC. NO.: 29-07213-03 P.O. NO: C-0382
PIC: John Marzocca, R.Ph.

ADDRESS: 495 NORTH 13TH STREET, NEWARK,
DOCTOR: Freyne,J
PATIENT: Per Physician's Order
PROCEDURE: Skeletal Imaging

SPECIAL INSTRUCTIONS:
Mo-99 content < 0.15 uCi/mCi at expiration time Hydrate Patient Prior to Imaging.

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

CAUTION RADIOACTIVE MATERIAL

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-015
[redacted]
Nuclear Medicine

Order #2450742 Date 03/31/04

Tc-99m DTPA
25.0000 mCi
0.8970 ml
14:00 On 03/31/04 Calibration Time

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 30-03/31/04 RX-2416421
ASSAY: 27.8707 mCi/ml MFGR: In-House Prep
EXP TIME: 20:35 EXP DATE: 03/31/04
LIC. NO.: 29-07213-03 P.O. NO.
PIC: John Marzocca, R.Ph.

ADDRESS: 495 NORTH 13TH STREET, NEWARK,
DOCTOR: Freyne,J
PATIENT: Per Physician's Order
PROCEDURE: Renal Imaging

SPECIAL INSTRUCTIONS
Mo-99 content < 0.15 uCi/mCi at expiration time

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

CAUTION RADIOACTIVE MATERIAL

Amersham Health New Jersey
1 Nayton Place
Livingston, NJ, 07039
TEL#: 973-533-9109 NJ1-296
[redacted]
18

Order #2448221 Date 03/31/04

Tc-99m Myoview
25.0000 mCi
0.7774 ml
13:30 On 03/31/04 Calibration Time

ACT DISP: 25.0000 mCi 925.0000 MBq (+/- 10%)
LOT NO. 99-03/31/04 RX-2413964
ASSAY: 32.1585 mCi/ml MFGR: In-House Prep
EXP TIME: 20:05 EXP DATE: 03/31/04
LIC. NO.: 29-30100-01 P.O. NO.:
PIC: John Marzocca, R.Ph.

ADDRESS: 585 NEW BRUNSWICK AVE, FORDS,
DOCTOR: SODHI,A
PATIENT: Per Physician's Order
PROCEDURE: Myocardial Perfusion

SPECIAL INSTRUCTIONS
Mo-99 content < 0.15 uCi/mCi at expiration time

CAUTION WARNING To be used under the direct supervision of a physician. The USNRC has approved distribution of this product to persons licensed pursuant to 10CFR35.200, or under equivalent licenses issued by an Agreement or Licensing State

Filled By:

CAUTION RADIOACTIVE MATERIAL

State of New Jersey

OFFICE OF THE ATTORNEY GENERAL
DEPARTMENT OF LAW AND PUBLIC SAFETY
DIVISION OF CONSUMER AFFAIRS
BOARD OF PHARMACY
124 HALSEY STREET, 6TH FLOOR, NEWARK NJ

JAMES E. MCGREEVEY
Governor

PETER C. HARVEY
Attorney General
RENI ERDOS
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

July 22, 2004

John Marzocca, RPIC GE
Amersham Health Nuclear 4403
1 Naylon Place
Livingston NJ 07039

RE: Inspection Report #8-1066.6

Dear Mr. Marzocca:

The Board reviewed your letter of March 31, 2004 in which you offered mitigation concerning the above referenced Inspection Report.

It was the decision of the Board at the May 26, 2004 meeting, to mitigate the following violation(s):

N.J.A.C.13:39-12.2(e) for $25.00 and deny the mitigation for N.J.A.C.13:39-12.4(c)for $200.00

Please submit the remaining balance in the amount of $200.00 along with a letter of corrective action.

Yours truly,

Joanne Boyer

Joanne Boyer, RPh
Executive Director

JB/sm

PHM-2017-03364

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

CHRISTOPHER S. PORRINO
Attorney General

STEVE C. LEE
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

May 19, 2017

John Marzocca, RPIC
Med-Physics, Inc., d/b/a GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039

Re: Inspection #8-1066-16-X
Date of Inspection: August 10, 2016

Dear Mr. Marzocca:

This letter is to advise you that the New Jersey State Board of Pharmacy has had an opportunity to review information concerning the above inspection report.

Upon review of all available information, the Board has preliminarily found that you have violated those items listed on Attachment A.

The Board has determined that it will offer you an opportunity to settle this matter and thereby avoid the initiation for disciplinary proceedings. Should you wish to avail yourself of this opportunity, you **MUST SIGN THE ATTACHED CERTIFICATION** and agree to the following:

PAY A PENALTY IN THE AMOUNT OF $5,500.00 and **PROVIDE TO THE BOARD A LETTER OF CORRECTIVE ACTION.** (To be paid immediately upon your signing of the attached acknowledgment.)

Alternatively you may waive your right to a hearing and submit a written statement or explanation to the Board. The Board will then consider your submission and render a final decision, which may include any of the terms set forth above. This disposition will be a public record. Please take notice that if the Board determines that the initial inspection findings require a reinspection to ensure that cited deficiencies have been properly addressed, you may be subject to any costs associated with the reinspection.

If you do not wish to settle this matter, you may request a hearing. In that event, this letter will serve as notice of the charges against you and a hearing will be scheduled before the Board. At that hearing you may, either personally or with the assistance of an attorney, submit

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determination concerning the charges of unlawful activity. You should be aware that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in this letter. Additionally, the Board may, if the facts are found to so warrant, enter an order, requiring you to reimburse certain monies, direction you to cease and desist from engaging in unlawful acts and/or requiring you to pay costs incurred by the Board. Should you have any questions concerning this letter or the settlement offer herein, I suggest that you contact the Board at (973) 504-6450.

The enclosed Certification MUST be completed and returned to the Board within fifteen (15) days following your receipt of this letter. In the event that the Board receives no response from you within this time, the Board's settlement offer will be withdrawn, and the allegations contained herein shall be deemed admitted, and the Board will proceed to finally review that matter and enter an appropriate order.

NEW JERSEY STATE BOARD OF PHARMACY

By: _____
Anthony Rubinaccio, RPh
Executive Director

AR/rh
(1/17)

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CERTIFICATION

I, JOHN MARZOCCA, hereby acknowledge that I have read and reviewed the Board's letter dated May 19, 2017 regarding allegations of violations of the Board's enabling act and/or regulations.

Please Check One:

[✓] I acknowledge the conduct which has been charged and agree to:

1. **Cease and desist from engaging in the conduct alleged and pay a penalty in the amount of $5,500.00** (to be paid upon signing of this Certification).

2. **Send a Letter of Corrective Action,** as requested by the Board, with this Certification.

I am also aware that the action taken against me by the Board herein is a matter of public record, and that the Board's letter and this Certification are public documents.

[ ] I hereby waive any rights I may have to a hearing in this matter and defend myself against any charges, but ask the Board to consider my explanation before rendering its final decisions. I understand that the Board may order any of the terms specified in its letter and that the Certification are public documents.

[ ] I request a formal administrative hearing to contest the charges specified by the Board. I understand that I will be advised of the time, date and place for that hearing at another time. I am aware that I may be represented by an attorney and that at the time of the hearing I may submit to the Board, testimony and documentation relevant to the charges. I understand that in making its final decision, the Board may, if unlawful activity has been proven, assess civil penalties in an amount greater than that herein offered in its letter and may order such other remedies as it may deem appropriate. I am also aware that this proceeding is a matter of public record and that the Board's letter and this Certification are public documents.

(Signature)

Dated: 6/12/17

JOHN MARZOCCA
(Print Name)

Ref: John Marzocca, RPIC
Med-Physics, Inc., d/b/a GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
(28RS00446300)
Inspection #8-1066-16-X
AR/rh
(1/17)

6012

ATTACHMENT A

36. **Med-Physics, Inc., d/b/a GE Healthcare** - 1 Naylon Place, Livingston, New Jersey 07039
Pharmacist-In-Charge: John Marzocca
Bureau File #8-1066-16-X, **Period:** 8/10/16
Reference: Board of Pharmacy inspection conducted per N.J.S.A.45:1-18, N.J.S.A.45:14-48(a)11&12 and a request from the Board to inspect all pharmacies that engage in compounding sterile preparations.

Details

CITE	DESCRIPTION	FINE
N.J.A.C.13:39-11.24(a)6	Adequate efforts were not made to ensure the pharmacy's quality assurance program. Specifically, on June 17, 2015, the pharmacy's internal surface sampling detected a total of twenty-two (22) Colony Forming Units (CFUs) from various locations, including support table used in sterile compounding, the prep room and the pass through. On January 11, 2016, internal surface sampling detected one (1) CFU from the ISO 5 hood, one (1) CFU from Tech Hood 2 and one (1) CFU from Biologic Safety Cabinet (BSC) 6. Sixty-nine (69) CFUs were detected at various testing sites, including support tables, support cars and the dispensing room. On June 27, 2016, according to the pharmacy's internal surface sampling, four (4) CFUs were detected at BSC support table 1, four (4) CFUs were detected at BSC support table 6, one (1) CFU at cart 2 and three (3) CFUs at a general support table. Additionally, a total of twenty-one (21) CFUs were found in the gowning room. On all of these occasions, the pharmacy failed to analyze the species to the genus level in order to exclude the possibility of the existence of highly pathogenic species. By reviewing the cleaning log for the month of June 2016, the pharmacy failed to specify the details of cleaning in the event of CFU detection.	**$3,000.00**

N.J.A.C.13:39-11.24(a)10	When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the cleanroom that was out of compliance until such time that the cleanroom met the requisite standards. Specifically, on September 28, 2015, during the environmental monitoring tsts conducted by ENV Services, a laboratory equipment certification company, air sampling detected multiple CFUs in the dispensing room, the gowning room, the prep room, the White Blood Cell (WBC) anteroom and the WBC prep room. The nature of the CFUs detected in these areas was deemed non-highly pathogenic. The quantities of CFUs were below action level. Air Sample number 10 detected one (1) CFU in the center of the WBC Room and the species was identified as fungal in nature. This finding was deemed as Out-of-Compliance (OOC). On the following day, September 29, 2015, ENV Services detected one (1) CFU in the dispensing room, classified as ISO Class 7. The species was identified as fungal in nature. This finding was again deemed as OOC. John Marzocca, RPIC acknowledged that upon learning the test results on October 9, 2015, the pharmacy failed to cease using the affected equipment. The cleaning log for the month of October 2015 failed to indicate that the pharmacy performed triple cleaning in order to address these findings. On October 19, 2016, during a follow-up visit by Inv. Qi to the pharmacy, Mr. Marzocca stated that during the most recent environmental monitoring test performed by ENV Services, the maximum CFU count for two (2) ISO classified areas was exceeded. Air sampling detected one (1) CFU of genus in fungi nature from one of the BSC units, ISO Class 5, as well as thirteen (13) CFUs from one of the support tables. The CFUs detected were a highly pathogenic species. Mr. Marzocca stated that the pharmacy followed the N.J.A.C. regulation this time and ceased using the affected equipment.	**$2,500.00**

	Daily and weekly cleaning procedures were reviewed in detail. Upon review, it appeared that the pharmacy updated the cleaning frequency, cleaning methods and cleaning materials since my August 2016 visit.	
TOTAL: $5,500.00		

2/17

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

June 12, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated May 19, 2017 concerning inspection #8-1066-16-X, please find the enclosed signed certification letter with a check for $5500. Below are the corrective actions:

1. Contact plate surface samples are currently conducted in-house biannually. Any microbial recovery will be analyzed by an independent third party company, such as Nelson Labs 6280 South Redwood Road, Salt Lake City Utah. This is in addition to our cleanroom certification company (ENV) collecting and analyzing environmental air and surface samples biannually and identifying all recovered microbes to the genus level.
2. In 2016, we and our third-party certification vendor (ENV) enacted more stringent garbing, cleaning, and clean room entry procedures. Prior to these new protocols ENV would wheel in testing equipment from the street into our clean room without thoroughly cleaning the equipment and transportation carts. ENV now requires and supplies their technicians with clean room coveralls to wear during certification procedures. ENV technicians also thoroughly clean their testing equipment which is properly maintained for clean room entry and transfer all necessary equipment to GE clean room carts prior to certification testing.
3. In 2016 we have also changed our protocols to a more aggressive daily "cleaning and disinfection" of our primary and secondary engineering controls. We now use germicidal cleaning and disinfecting agents daily in addition to using sterile 70% isopropyl alcohol in the primary engineering controls. Prior to this change we used germicidal agents weekly and 70% isopropyl alcohol daily. We have also started a rotation of a sporicidal agent in our cleaning and disinfecting procedures.

If you have any questions, please do not hesitate to contact me at 973-533 9109

Sincerely,

John Marzocca R.Ph

General Electric Company

APR 0 4 2017

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

In response to NJ Board of Pharmacy letter Dated march 9, 2017 concerning the observations identified during an inspection of our Livingston New Jersey Nuclear Pharmacy conducted August 10, 2016. The observations stated in your letter are listed below for ease of reference:

[N.J.A.C.13:39-1124(a)6]- Adequate efforts were not made to ensure the pharmacy's quality assurance program.

Although this regulation does not make any reference to internal sampling to be analyzed for species to the genus to exclude the possibility of the existence of highly pathogenic species, Medi-Physics, Inc. d/b/a/ GE Healthcare Livingston NJ, has added this to our environmental monitoring protocols. Contact plate samples incubated on site which show organism growth will be analyzed by an independent certified third party laboratory for ID'ing to genus level. Additionally, our cleanroom certification company (ENV) shall continue to take environmental samples for air and surface contamination biannually during re-certification procedures. All growth recovered from third party vendor sampling shall also be ID'd to genus level.

[N.J.A.C.13:39-24(a)10]-When test results indicated that the cleanroom did not meet the standards established, the pharmacy failed to immediately cease using the primary engineering controls or cleanroom that was out of compliance until such time that the cleanroom met the requisite standards.

The Livingston Pharmacy did not take action to immediately cease using secondary engineering controls on September 28, 2015, as a result of the environmental monitoring tests, due to the fact the we were unaware of this requirement per 13:39-24(a)10 until the **January 2016** New Jersey Board of Pharmacy newsletter article titled- Regulation Regarding Out-of-Compliance Cleanrooms and Primary Engineering. Our Standard Operating Procedures, at the time required us to immediately deep clean the area of concern, perform an investigation to determine action necessary to eliminate recurrence of the contamination, and retest prior to reuse. After further review of the information in that newsletter, the Livingston Pharmacy is in the process of updated

6017

protocols to include 13:39-24(a)10. At this time, we are in compliance with this regulation as evidenced by our SOP's as well as Mr. Qi's follow up visit on October 19, 2016 stating that ENV services monitoring found a maximum CFU count exceeded in a BSC hood which was taken out of service until an EVN re-test was performed.

If you any questions or require any additional information, please contact me at (973) 533-9009.

Sincerely,

John Marzocca R.Ph

CHRIS CHRISTIE
Governor

KIM GUADAGNO
Lt. Governor

New Jersey Office of the Attorney General

Division of Consumer Affairs
Board of Pharmacy
124 Halsey Street, 6th Floor, Newark NJ 07102

CHRISTOPHER S. PORRINO
Acting Attorney General

STEVE C. LEE
Director

Mailing Address:
P.O. Box 45013
Newark, NJ 07101
(973) 504-6450

March 9 , 2017

Medi-Physics, Inc. dba GE Healthcare
1 Naylon Place
Livingston, New Jersey 07039
Attn: Jon Marzocca, RPIC

RE: Inspection Report #8-1066-16X for the period:08/10/2016

Dear Mr. Marzocca:

The New Jersey Board of Pharmacy (the "Board") has received the above mentioned inspection report, a copy of which is included with this letter, and has requested that you respond to the following items within **ten (10) days** of receipt of this letter:

1) Please provide a detailed response to the inspector's observations and any "areas of concern" noted for each citation in the "Report of Inspection" on pages #1 through #5. Your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

2) Please provide a detailed response for each citation and any "areas of concern" noted on page #1 of "Exhibit #15". You do not need to respond to items a second time, if you addressed a citation as part of your response to the "Report of Inspection" section. Again, your response should include an explanation for each issue noted, as well as what steps you have taken (or are planning to take) to address each item.

Feel free to include any additional supporting documentation you feel the Board should consider when reviewing your response. The Board will review this report and your response to this letter at the next available Board meeting.

Failure to respond and provide this information within ten (10) days from receipt of this letter will constitute a failure of a duty to cooperate pursuant to N.J.A.C. 13:45C-1.3 and may result in disciplinary action by the Board, including suspension of your permit to operate a pharmacy and/or to engage in sterile compounding.

Sincerely,

Anthony Rubinaccio, RPh
Executive Director
New Jersey Board of Pharmacy

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MEDi physics

GE Healthcare

1 Naylon Place
Livingston, NJ 07039
USA

T 973 533 9109
F 973 533 1116

March 28, 2017

Anthony Rubinaccio R.Ph
Executive Director
New Jersey Board of Pharmacy
124 Halsey Street
Newark, NJ 07101

Dear Mr. Rubinaccio

Please see the enclosed Biological Sampling Report that was requested with regards to inspection report #8-1066-16-X. Should you have any questions please do not hesitate to contact me at 973- 533 9109.

Sincerely

John Marzocca R.Ph

MAY 24 2017

General Electric Company

2880 Bergey Road, Ste. K
Hatfield, PA 19440
www.envservices.com
800 - 345 - 6094

Presents:

Biological Sampling Report

Control ID #: 802-136385-2114V

Prepared for:

GE HEALTHCARE - LIVINGSTON
ONE NAYLON PLACE
LIVINGSTON, NJ 07039

CLEANROOM

Attention:

MIKE AGNELLO
1-973-533-9109
MICHAEL.AGNELLO@GE.COM

Date(s) Tested:

21 MARCH 2017

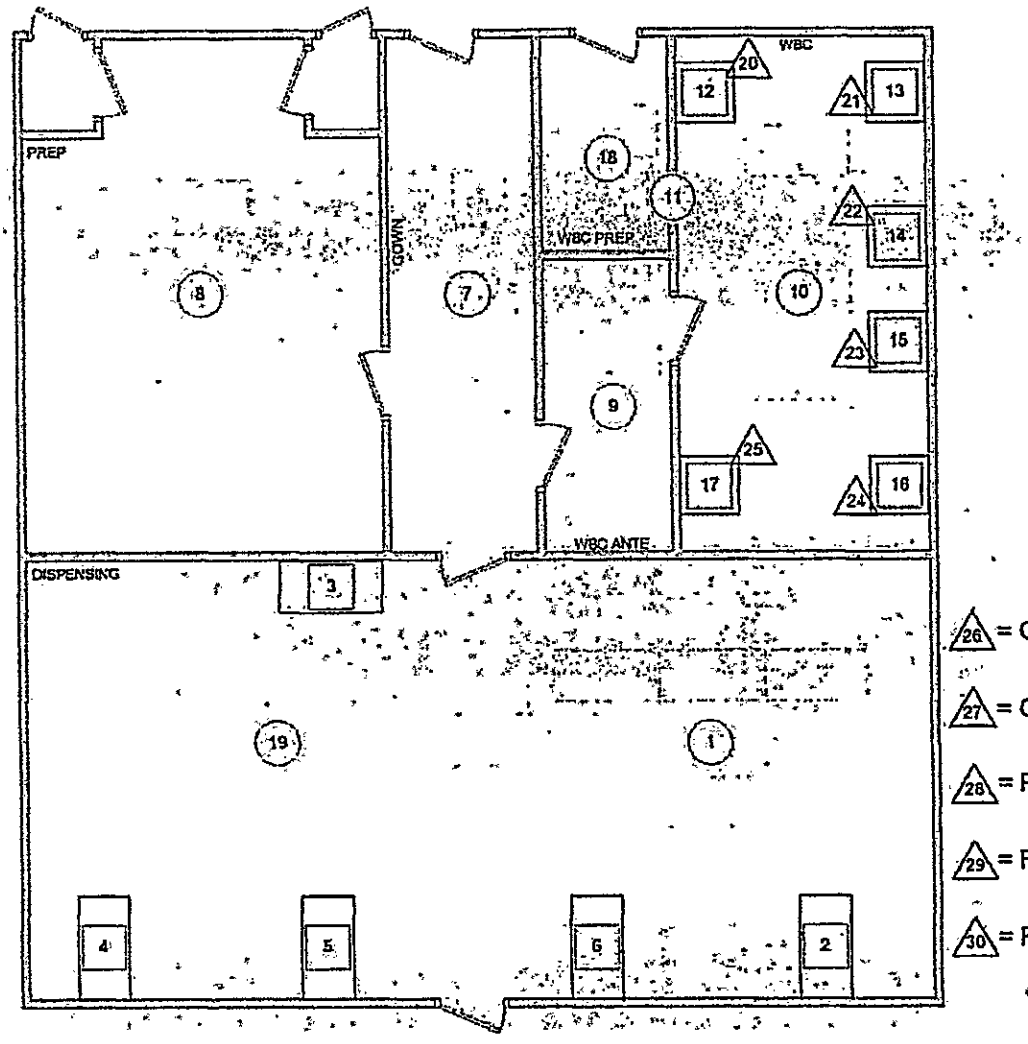
Field Service Technician(s):

JONATHAN STETTLER

BIOLOGICAL SAMPLING LOCATIONS

OPERATIONAL / DYNAMIC

CLEANROOM



Simple Location Key

Air and Surface, Bacteria and Fungal

Surface Only, Bacteria and Fungal

Air Only, Bacteria and Fungal

MAY 24 2017

Test Result
For Reference Only

ENV SERVICES, Inc. PROVIDING NATIONWIDE SOLUTIONS, CERTIFICATION, CALIBRATION, VALIDATION, CLEANROOMS	Project: GE HEALTHCARE - LIVINGSTON ONE NAYLON PLACE LIVINGSTON, NJ 07039
	Control ID #: 802-136385-2114V

TEST EQUIPMENT

GE HEALTHCARE - LIVINGSTON
LIVINGSTON, NJ 07039
CLEANROOM

Equipment Name	Manufacturer	Model	Serial	Calibration Due Date
AIR SAMPLER	PBI	SAS SUPER 360	16-D-11262	21 NOV 17

Test equipment calibration certificates available upon request.
Company ID: NJ0795-024 Unique ID: 350931

RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

USP <797>Viable Sample Report

Client Project ID:

802-136385 NJ0795-024 GE LIVNGSTON

Reported To:
Client Name: ENV Services, Inc.
Client Address: 2880 Bergey Rd, Suite K
City, State, Zip: Hatfield, PA 19940
Attn: REPORTS DEPT
Sample(s) Condition: Acceptable

Sampling Date: 03/21/2017
Date Received: 03/22/2017
Final Analyzation: 03/27/2017
Report Generation: 03/27/2017
Job ID: 17032214

Failed Sample Summary

COC No.	Location of Sample	Test Method	ISO Class	Result (Total CFUs)	Comments

* Microorganisms above the action levels per USP <797> or CAG-009-00 or deemed highly pathogenic.
Overall Comments: Growth Found On Client Samples

USP <797> Recommended Action Levels for Microbial Contamination

ISO Class	Particulate Size ($0.5m/m^3$)	Air (400-1000L) (CFU/m^3/plate)	Surface CFU/Plate	Post Media-Fill Gloved Fingertip (CFU/plate, combined hands, all risk levels)	Gloved Fingertip (CFU/plate, combined hands, all risk levels)	Media-Fill Test
5	3,520	>1	>3	>3	0	+ or -
7	352,000	>10	>5	N/A	N/A	N/A
8 or worse	3,520,000	>100	>100	N/A	N/A	N/A

Approved By:
Jerritt Nunneley, M.S., CNBT
Laboratory Director

Approved Date: 03/27/2017

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

Pass: Less than the limit of detection.

Acceptable: Microorganisms under the action levels per USP <797> or CAG-009-00.

Fail: Microorganisms above the action levels per USP <797> or CAG-009-00 or deemed highly pathogenic.

Unclassified: (non-HEPA filtered area).

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
1	Accept	1 (CFU/m³)	7	DISPENSING ROOM	BACTERIA - AIR USP	1000 (L)	17032214.01	1
					Raw CFU	CFU/m³	Origin	
Micrococcus luteus					1	1	Human	

Comments :

1	Pass	No Growth (CFU/m³)	7	DISPENSING ROOM	FUNGAL - AIR USP	1000 (L)	17032214.02	1

Comments :

2	Pass	No Growth (CFU/m³)	5	LFU S/N:20012084	BACTERIA - AIR USP	1000 (L)	17032214.03	1

Comments :

2	Pass	No Growth (CFU/m³)	5	LFU S/N:20012084	FUNGAL - AIR USP	1000 (L)	17032214.04	1

Comments :

2	Pass	No Growth (25cm²)	5	LFU S/N:20012084	BACTERIA - SURFACE USP	25cm²	17032214.05	1

Comments :

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC.#	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
3	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012083	BACTERIA - AIR USP	1000 (L)	17032214.06	1

Comments :

3	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012083	FUNGAL - AIR USP	1000 (L)	17032214.07	1

Comments :

3	[redacted]	No Growth (25cm²)	5	LFU S/N:20012083	BACTERIA - SURFACE USP	25cm²	17032214.08	1

Comments :

4	[redacted]	No Growth (CFU/m³)	5	LFU S/N:206000075	BACTERIA - AIR USP	1000 (L)	17032214.09	1

Comments :

4	[redacted]	No Growth (CFU/m³)	5	LFU S/N:206000075	FUNGAL - AIR USP	1000 (L)	17032214.10	1

Comments :

4	[redacted]	No Growth (25cm²)	5	LFU S/N:206000075	BACTERIA - SURFACE USP	25cm²	17032214.11	1

Comments :

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
5	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012082	BACTERIA - AIR USP	1000 (L)	17032214.12	1

Comments :

5	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20012082	FUNGAL - AIR USP	1000 (L)	17032214.13	1

Comments :

5	[redacted]	No Growth (25cm²)	5	LFU S/N:20012082	BACTERIA - SURFACE USP	25cm²	17032214.14	1

Comments :

6	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20207024	BACTERIA - AIR USP	1000 (L)	17032214.15	1

Comments :

6	[redacted]	No Growth (CFU/m³)	5	LFU S/N:20207024	FUNGAL - AIR USP	1000 (L)	17032214.16	1

Comments :

6	[redacted]	No Growth (25cm²)	5	LFU S/N:20207024	BACTERIA - SURFACE USP	25cm²	17032214.17	1

Comments :

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
7	Pass	No Growth (CFU/m³)	8	GOWN ROOM	BACTERIA - AIR USP	1000 (L)	17032214.18	1

Comments :

8	Pass	No Growth (CFU/m³)	8	PREP ROOM	BACTERIA - AIR USP	1000 (L)	17032214.19	1

Comments :

9	Accept	2 (CFU/m³)	7	WBC ANTE ROOM	BACTERIA - AIR USP	1000 (L)	17032214.20	1

	Raw CFU	CFU/m³	Origin
Staphylococcus epidermidis	2	2	Human

Comments :

10	Pass	No Growth (CFU/m³)	7	CENTER OF WBC ROOM	BACTERIA - AIR USP	1000 (L)	17032214.21	1

Comments :

10	Pass	No Growth (CFU/m³)	7	CENTER OF WBC ROOM	FUNGAL - AIR USP	1000 (L)	17032214.22	1

Comments :

11	Pass	No Growth (CFU/m³)	7	HEPA PASS THRU	BACTERIA - AIR USP	1000 (L)	17032214.23	1

Comments :

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
12	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10052	BACTERIA - AIR USP	1000 (L)	17032214.24	1

Comments :

12	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10052	FUNGAL - AIR USP	1000 (L)	17032214.25	1

Comments :

12	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10052	BACTERIA - SURFACE USP	25cm²	17032214.26	1

Comments :

13	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10053	BACTERIA - AIR USP	1000 (L)	17032214.27	1

Comments :

13	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10053	FUNGAL - AIR USP	1000 (L)	17032214.28	1

Comments :

13	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10053	BACTERIA - SURFACE USP	25cm²	17032214.29	1

Comments :

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RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
14	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10054	BACTERIA - AIR USP	1000 (L)	17032214.30	1

Comments :

14	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10054	FUNGAL - AIR USP	1000 (L)	17032214.31	1

Comments :

14	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10054	BACTERIA - SURFACE USP	25cm²	17032214.32	1

Comments :

15	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10384	BACTERIA - AIR USP	1000 (L)	17032214.33	1

Comments :

15	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10384	FUNGAL - AIR USP	1000 (L)	17032214.34	1

Comments :

15	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10384	BACTERIA - SURFACE USP	25cm²	17032214.35	1

Comments :

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 I Toll: (877) 659-4353 I Fax: (844) 849-5313 I www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
16	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10055	BACTERIA - AIR USP	1000 (L)	17032214.36	1

Comments :

16	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10055	FUNGAL - AIR USP	1000 (L)	17032214.37	1

Comments :

16	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10055	BACTERIA - SURFACE USP	25cm²	17032214.38	1

Comments :

17	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10619	BACTERIA - AIR USP	1000 (L)	17032214.39	1

Comments :

17	[redacted]	No Growth (CFU/m³)	5	BSC S/N:2515CH10619	FUNGAL - AIR USP	1000 (L)	17032214.40	1

Comments :

17	[redacted]	No Growth (25cm²)	5	BSC S/N:2515CH10619	BACTERIA - SURFACE USP	25cm²	17032214.41	1

Comments :

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M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 | Toll: (877) 659-4353 | Fax: (844) 849-5313 | www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
18	Accept.	1 (CFU/m³)	8	WBC PREP ROOM	BACTERIA - AIR USP	1000 (L)	17032214.42	1
					Raw CFU	**CFU/m³**	**Origin**	
Staphylococcus epidermidis					1		Human	

Comments :

19	[redacted]	No Growth (CFU/m³)	7	DISPENSING ROOM #2	BACTERIA - AIR USP	1000 (L)	17032214.43	1

Comments :

20	[redacted]	No Growth (25cm²)	7	2515CH10052 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.44	1

Comments :

21	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10053 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.45	1

Comments :

22	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10054 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.46	1

Comments :

23	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10384 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.47	1

Comments :

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RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 I Toll: (877) 659-4353 I Fax: (844) 849-5313 I www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
24	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10055 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.48	1

Comments :

25	[redacted]	No Growth (25cm²)	7	BSC S/N:2515CH10619 TABLE	BACTERIA - SURFACE USP	25cm²	17032214.49	1

Comments :

26	[redacted]	No Growth (25cm²)	7	GENERATOR LID HANDLE	BACTERIA - SURFACE USP	25cm²	17032214.50	1

Comments :

27	[redacted]	No Growth (25cm²)	7	GENERATOR SUPPORT TABLE	BACTERIA - SURFACE USP	25cm²	17032214.51	1

Comments :

28	[redacted]	No Growth (25cm²)	7	PHARMACISTS COMPOUNDING TABLE	BACTERIA - SURFACE USP	25cm²	17032214.52	1

Comments :

29	Accept.	1 (25cm²)	7	RANDOM CART	BACTERIA - SURFACE USP	25cm²	17032214.53	1

	Raw CFU	CFU/25cm²	Origin
Bacillus infantis	1	1	Environment

Comments :

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RP17032718

M-BioLabs
12815 Wetmore Rd., San Antonio, TX 78247 I Toll: (877) 659-4353 I. Fax: (844) 849-5313 I www.mbiolabs.com

Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

COC #	Status	Result (Total CFUs)	ISO Class	Location	Test Method	Sampling	Lab Sample ID	MRL
30	[redacted]	No Growth (25cm²)	7	RANDOM CART	BACTERIA - SURFACE USP	25cm²	17032214.54	1

Comments :

	[redacted]	Growth (CFU/m³)	N/A	(+) Controls	(+) BACTERIA CNTL- AIR/SURF. USP	0 (L)	17032214.55	1

Comments :

	[redacted]	Growth (CFU/m³)	N/A	(+) Controls	(+) FUNGAL CNTL - AIR/SURF. USP	0 (L)	17032214.56	1

Comments :

	[redacted]	No Growth (CFU/m³)	N/A	(-) Controls	(-) BACTERIA CNTL- AIR/SURF. USP	0 (L)	17032214.57	1

Comments :

	[redacted]	No Growth (CFU/m³)	N/A	(-) Controls	(-) FUNGAL CNTL - AIR/SURF. USP	0 (L)	17032214.58	1

Comments :

Control Media

Test	Type	Media	Manufacturer	Lot#	Exp. Date
(+) BACTERIA CNTL	AIR/SURF.	TSA	Remel	990985	05/08/2017
(-) BACTERIA CNTL	AIR/SURF.	TSA	Remel	990985	05/08/2017
(+) FUNGAL CNTL	AIR/SURF.	SabDex	Remel	993957	04/13/2017
(-) FUNGAL CNTL	AIR/SURF.	SabDex	Remel	993957	04/13/2017

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M-BioLabs
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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

GLOSSARY

OrganismName	Description
Bacillus infantis	
Micrococcus luteus	Can be found in many places such as the human skin, water, dust, and soil. Generally thought of as harmless bacterium, but there have been rare cases of Micrococcus infections in people with compromised immune systems.
Staphylococcus epidermidis	A coagulase-negative Staphylococcus that is part of the normal human flora, typically the skin flora, and less commonly the mucosal flora. Although S. epidermidis is not usually pathogenic, patients with compromised immune systems are at risk of developing infection. These infections are generally hospital-acquired. S. epidermidis is a particular concern for people with catheters or other surgical implants because it is known to form biofilms that grow on these devices.

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Client Name: ENV Services, Inc. Job ID: 17032214

Client Project ID: 802-136385 NJ0795-024 GE LIVNGSTON Final Analyzation: 03/27/2017

USP <797>Supplemental Information

1. Growth Media
   - 1.1. A general microbiological growth medium such as Soybean-Casein Digest Medium (also known as Trypticase Soy Broth (TSB) or agar (TSA) shall be used to support the growth of bacteria.
   - 1.2. Malt Extract Agar (MEA) or suitable substitute shall be used to support the growth of fungi.
   - 1.3. Media used for surface sampling shall be supplemented with additives to neutralize the effects of disinfecting agents (e.g., TSA with Lethicin and Polysorbate 80).
   - 1.4. Incubate inverted bacterial media for 2-3 days at 33-37°C and fungal for 5-7 days at 26-30°C.

2. Viable Sampling
   - 2.1. Air:
     - 2.1.1. Shall be performed dynamically at least semiannually (i.e. every 6 months) in ALL ISO Class environments.
     - 2.1.2. Impact shall be the preferred method volumetric sampling, settling plates are not sufficient.
     - 2.1.3. 400-1000 litersof air shall be tested at each location and reported as CFU/m³ of air.
   - 2.2. Surface:
     - 2.2.1. Shall be performed dynamically in ALL ISO classified areas on a periodic basis (contact plates and/or swabs) and shall be done at the conclusion of compounding.
     - 2.2.2. Results are reported as CFU per sampled unit area.

3. Gloved Fingertip Testing
   - 3.1. Shall be performed for all CSP risk level compounding.
   - 3.2. Immediately after gowning, the evaluator shall collect a gloved fingertip and thumb sample from both hands on a general microbiological media (TSA).
   - 3.3. Initial gloved fingertip/thumb sampling procedure requires (0 CFU) no less than 3 times before initially being allowed to compound CSPs for human use.
   - 3.4. Re-evaluation of all compounding personnel shall occur at least annually for low- and medium-risk level CSPs and semianmually for high-risk.
   - 3.5. CFU action level shall be based on the total number of CFU on both gloves and not per hand.
   - 3.6. Should be reported separately as number of CFU per employee per hand (left hand, right hand).

4. Media-Fill Testing
   - 4.1. Shall be performed initially before beginning to prepare CSPs and at least annually thereafter for low- and medium-risk level; and semiannually for high-risk.
   - 4.2. Shall be evaluated using sterile fluid bacterial (TSA) culture media-fill verification.
   - 4.3. Media-filled vials shall be incubated with a range of 33-37° C for 14 days.

5. Reporting Information
   - 5.1. Highly pathogenic microorganisms (e.g., Gram-negative rods, coagulase positive staphylococcus, molds, and yeasts) must be immediately remedied, regardless of CFU count. Any CFU count that exceeds its respective action level shall have an investigation into the source of contamination, shall be eliminated, the affected area cleaned, and resampling performed.
   - 5.2. Positive controls are unopened samples submitted for growth promotion testing (inoculation) which eliminates false negatives. Negative controls are unopenedsamples submitted for incubation solely which eliminates false positives.
     - 5.2.1. There should be a positive and negative control for each lot number of every media type used.
   - 5.3. MRL is the minimum reporting limit for a sample.
   - 5.4. Results found in this report are solely tied to the project above and the samples therein.

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California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

February 14, 2024

DATED MATERIAL ENCLOSED

RLS USA INC
ATTN: WERNER GRUNER, PRS
1283 MOUNTAIN VIEW ALVISO RD STE A-B
SUNNYVALE, CA 94089

RE: CI 2023 103137
RLS USA INC
PHY 57865

The attached Citation, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Forms and Publications).

The attached Citation references the specific statutes and regulations violated, and defines each violation charged. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND IF CONTESTING THE CITATION TO RESPOND WITHIN THE FOLLOWING TIME FRAMES:

- February 28, 2024: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- March 15, 2024: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. The acceptance of the Citation(s) shall not constitute an admission of the violation(s) charged.

No fine has been assessed with this Citation and no proof of abatement has been ordered.

If the Board does not receive a written request to contest this Citation within 30 days of the issue date, you will be deemed to have waived your right to contest this Citation. The Citation shall then become the final order of the Board. Please be advised that if not contested this Citation will become a part of the Board's records and constitute a public record for purposes of disclosure.

If you have any questions regarding this Citation please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

Anne Sodergren
EXECUTIVE OFFICER

By:

Joshua Monforte
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

Unless contested, Citations are final 30 days from the date of service. Acceptance of a Citations is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than February 28, 2024 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than March 15, 2024 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any enclosed documents please contact Joshua Monforte, Citation and Fine Analyst at (916) 518-3014.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number **Name, License No**
CI 2023 103137 **RLS USA INC, PHY 57865**

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE
CCR, Title 16, § 1751.3 subd. (a)	**Sterile Compounding Policies and Procedures; Any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding...**
CCR, Title 16, § 1751.4(a)	**Facility and Equipment Standards for Sterile Compounding; No sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations**

CONDUCT:

Failure to follow policies and procedures: CCR 1751.3(a) states in pertinent part, any pharmacy engaged in compounding sterile drug preparations shall maintain written policies and procedures for compounding. Any material failure to follow the pharmacy's written policies and procedures shall constitute a basis for disciplinary action. RLS USA Inc. located at 1283 Mountain View, Alviso Rd Ste A-B, Sunnyvale, CA 94089 was not compliant. Specifically, on at least 12/30/22 and 6/26/23 RLS USA Inc. failed to immediately remove its ISO Class 5 PEC from use following air microbial contamination action level exceedance as required in RLS USA Inc.'s Standard Operating Procedure "6.3.1 Certification of ISO Classified Environments." This was a violation of pharmacy law.

Unsafe compounding of sterile drug preparations: CCR 1751.4(a) states, no sterile drug preparation shall be compounded if it is known, or reasonably should be known, that the compounding environment fails to meet criteria specified in the pharmacy's written policies and procedures for the safe compounding of sterile drug preparations. RLS USA Inc. located at 1283 Mountain View, Alviso Rd Ste A-B, Sunnyvale, CA 94089 was not compliant. Between at least 12/30/22 and 1/11/23, and between at least 6/26/23 and 7/14/23, RLS USA Inc. compounded sterile preparations in a laminar flow work bench which was identified as having microbial growth exceeding the action level defined in the pharmacy's written policies and procedures. This was a violation of pharmacy law.

CITATION ISSUED ON: February 14, 2024

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA
CITATION

Citation Number **Name, License No**
CI 2023 103137 **RLS USA INC, PHY 57865**

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CONDUCT:

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CITATION ISSUED ON: February 14, 2024

California State Board of Pharmacy
REQUEST FOR OFFICE CONFERENCE

Licensee: RLS USA INC

License No: PHY 57865

Citation Number : CI 2023 103137

I hereby acknowledge receipt of the Citation referenced above and notification of my rights to contest the Citation.

Check I contest the Citation and request an Office Conference.

Check One:

I contest the entire Citation or

specific violations for the following reasons (list each violation with your specific reason):

If more space is needed attach additional sheets of paper.

Name:

Signature: Dated:

Address of Service:

City: State: Zip:

Daytime Number: ( ) Email Address: ( )

NOTE: Any written documentation or evidence you wish to be considered for the office conference review or hearing should be submitted with this request.

Mailing Address: California State Board of Pharmacy
Attn: Citation and Fine Unit
2720 Gateway Oaks Drive, Suite #100
Sacramento, CA 95833
(916) 518-3100

REQUEST FOR APPEAL

BEFORE THE
BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

Check I contest the Citation and request an administrative hearing before an Administrative Law Judge.

In the Matter of the Citation Against:
RLS USA INC
PHY 57865

Respondent

Citation Case No : CI 2023 103137
NOTICE OF APPEAL
(Pursuant to sections 11505, and 11506 Government Code)

I, the undersigned, the respondent named in the above-entitled proceeding, hereby acknowledge receipt of a copy of the Citation.

I hereby request a hearing in said proceeding to permit me to present my defense to charges contained herein in said Citation.

DATE

(Respondent)

Mailing Address of Respondent:

(Street Address)

(City (State) (Zip) ( ) (Telephone)

Please indicate whether or not you intend to be represented by counsel. If you intend to have counsel, please complete the following:

Mailing Address of Attorney

(Attorney's Name

(Street Address)

(City (State) (Zip) ( ) (Telephone)

California State Board of Pharmacy

DECLARATION OF SERVICE BY CERTIFIED MAIL

Name: RLS USA INC, PHY 57865
Citation and Fine CI 2023 103137

I declare:

I am employed in the County of Sacramento, California. I am over 18 years of age and not a party to the within entitled cause. My business address is 2720 Gateway Oaks Drive, Suite 100, Sacramento, California 95833.

On February 14, 2024, I served the attached:

Cover Letter, Instructions to Respondent, Citation, Copy of Citation, Request for Office Conference, Request for Appeal.

in said cause, by placing a true copy thereof enclosed in a sealed envelope with postage thereon fully prepaid by Certified Mail, in the United States mail at Sacramento, California,

NAME	CERTIFIED MAIL NO
RLS USA INC ATTN: WERNER GRUNER, PRS 1283 MOUNTAIN VIEW ALVISO RD STE A-B SUNNYVALE, CA 94089	7019 2970 0002 2051 5965

I declare under penalty of perjury that the forgoing is true and correct.

Executed on February 14, 2024, at Sacramento, California.

DECLARANT
Joshua Monforte
Citation and Fine Analyst

California State Board of Pharmacy
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833
Phone: (916) 518-3100 Fax: (916) 574-8614
www.pharmacy.ca.gov

Business, Consumer Services and Housing Agency
Department of Consumer Affairs
Gavin Newsom, Governor

October 11, 2024

DATED MATERIAL ENCLOSED

RLS USA INC
ATTN: MANNON BANKSON, COO
16259 STAGG ST STE A
VAN NUYS, CA 91406

RE: CI 2024 105586
RLS USA INC
PHY 57866

The attached Citation and Fine, ("Citation") is being issued pursuant to Business and Professions Code section 125.9 and California Code of Regulations, title 16, section 1775 et. seq., for violations of the laws and regulations that govern the practice of pharmacy in California. (For exact language refer to the California Pharmacy Law and Index, located on the Board's web site, at www.pharmacy.ca.gov, under Pharmacy Law and Regulation).

The attached Citation references the specific statutes and regulations violated, defines each violation charged and specifies any fine(s) assessed. The attached Citation details the conduct that resulted in the issuance of the Citation.

IT IS YOUR RESPONSIBILITY TO READ THE ENTIRE CITATION AND INSTRUCTIONS, TO UNDERSTAND THE PROCESS FOR CONTESTING THE CITATION AND TO RESPOND TO THE CITATION WITHIN THE FOLLOWING TIME FRAMES:

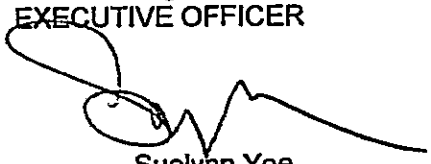
- November 10, 2024: Unless the Citation is contested payment of fine(s) must be received by the Board.
- October 25, 2024: Any contest of the Citation by request for an informal Office Conference must be received by the Board.
- November 10, 2024: Any contest of the Citation by request for a formal Appeal must be received by the Board.

The issuance of a Citation by the Board of Pharmacy is considered an administrative action and substantiated resolution of a complaint and/or investigation. If a hearing is not requested to contest the Citation(s), payment of any fine(s) shall not constitute an admission of the violation(s) charged. Payment in full of the fine(s) assessed shall be represented as a satisfactory resolution of the matter in any public disclosure. (Business and Professions Code section 125.9; California Code of Regulations section 1775).

Additionally, if, at the time of license renewal, the Board has not received full payment of assessed fine(s) and a request to contest the Citation has not been received within the time frames specified, the license shall not be renewed until the assessed fine(s) and renewal fee/s are paid in full.

If you have any questions regarding this Citation please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

Anne Sodergren
EXECUTIVE OFFICER

By: 

Suelynn Yee
Citation and Fine Analyst

Attachments

INSTRUCTION

Read the Following Carefully and Thoroughly

You are hereby served with a Citation issued by the Executive Officer of the California State Board of Pharmacy or her designee. The following instructions are provided to assist you in your timely completion of the Citation process.

PAYMENT OF FINE

- Payment must be made by **November 10, 2024.**
- Make check or money order payable to the Board of Pharmacy. Do not submit cash.
- Attach the enclosed "copy" of your Citation

Mail payment to: State Board of Pharmacy
Attn: Cashier
2720 Gateway Oaks Drive, Suite 100
Sacramento, CA 95833

Unless contested, Citations are final 30 days from the date of service. Payment of a fine is not an admission of the violation charged. A Citation becomes part of your record, and remains there for five years. It can be used as an aggravating factor for future violations. Citations are public information and as such may be released to the public in accordance with the Public Records Act and Information Practices Act.

CONTESTING THE CITATION (CCR §1775.4)

If you wish to contest all or part of your Citation you may request an informal office conference or an appeal before an administrative law judge, or both. If you wish to request both you must submit both forms. If you prevail at the office conference your request for an appeal shall be deemed withdrawn. Please note that the time frames that allow you to request an office conference and an appeal run concurrently. You must submit your request(s) according to the following instructions:

REQUEST FOR OFFICE CONFERENCE (CCR §1775.4 subd. (b))

- Complete attached "Request for Office Conference".
- Mail form to arrive at the Board office no later than October 25, 2024 to the address at the bottom of the form.
- You will be advised by the Board in writing as to the date and time of your appearance.
- You are allowed one postponement.

An office conference is not a hearing. It is an informal discussion of the events that took place, and an opportunity for you to present information and mitigating factors pertaining to the Citation that you would like considered. The Executive Officer and or her designee represent the Board of Pharmacy at this meeting. One other individual of your choice may accompany you to this meeting. Office conferences are not open to the public. There is no discovery available in this process. You will not be allowed to present or question witnesses. However, you may present any written statements or documents that you believe are relevant.

After your office conference, the Citation may be affirmed, modified or dismissed. You will be advised of the decision in writing within 14 calendar days from the date of the conference. If the Citation is affirmed you will have 30 days from the date of the decision letter to comply with the conditions of your Citation. If the Citation is modified, the Citation originally issued shall be considered withdrawn and a new Citation will be issued. The decision issued after the office conference shall be deemed to be a final order with regard to the Citation issued, including the administrative fine levied, and/or an order of abatement.

REQUEST FOR APPEAL (CCR § 1775.4 subd. (a))

- Complete attached "Request for Hearing".
- Mail form to arrive at the Board office no later than November 10, 2024 to the address at the bottom of the form.
- You will be advised in writing as to the date and time of your hearing.

An appeal is a formal adjudicative hearing before an Administrative Law Judge. A Deputy Attorney General will represent the Board of Pharmacy at this hearing. These proceedings shall be conducted in accordance with the provisions of Chapter 5, commencing with Section 11500 of Part 1 of Division 3 of Title 2 of the Government Code.

If you have any questions regarding any documents enclosed please contact Suelynn Yee, Citation and Fine Analyst at (916) 518-3013.

BOARD OF PHARMACY
DEPARTMENT OF CONSUMER AFFAIRS
STATE OF CALIFORNIA

CITATION AND FINE

Citation Number	Name, License No
CI 2024 105586	RLS USA INC, PHY 57866

JURISDICTION: Bus. & Prof. Code § 4314; CCR, title 16, § 1775; Bus. & Prof. Code § 4301, subd. (o)

VIOLATION CODE SECTION	OFFENSE	AMT OF FINE
Bus. & Prof. Code § 4113(F)	Pharmacist-in-Charge: Notification to Board; if a pharmacy is unable, in the exercise of a reasonable diligence, to identify within 30 days a permanent replacement pharmacist-in-charge to propose to the board on the notification form, the pharmacy may instead provide on that form the name of any pharmacist who is an employee, officer or administrator of the pharmacy...	$500.00
Bus. & Prof. Code § 4305 subd. (b)	Operation of a pharmacy for more than 30 days without supervision or management by a pharmacist-in-charge shall constitute grounds for disciplinary action	$1,000.00

CONDUCT:

Business and Professions Code section 4113(f) requires a licensee to, when unable to identify a permanent pharmacist-in-charge within 30 days of the date when a pharmacist-in-charge (PIC) ceases to act, provide the name of a pharmacist, owner, or manager to act as an interim pharmacist-in-charge for a period not to exceed 120 days. Specifically, on March 13, 2024, the Board received an Application for Change of Pharmacist-In-Charge from RLS USA Inc, which had been signed under penalty of perjury by a corporate officer, the disassociated PIC, and the newly designated PIC. The form indicated that the prior interim PIC, Anahita Malekakhlagh (RPH 73484), had disassociated on March 11, 2024 and that Scott Hudek (RPH 49826) took over as the permanent PIC on the same date. However, Anahita Malekakhlagh's (RPH 73484) interim period, which had begun on August 25, 2023, had previously expired on December 22, 2023. Anahita Malekakhlagh (RPH 73484) acted as the interim PIC from August 25, 2023 to March 11, 2024, 199 days.

Business and Professions Code section 4305(b) authorizes the Board to take disciplinary action against a licensee for operation of a pharmacy for more than 30 days without the supervision or management of a pharmacist-in-charge (PIC). Specifically, on March 13, 2024, the Board received an Application for Change of Pharmacist-In-Charge from RLS USA Inc, which had been signed under penalty of perjury by a corporate officer, the disassociated PIC, and the newly designated PIC. The application declared that Scott Hudek (RPH 49826) had taken over as the permanent PIC on March 11, 2024. However, as RLS USA Inc failed to pay their Application for Change of Pharmacist-In-Charge's application fee until July 11, 2024, the Board was unable to approve Scott Hudek (RPH 49826) as the permanent PIC until July 11, 2024. RLS USA Inc operated without a Board approved PIC from March 11, 2024 through July 10, 2024, 121 days.

CITATION ISSUED ON: October 11, 2024	TOTAL AMOUNT OF FINE(S): $1,500.00
PAYMENT OF FINE(S) DUE BY: November 10, 2024	

NEVADA STATE BOARD OF PHARMACY
985 Damonte Ranch Parkway, Suite 206 – Reno, NV 89521 – 775-850-1440

Designated Representative Application

Rev (05/12/2022)

Section 1: Pharmacy/Wholesaler Information

Name of Pharmacy/Wholesaler: RLS (USA) Inc.
Pharmacy/Wholesaler License # (if applicable): PH04663
Physical Address: 945 N. Edgewood Ave., Suite A-1
City: Wood Dale State: IL Zip: 60191
Mailing Address (if different from physical address): Same as Physical Address
City: State: Zip:
Telephone: 603-595-6642 Website: https://rls.bio/
Licensing Company Email: licensing@rls.bio

Section 2: Personal Information

First: Arasally Middle: Last: Rodriguez
Alias(es, nicknames, name changes, etc.): Dubinski
Date of Birth: [redacted] SSN or ITIN: [redacted] Sex ☐ M ☒ F ☐ X
Mailing Address: [redacted]
City: Algonquin State: IL Zip: [redacted]
Telephone: [redacted] Email: [redacted]
Are you a citizen of the United States? ☒ Yes ☐ No

Section 3: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		X

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		X
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?		X

Section 5: List your high school and college experience beginning with the most current. (Use a separate piece of paper if additional space is needed.)

School Name			From - To (MM/YY – MM/YY)	
University of Illinois at Chicago- College of Pharmacy			08/2000-05/2004	
Address: 833 S. Wood St	City: Chicago	State: IL	Zip: 60612	
Diploma/Degree obtained, if any: PharmD				
School Name: University of Illinois at Urbana-Champaign			From - To (MM/YY – MM/YY): 08/1996-05/2000	
Address: 306 N Wright St	City: Urbana	State: IL	Zip: 61801	
Diploma/Degree obtained, if any: Bachelors in Liberal Arts & Science				
School Name: Curie Metropolitan High School			From - To (MM/YY – MM/YY): 09/1992-06/1996	
Address: 4959 S Archer Ave	City: Chicago	State: IL	Zip: 60632	
Diploma/Degree obtained, if any: High School Diploma				
School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				
School Name			From - To (MM/YY – MM/YY)	
Address	City	State	Zip	
Diploma/Degree obtained, if any				

Section 6: List all residences you have had for the last 10 years beginning with the most current. (Use a separate piece of paper if additional space is needed.)

From - To (MM/YY – MM/YY)	Address	City	State	Zip
03/2021-current	[redacted]			
08/2006-3/2021				

Designated Representative Application (Applicant's Initials:) 3 of 9

6052

Section 7: A designated representative must provide proof that he or she has been employed for at least 6,000 hours in pharmacies (NAC 639.5005) or wholesalers (NAC 639.5935) in a capacity related to the dispensing and distribution of, and record keeping related to, prescription drugs. Beginning with the most current, list your hours of employment related to the above:

Business Name: RLS (USA) Inc			From - To (MM/YY – MM/YY): 09/2003-current
Business Address: 945 N Edgewood Ave Suite A1	City: Wood Dale	State: IL	Zip: 60191
Phone: 630-595-6642	Title: RPh, RSO		Number of Employed Hours: 40
Description of Duties: compounding, filling, processing, radiation safety, record keeping, shipping,distribution.			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Business Name			From - To (MM/YY – MM/YY)
Business Address	City	State	Zip
Phone	Title		Number of Employed Hours
Description of Duties			

Continue on next page if additional space is needed.

Section 8: Arrests; Detentions; Litigations; Arbitrations.	Yes	No
1. Have you ever been convicted of, or entered, a plea of guilty, guilty by mentally ill or nolo contendere to any criminal offense or civil violation, federal or state, for any reason whatsoever, regardless of the disposition of the event? (Except minor traffic citations.)		X
2. If you answered "yes" to question 1, was the offense or violation related to drugs, including prescription drugs and/or controlled substances, the manufacturer or distribution of drugs or the practice of pharmacy?		X
3. Have you ever had a civil or criminal record expunged or sealed by a court order?		X
4. Have you, as an individual, member or a company, partner, or owner, director or officer of a corporation, ever been a party to a lawsuit as either a plaintiff or defendant (including any administrative proceedings before a licensing board) or of an arbitration as either a claimant or respondent? (Other than divorces.)		X
5. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) been a party to a lawsuit (including any administrative proceedings before a licensing board), arbitration or bankruptcy?		X
6. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer or director) ever appeared before any licensing agency or similar authority in or outside the State of Nevada for any reason whatsoever (including any disciplinary or board citation)?		X
7. Have you ever been denied a personal license, permit, certificate or registration for a privileged, occupational or professional activity?		X
8. Has any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner member, officer or director) ever been refused a business license.		X
9. Have you or any general or limited partnership, company or limited liability company, business venture, sole proprietorship or closely held corporation, corporation (while you were associated with it as an owner, partner, member, officer, or director) ever surrendered a license, permit, certificate or registration relating to the pharmaceutical industry voluntarily or otherwise (other than upon voluntary closure of a manufacturer).		X
10. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		X

I, Arasally Rodriguez, **certify that as the designated representative for** RLS (USA) Inc.,

that I (initial that you have read and meet the following requirements) (NAC 639.5005, NAC 639.5935):

1. x I am at least 21 years of age;
3. x I have been employed for at least 6,000 hours in a pharmacy or with a wholesaler in a capacity related to the dispensing and distribution of, and recordkeeping related to, prescription drugs.
4. x I will be actively involved in and aware of the actual daily operations of the pharmacy or wholesaler;
5. x I will be employed full-time in a managerial level position with the pharmacy or wholesaler;
6. x I will be physically present at site of the pharmacy or at the facility of the wholesaler during regular business hours, except when the absence of the representative is authorized, including sick leaves, vacation leaves and other authorized absences; and
7. x I will serve in this representative capacity for only one pharmacy or wholesaler at a time.

Arasally Rodriguez

Print Name (First, Last)

Arasally Rodriguez

Original Signature (electronic, copies or stamps not accepted)

4-9-2025

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Arasally Rodriguez
Print Name (First, Last)

Arasally Rodriguez
Original Signature (electronic, copies or stamps not accepted)

4-9-2025
Date

Please have this section completed in the presence of a Notary Public.

State of ILLINOIS, ss. County of McHenry

I, Arasally Rodriguez, being duly sworn, depose and say I have read the foregoing application and know the contents thereof; that the statements contained herein are true and correct and contain a full and true account of the information requested; that I executed this statement with the knowledge that misrepresentation or failure to reveal information requested may be deemed sufficient cause for denial or revocation of the license, registration, permit, certificate or certification for which I am applying for.

Arasally Rodriguez
Original Signature

4-9-2025
Date

Subscribed and Sworn to before me this 9 day of April 2025.

Belinda D Husak
Notary Public Signature

OFFICIAL SEAL
BELINDA D HUSAK
NOTARY PUBLIC, STATE OF ILLINOIS
My Commission Expires December 28, 2027
(Seal)

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Sterile Compounding Questionnaire

Rev (09/11/2024)

This application cannot be returned by fax or email.
We must have an original signature to process.

Approval of this completed questionnaire is required for an existing pharmacy, new pharmacy and/or out-sourcing facility applicant who wish to engage in preparing, compounding, dispensing, and furnishing sterile compounded products to Nevada patients or consumers.

Please provide a thorough response to the questions below and provide any necessary supporting documents.
-For a new pharmacy or out-sourcing facility applicant, submit this completed form with your application.
-For an existing pharmacy, send the completed form to the address indicated above.

Section 1: General Information

Pharmacy Name: RLS (USA) Inc.

NV Pharmacy or Outsourcing facility license # (if applicable): PH04663

Physical Address: 945 N. Edgewood Ave., Ste A-1

City: Wood Dale State: IL Zip: 60191

Mailing Address (if different from physical address): Same as physical Address

City: N/A State: N/A Zip: N/A

Telephone: 603-595-6642 Toll Free # (NAC 639.708, NRS 639.23286): 800-242-8004

Fax: 603-595-8583 Contact Email: licensing@rls.bio

Website: https://rls.bio/

Nevada Business License # (if applicable) N/A

Supervising/Managing Pharmacist Name (NRS 639.220): Arasally Rodriguez

Supervising/Managing Pharmacist NV Pharmacist Registration #: 24298

Name of Designated Person(s) as defined by revised USP-797 guidelines: Arasally Rodriguez

Email of Designated Person(s): licensing@rls.bio

Telephone of Designated Person(s): 603-595-6642

Section 2: Sterile Compounding Questions (Use a separate piece of paper if additional space is needed.)

1. What risk level sterile compounding will your facility be performing (check all that apply)?

☐ Category 1 ■ Category 2 ☐ Category 3

If you marked **"Category 3"**, you must also complete **section 4.**

2. If compounding Category 2 products is the location performing sterility and endotoxin testing (if required) to obtain extended beyond-use dates? ☐ Yes ■ No

3. If compounding Category 2 products is the location performing aseptically processed CSPs or terminally sterilized CSPs? ■ Aseptic ☐ Terminal

4. Is the pharmacy following the new garbing requirements listed in the revised USP-797 guidelines? ■ Yes ☐ No

5. When was the most recent certification for the ISO classified areas? 2/4/25

6. What is the frequency of the recertification for the ISO classified areas? every 6 months

7. Were there any follow-up items required from the most recent certification report? ☐ Yes ■ No

8. If preparing Category 2 or Category 3 CSPs from non-sterile starting components are the pre-sterilization procedures such as weighing and mixing completed in an ISO Class 8 or better environment? ☐ Yes ■ No

9. If compounding Category 1 CSPs and Category 2 CSPs how often is surface sampling of all classified areas and pass-through chambers conducted? Monthly

10. Will you be performing sterile hazardous drug compounding? ☐ Yes ■ No

If you marked **"Yes"**, you must also complete **section 3.**

11. List the sterile compounded products that you will be compounding for Nevada patients or consumers:

Radiopharmaceutical only pepared or compounded in compliance with USP <825>

12. What laboratory performs your sterility or endotoxin testing?

Name: N/A

Address: _____

City: _____ State: _____ Zip: _____

Telephone: _____

13. What is your procedure for visual inspection of compounded sterile products?

Visual inspection of Radiopharmaceuticals in compliance with radiation safety ALARA principals.

14. How often do you perform glove fingertip and medial fill testing?

Every 6 Months

15. Describe your initial and ongoing training program for all personnel performing sterile compounding:

All new hires personnel performing sterile compounding must be licensed or registered in compliance with local regulations. Initial training is assigned based on job titles/duties performed through an electronic platform. Personnel are trained on all policies and procedures associated with their job duties. Annual retraining is tracked, completed, and maintained using the electronic platform.

16. Describe the cleaning procedure for your primary and secondary engineering controls, including the frequency of cleaning and the names of cleaning, disinfectant, sporicidal, and/or deactivation and decontamination agents used:

See attached SOP's 6.4.1, 6.4.1.1 and 6.4.1.2

17. Who performs the sterile compounding process at your facility?

All products are prepared by or under the direct supervision of the licensed, authorized nuclear pharmacist on duty.

18. Who is responsible and accountable for the sterile compounding process at your facility?

The PIC is responsible and accountable for the sterile compounding process.

19. If products are shipped/mailed, what shipping conditions are used to ensure product safety/efficacy?

RLS (USA) Inc. is a Nuclear Pharmacy dispensing radiopharmaceuticals in compliance with USP <825>. All transportation of prepared radiopharmaceuticals are completed by trained staff or contracted courier services in climate controlled vehicles in DOT-7A, Type A certified packaging designed and tested to maintain the quality and integrity of the product. Where temperature monitoring is required. RLS (USA) Inc. utilizes appropriate ColdMark indicators to ensure proper temperature is maintained during shipping.

Section 3: Sterile Hazardous Compounding Questions (Complete this section ONLY if you be performing Sterile Hazardous Compounding.)		
1. What type of primary engineering controls will you be using in your facility? N/A		
2. Are you complying with all USP 800 guidelines?	☐ Yes	☐ No
3. Have your employees who compound with hazardous drugs signed an acknowledgement that they understand the risks associated with this process?	☐ Yes	☐ No
4. Is your BSC or CACI vented 100% to the outside?	☐ Yes	☐ No
5. Do you have a negative pressure buffer room at your facility?	☐ Yes	☐ No
6. Will you be compounding with antineoplastic HDs or HD API?	☐ Yes	☐ No
7. If yes, are the drugs stored in an externally ventilated, negative pressure room?	☐ Yes	☐ No
8. Will you be utilizing a closed system transfer device?	☐ Yes	☐ No
9. If yes, list the name of the device:		

10. What information is provided to the patient or consumer on the proper handling and disposal of hazardous drugs products/containers?

11. Describe your initial process for training new employees prior to compounding sterile hazardous drugs?

Section 4: Sterile Category 3 Compounding Questions (Complete this section ONLY if you will be performing Category 3 Compounding.)

1. List the specific Category 3 sterile products that your facility compounds:
N/A

2. What is the frequency for ongoing garbing, gloved fingertip and thumb sampling, and media fill testing for compounding personnel?

3. Is the pharmacy meeting all of the additional garbing requirements for compounding Category 3 CSPs as defined by the revised USP-797 guidelines? ☐ Yes ☐ No

4. What is the frequency for completing volumetric active air sampling?

5. What is the frequency for completing surface sampling?		
6. What is the frequency for using sporicidal agents?		
7. Is an endotoxin test performed for all products compounded from one or more nonsterile component?	☐Yes	☐No
8. Is the BUD assigned supported by stability data obtained using a stability-indicating analytical method?	☐Yes	☐No

I certify under penalty of perjury that the information contained in this form is accurate, true and complete in all material respects. I understand that making any false representation in this form is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire form and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event the form is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Arasally Rodriguez

Name of Person who Completed the Form

RPh, RSO

Title

Arasally Rodriguez

Signature (copies or stamps not accepted)

4-10-2025

Date

Board Use Only	Date Received:_____ Date Approved:_____ Approved By:_____

RLS (USA), Inc. Nevada Resident Pharmacy Application Change of Ownership Officers and Ownership Information		
Name	**Title**	**Percent Ownership**
Telix Pharmaceuticals (US) Inc.	Owner	100%
Darren Patti	Group Chief Operating Officer	0%
Darren Smith	Group Chief Financial Officer	0%
Sarah Robison	Chief Financial Officer - Americas	0%
Oliver Newman	Company Secretary	0%

Darren Patti
Registered Pharmacist Licenses

License Type	License Number	State	Status
Registered Pharmacist	051290696	IL	Active
Registered Pharmacist	2007031818	MO	Active
Registered Pharmacist	5502043469	MI	Active

File Number 7206-604-9

STATE OF ILLINOIS

OFFICE OF THE SECRETARY OF STATE

To all to whom these Presents Shall Come, Greeting:

I, **Alexi Giannoulias,** *Secretary of State of the State of Illinois, do hereby certify that I am the keeper of the records of the Department of Business Services. I certify that*

RLS (USA) INC., INCORPORATED IN DELAWARE AND LICENSED TO TRANSACT BUSINESS IN THIS STATE ON SEPTEMBER 12, 2019, APPEARS TO HAVE COMPLIED WITH ALL THE PROVISIONS OF THE BUSINESS CORPORATION ACT OF THIS STATE, AND AS OF THIS DATE, IS A FOREIGN CORPORATION IN GOOD STANDING AND AUTHORIZED TO TRANSACT BUSINESS IN THE STATE OF ILLINOIS.

In Testimony Whereof, *I hereto set my hand and cause to be affixed the Great Seal of the State of Illinois, this* 20TH *day of* FEBRUARY *A.D.* 2025 .

Authentication #: 2505100274 verifiable until 02/20/2026

Authenticate at: https://www.ilsos.gov

SECRETARY OF STATE

State of Illinois

Department of Financial and Professional Regulation

Division of Professional Regulation

LICENSE NO.
054.021668
051.286793

The person, firm, or corporation whose name appears on this certificate has complied with the provisions of the Illinois Statutes and/or rules and regulations and is hereby authorized to engage in the activity as indicated below:

EXPIRES:
03/31/2026

LICENSED PHARMACY

NUCLEAR, STERILE COMPOUNDING

RLS (USA) INC
JOHN PERINO
945 N EDGEWOOD AVE STE A1
WOOD DALE, IL 60191-1252

MARIO TRETO, JR.
SECRETARY

CAMILE LINDSAY
ACTING DIRECTOR

The official status of this license can be verified at IDFPR.Illinois.gov

19097715

Cut on Dotted Line

For future reference, IDFPR is now providing each person/business a unique identification number, 'Access ID', which may be used in lieu of a social security number, date of birth or FEIN number when contacting the IDFPR. Your Access ID is: 4348997

Illinois Department of Financial and Professional Regulation

Lookup Detail View

Contact

Contact Information

Name	City/State/Zip	DBA / AKA
RLS (USA) INC	Wood Dale, IL 60191	•

License

License Information

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
054021668	LICENSED PHARMACY	ACTIVE	08/12/2021	03/12/2024	03/31/2026	N

Other Licenses

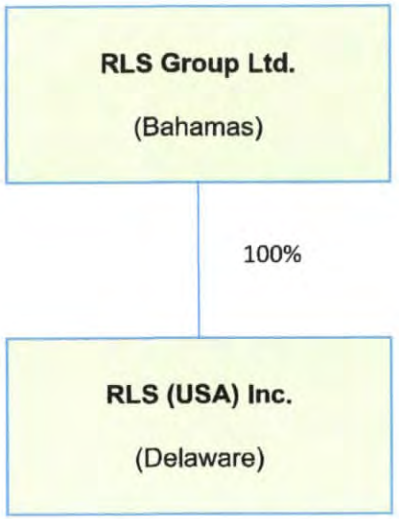
Other Licenses

License Number	Description	Status	First Effective Date	Effective Date	Expiration Date	Ever Disciplined
004004913	LICENSED WHOLESALE DRUG DISTRIBUTOR	ACTIVE	08/12/2021	12/23/2024	12/31/2026	N
054022447	LICENSED PHARMACY	ACTIVE	01/26/2023	03/12/2024	03/31/2026	N
054022853	LICENSED PHARMACY	INOPERATIVE	08/29/2024	08/29/2024	03/31/2026	N
054022854	LICENSED PHARMACY	ACTIVE	10/21/2024	10/21/2024	03/31/2026	N

Generated on: 2/7/2025 1:44:43 PM

FOIA CONFIDENTIAL TREATMENT REQUESTED/FOIA EXEMPT PURSUANT TO 5 U.S.C. § 552(b)(4)

Pre-Closing Structure



FOIA CONFIDENTIAL TREATMENT REQUESTED/FOIA EXEMPT PURSUANT TO 5 U.S.C. § 552(b)(4)

Post-Closing Structure



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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Nuclear USP <825> Inspection Form

Nuclear Pharmacy Inspection

Business e-Profile ID:	1803196		**Inspection Information**
Legal Business Name:	RLS (USA) Inc.	**Conference Call Date:**	4/29/2024
Doing Business As (DBA):	N/A	**Start Time: 24-hour format (13:00)**	12:00
Address:	945 North Edgewood Ave Ste A1	**End Time: 24-hour format (13:00)**	14:16
City:	Wood Dale	**Onsite Inspection Date(s):**	5/2/2024
State:	Illinois	**Start Time(s): 24-hour format (13:00)**	5:20
Zip Code:	60191	**End Time(s): 24-hour format (13:00)**	11:45
Telephone number:	630-595-6642	**Inspector Name(s):**	Howard Kramer RPh
Toll free number:	N/A	**Inspection performed by (NABP, State, etc):**	NABP
Fax number:	630-595-8583	**Observer Name/Affiliation (if applicable):**	N/A
Website:	www.rls.bio	**Observer Name/Affiliation (if applicable):**	N/A

Focused Information

The following, if any, are specific Section(s) and/or Question(s) to which the facility may want to consider further response. The facility is encouraged to read the inspection report in its entirety and carefully. As this Focused Information section is not all-inclusive, there may be Section(s) and/or Question(s) not noted below to which the facility may want to consider further response.
Nuclear-59.00, 59.01, 115.01, 339.00 and 340.00

Additional information on NABP's Inspection website.

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Pharmacy Hours of Operation	Check if 24/7 ☐		
	Open		Closed
	Start Time: (24-hour format)	End Time: (24-hour format)	(X)
Sunday	3:00	7:00	
Monday	23:30	15:00	
Tuesday	23:30	15:00	
Wednesday	23:30	15:00	
Thursday	23:30	15:00	
Friday	23:30	15:00	
Saturday	1:00	9:30	

Key Pharmacy Personnel	Name	Contact (e-mail)	e-Profile ID
Designated Person	Otha Bright, Jr.	otha.bright@rls.bio	278319
Designated Person	N/A	N/A	N/A
Pharmacist in Charge	Otha Bright, Jr.	otha.bright@rls.bio	278319
Radiation Safety Officer (RSO)	Arasally Rodriguez	arasally.rodriguez@rls.bio	242723
HIPAA privacy officer	Jayne Carney Senecal (corporate)	jayne.carneysenecal@rls.bio	N/A

Personnel Present at Time of Inspection	Name	Title	License or registration available and current
1	Otha Bright, Jr.	PIC	Y
2	Arasally Rodriguez	RSO/Pharmacist	Y
3	Sara Steelglove	Technician	Y
4	John Perino	Pharmacist	Y
5	Tiffany Sisson	Courier	N/A
6	Ubaldo Medina Sisson	Courier	N/A
7	Edward Garcia	Courier	N/A
8	Tyler Carter-Koonce	Courier	N/A
9	Ryszarda Turala	Technician	Y
10	Brian Worden	Courier	N/A

There were two couriers in addition to the above personnel.

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Business Licensure Information for State of Residence and Federal (Board of Pharmacy, State Controlled Substance, State Radiation Control Agency, Drug Enforcement Administration (DEA), Food and Drug Administration (FDA), Nuclear Regulatory Commission (NRC))

License/Registration Agency	Business Name on License/Registration	Registration/License Type	Registration/License Number / Expiration Date
Illinois Department of Financial and Professional Regulation - State Board of Pharmacy	RLS (USA) INC JOHN PERINO	Pharmacy	054.021668 Exp: 3/31/2026
Illinois Department of Financial and Professional Regulation - State Board of Pharmacy	RLS (USA) INC OTHA BRIGHT	Wholesale Drug Distributor	004.004913 Exp: 12/31/2024
Illinois Emergency Management Agency and Office of Homeland Security Office of Nuclear Safety	RLS (USA) Inc.	RAM	IL-01052-01 Exp: 3/31/2028

Inspector Notes: Facility non-resident licenses are held in Indiana and Wisconsin. The wholesale distributor license is maintained and was previously used for the distribution of I-123 Ioflupane, a C-II drug. Per the PIC, the wholesale distribution license was required by the DEA. The WD license is no longer used. There is no wholesale distribution at this time. There is no insulin stocked and no ReliOn insulin was observed. There are no platforms used that are a marketplace for pharmacies to buy, sell, or bid on overstock and short-date prescription drugs. There is no semaglutide compounded.

Documents collected as part of the inspection.
To obtain a copy of these documents please contact the facility directly. They are not included in the final report.

Document Name	Description
Doc01_Gen8.01_RLS(USA)Inc	Facility's response to deficiencies noted in the IMEA inspection report dated 3/21/2023
Doc02_Gen17.00_RLS(USA)Inc	The last internal audit, deficiencies and action plan
Photo01_Nuclear115.01_RLS(USA)Inc	Rust and deterioration on the sink located outside of the anteroom

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	Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT		Type(s) of practice Type "X" for all that apply and "N/A" when they do NOT
Ship/Deliver (in state)	X	Manufacturer	
Ship/Deliver (out-of-state, list below)	X	Wholesale Distributor (WD)	X
Central Fill/Processing/Shared Services		Handles Positron Emission Tomography (PET) Preparations	X
Institutional		Handles Nonsterile Preparations	X
Free Standing	X	Handles Sterile Preparations (eg including minor deviations)	X
Telepharmacy		Handles Investigational New Drugs (IND)	
Provide radiopharmaceuticals for 'Office Use'		Handles Blood Preparations	X
Provide radiopharmaceuticals for 'Physician Use'	X	Handles Volatile Isotopes (Xe-133 gas, liquid I-131 NaI)	X
Outsourcing Facility		Provide radiopharmaceuticals for Immediate Use	
Handles Sterile dispensing and repackaging	X		

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Facility Size (in Square Feet) and Number of PECs		Personnel	
Total Nuclear Pharmacy size:	11,000	Total Nuclear Pharmacists:	5
Nonsterile Processing area size:	117	Total Nuclear Pharmacy Technicians:	2
Sterile Processing Anteroom size:	98	Total Interns or Students:	1
Sterile Processing Clean/Buffer Room size:	1020	Total Other Personnel:	10
Blood Preparations Processing Room size:	135	Total Nuclear Pharmacist Hours Per Week:	200
Size of the decay storage area:	242	Total Nuclear Pharmacy Technician Hours Per Week:	80
Sterile number of PECs:	4	Board Certified Nuclear Pharmacist (BCNP):	3
Nonsterile number of PECs:	2		
Blood Preparations - number of PECs (eg BSC):	3		
Segregated Radiopharmaceutical processing area (SRPA) size:	N/A		
Number of Hot Cells:	0		

Volume Dispensed		Volume Distributed	
Total Prescriptions Dispensed/day:	285	Total Orders Distributed/day:	15
% Veterinary	0%	% Veterinary	0%
% Controlled Substances	0%	% Controlled Substances	0%
% Nonsterile Compounded	15%	% Nonsterile Compounded	0%
% Sterile Compounded	0%	% Sterile Compounded	100%
% of Sterile preparations	85%	% of Sterile preparations	0%
% of Nonsterile preparations	0%	% of Nonsterile preparations	0%

Definitions: DISPENSE means to provide a prescription product or compound pursuant to a patient-specific prescription.
DISTRIBUTE means to provide a prescription product or compound to a prescriber or health care entity for office use or stock and is NOT patient specific - is not labeled with the patient name at the pharmacy. HD means drugs on the National Institute for Occupational Safety and Health (NIOSH) list of HD such as hormones, chemotherapy, etc. There are currently no radiopharmaceuticals which are considered NIOSH HDs.

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States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Alabama (AL)			
Alaska (AK)			
Arizona (AZ)			
Arkansas (AR)			
California (CA)			
Colorado (CO)			
Connecticut (CT)			
Delaware (DE)			
District of Columbia (DC)			
Florida (FL)			
Georgia (GA)			
Hawaii (HI)			
Idaho (ID)			
Illinois (IL)	68	35	Week of 4/22/2024 through 4/28/2024
Indiana (IN)	9	0	Week of 4/22/2024 through 4/28/2024
Iowa (IA)			
Kansas (KS)			
Kentucky (KY)			
Louisiana (LA)			
Maine (ME)			
Maryland (MD)			
Massachusetts (MA)			
Michigan (MI)			
Minnesota (MN)			
Mississippi (MS)			
Missouri (MO)			
Montana (MT)			

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States to which the pharmacy ships/delivers prescription products and volume dispensed, and volume distributed per day (or week or month): Note: if not available, request information be sent to VPP and note that information was requested in grid.			
State	**Volume Dispensed**	**Volume DISTRIBUTED**	**/day, week, month**
Nebraska (NE)			
Nevada (NV)			
New Hampshire (NH)			
New Jersey (NJ)			
New Mexico (NM)			
New York (NY)			
North Carolina (NC)			
North Dakota (ND)			
Ohio (OH)			
Oklahoma (OK)			
Oregon (OR)			
Pennsylvania (PA)			
Rhode Island (RI)			
South Carolina (SC)			
South Dakota (SD)			
Tennessee (TN)			
Texas (TX)			
Utah (UT)			
Vermont (VT)			
Virginia (VA)			
Washington (WA)			
West Virginia (WV)			
Wisconsin (WI)	58	0	Week of 4/22/2024 through 4/28/2024
Wyoming (WY)			
Other:			

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
	General Pharmacy		
1.00	Is the Designated Person present for the inspection?	Yes	
2.00	Is the PIC (or nuclear pharmacy manager/director) present for the inspection? *If no, list the nuclear pharmacist on duty.*	Yes	
3.00	Are photographs allowed during the inspection (no Protected Health Information (PHI))?	Yes	
	General Operations and Licensure		
4.00	Are pharmacy licenses, permits and registrations (state, controlled substance, DEA, etc.) posted?	Yes	All facility and personnel licenses are posted on a bulletin board in the office area.
5.00	Is the RSO the same as is listed on the radioactive materials (RAM) license?	Yes	
6.00	Is the PIC an Authorized Nuclear Pharmacist (ANP) on the RAM license or other retrievable documentation as confirmed by the NRC or agreement state?	Yes	
7.00	Is the most recent board of pharmacy inspection report available for review? *Record the date of the last inspection and how frequently the pharmacy is routinely inspected by the board.*	N/A	There has been no inspection by the Illinois Board of Pharmacy.
7.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	N/A	
8.00	Is the most recent NRC (and/or state radiation control agency) inspection report available for review? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	Yes	The last Illinois Emergency Management Agency inspection was dated 3/21/2023. The PIC is not aware of any regularly scheduled inspections by Illinois or any state.
8.01	Were any deficiencies noted? *Indicate the deficiencies and note whether they were corrected.*	Yes	Please see Doc01_Gen8.01 for the inspection deficiencies and the facility's response to and action plan for the noted deficiencies.

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
9.00	Has this pharmacy been inspected by any other state for which it holds a license? *If yes, note the state and the date of the inspection and frequency of inspections by other states.*	No	
10.00	Is the pharmacy operating under an exemption or restriction granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the exemption or restriction.*	No	
11.00	Is the pharmacy operating under a waiver or variance granted by the state in which the pharmacy is located or by any other state in which the pharmacy is licensed? *If yes, note the waiver or variance.*	No	
12.00	Has the pharmacy been inspected or visited by the DEA? *If yes, indicate the inspection/visit date and note any deficiencies. Also note how frequently the pharmacy is inspected/visited by the DEA.*	Yes	The DEA inspected the facility on 8/11/2014 and left a Notice of Inspection Form DEA-82. The DEA does not regularly inspect the facility.
13.00	Has the pharmacy been inspected by the FDA? *If yes, indicate the inspection date and note any deficiencies, significant correspondence, or if a "483" was issued and date, and response and date. Also note how frequently the pharmacy is inspected by the FDA.*	No	
14.00	Has the pharmacy been inspected by the Environmental Protection Agency (EPA), Department of Transportation (DOT) or any other outside agency? *If yes, indicate the inspection date and note any deficiencies related to pharmacy practice.*	Yes	The DOT inspected the facility on 2/9/2006. The deficiency documented as a "Probable Violation" was "Failure to provide security awareness to a new employee. The company has no record of security awareness training for Dorsey Chappelle, hired Sept 2005." The deficiency was corrected.
15.00	Does the pharmacy hold any accreditations or certifications? *If yes, indicate which and collect most recent date of survey.*	Yes	The pharmacy holds an accreditation from The Joint Commission for Home Care Accreditation # 535863. dated 9/9/2022 and valid for 36 months.
16.00	Has the pharmacy held any accreditations or certifications in the past that they no longer hold?	No	

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Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
17.00	Were any deficiencies detected on the last internal audit? *List date of last audit and note any deficiencies found and action plan to correct.*	Yes	The last internal audit was dated 12/14/2023. Please see Doc02_Gen17.00 for the full report including deficiencies and the corrective action plan.
	Policy and Management		
18.00	Are policies and procedures for the program maintained in the pharmacy in an immediately retrievable form? *Indicate if hard copy, electronic, or both.*	Yes	P & P are electronic and on the corporate shared drive.
19.00	Are the P&Ps reviewed and updated regularly? *Indicate the review frequency and who performs the reviews.*	Yes	The Management of Change program requires the PIC to review the P & P quarterly and make suggestions for improvement.
20.00	Are systems in place for the ongoing monitoring of state and federal laws/regulations for changes? *Give details of the system and resources, or indicate if it is a corporate process and who is responsible overall as well as at the site.*	Yes	The corporate RSO reviews state and federal regulations and communicates them to the facility. The PIC receives bulletins and emails from the boards of pharmacy for the licensed states.
21.00	Is there a statement in the P&P, or are other means used to ensure that the most stringent laws/regulations are followed? *Describe system details.*	Yes	This is part of the corporate P & P.
22.00	Does the pharmacy maintain all required records, including but not limited to prescription files, on site? *Record how long records are kept. If not on site, where?*	Yes	All records are maintained onsite. Record retention varies with the record type, with prescription records maintained for five years.

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Facility Name: RLS (USA) Inc.
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Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
23.00	Does the pharmacy have access to appropriate law references including state and federal regulations (including state regulations for all states in which the facility is licensed and NRC)? *Indicate if they are hard copies or are accessed online (demonstrate access) or both.*	Yes	Access to law references is both hard copy and electronic.
24.00	Does the pharmacy have access to other references as required by state law? (eg appropriate dosage and toxicology references). *Indicate if they are hard copies or are accessed online or both.*	Yes	Dosage and toxicology references are both hard copy and electronic.
25.00	Does the pharmacy have access to appropriate practice specific references? Nuclear, geriatric, pediatric, etc. *List and indicate if hard copy or online or both.*	Yes	Practice-specific references are both electronic and hard copy. The most frequently used are the hard copies of Fundamentals of Nuclear Medicine, by Stabin, and Radiopharmaceuticals in Nuclear Pharmacy and Nuclear Medicine, by Kowalsky.
26.00	Are Safety Data Sheets (SDS) [formerly known as Material Safety Data Sheets (MSDS)] up to date and available to personnel for drugs and chemicals used in the pharmacy (including those for compounding, if applicable)? *Verify that personnel can access them and are familiar with the format.*	Yes	
27.00	Does the pharmacy have a hazardous waste handling and collection system? *Indicate how often waste is collected and the vendor(s) used.*	Yes	Hazardous waste is picked up by Stericycle on as needed basis.
	Product Ordering, Receipt and Inventory		
28.00	Is the pharmacy restricted to buying prescription drugs from certain WDs or manufacturers?	Yes	
28.01	If restricted, does the PIC approve the vendors? *If not, who does approve (corporate)?*	No	
29.00	Are all orders received when the pharmacy is open or placed in a secure area if the pharmacy is closed?	Yes	Orders are received only when the pharmacy is staffed and a pharmacist present.

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
30.00	Does the pharmacy purchase any compounded radiopharmaceuticals from other entities for dispensing to patients? *If so, describe which compounded radiopharmaceuticals and from where they are purchase (collect name and license of other entity).*	No	
31.00	Does the pharmacy make any sterile or nonsterile compounded radiopharmaceuticals using bulk powder or liquid (APIs)? *Indicate bulk products and vendors used.*	No	
32.00	Does the pharmacy use active ingredients that are not from an FDA facility? *If so, indicate sources.*	No	
33.00	Does the computer system track on-hand quantities of products? *Who can adjust the on-hand quantities, and are adjustments tracked?*	Yes	Only a pharmacist can adjust quantities and all entries and adjustments are tracked.
34.00	Are orders generated and sent by the computer for prescription products, including controlled substances? *Who can alter the orders before they are sent?*	No	A pharmacist must process the order. There are standing orders for generators.
35.00	Does the pharmacy maintain required inventories (such as change in PIC, theft/loss, etc)? *Indicate which.*	N/A	There are no controlled substances stocked.
36.00	Are incidents of diversion or resignation/termination of personnel for cause reported? *Indicate agencies/law enforcement to whom reports are made.*	Yes	The Board of Pharmacy would be notified and local law enforcement may be contacted dependent on the circumstances.
37.00	Does the pharmacy have a complete physical inventory of products performed at least once yearly? *If cycle counting, indicate the process.*	Yes	There is a monthly inventory and reconciliation with the system records.
38.00	Does the pharmacy have a system in place to track prescription drug products in order to detect diversion or theft? *Describe process (for example, inventory or shrink report tools used, perpetual inventory in computer, etc).*	Yes	There is a perpetual inventory in the pharmacy system.
39.00	Are all products inspected upon receipt to detect any packaging issues, damage, etc.? *Describe what happens if products are damaged.*	Yes	Damaged RAM material requires a notification to the RSO who determines handling. Non-RAM material is quarantined and the source is notified of the issue.

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e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
40.00	How are outdated, damaged, or recalled products segregated? *Indicate how often the pharmacy checks for out-of-date products.*	Yes	The system maintains expiration dates and expiration dates are reviewed at the time of use. There is no regularly scheduled review of expiration dates.
41.00	Are non-RAM expired or damaged products destroyed on site? *View documentation. If "no", note the name of the reverse distributor.*	No	Stericycle is the reverse distributor.
	Prescription/Order Processing		
42.00	Are any portions of the prescription processing performed at a different location? *If so, explain. Indicate whether there is a central fill/central processing agreement in place.*	No	
43.00	Does the pharmacy obtain a copy or verify of the RAM license (of the facility to which the radiopharmaceutical will be delivered) issued by the State Radiation Control Agency or the NRC?	Yes	
44.00	Is there a procedure to obtain a RAM license for the facility when a license cannot be obtained or verified?	Yes	The facility is contacted for license verification or a timely renewal letter. The state may be contacted for validation of the facility RAM license if necessary.
45.00	Does the pharmacy have electronic prescription capability? *Indicate whether it is for non-controlled substances, controlled substances, or both.*	Yes	The facility uses WebOLO for online ordering.
46.00	Is the pharmacy computer system provided routine maintenance and is the information backed up? *Indicate the frequency of backup and if the backup data is stored off site .*	Yes	The system is backed up daily, and maintained on corporate servers and a cloud.
47.00	Is there a continuity plan should the system become inoperable? *Describe how data will be retrieved.*	Yes	There is a local backup system that allows full operation. When the main system is operable, the data from the backup system must be re-entered.

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		Observations	Notes
	Patient Profiles and Communication		
48.00	Does the patient information gathered include patient contact information, age or date of birth, and gender, as required by the State Board of Pharmacy?	Yes	Only the patient's name is normally provided. The facility may require and request the patient's weight for some doses.
49.00	For therapy doses, does the pharmacy receive appropriate information to assess correct dosage, such as geriatric or pediatric weight-based doses, as required by the State Board of Pharmacy and/or Radioactive Materials Regulatory Agency?	Yes	
50.00	Does the pharmacist perform an evaluation of the dose, safety, and intended use of the preparation to be compounded?	Yes	The radiologist may be contacted for information if necessary.
51.00	Does the pharmacy take back prescription drugs from customers (eg clinic, prescriber, etc.)? If so, describe.	Yes	Unused doses may be accepted from prescribers or clinics and destroyed.
52.00	Are providers instructed on the signs of product instability or contamination (as appropriate) and to report any changes in the physical characteristics of the product to the pharmacy?	Yes	
	Patient Confidentiality		
53.00	Is there a HIPAA policy in place for employees, vendors, and contractors?	Yes	
54.00	Do employees deemed nonessential to patient care have access to confidential patient information, such as delivery personnel, etc.?	No	

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e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
55.00	Is access to the pharmacy system limited to appropriate personnel? *Password protected, access limited by job type, access revoked as appropriate such as upon termination, access to patient information in the computer is tracked.*	Yes	Passwords are assigned by corporate IT with access based on the employee's role. Access is revoked upon termination of employment. All access into the system is tracked.
56.00	Are confidential documents shredded? *Indicate if In-house or by a service and list service in notes if applicable.*	Yes	Shred-It is used.
57.00	Does the pharmacy destroy PHI including labeled prescription vials?	Yes	There are no vials used.
58.00	Does the crisis plan include security of paper and electronic patient information?	Yes	
	Prescription Packing and Transporting		
59.00	Does the pharmacy utilize employee drivers to deliver prescriptions to patients and/or facilities?	Yes	
60.00	Does the pharmacy utilize other services/carriers to deliver prescriptions to patients and/or facilities? *Indicate carriers used.*	No	
61.00	Is there is a tracking system in place to verify delivery of prescription products? *Indicate if signatures obtained or how tracked.*	Yes	An Apple Encore GPS tracking system is used with iPhones assigned to each driver. The package barcode is scanned and the barcode at the facility is scanned and must be a match.
62.00	Are deliveries of RAM directly to a secure location at a health care facility?	Yes	
63.00	Is only authorized packaging used?	Yes	
64.00	Is the packaging tamper-evident?	Yes	WBC packages are padlocked. Other deliveries use shrink wrap on the pig and zip ties on the carton.

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection - General

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
	Personnel Qualifications		
65.00	Is there a process for periodic verification of validity of personnel licenses (registrations)? *Describe the process.*	Yes	The PIC maintains a spreadsheet of all personnel licenses and reviews the primary source verification website annually.
66.00	Are all personnel wearing name tags that clearly identify if they are a pharmacist or a technician? *What about other positions?*	Yes	All employees wear a picture ID with name and position held.
67.00	If the pharmacy uses relief personnel from outside agencies to perform sterile compounding, the training and certifications are verified. *View documentation.*	N/A	
68.00	Does the pharmacy have a technician policy that specifies what a technician is allowed and not allowed to do?	Yes	
69.00	Does the pharmacy maintain the proper technician-to-pharmacist ratio? *Indicate ratio used and the maximum number of staff who work at the same time.*	Yes	The maximum number of licensed personnel working at any time is one technician and three pharmacists
70.00	Do employees undergo background checks upon hire? *Indicate if performed periodically for existing employees.*	Yes	Only initial criminal background checks are performed.
71.00	Do employees undergo drug testing upon hire? *Indicate if performed periodically for existing employees and if it is random, for cause, or both.*	Yes	There is a voluntary post-accident drug testing policy.
72.00	Is there a performance review process and is it documented? *If yes, how often?*	Yes	The performance review is an annual process.
73.00	Is a procedure for corrective or disciplinary action in place and documented?	Yes	

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Nuclear Pharmacy Inspection - General

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Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes
	Facility and Security		
74.00	Is entry to prescription product storage and processing areas limited to task-critical employees?	Yes	
75.00	Is entry into the handling areas limited to task-critical employees (limited to only the pharmacist(s) and other trained and authorized pharmacy personnel)?	Yes	
76.00	Are drugs secured to prevent unauthorized removal or access?	Yes	
77.00	Does the pharmacy have a working security/alarm system in place? *If yes, describe.*	Yes	ADT manages the security system which consists of magnetic door sensors, motion detection devices, and glass break sensors. The main door is a keyed lock with key pass access for all other doors. Access is based on the employee's job description and role. Alarms are sent by phone call and text message to the PIC, and a phone tree if there is no response.
78.00	Does the pharmacy have cameras? *If yes, record how long images are retained.*	Yes	Images are maintained for 90 days or more.
79.00	Does anyone have access to the pharmacy after hours in the absence of the pharmacist? *Explain.*	No	
80.00	Do pharmacy staff remain in the pharmacy if the pharmacist is absent on a meal break?	Yes	
80.01	If so, is there a policy regarding what activities may or may not be allowed during the pharmacist's absence?	Yes	

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The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Nonsterile Radiopharmaceuticals			1.1
1.00	Does the pharmacy compound nonsterile radiopharmaceuticals? *If so, list which of the following do they compound (eg Oral Capsules, oral solutions, other (if other, list those products in the notes)).*	Yes	Oral capsules and oral solutions are compounded.	1.1
2.00	Does the pharmacy obtain conventionally manufactured nonsterile drug products for dispensing? *If so, list those products in the notes.*	No		1.1
3.00	Does the pharmacy obtain compounded nonsterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	No		1.1
	Sterile Radiopharmaceuticals			1.2
4.00	Does the pharmacy compound sterile radiopharmaceuticals? *If so, list which of the following do they compound in the notes. (eg, intravenous, intrathecal, intraperitoneal, subcutaneous, intradermal, inhalations, ophthalmics, intra-organ instillations)*	Yes	The pharmacy compounds intravenous and inhalation radiopharmaceuticals.	1.2
5.00	Does the pharmacy obtain conventionally manufactured sterile drug products for dispensing? *If so, list those products in the notes.*	Yes	In111 DTPA	1.2
6.00	Does the pharmacy obtain compounded sterile preparations from 503B-registered outsourcing facilities for dispensing? *If so, list those products/outsourcers in the notes.*	No		1.2
7.00	Does the pharmacy compound sterile preparations involving one or more nonsterile components?	No		1.2
8.00	If the pharmacy compounds sterile preparations requiring a sterilization procedure, is testing (eg filtration with bubble point testing) performed prior to dispensing?	N/A		1.2
9.00	If the pharmacy compounds injectable sterile preparations involving one or more components that are not certified to be pyrogen-free, is pyrogen testing performed prior to dispensing?	N/A		1.2

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Facility Name: RLS (USA) Inc.
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Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Immediate Use of Sterile Radiopharmaceuticals			3
10.00	Does the pharmacy prepare and dispense sterile radiopharmaceuticals in a patient care setting as immediate use?	No		3
11.00	Does the pharmacy prepare immediate use sterile radiopharmaceuticals in an ambient environment without primary or secondary engineering controls?	N/A		3
12.00	Does handling for immediate use sterile radiopharmaceuticals in an ambient environment lacking primary and secondary engineering controls when intended for a single patient meet the following requirements? as applicable:	N/A		3
12.01	Are preparations (including minor deviations) and/or dispensing limited to use for a single patient?	N/A		3
12.02	Are preparation (including preparations with minor deviations) components sterile, conventionally manufactured drug products (eg, NDA, ANDA)?	N/A		3
12.03	Are dispensing of drug products produced under an approved IND or RDRC protocol?	N/A		3
12.04	Are manipulations for any unit doses (eg, decreasing the dosage, needle changes) or dispensing for one patient (eg, withdrawing a dose) ?	N/A		3
12.05	Are preparations labeled for administration within 1 hour of the first container puncture or exposure of any critical site involved (eg, syringe tip, needle hub or needle) to ambient air, whichever is first?	N/A		3
12.06	Are all components involved (eg, Tc-99m sodium pertechnetate syringe or vial, final prepared radiopharmaceutical kit vial, diluent vial) discarded within 1 hour of being punctured or after use for a single patient administration, whichever is first?	N/A		3
12.07	Does the pharmacy indicate that dose pooling (combining doses from two or more syringes to meet one patient's need) is performed as immediate use? Is any residual activity that remains is immediately discarded and not utilized for any other patient?	N/A		3

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		Observations	Notes	USP Reference(s)
12.08	Does pharmacy staff follow proper hand hygiene and garbing?	N/A		3
12.09	Does the pharmacy follow 10.4 Preparation of Radiolabeled Red Blood Cells for Immediate Use for red blood cell labeling?	N/A		10.4
12.10	Does the pharmacy follow 12.2 Labeling for labeling?	N/A		12.2
12.11	Is area for sterile preparation and/or dispensing functionally separate from nonsterile compounding area (eg, radiolabeling food) during the time of use?	N/A		
12.12	Does the pharmacy require a segregated radiopharmaceutical processing area (SRPA), classified area, or PEC?	N/A		
12.13	Are the number of steps or punctures limited?	N/A		
12.14	Does the pharmacy require personnel to complete the aseptic qualifications as detailed in 4.1 Aseptic Qualifications (eg, aseptic technique training with documented assessment, media fill challenge, gloved fingertip testing)?	N/A		4.1
12.15	Is adding non-radioactive, sterile and commercially manufactured pharmaceutical(s) only applicable if performing immediate use. *While adding a non-radioactive, sterile and commercially manufactured pharmaceutical (eg, lidocaine) to a unit dose is otherwise considered compounding, it is allowed for immediate use purposes as long as all of the above are adhered to.*	N/A		
12.16	Is dose splitting (splitting a unit dose for administration to more than one patient) performed as immediate use?	N/A		

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		Observations	Notes	USP Reference(s)
12.17	If performed, is dose splitting done in an ISO class 5 PEC in either an SRPA or in an ISO class 8 or better buffer area? *Note where this is performed.*	N/A		
	Personnel Qualifications, Training, and Hygiene			4
13.00	Are personnel trained to work with radiopharmaceuticals per policies and standard operating procedures (SOPs) authorized by an ANP or AU (eg physician)?	Yes		4
14.00	Do personnel follow these policies or SOPs of the ANP or AU (eg physician) and work under their supervision?	Yes		4
14.01	Are personnel trained in blood-borne pathogens (as appropriate)?	Yes		4
15.00	Are individuals entering a handling area properly garbed and maintain proper personal hygiene to minimize the risk of contamination to the environment and/or radiopharmaceuticals?	Yes		4
15.01	Are individuals who have a condition that may pose a higher potential of contaminating the radiopharmaceutical and the environment with microorganisms (eg, rashes, sunburn, recent tattoos, oozing sores, conjunctivitis, or active respiratory infection) reported to their supervisor?	Yes		4
15.02	Is the designated person responsible for evaluating whether these individuals should be excluded from working in sterile processing areas before their conditions are resolved?	Yes		4
16.00	Have all personnel of reproductive capability who handle, or compound radiopharmaceuticals/radioactive materials confirmed in writing they understand the risks of handling radiopharmaceuticals/radioactive materials?	Yes		4
17.00	Is there documentation of training for other employees (including drivers, warehouse, receiving, administrative, clerks, etc.) who may have contact with radiopharmaceuticals/radioactive materials on handling the spills associated with these?	Yes		4

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		Observations	Notes	USP Reference(s)
18.00	Can personnel demonstrate knowledge and can verbalize the principles of the safe use of RAM – time (working quickly/efficiently), distance (not handling RAM directly, using tongs), and shielding (using lead containers and shields in work areas)?	Yes		4
19.00	Can personnel demonstrate a knowledge of emergency procedures and are able to point out the locations of the eyewash station, emergency spill kit, and can verbalize how to handle contamination including reporting?	Yes		4
	Aseptic Qualifications		***Note to Inspector:*** *Check two (2) employee personnel files for documentation (1 RPh and 1 Tech), as appropriate*	4.1
20.00	Do personnel prove competency under the observation of a designated person, as applicable to their jobs, prior to performing radiopharmaceutical aseptic tasks (that are beyond immediate use). *Note– these can be completed at a different site if all SOPs are identical for the applicable job function.*	Yes	Files were reviewed for John Perino, pharmacist and Ryszarda Turala, technician.	4.1
21.00	Do the minimum qualifications include the following?	Yes		4.1
21.01	Aseptic technique with a documented assessment (written or electronic)	Yes		4.1
21.02	Garbing and hand hygiene, as defined by policies and SOPs	Yes		4.1
21.03	PEC cleaning and disinfecting	Yes		4.1

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		Observations	Notes	USP Reference(s)
21.04	Gloved fingertip and thumb sampling	Yes		4.1
21.05	Media-fill testing (not required for non-compounding personnel)	Yes		4.1
	Gloved Fingertip and Thumb Sampling			4.1
22.00	Is gloved fingertip and thumb sampling required for all personnel who enter and perform tasks in an ISO Class 5 PEC (eg, aseptic manipulations, cleaning the PEC)?	Yes		4.1
23.00	Is gloved fingertip and thumb sampling performed initially on both hands, immediately following hand hygiene and garbing?	Yes		4.1
23.01	Is successful completion of initial gloved fingertip and thumb sampling defined as zero colony- forming units (cfu)?	Yes		4.1
24.00	Is subsequent gloved fingertip and thumb sampling after media-fill testing defined as ≤3 cfu (total for both hands)?	Yes		4.1
25.00	Is the gloved fingertip and thumb sampling performed with touch plates or other devices (eg, plates, paddles, or slides) that contain a general microbial growth agar [eg, trypticase soy agar (TSA) soybean–casein digest media] supplemented with neutralizing additives (eg, lecithin and polysorbate 80) which support both bacterial and fungal growth?	Yes		4.1

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		Observations	Notes	USP Reference(s)
26.00	Per P&P review, gloves are not disinfected immediately before touching the sampling device.	Yes		4.1
27.00	Is a gloved fingertip and thumb sample from both hands collected by rolling finger pads and thumb pad over the agar surface, using a separate sampling device for each hand?	Yes		4.1
28.00	Are the plates incubated in an incubator at 30°–35° C for no less than 48 h, and then at 20°–25° C for no less than 5 additional days?	Yes		4.1
	Media-Fill Testing			4.1
29.00	Is media-fill testing done for all personnel who prepare, compound, dispense, and repackage sterile radiopharmaceuticals?	Yes		4.1
30.00	Is testing reflective of the actual manipulations to be carried out by the individual and simulate the most challenging and stressful conditions to be encountered in the worker's duties?	Yes		4.1
31.00	Are media-fill tests documented as defined by the facility's policies and SOPs?	Yes		4.1
32.00	*Recommendation: Are media-fill tests be performed at the end of a work session in the PEC.*	Yes		4.1
33.00	Are media-fill tests performed with a commercial source of soybean–casein digest medium?	Yes		4.1
34.00	Do those performing sterile-to-sterile processing activities start with sterile media?	Yes		4.1
35.00	Do those performing nonsterile-to-sterile compounding use a nonsterile soybean–casein digest powder to make a solution?	N/A		4.1

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		Observations	Notes	USP Reference(s)
35.01	Is dissolved nonsterile commercially available soybean–casein digest medium in nonbacteriostatic water to make a 3% nonsterile solution?	N/A		4.1
35.02	Is the final media manipulated in a manner that simulates nonsterile-to-sterile compounding activities?	N/A		4.1
35.03	Is the final media prepared with at least 1 container as the positive control to demonstrate growth promotion, which is indicated by visible turbidity upon incubation?	N/A		4.1
36.00	Does the certificate of analysis (CoA) include documentation of growth promotion testing for each lot of media used?	Yes		4.1
37.00	Once the media-fill simulation is completed and the final containers are filled with the test medium, are the media filled containers incubated for 7 days at 20°–25° C followed by 7 days at 30°–35° C to detect a broad spectrum of microorganisms? Note: Failure is indicated by visible turbidity or other visual manifestations of growth in the medium in 1 or more container–closure unit(s) on or before 14 days.	Yes		4.1
38.00	In the event of failure, are results of the evaluation and corrective actions documented and the documentation maintained to provide a record and long-term assessment of personnel competency?	Yes		4.1
39.00	Do media and components used include the following?	Yes		4.1
39.01	manufacturer	Yes		4.1
39.02	expiration date	Yes		4.1
39.03	lot number	Yes		4.1
40.00	Does the documentation include at a minimum the following?	Yes		4.1

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		Observations	Notes	USP Reference(s)
40.01	starting temperature for each interval of incubation	Yes		4.1
40.02	dates of incubation	Yes		4.1
40.03	results	Yes		4.1
40.04	name of the person evaluated	Yes		4.1
40.05	evaluation date	Yes		4.1
40.06	evaluation time	Yes		4.1
	Reevaluation, Retraining, and Requalification			4.2
41.00	Do personnel who fail visual observation of hand hygiene, garbing, and aseptic technique, gloved fingertip and thumb sampling, or media-fill testing successfully pass reevaluations in the deficient area(s) before they can resume processing of sterile radiopharmaceuticals?	Yes		4.2
42.00	Are all failures, retraining, and re-evaluations documented?	Yes		4.2
43.00	Do personnel successfully complete requalification in the core competencies via demonstrated through observation, written testing, and hands-on demonstration of skills?	Yes		4.2

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		Observations	Notes	USP Reference(s)
	Timing of Reevaluation and Requalification			4.2
44.00	**Visual observation**: Are personnel visually observed while performing hand hygiene, garbing SOPs, and aseptic technique procedures both initially, and then at least once every 12 months?	Yes		4.2
45.00	**Gloved fingertip and thumb sampling**: Do personnel perform fingertip and thumb sampling 3 times initially, and then every 12 months (in conjunction with media-fill testing).	Yes		4.2
46.00	**Media-fill testing:** After initial qualification, is a media-fill test of all personnel engaged in sterile radiopharmaceutical processing performed at least every 12 months (in conjunction with gloved fingertip and thumb sampling)?	Yes		4.2
47.00	**Cleaning and disinfecting:** Does the pharmacy retrain and requalify personnel in the cleaning and disinfecting of sterile processing areas every 12 months or in conjunction with any change(s) in cleaning and disinfecting SOPs, whichever is sooner?	Yes		4.2
48.00	**After a pause in sterile radiopharmaceutical processing:** Are personnel that have not performed radiopharmaceutical processing in more than 6 months requalified in all core competencies before resuming duties?	Yes		4.2
49.00	**Sterile compounding using a nonsterile drug substance or components:** Are personnel who perform sterile compounding using a nonsterile drug substance or components requalified in all core competencies every 6 months?	N/A	There are no nonsterile drugs or components used.	4.2

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		Observations	Notes	USP Reference(s)
	Ancillary Personnel			4.3
50.00	Are personnel who are authorized to be within the sterile processing area and do not handle sterile preparations required to complete all training and testing other than training on media-fill testing ?	N/A	There are no personnel authorized to be within the sterile processing area who do not handle sterile preparations.	4.3
51.00	Do other personnel or visitors (eg, auditors, regulators, student observers) comply with garbing and gloving SOPs without the need to prove competency?	Yes		4.3
	Hand Hygiene and Garbing for Immediate Use Preparations			4.4
52.00	**Hand hygiene:** Do personnel wash hands and arms to the wrists with soap and water or use a suitable alcohol-based hand rub with a time based on institution policies to reduce bioburden on the hands?	Yes		4.4
53.00	**Garbing:** Immediately after hand hygiene, do personnel don a clean coat/gown that has not been exposed to a patient or patient care area, and either don sterile gloves or don nonsterile disposable gloves and then disinfect the gloves with sterile 70% IPA?	Yes		4.4
54.00	Is a different lab coat worn to care for a patient than the coat/gown used for radiopharmaceutical preparation?	N/A	There is no patient care area.	4.4
	Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area			4.5
55.00	Before entering the SRPA or buffer area, do personnel remove all the following (as applicable)? *(Radiation dosimetry devices are allowed, as required by the RAM license).*	Yes		4.5
55.01	Outer garments (eg, bandanas, coats, hats, jackets, sweaters, vests)	Yes		4.5
55.02	All cosmetics	Yes		4.5

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		Observations	Notes	USP Reference(s)
55.03	All hand, wrist, and other exposed jewelry including piercings that could interfere with the effectiveness of the garbing	Yes		4.5
55.04	Nail products (eg, artificial nails, polish, extenders). {Natural nails kept neat and trimmed.}	Yes		4.5
55.05	Ear buds	Yes		4.5
55.06	Headphones	Yes		4.5
56.00	Are electronic devices that are not necessary for compounding or other required tasks banned from the SRPA?	N/A	There is no SRPA.	4.5
57.00	Do personnel don shoe covers, head/hair/facial hair cover(s) and face masks? Note – these items are donned in an order that eliminates the greatest risk of contamination, as defined in facility SOPs.	Yes	Dedicated shoes are used, or shoe covers for visitors.	4.5
58.00	Does the process before entering the buffer area or SRPA include the following?	Yes		4.5
58.01	Remove visible debris from underneath fingernails under warm running water using a disposable nail cleaner	Yes		4.5
58.02	Wash hands and arms up the elbows with soap and water for at least 30 seconds and then dry using low-lint towels	Yes		4.5
58.03	Electronic hand dryers are not permitted	Yes		4.5

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Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
58.04	Hand antisepsis cleansing is performed using a suitable alcohol-based hand rub	Yes		4.5
58.05	Don a low-lint gown with sleeves that fit snugly around the wrist and enclosed at the neck. *Note: Disposable gowns are preferred.*	Yes	Gowns are laundered and not disposable.	4.5
58.06	If reusable gowns are used, a clean gown is donned daily.	Yes		4.5
58.07	Aseptically don sterile, powder-free gloves. Gloves completely and snugly cover the ends of the gown cuffs so that skin on the wrists and upper hands is completely enveloped.	Yes		4.5
59.00	Does the routine process include the following?	No		4.5
59.01	Do personnel periodically apply sterile 70% IPA to gloves while balancing the risk of radioactivity contamination; due to touching or handling potentially nonsterile materials?	No	The pharmacist observed during compounding frequently used sterile 70% IPA to sanitize the gloves. However, on one occasion during the observation, the pharmacist used the IPA, made notes on the documents, and then re-entered the hood without further sanitizing.	4.5
59.02	Do personnel inspect the gloves they are wearing for holes, punctures, radioactivity contamination, or tears?	Yes		4.5
59.03	If a defect, radioactivity contamination, or malfunction is detected, do personnel immediately do the following?	Yes		4.5
59.04	Remove the gloves	Yes		4.5
59.05	Repeat antiseptic hand cleansing using an alcohol-based hand rub	Yes		4.5
59.06	Don new sterile gloves	Yes		4.5
59.07	Personnel avoid touch contamination of container septa, needles, syringe and needle hubs, and other critical sites	Yes		4.5

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		Observations	Notes	USP Reference(s)
60.00	Do exiting processes for buffer area or SRPA include the following?	Yes		4.5
60.01	Shoe covers, head/hair/facial hair cover(s), face masks and gloves are properly disposed of	Yes		4.5
60.02	New PPE is used for each re-entry	Yes		4.5
60.03	Gowns may be re-used within the same shift if maintained to minimize contamination (eg away from sinks)	Yes		4.5
60.04	Gowns are in a classified area or,	Yes		4.5
60.05	Gown are kept in (or immediately outside of) the SRPA	N/A	There is no SRPA.	4.5
	Facility Design and Environmental Controls			5.1
61.00	Is the facility is designed to minimize airborne contamination (for sterile radiopharmaceutical facilities)?	Yes		5.1
62.00	Is the facility is well-lighted?	Yes		5.1
63.00	Are the refrigerator and freezer restricted to drug products only (no food)?	Yes		5.1
64.00	Are the temperatures in classified areas and SRPA continuously maintained at 25 degrees C or cooler?	Yes		5.1

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		Observations	Notes	USP Reference(s)
65.00	Are the temperatures monitored in the classified areas and SRPA each day that they are used, either manually or by a continuous recording device?	Yes	Temperatures are recorded manually once daily.	5.1
66.00	Are the temperature readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Yes	Temperatures are recorded manually once daily.	5.1
67.00	Are the temperature readings reviewed as described in the facility's SOPs?	Yes		5.1
68.00	Are free-standing air conditioners used within the classified area or SRPA?	No		5.1
69.00	Are temperature monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Yes		5.1
70.00	*Recommendation: The humidity in classified areas and SRPA are continuously maintained at a relative humidity (RH) below 60%.*	Yes		5.1
71.00	Is the humidity monitored in the classified areas and SRPA each day that it is used, either manually or by a continuous recording device?	Yes	The humidity is recorded manually once daily.	5.1
72.00	Are the humidity readings of the classified areas and SRPA documented at least once daily or stored in a continuous recording device and retrievable?	Yes	The humidity is recorded manually once daily.	5.1
73.00	Are the humidity readings reviewed as described in the facility's SOPs?	Yes		5.1
74.00	Are free-standing humidifiers/dehumidifier used within the classified area or SRPA?	No		5.1

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		Observations	Notes	USP Reference(s)
75.00	Are humidity monitoring devices calibrated and verified for accuracy at least every 12 months or as required by the manufacturer?	Yes		5.1
76.00	Is the designated person responsible to ensure the following?	Yes		5.1
76.01	Does each area related to sterile radiopharmaceutical processes meet the classified air quality standard appropriate for the activities to be conducted in that area?	Yes		5.1
76.02	Are ISO Class 5 PECs located, operated, maintained, monitored, and certified to have appropriate air quality?	Yes		5.1
	Types of Secondary Engineering Controls and Design:			5.1
77.00	Were placement of doors, door surfaces, and movement of the door, all of which can affect airflow, considered when designing doors for a sterile radiopharmaceutical processing facility?	Yes		5.1
78.00	Are tacky surfaces not used in ISO-classified areas?	Yes		5.1
79.00	Are the PEC located in a SEC?	Yes		5.1
80.00	When the PEC is located in an SEC which is an ISO-classified buffer room with an ante room, does all of the following apply?	Yes		5.1
80.01	Is the ISO-classified ante-room and buffer area separated from the surrounding unclassified areas of the facility with fixed walls and doors?	Yes		5.1

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		Observations	Notes	USP Reference(s)
80.02	Are facility design and controls in place to minimize the flow of lower-quality air into the more controlled areas?	Yes		5.1
80.03	Is the air supplied to the classified areas introduced through HEPA filters that are located in the ceiling?	Yes		5.1
80.04	Are returns low on the wall unless a visual smoke study demonstrates an absence of stagnant airflow where particulate will accumulate?	Yes		5.1
80.05	Is a smoke study of the PEC repeated whenever a change to the placement of the PEC within the area is made?	Yes		5.1
80.06	Is the classified areas equipped with a pressure-differential monitoring system?	Yes		5.1
80.07	Does the ante-room have a line of demarcation to separate the clean side from the less clean side?	Yes		5.1
80.08	Is the ante-room entered through the less clean side, and the clean side is the area closest to the buffer area?	Yes		5.1
80.09	Is required garb worn prior to crossing the line of demarcation?	Yes		5.1
81.00	When the PEC is located in an SEC, which is an unclassified area, without an ante room or buffer area (aka SRPA), the following apply:	N/A		5.1
81.01	Only sterile radiopharmaceutical preparation, preparation with minor deviations, dispensing, and repackaging may be performed in an SRPA	N/A		5.1
81.02	The SRPA is located away from unsealed windows, doors that connect to the outdoors, and traffic flow which may adversely affect the air quality in the PEC.	N/A		5.1
81.03	A visible perimeter establishes the boundaries of the SRPA.	N/A		5.1

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		Observations	Notes	USP Reference(s)
81.04	Access to the SRPA is restricted to authorized personnel and required materials.	N/A		5.1
81.05	An SRPA is not located adjacent to environmental control challenges	N/A		5.1
81.06	If the SRPA meets ISO Class 8 total airborne particle count specifications, it can also be used for storage and elution of non-direct infusion radionuclide generators (eg, Tc-99m)	N/A		5.1
82.00	If a pass-through is used to prevent influx of contaminants, both doors are never opened at the same time.	Yes		5.1
83.00	*Recommendation: Interlocking mechanisms are used in the pass-through(s).*	Yes		5.1
	The Radiopharmaceutical Processing Environment:			5.1
84.00	Is the PEC certified to meet ISO Class 5 or better conditions (3520 particle count (with limit ≥0.5 µm) per cubic meter) under dynamic operating conditions?	Yes		5.1
85.00	Is the airflow in the PEC unidirectional (laminar flow)?	Yes		5.1
86.00	Is "first air" at the face of the filter free from airborne particulate contamination?	Yes		5.1

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		Observations	Notes	USP Reference(s)
87.00	Is the HEPA-filtered air supplied in the direct processing area (DPA) at a velocity sufficient to sweep particles away from aseptic processing areas and maintain unidirectional airflow as much as possible during operations, given the limitations added from the radiation shielding in the DPA?	Yes		5.1
88.00	Are in situ air pattern analyses via smoke studies conducted at the critical area to demonstrate unidirectional airflow and sweeping action under dynamic conditions?	Yes		5.1
	Types of PECs and Placement:			5.1
89.00	Does the placement of the PEC allow for cleaning around the PEC?	Yes		5.1
90.00	**Laminar airflow workbench (LAFW):** Does a LAFW used for preparing radiopharmaceuticals provide vertical unidirectional HEPA-filtered airflow?	Yes		5.1
91.00	In cases where the LAFW is located within the segregated containment area of a hot-cell, it is acceptable for a horizontal unidirectional HEPA-filtered airflow pattern to be utilized.	Yes		5.1
92.00	**Placement of PEC:** Is the PEC located out of traffic patterns and away from area air currents that could disrupt the intended airflow patterns inside the PEC?	Yes		5.1

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		Observations	Notes	USP Reference(s)
92.01	If used only to prepare, prepare with minor deviations, dispense, or repackage sterile radiopharmaceuticals the ISO Class 5 PEC may be placed in an unclassified SRPA.	N/A	There is no SRPA.	5.1
92.02	If used to compound sterile radiopharmaceuticals, the PEC is located within an ISO Class 7 or better buffer area with an ISO Class 8 or better anteroom.	Yes		5.1
93.00	Is a dynamic airflow smoke pattern test performed initially and at least every 6 months to ensure that the PEC is properly placed into the facility and that workers understand how to utilize the unidirectional airflow to maintain first air as much as possible given the limitations added from the radiation shielding in the DPA?	Yes		5.1
	Air-Exchange Requirements		***Note to Inspector:*** *Airflow is measured in terms of the number of HEPA-filtered air changes per hour (ACPH). SRPA do not have an ACPH requirement.*	
94.00	For ISO-classified rooms, does the total ACPH maintain the ISO class under dynamic operating conditions?	Yes		
95.00	Are at least 15 ACPH of the total air change rate in a room come from the HVAC through HEPA filters located in the ceiling?	Yes		
96.00	Is there a minimum of 30 total HEPA-filtered ACPH supplied to ISO Class 7 areas?	Yes		
96.01	Does HEPA-filtered air from the PEC, added to the HVAC-supplied HEPA-filtered air, increase the total HEPA-filtered ACPH to at least 30 ACPH?	Yes		

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		Observations	Notes	USP Reference(s)
96.02	If the PEC is used to meet the minimum total ACPH requirements, is the PEC not turned off except for maintenance?	Yes		
96.03	Are both the ACPH from HVAC contributed from the PEC, and the total ACPH documented on certification reports?	Yes		
97.00	Is a minimum of 20 ACPH of HEPA-filtered air supplied to ISO Class 8 areas?	Yes		
97.01	Are ante-rooms where activity levels are high, required more HEPA-filtered ACPH to maintain ISO Class 8 under dynamic operating conditions?	Yes		
97.02	Are the total ACPH documented on certification reports?	Yes		
	Creating Areas to Achieve Easily Cleanable Conditions			5.2
	Classified Areas:			5.2
98.00	Are the surfaces of ceilings, walls, floors, doors, door frames, fixtures, shelving, work surfaces, counters, and cabinets in the classified area smooth, impervious, free from cracks and crevices, and non-shedding, so they can be cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate?	Yes		5.2
99.00	*Recommendation: Surfaces are resistant to damage by cleaning agents, disinfectants, and tools used to clean.*	Yes		5.2
100.00	Are junctures between the ceiling and the walls and between the wall and the floor sealed to eliminate cracks and crevices where dirt can accumulate?	Yes		5.2
101.00	If ceilings consist of inlaid panels, are each panel caulked or otherwise sealed and secured to seal them to the support frame?	Yes		5.2
102.00	Are walls constructed of or covered with a durable material (eg, epoxy-painted walls or heavy-gauge polymer) and the integrity of the surface maintained?	Yes		5.2

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		Observations	Notes	USP Reference(s)
103.00	Are panels joined together and sealed to each other and the support structure?	Yes		5.2
104.00	Do floors include coving to the sidewall or the juncture between the floor and wall are caulked?	Yes		5.2
105.00	*Recommendation: Classified areas minimize dust-collecting overhangs such as utility pipes, ledges, and windowsills.*	Yes		5.2
106.00	If overhangs or ledges are present, are they easily cleanable?	Yes		5.2
107.00	Is the exterior lens surface of ceiling light fixtures smooth, mounted flush, and sealed?	Yes		5.2
108.00	Are any other penetrations through the ceiling or walls sealed?	Yes		5.2
	SRPA:			5.2
109.00	Is the SRPA and all surfaces (eg, walls, floors, counters, equipment) within the SRPA clean, uncluttered, and dedicated to sterile radiopharmaceutical processing activities?	N/A		5.2
110.00	*Recommendation: Surfaces in the SRPA are smooth, impervious, free from cracks and crevices, and non-shedding, so they can be easily cleaned and disinfected, and to minimize spaces in which microorganisms and other contaminants can accumulate.*	N/A		5.2
111.00	*Recommendation: Surfaces are be resistant to damage by cleaning agents, disinfectants, and tools used to clean.*	N/A		5.2
112.00	*Recommendation: Dust-collecting overhangs such as utility pipes, ledges, and windowsills are minimized.*	N/A		5.2
113.00	If overhangs or ledges are present, are they easily cleanable?	N/A		5.2

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		Observations	Notes	USP Reference(s)
	Water Sources:			5.3
114.00	*Recommendation: Sinks are hands-free use with a closed system of soap (ie, non-refillable).*	Yes		5.3
115.00	In facilities with an ante room and buffer room, is the sink placed inside or outside of the ante room? *Note placement, inside or outside.*	Yes	The sink is outside of the ante room.	5.3
115.01	If the sink is located outside of the ante-room, it is located in a clean space to minimize the risk of bringing in contaminants into the anteroom.	Yes	The sink is located in a clean space and well away from the anteroom door. The sink faucet showed significant signs of rust and deterioration. Please see Photo01_Nuclear115.01	5.3
115.02	If the sink is located inside the ante-room, describe where it is located.	N/A		5.3
115.03	The buffer area does not contain plumbed water sources [eg, sink(s), eyewash(es), shower(s), or floor drain(s)].	Yes		5.3
115.04	The ante room does not contain floor drain(s).	Yes		5.3
116.00	*Recommendation: If installed, sprinkler systems in classified areas are recessed & covered and are easily cleanable.*	Yes		5.3
117.00	In facilities with a SRPA design:	[redacted]	N/A	5.3
117.01	Is the sink accessible but located at least 1 m from the PEC and generators, if present?	N/A		5.3
117.02	Is the sink not located inside the perimeter of the SRPA?	N/A		5.3

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		Observations	Notes	USP Reference(s)
	Placement and Movement of Materials:			5.4
118.00	Are only furniture, equipment, and other materials necessary permitted in the classified area or SRPA?	Yes		5.4
118.01	*Recommendation: Are furniture, equipment and materials low-shedding and easily cleaned & disinfected.*	Yes		5.4
118.02	Does the number, design, location, and manner of furniture, equipment and material installation not adversely impact environmental air quality and promote effective cleaning and disinfecting?	Yes		5.4
119.00	Are shipping carton(s) or other corrugated or uncoated cardboard not allowed in the classified area or SRPA?	Yes		5.4
120.00	Are carts used to transport components or equipment into classified areas constructed from nonporous materials with cleanable casters and wheels?	Yes		5.4
121.00	In a classified area, are carts not moved from the dirty side to the clean side of the anteroom unless the entire cart, including casters, is cleaned and disinfected?	N/A	Carts are not used to move materials in the anteroom. Carts are dedicated to the clean room only.	5.4
122.00	Are all items wiped with low-lint wipers and an appropriate disinfectant by personnel wearing gloves before they are brought into the clean side of ante-room(s), pass-through(s), into an SRPA or into an ISO 5 PEC?	Yes		5.4

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		Observations	Notes	USP Reference(s)
	Classified Areas:			5.5
123.00	Are activities and tasks carried out within the buffer area limited to only those necessary?	Yes		5.5
124.00	Are food and drinks exposed in patient care and treatment areas not in the ante-rooms or buffer areas?	N/A	There are no patient care and treatment areas.	5.5
125.00	When processing activities require the manipulation of blood-derived or other biological material (eg, radiolabeling patient's or donor's blood cells) do the following occur?	Yes		5.5
125.01	Are the manipulations clearly separated from routine material-handling procedures and equipment used in radiopharmaceutical preparation activities?	Yes		5.5
125.02	Are manipulations controlled by specific SOPs to avoid any cross-contamination?	Yes		5.5

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		Observations	Notes	USP Reference(s)
	Remote Aseptic Processing Involving a Hot-Cell:		*Note to Inspector: In settings where tasks are carried out within the hot-cell enclosure not within an ISO-classified space by remote means (ie, no direct intervention by personnel into the ISO Class 5 space), it is not necessary for personnel to don the garbing described in this chapter for that environment to carry out these aseptic manipulations or to perform other routine tasks in the general area where the hot-cell is located.*	5.6
126.00	Does a hot-cell device provide an inherent physical segregation for the ISO Class 5 aseptic processing area?	N/A	There is no hot cell in this facility.	5.6
127.00	If the hot-cell is located in an ISO-classified space, do personnel garb according to requirements of <825> for that environment?	N/A		5.6
128.00	If hand and arm incursions into the interior of the hot-cell occur causing personnel to stage the required materials and supplies, do personnel garb in relation to the contamination risk associated with the individual hot-cell/ISO Class 5 relationship?	N/A		5.6
129.00	For situations where a PEC device is located within a hot-cell, all the following apply:	N/A		5.6
129.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials in the demarcated PEC area does not allow the influx of unclassified air into the PEC?	N/A		5.6
129.02	For interventions that are outside of the PEC, do personnel garb in nonsterile gloves and a low-particulate lab coat?	N/A		5.6
129.03	If the hot-cell has failed the airflow smoke pattern test, are personnel required to garb differently?	N/A		5.6
130.00	For situations where the hot-cell is an integrated HEPA filtration system with a clear demarcated area that is a PEC, the following apply:	N/A		5.6
130.01	Do dynamic airflow smoke pattern tests show that the staging of supplies and materials into the demarcated PEC area does not allow the influx of less than ISO Class 5 quality air into the PEC?	N/A		5.6

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Nuclear Pharmacy Inspection

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Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
130.02	If a failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the PEC.	N/A		5.6
131.00	For other hot-cell/PEC configurations and technologies that may exist, the following apply:	N/A		5.6
131.01	Does verification (either by airflow smoke pattern tests or other manufacturer specified methods) ensure, upon each certification, that the staging of materials and supplies does not allow for the intrusion of less than ISO Class 5 air into the designated ISO Class 5 space?	N/A		5.6
131.02	Does failure of the airflow smoke pattern test require personnel to garb in accordance with 4.5 Hand Hygiene and Garbing for Buffer Areas and Segregated Radiopharmaceutical Processing Area for all incursions into the hot-cell?	N/A		5.6
	Environmental Controls:			5.7
132.00	Do all RAM users comply with the conditions specified in their approved RAM license application and regulations, and RAM license conditions may supersede the following requirements for environmental controls? Refer to the RAM license for pressure requirements, as applicable.	Yes		5.7
133.00	Do positive pressure environments have a minimum differential positive pressure of 0.02-inch water column between each ISO-classified area (eg, between the buffer area and ante-room)?	Yes		5.7
134.00	Is the pressure differential between the ante-room and the unclassified area no less than a positive 0.02-inch water column?	Yes		5.7
134.01	Is the buffer area, if present, positive pressure compared to the ante-room?	Yes		5.7

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		Observations	Notes	USP Reference(s)
134.02	Is the ante-room, if present, positive pressure compared to unclassified portions of the restricted area?	Yes		5.7
135.00	Is the restricted area, in the presence of volatile or airborne radiopharmaceuticals, negative pressure compared to the unrestricted area?	Yes		5.7
136.00	Is the SRPA negative pressure compared to unrestricted areas in the presence of volatile or airborne radiopharmaceuticals (eg, I-131 sodium iodide and Xe-133 gas)?	N/A	There is no SRPA.	5.7
	Establishing and Maintaining Pressure Differentials:			5.7
137.00	Any time a pressure differential is required, is there a pressure monitoring device?	Yes		5.7
138.00	In a classified area, is a pressure differential monitoring system used to continuously monitor the pressure differential between the ante-room(s) and buffer area(s) and between the ante- room and the general environment outside the classified area(s) or area(s)?	Yes		5.7
139.00	Are the results from the pressure monitoring system reviewed and documented at least daily on days the area is used?	Yes		5.7
140.00	All pressure monitoring devices are tested for accuracy and required performance at least every 6 months.	Yes		5.7

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		Observations	Notes	USP Reference(s)
	Ambient Atmosphere for Immediate Use Preparations:			5.7
141.00	All of the following requirements met in ambient atmosphere environments:	N/A		5.7
141.01	Is non-patient care space, functionally separate (not necessarily a different area) from the patient care area, such as a radiopharmaceutical handling space, or hot lab, in a hospital, clinic, or mobile coach?	N/A		5.7
141.02	Is there a designated area for medication preparation that is clean and free from clutter?	N/A		5.7
141.03	Is it a low traffic area (ie, limited number of people going in and out or moving around the area during times that radiopharmaceutical processing is being carried out)?	N/A		5.7
	SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations:			5.7
142.00	Does the SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations meet the following requirements?	N/A		5.7
142.01	Area surrounding the PEC may be ambient (unclassified) atmosphere.	N/A		5.7
142.02	Area is clean, uncluttered, and dedicated to the processing of radiopharmaceuticals.	N/A		5.7
142.03	Appropriate for preparation, preparation with minor deviations, repackaging, and dispensing of radiopharmaceuticals.	N/A		5.7
142.04	An area that is used to store and elute non-direct infusion radionuclide generators (eg, Tc-99m) must meet ISO Class 8 total airborne particle-count specifications.	N/A		5.7

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		Observations	Notes	USP Reference(s)
	An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector** : Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
143.00	ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	N/A	The anteroom is ISO Class 7.	5.7
	An ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room:		***Note to Inspector** : Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
144.00	ISO Class 7 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room environment is appropriate for all activities listed in An ISO Class 8 Buffer Area with Vertical Flow ISO Class 5 PEC(s) with an Adjacent ISO Class 8 Ante-Room and sterile compounding.	N/A	The anteroom is ISO Class 7.	5.7
	Hot-Cell:		***Note to Inspector** : Activities - preparation, preparation with minor deviations, repacking, and dispensing of radiopharmaceuticals; storage & elution of non-direct infusion radionuclide generators.*	5.7
145.00	Hot-Cell environment is appropriate for all activities listed in SRPA with Vertical Flow ISO Class 5 PEC(s) for Radiopharmaceutical Preparations.	N/A	There is no hot cell.	5.7
	Certification of PEC and Environment in which the PEC is located:			5.7
146.00	Certification of the classified areas, including the PEC, is performed initially.	Yes		5.7
147.00	Recertification is performed at least every 6 months.	Yes		5.7
148.00	Procedures outlined in the current CETA certification guide for Sterile Compounding Facilities, or an equivalent guideline, are followed.	Yes		5.7

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		Observations	Notes	USP Reference(s)
149.00	Airflow testing is performed to determine acceptability of the air velocity, the air exchange rate, and area pressure cascade to ensure that air consistently flows from most to least clean areas, and that the appropriate quality of air is maintained under dynamic operating conditions.	Yes		5.7
150.00	HEPA filter integrity testing is performed (HEPA filters are leak tested after installation and as part of recertification).	Yes		5.7
151.00	Total Particle Counts testing is performed and conducted under dynamic operating conditions using calibrated electronic equipment.	Yes		5.7
152.00	Smoke Visualization Studies are performed under either simulated or dynamic operating conditions to demonstrate unidirectional airflow and sweeping action over and away from the preparation(s).	Yes		5.7
153.00	Are other equivalents for certifying the PEC performed and documented per facility SOPs, in cases where technologies exist for hot-cell and PEC configurations that are not consistent for certification by the current CETA standards?	N/A		5.7
154.00	In this case, the PEC maintains the environmental equivalent for total particle counts and the protection of the ISO Class 5 area from intrusions of lesser controlled air.	N/A		5.7
	Daily Monitoring of Environment:			5.7
155.00	The temperature and humidity is monitored in the SRPA or area containing a hot-cell, and if in a classified area the pressure is monitored, each day that radiopharmaceutical handling occurs, either manually or by a continuous recording device.	Yes	This is performed manually.	5.7
156.00	Does Monitoring include the following?	Yes		5.7
156.01	*Recommendation: Relative humidity is kept at 60% or lower*	Yes		5.7

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		Observations	Notes	USP Reference(s)
156.02	Are temperature continuous readings confirmed daily to have remained within the acceptable range?	Yes		5.7
156.03	Are relative humidity continuous readings confirmed daily to have remained within the acceptable range?	Yes		5.7
156.04	Are excursion documented and, if applicable, appropriate corrective actions taken?	Yes		5.7
156.05	Are temperature monitoring devices verified for accuracy every 12 months or as required by the manufacturer?	Yes		5.7
156.06	Are monitoring of pressure differentials performed?	Yes		5.7
	Microbial Air and Surface Monitoring:			6
157.00	Has the pharmacy developed and implemented written air and surface monitoring procedures for all sterile radiopharmaceutical classified areas?	Yes		6
158.00	Are air and surface monitoring results and the corrective actions documented, and records readily retrievable as required by jurisdictional laws and regulations?	Yes		6
	General Monitoring Requirements:			6.1
159.00	Is the air and surface monitoring program clearly described in the established SOPs of the facility and include a diagram of the sampling locations, SOPs for collecting samples, frequency of sampling, size of samples (eg, surface area, volume of air), time of day of sampling in relation to activities in the classified areas, and action levels that will trigger corrective action?	Yes		6.1
159.01	Are samples obtained from locations that pose the highest possible contamination risk to the sterile radiopharmaceuticals involved with the operation's processes and are likely to be representative of the conditions throughout the area?	Yes		6.1

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160.00	Are personnel who operate the equipment trained in the proper operation of the air and surface sampling equipment to ensure accurate and reproducible sampling?	Yes		6.1
161.00	Are all air sampling devices serviced and calibrated as recommended by the manufacturer?	Yes		6.1
162.00	Does the microbiological air and surface monitoring program include viable impact volumetric airborne particulate sampling and surface sampling?	Yes		6.1
163.00	Are air and surface sampling performed initially for PECs & classified areas in a facility to establish a baseline level of environmental quality?	Yes		6.1
164.00	After initial sampling, are the PECs & classified area(s) monitored according to the minimum frequencies?	Yes		6.1
165.00	Are air and surface sampling conducted during actual or simulated dynamic operating conditions to confirm that the required environmental quality in classified areas is maintained?	Yes		6.1
166.00	Is sampling carried out at the conclusion of sterile radiopharmaceutical processing but prior to cleaning and disinfecting the surface area?	Yes		6.1
167.00	Is sampling performed in all of the following circumstances?	Yes		6.1
167.01	In conjunction with the certification of new facilities and equipment?	Yes		6.1
167.02	After any modification of facilities or equipment	Yes		6.1
167.03	In response to identified problems (eg, positive growth in sterility tests of compounded radiopharmaceuticals)?	Yes		6.1

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		Observations	Notes	USP Reference(s)
167.04	In response to identified trends (eg, repeated positive gloved fingertip sampling results or failed media-fill testing involving more than one operator where a review of the operator technique shows no reasonable flaws in process; repeated observations of air or surface contamination)?	Yes		6.1
167.05	In response to changes that could impact the controlled area environments (eg, significant change in cleaning process or the agents involved)?	Yes		6.1
168.00	Is regular review of the sampling data performed to detect trends such as elevated levels of microbial bioburden, elevated levels of nonviable particulates, or other adverse changes within the environment?	Yes		6.1
169.00	Are results reviewed in conjunction with personnel data (ie, training records, visual observations, competency assessments) to assess the state of control and to identify potential risks of contamination?	Yes		6.1
170.00	Is Prompt corrective action in response to any adverse findings taken to maintain the necessary environmental quality for handling sterile radiopharmaceutical?	Yes		6.1
171.00	Is data also reviewed following corrective actions to confirm that the actions taken have been effective in achieving the required air and surface quality levels?	Yes		6.1
	Monitoring Air Quality for Viable Airborne Particles:			6.2
	Viable Air Sampling: Timing and Locations			6.2
172.00	Volumetric active air sampling of all classified areas (eg, ISO Class 5 PEC and ISO Class 7 and 8 areas) using an impaction device are conducted during dynamic operating or simulated operating conditions at least every 6 months.	Yes		6.2
173.00	Does viable air sampling include the following?	Yes		6.2

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		Observations	Notes	USP Reference(s)
173.01	Following the manufacturer's instructions for operation of the air sampling device, including placement of media?	Yes		6.2
173.02	Using the sampling device, test at least 1 cubic meter or 1000 liters of air from each location sampled?	Yes		6.2
173.03	At the end of the sampling, retrieve the media plates/devices and cover?	Yes		6.2
173.04	Inverting the media and incubate at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (ie, viable air). Include sample location and date?	Yes		6.2
173.05	Incubates the inverted media at 20°–25° C for no less than 5 additional days? Examines the media plates for growth? Records the total number of discrete colonies of microorganisms on each plate as cfu/m3 of air on an environmental sampling form based on sample type (ie, viable air)? Includes sample location and date?	Yes		6.2
174.00	To shorten the overall incubation period, can two samples be collected for each sample location and incubated concurrently?	No	The two-sample procedure is not used.	6.2
175.00	Both samples could be TSA, or one sample could be TSA and the other fungal media [eg, malt extract agar (MEA) or sabouraud dextrose agar (SDA)]. Describe samples in notes.	N/A		6.2
176.00	Each sample is incubated in a separate incubator.	N/A		6.2
177.00	One sample is incubated at 30°–35°C for no less than 48 hours and the other sample is incubated at 20°–25° C for no less than 5 days.	N/A		6.2

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178.00	Fungal media samples are incubated at 20°–25° C for no less than 5 days.	N/A		6.2
179.00	The count of the total number of discrete colonies of microorganisms are done on each sample and these results are recorded as cfu per sample.	N/A		6.2
180.00	Are the results of the sampling recorded on an environmental sampling form based on sample type (ie, viable air) and include the sample location, and sample date?	N/A		6.2
181.00	Are general microbiological growth medium that supports the growth of bacteria and fungi used (eg, TSA medium)?	Yes		6.2
182.00	Do CoA(s) from the manufacturer verify that the medium meets the expected growth promotion, pH, and sterilization requirements?	Yes		6.2
183.00	Are samples incubated in a temperature monitored incubator with a calibrated measuring device?	Yes		6.2
184.00	Is the incubator temperature monitored during incubation, either manually or by a continuous recording device, and the results reviewed and documented?	Yes	Monitoring is manual.	6.2
185.00	Are the incubators used for microbiological testing placed in a location outside of any classified area or SRPA and kept away from areas where compounding or sterile processing activities are carried out?	Yes		6.2

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	Data Evaluation and Action Levels:			6.2
186.00	Air Sampling Action Levels (cfu/cubic meter (1000L) of air per plate) are within the appropriate range: *ISO Class 5 - >1* *ISO Class 7 - >10* *ISO Class 8 - >100*	Yes		6.2
187.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Yes		6.2
187.01	If two pieces of media were collected at a single location, are all recovered growth documented and action levels are applied individually to each plate/device (ie, results from each cubic meter of air sampled are compared to the action level for that area)?	N/A		6.2
188.00	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?	Yes		6.2
188.01	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Yes		6.2
188.02	If levels measured during viable air sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?	Yes		6.2
188.03	Is the corrective action plan documented?	Yes		6.2
188.04	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Yes		6.2

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		Observations	Notes	USP Reference(s)
	Monitoring Surfaces for Viable Particles:			6.3
189.00	Are all sampling sites and procedures described in the facility's SOP?	Yes		6.3
	Surface Sampling: Timing and Locations			6.3
190.00	Is surface sampling of all classified areas and all PECs conducted at least monthly for the detection of microbial contamination?	Yes		6.3
191.00	Is each classified area sampled?	Yes		6.3
192.00	Is the DPA of the PEC, and any equipment permanently contained in the PEC, sampled?	Yes		6.3
193.00	Are work surfaces in classified areas near the PEC, frequently touched surfaces in classified areas, and pass-through enclosure(s) for all classified areas evaluated to determine the locations that pose the greatest risk of harboring microbial contamination?	Yes		6.3
194.00	Is surface sampling performed at the end of the radiopharmaceutical aseptic activities or shift, but before the area has been cleaned and disinfected?	Yes		6.3
195.00	Do radiopharmaceutical personnel consider the appropriate exposure and contamination prevention measures prior to and while collecting samples?	Yes		6.3
196.00	If the worker assesses that the risk for exposure is not in conformance with ALARA safety standards, are measures taken to eliminate the risk (eg, implementation of appropriate shielding, performing the sampling at a later time or alternate day)?	Yes		6.3

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		Observations	Notes	USP Reference(s)
	Sampling Procedures:			6.3
197.00	Are surface sampling devices (eg, plates, paddles, or slides) containing microbial growth media used for sampling flat surfaces?	Yes		6.3
198.00	Are CoAs from the manufacturer verified that the media meet the expected growth promotion, pH, and sterilization requirements?	Yes		6.3
199.00	Do surface sampling devices contain general microbial growth media (eg, TSA) supplemented with neutralizing additives (eg, lecithin and polysorbate 80) to neutralize the effects of any residual disinfecting agents?	Yes		6.3
200.00	If used, do contact plates have a raised convex surface?	Yes		6.3
201.00	Are sterile swabs wetted with sterile water or a sterile neutralizing buffer used when sampling irregular surfaces and difficult-to-reach locations, such as crevices, corners, and spaces between surfaces?	No		6.3
202.00	After sampling, is the sampled area thoroughly cleaned and disinfected?	Yes		6.3
203.00	Are the following procedures for surface sampling on flat surfaces used?	Yes		6.3
203.01	Remove the cover from the surface sampling device. Firmly press, using a rolling motion, if possible, the media surface onto the surface to be sampled. The surface sampling device will leave a residue of growth medium on the sample site. After sampling, use sterile 70% IPA to remove residue. Cover each surface sampling device.	Yes		6.3
203.02	If using plates, invert the plates.	Yes		6.3

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Nuclear Pharmacy Inspection

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Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
203.03	Incubate the surface sampling devices at 30°–35° C for no less than 48 hours. Examine for growth. Record the total number of discrete colonies of microorganisms on each media device as cfu/sample on an environmental sampling form based on sample type (ie, surface). Include sample location and date.	Yes		6.3
203.04	Incubate the sampling device at 20°–25° C for no less than 5 additional days. Examine the media plates for growth. Record the total number of discrete colonies of microorganisms (cfu/sample) on the environmental sampling record based on sample type (ie, surface). Include sample location and date.	Yes		6.3
204.00	Does the facility use two samples for each sampling location?	No		6.3
204.01	Are both TSA?	N/A		6.3
204.02	Is one TSA and one Fungal?	N/A		6.3
204.03	Is each sample incubated in a separate incubator?	N/A		6.3
204.04	Is one sample media incubated at 30°–35° C for no less than 48 hours?	N/A		6.3
204.05	If fungal media are used as one of the samples, is it fungal media sample incubated the at 20°–25° C or no less than 5 days?	N/A		6.3
204.06	Are the total number of discrete colonies of microorganisms on each sample counted as cfu per sample?	N/A		6.3
204.07	Are the results of the sampling recorded?	N/A		6.3

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		Observations	Notes	USP Reference(s)
	Data Evaluation and Action Levels:			6.3
205.00	Surface Sampling Action Levels (cfu/device or swab) are within the appropriate range: *ISO Class 5 - >3* *ISO Class 7 - >5* *ISO Class 8 - >50*	Yes		6.3
206.00	Are cfu counts evaluated against the action levels and in relation to previous data to identify adverse results and/or trends?	Yes		6.3
206.01	If two pieces of media were collected at a single location, is all recovered growth on each documented and action levels are applied to each piece of media individually (ie, results from each sampling device are compared to the action level for that area)?	N/A		6.3
207.00	If levels measured during the viable air monitoring program exceed the action levels for the ISO classification levels of the area sampled, is the cause investigated, and corrective action is taken?	Yes		6.3
207.01	Is data collected in response to corrective actions reviewed to confirm that the actions taken have been effective?	Yes		6.3
207.02	Is the corrective action plan dependent on the cfu count and the microorganism recovered?	Yes		6.3
207.03	If levels measured during surface sampling exceed the levels, is an attempt made to identify any microorganism recovered to the genus level with the assistance of a qualified individual?	Yes		6.3
207.04	Is the corrective action plan documented?	Yes		6.3
207.05	*Recommendation: The extent of the investigation is consistent with the deviation and includes an evaluation of trends.*	Yes		6.3

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		Observations	Notes	USP Reference(s)
	Cleaning and Disinfecting			7
208.00	Are all cleaning and disinfecting activities performed by trained and appropriately garbed personnel using facility approved agents and procedures described in written SOPs?	Yes		7
209.00	Is cleaning performed in the direction of most to least clean areas?	Yes		7
210.00	Are the frequency, method(s), and location(s) of cleaning, disinfecting, and sporicidal agent use established in written SOPs, in accordance with the manufacturer's instructions when available, or based on sound microbiological cleaning techniques when unavailable, and followed by all cleaning personnel?	Yes		7
210.01	Is the manufacturer's direction or published data for the minimum contact time followed for the cleaning, disinfecting, and sporicidal agents used?	Yes		7
210.02	When sterile 70% IPA is used, is it allowed to dry?	Yes		7
211.00	Are all cleaning, disinfecting, and application of sporicidal agents documented according to facility SOPs?	Yes		7
212.00	Are surfaces cleaned prior to being disinfected unless an Environmental Protection Agency (EPA)-registered (or equivalent) one-step disinfectant cleaner is used to accomplish both the cleaning and disinfection in one step?	Yes	One-step Envirocide Surface Disinfectant Cleaner is used.	7
212.01	After cleaning and disinfecting or the application of a one-step disinfectant cleaner in a PEC, is sterile 70% IPA applied to remove any residue?	Yes		7

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		Observations	Notes	USP Reference(s)
213.00	Does cleaning and disinfecting surfaces occur at the minimum frequencies in Table 5 or if activities are not performed daily, cleaning and disinfecting completed before initiating activities?	Yes		7
214.00	Is the act of reducing or removing radioactivity (radioactive decontamination) from an object or surface balanced with the risk of spreading radioactive contamination?	Yes		7
214.01	*Recommendation: Areas shielded until radiation exposure levels lowered.*	Yes		7
214.02	Is this balance specified in SOPs (eg, trigger levels for safe cleaning)?	Yes		7
214.03	*Recommendation: The PEC is checked for radioactive contamination prior to cleaning and disinfecting to prevent spreading radioactive contamination in the PEC.*	Yes		7
	Minimum Frequency for Cleaning and Disinfecting Surfaces in Classified Areas and within the perimeter of the SRPA:			7
215.00	Does Cleaning of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occurs in the following situations?	Yes		7
215.01	Prior to performing sterile processing of radiopharmaceuticals on each day that activities are carried out, are the walls, bars, torso shield and any exposed surface of equipment inside the PEC cleaned to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (eg, microbiologist or industrial hygienist)?	Yes		7
215.02	Is radioactive contamination shielded with appropriate temporary material, providing the material is covered with low-lint absorbent pads or has equivalent low shedding properties?	Yes		7

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		Observations	Notes	USP Reference(s)
216.00	Does disinfecting of the PEC(s) and equipment inside the PEC(s) and/or PEC and the equipment inside the PEC(s) located in a hot-cell occur in the following situations?	Yes		7
216.01	Following cleaning on each day that activities are carried out, are exposed surfaces of the equipment disinfected to the extent possible as specified by the equipment manufacturer or the assessment of a qualified individual (eg, microbiologist or industrial hygienist)?	Yes		7
216.02	When used, are low-lint absorbent pads removed and the PEC surveyed for radioactive contamination prior to disinfecting?	Yes		7
216.03	Are new pads replaced after disinfecting or as required after spills?	Yes		7
217.00	Does Cleaning and Disinfecting occurs **DAILY** for the following?	Yes		7
217.01	PEC(s) and equipment inside the PEC(s)	Yes		7
217.02	Surface of sink(s)	Yes		7
217.03	PEC and equipment inside the PEC(s) located in a hot cell.	N/A		7
217.04	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	N/A		7
217.05	Work surface(s) outside the PEC	Yes		7
217.06	Floor(s)	Yes		7
218.00	Does Cleaning and Disinfecting occurs **MONTHLY** for the following?	Yes		7

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		Observations	Notes	USP Reference(s)
218.01	Ceiling(s)	Yes		7
218.02	Wall(s), door(s), door frame(s), and other fixtures	Yes		7
218.03	Storage shelving and storage bins	Yes		7
219.00	Does Sporicidal application occurs **MONTHLY** for the following?	Yes		7
219.01	PEC(s) and equipment inside the PEC(s)	Yes		7
219.02	Surface of sink(s)	Yes		7
219.03	Hot-cells (all interior surfaces, dependent on design, equipment, and shielding present)	N/A		7
219.04	PEC and the equipment inside the PEC(s) located in a hot-cell	N/A		7
219.05	Work surface(s) outside the PEC	Yes		7
219.06	Ceiling(s)	Yes		7
219.07	Wall(s), door(s), door frame(s), and other fixtures	Yes		7
219.08	Floor(s)	Yes		7
219.09	Storage shelving and storage bins	Yes		7

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		Observations	Notes	USP Reference(s)
	Cleaning, Disinfecting and Sporicidal Agents:		***Note to Inspector**: Some EPA-registered (or equivalent) one-step disinfectant cleaners may have sporicidal properties.*	7.1
220.00	Are cleaning and disinfecting agents selected and used with careful consideration of compatibilities, effectiveness, and user safety?	Yes	All agents used are determined by corporate.	7.1
221.00	Are considerations when selecting and using disinfectants include their anti-microbial activity, inactivation by organic matter, residue, shelf life, preparation requirements of the agent, and suitability for surfaces being disinfected?	Yes		7.1
221.01	After the disinfectant is applied on the surface to be disinfected, is the disinfectant allowed to dwell for the minimum contact time specified by the manufacturer, during which time the surface cannot be disturbed?	Yes		7.1
222.00	Is only sterile 70% IPA used in the ISO Class 5 PEC?	Yes		7.1
223.00	Are sporicidal agents used at least monthly on all surfaces in classified areas and SRPAs?	N/A	There is no SRPA.	7.1
	Cleaning Supplies:			7.2
224.00	Are all cleaning supplies (eg, wipers and mop heads), with the exception of tool handles and holders, low-lint?	Yes		7.2
225.00	*Recommendation: All cleaning supplies (eg, wipers and mop heads), with the exception of tool handles and holders are disposable.*	Yes		7.2

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		Observations	Notes	USP Reference(s)
225.01	If disposable cleaning supplies are used, are they discarded after each cleaning activity?	Yes		7.2
226.00	Are reusable cleaning tools made of cleanable materials (eg, no wooden handles) and are cleaned and disinfected before and after each use?	Yes	All are stainless steel.	7.2
227.00	Are reusable cleaning tools dedicated for use in the classified areas or SRPAs and are not removed from these areas except for disposal?	yes		7.2
228.00	Are reusable cleaning tools discarded after an appropriate amount of time, to be determined based on the condition of the tools?	yes	Only handles and heads are reusable and are made of stainless steel.	7.2
229.00	*Recommendation: Cleaning supplies and solutions used in the classified areas and SRPAs are be monitored for radioactive contamination after use and prior to disposal, as per facility SOPs.*	Yes		7.2
230.00	Are cleaning supplies used in the classified areas and SRPAs disposed in a manner that minimizes the potential for dispersing particulates into the air (eg, with minimal agitation, away from work surfaces)?	Yes		7.2
	Cleaning and Disinfecting the PEC:			7.3
231.00	Is the PEC cleaned and disinfected at the minimum frequencies specified in Table 5?	Yes		7.3
232.00	If the PEC contains a removable work tray, are all sides of the work tray and the area underneath the work tray cleaned and disinfected at least monthly?	N/A	There is no removable work tray.	7.3

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		Observations	Notes	USP Reference(s)
233.00	If necessary are all surfaces of the PEC surveyed for radioactive contamination and follow facility SOPs to decontaminate?	Yes		7.3
234.00	If necessary, any particles, debris, or residue removed with an appropriate solution (eg, Sterile Water for Injection or Sterile Water for Irrigation) using sterile, low-lint wipers?	Yes		7.3
235.00	Is a cleaning agent applied followed by a disinfecting agent or an EPA-registered (or equivalent) one-step disinfectant cleaner and ensure that the contact time specified per manufacturer instructions is achieved?	Yes		7.3
236.00	Is sterile 70% IPA applied?	Yes		7.3
237.00	Are the surfaces allowed to dry completely before beginning activities?	Yes		7.3
238.00	Is the PEC wiped with a sporicidal agent at least monthly?	Yes		7.3
	Disinfecting Supplies for Classified Areas and SRPAs:			7.4
239.00	Are shipping carton(s) or other corrugated or uncoated cardboard prohibited in the classified area (eg, clean side of ante-room) or within the perimeter of the SRPA?	Yes		7.4
240.00	Before items are introduced into a classified area or SRPA, are they wiped with a sporicidal agent, EPA-registered (or equivalent) one-step disinfectant cleaner, or sterile 70% IPA using low-lint wipers?	Yes	Oxivir 1, a disinfectant cleaner is used, followed by sterile 70% IPA.	7.4

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		Observations	Notes	USP Reference(s)
241.00	After the sporicidal or sterile disinfectant is applied onto the surface, is the agent allowed to dwell on the surface for the minimum contact time specified by the manufacturer?	Yes		7.4
241.01	Is the agent used for disinfecting the packaging compatible with the packaging and not render the product label unreadable?	Yes		7.4
242.00	Are any items to be transferred into the PEC from the classified area or SRPA disinfected with a sterile disinfectant (eg, sterile 70% IPA)?	Yes		7.4
243.00	If radiopharmaceuticals are being processed by remote means in a hot-cell, the opening of sterile packages (eg, syringes, luer lock caps) may not be possible by remote means within the ISO Class 5 area.	[redacted]	N/A	7.4
243.01	In this case, are the syringes opened and appropriately labeled outside of the ISO Class 5 environment and placed in disinfected shielding, immediately prior to the forthcoming dispensing cycle?	N/A		7.4
	Disinfecting Critical Sites:			7.5
244.00	Are critical sites (eg, vial stoppers) wiped with sterile 70% IPA? Note: If the vial shield top is then closed, the septum is disinfected again with sterile 70% IPA prior to another needle puncture.	Yes		7.5
245.00	Is the critical site wiped ensuring that both chemical and mechanical actions are used to remove contaminants?	Yes		7.5
246.00	Is the sterile 70% IPA allowed to dry before piercing critical sites?	Yes		7.5
247.00	Is the septum wiped with sterile 70% IPA frequently whenever multiple punctures are occurring (eg, removing several individual doses from a multiple-dose container)?	Yes		7.5

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		Observations	Notes	USP Reference(s)
	Cleaning and Disinfecting Items from Patient Care Area:			7.6
248.00	Is radiation shielding and equipment used in the classified area/SRPA or PEC that is exposed to patient care areas during the process of administration cleaned and disinfected before returning to any classified area (eg, buffer or ante-room) or SRPA in accordance with the Centers for Disease Control and Prevention Guidelines 1 classified as noncritical equipment requiring low-risk disinfection?	N/A	There is no patient care area.	7.6
249.00	Are syringes that have been used in a patient care area not brought back into the classified area (eg, buffer or ante-room) or SRPA for re-assaying or disposal unless the syringe is sealed inside an impervious container (eg, sealed plastic bag) that is disinfected prior to entry into the classified area or SRPA?	N/A		7.6
250.00	Is equipment that has been exposed to needles and syringes contaminated with blood-borne pathogens and RAMs considered mixed waste (eg, syringe shields and syringe carrying containers)?	N/A		7.6
250.01	Is this equipment cleaned and disinfected through actions regulated by the facility's SOPs?	N/A		7.6
250.02	Is equipment that contained or was in contact with mixed waste cleaned and disinfected with an appropriate agent(s) for blood?	N/A		7.6
	Assigning BUDs:			8
251.00	Does the pharmacy have policies and SOPs appropriate to the assignment of BUD and maintain documentation of applicable study results and calculations?	Yes	All BUDs are assigned by corporate.	8
252.00	*Recommendation: Studies of radiolabeling efficiency and radiochemical stability employ quality control (QC) testing methods described in the manufacturer's package insert, USP monographs and general chapters, or other equivalent testing methods and are sufficiently rigorous to allow statistical confidence in the results.*	Yes		8

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253.00	Does the pharmacy have SOPs to collect and evaluate complaints associated with the use of radiopharmaceuticals having assigned BUDs?	Yes		8
254.00	*Recommendation: Policies and SOPs are also in place to reevaluate the assigned BUD based on complaints, which may include repeating studies and/or performing additional studies on radiolabeling efficiency and/or radiochemical stability.*	Yes		8
255.00	Does the individual responsible for the manipulation assign the BUD based on established testing data, either performed in-house or obtained from peer reviewed literature?	No	All BUDs are assigned by corporate.	8
256.00	Preparation Conditions for Sterile Radiopharmaceuticals: *Describe condition used at the pharmacy in notes section (Table 7).*	[redacted]	Dispensing, repackaging, preparation, preparation with minor deviations, and compounding using sterile components are completed in an ISO Class 5 PEC with an ISO Class 7 buffer room and anteroom. Radiolabeled blood components are manipulated in an ISO Class 5 BSC with an ISO Class 7 buffer room and anteroom.	8
257.00	For compounded preparations (sterile and nonsterile) plus preparations with minor deviations, is BUD dependent on maintenance of quality and purity including radiochemical purity, radionuclidic purity and other applicable parameters as specified in individual monographs or as clinically appropriate?	Yes		8
258.00	Assignment of BUD for a radiopharmaceutical considers several factors, as appropriate. Issues of concern include all but are not limited to the following:	Yes		8
259.00	*Recommendation: The assigned BUD does not exceed the sterility-related times listed in Table 7 unless a longer time is justified by Sterility tests per <71>.*	Yes		8
260.00	Radiochemical Purity - Is the assigned BUD based on stability studies in which these variables are controlled and are representative of the conditions of actual use?	Yes		8
261.00	*Recommendation: For factors that allow a range of values (eg, storage temperature, quantity of radioactivity, radioactivity concentration), studies are conducted at the extreme of the ranges.*	Yes		8

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262.00	Radionuclidic purity - USP monographs for Tc-99m radiopharmaceuticals require that the radionuclidic impurity Mo-99 not exceed 0.15 µCi Mo-99 per mCi Tc-99m at the time of administration.	Yes		8
263.00	Are calculations of radionuclidic purity at future times necessary to ensure compliance throughout the assigned BUD?	Yes		8
264.00	Age of the generator eluate - Extension of the BUD for Tc-99m pertechnetate intended for radiolabeling of kits take into account the build-up of Tc-99 and peroxides over time.	Yes		8
265.00	Number of particles - For radiolabeled particulates, the number of particles per unit radioactivity increases over time as the radionuclide decays. Calculation of the number of MAA particles in the patient dose is conducted to ensure compliance with the prescribed particle range throughout the assigned BUD.	Yes		8
266.00	Specific Activity - For some receptor-based radiopharmaceuticals, the mass quantity may influence uptake. In such situations, the assigned BUD ensures that the patient dose contains no more than the specified mass.	Yes		8
267.00	Container Type – The assigned BUD is determined in the proper storage container.	Yes		8
268.00	*Cell Viability – Recommendation: The assigned BUD is as short as circumstances reasonably allow so as to maximize cell viability.*	yes		8
269.00	In the case of manufactured radiopharmaceuticals that are distributed to nuclear pharmacies or other healthcare facilities for terminal distribution/dispensing, the assigned BUD of the dispensed dose cannot exceed the expiration date/time of the manufactured radiopharmaceutical(s).	yes		8
270.00	In the case of radiopharmaceuticals prepared from kits, the BUD of a dispensed dose cannot exceed the assigned BUD of the finished kit preparation.	Yes		8
271.00	A radiopharmaceutical may not exceed the shortest BUD of any of its components.	Yes		8

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
	Documentation:			9
272.00	Are applicable records (hard-copy or electronic), including policies and SOPs, maintained for all activities involved in repackaging, preparing, preparing with minor deviations, compounding, and dispensing radiopharmaceuticals?	Yes		9
273.00	Do such records include all but are not limited to the following?	Yes		9
273.01	Personnel training and testing including visual assessment of aseptic technique competency	Yes		9
273.02	Validation	Yes		9
273.03	Garbing	Yes		9
273.04	Hand hygiene	Yes		9
273.05	Equipment/environment cleaning and disinfecting	Yes		9
273.06	Gloved fingertip and thumb sampling	Yes		9
273.07	Media fill evaluation initially	Yes		9
273.08	Media fill follow up testing at specified intervals	Yes		9
273.09	Equipment maintenance and cleaning/disinfecting	Yes		9
273.10	End product radiochemical purity and other testing, as applicable, results of preparations, preparations with minor deviations, and compounded preparations	Yes		9
273.11	Master Formulation Record (MFR) for preparation with minor deviation(s) and compounding	Yes		9

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		Observations	Notes	USP Reference(s)
273.12	Validation of stability testing to support the assigned BUD from SOPs by the compounder or derived from accepted literature	Yes		9
273.13	Investigations and corrective actions and tracking of events to closure.	Yes		9
274.00	Do Testing and Monitoring of environmental controls include the following?	Yes		9
274.01	ISO classification	Yes		9
274.02	ACPH	Yes		9
274.03	Pressure differentials	Yes		9
274.04	Temperature	Yes		9
274.05	*Recommendation: Humidity*	Yes		9
274.06	Viable air	Yes		9
274.07	Viable surface	Yes		9
274.08	Total particle test results	Yes		9
	Master Formulation Record:			9.1
275.00	Preparations with minor deviations or compounding have a MFR. *Note: A MFR is not required for a preparation following the manufacturer's instructions.*	Yes		9.1
276.00	Do the elements of the MFR include at a minimum the following?	Yes		9.1
276.01	Name of the radiopharmaceutical	Yes		9.1

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		Observations	Notes	USP Reference(s)
276.02	Name or ID number, pharmacy, strength, purity, quality, and quantity of ingredients with validated documentation (eg, CoA)	Yes		9.1
276.03	Detailed procedure (eg, heating, components, incubation time)	Yes		9.1
276.04	Range of radioactivity	Yes		9.1
276.05	Range of volume	Yes		9.1
276.06	Equipment to be used	Yes		9.1
276.07	PEC and SEC to be used, if applicable	Yes		9.1
276.08	Quality control tests to be performed for final release of the radiopharmaceutical (eg, radiochemical purity, pH)	Yes		9.1
276.09	Procedures for depyrogenation and sterility procedures and validations, as applicable, including limits	N/A		9.1
276.10	Trained Personnel	Yes		9.1
276.11	Garbing procedure, if different than standard procedure	Yes		9.1
276.12	Container(s)	Yes		9.1
276.13	Reference source of the BUD assignment and storage conditions	Yes		9.1
	Records for Preparation with Minor Deviations/Compounding:			9.2
277.00	Does the record for preparation with minor deviation or compounding includes at a minimum, as applicable, the following?	Yes		9.2
277.01	Name of the radiopharmaceutical	Yes		9.2
277.02	Physical form (eg capsule or solution)	Yes		9.2

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		Observations	Notes	USP Reference(s)
277.03	Name and quantity of ingredients including calibration time for radioactive ingredients (eg, 100 mCi Tc 99m sodium pertechnetate @ 1300)	Yes		9.2
277.04	Total volume	Yes		9.2
277.05	Reference to the MFR	Yes		9.2
277.06	Any deviation from the MFR, if applicable	Yes		9.2
277.07	Name of vendor or manufacturer, lot numbers, and expiration dates of all ingredients and components	Yes		9.2
277.08	Name of the person who prepared and name of the supervising personnel (eg, ANP)	Yes		9.2
277.09	Date and time of preparation	Yes		9.2
277.10	Assigned internal identification number (eg, lot number)	Yes		9.2
277.11	Unique reference [eg, prescription, order number(s)]	Yes		9.2
277.12	Assigned BUD and storage requirements	Yes		9.2
277.13	Documentation of QC results	Yes		9.2
	Preparation			10
278.00	The individual responsible for preparing the radiopharmaceutical(s) ensures that the final preparation complies with quality and purity specifications throughout the assigned BUD.	Yes		10
279.00	Do the quality and purity specifications include, as appropriate for the preparation, the following?	Yes		10
279.01	Radionuclidic purity	Yes		10

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		Observations	Notes	USP Reference(s)
279.02	Radiochemical purity	Yes		10
279.03	Chemical purity	Yes		10
279.04	Physical and chemical properties	Yes		10
	Preparation Following Manufacturer Instructions			10.1
	Nonsterile Preparations			10.1
280.00	For nonsterile preparations, manufacturer preparation instructions are followed (eg, I-131 NaI capsules or solution), taking into account appropriate radiation safety considerations and environmental controls, if applicable (eg, negative air pressure area, chemical fume hood, activated charcoal filters when handling a potentially volatile radionuclide).	Yes		10.1
281.00	*Recommendation: The area is cleaned and uncluttered to ensure the overall integrity and quality of the prepared radiopharmaceutical(s).*	Yes		10.1
282.00	*Recommendation: There is a documented process for activities (eg, cleaning) between the preparation cycles of different nonsterile products, to decrease the likelihood of contamination from other prepared products.*	Yes		10.1
	Sterile Preparations			10.1
283.00	For sterile preparations (including intravascular devices), manufacturer preparation instructions are followed, taking into account appropriate radiation safety considerations, appropriate environmental controls, and aseptic handling practices to maintain sterility.	Yes		10.1
284.00	The minimum environmental standard for the preparation of sterile radiopharmaceuticals beyond immediate-use is within an ISO Classified area or device.	Yes		10.1

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		Observations	Notes	USP Reference(s)
	Preparation with Minor Deviations			10.2
285.00	In some cases, radiopharmaceuticals are prepared with minor deviations from manufacturer instructions that are necessary to accommodate circumstances not contemplated in the FDA approved labeling.	Yes		10.2
285.01	Deviations from manufacturer preparation instructions for radiopharmaceuticals maintain the same ingredients but may differ in their proportions.	Yes		10.2
286.00	The minor deviations utilized require appropriate in-house QC testing, designed to validate the radiochemical purity of the product for the entirety of the BUD or are supported by appropriate peer-reviewed publications.	Yes		10.2
287.00	Do the pharmacy radiopharmaceutical preparations with minor deviations include all of the following when applicable?	Yes		10.2
287.01	Altering the quantity of radioactivity or volume added to the vial	Yes		10.2
287.02	Changes in step-by-step operations (eg, dilute Tc-99m sodium pertechnetate after rather than before addition to the vial)	Yes		10.2
287.03	Using alternative devices or equipment (eg, a heating block rather than a hot water bath, using a different sized needle, different shielding materials)	Yes		10.2
287.04	Using QC test methods other than those described in the product labeling (eg, radiochemical purity)	Yes		10.2
287.05	Filtering Tc-99m sulfur colloid	Yes		10.2
287.06	Other, (if so, describe in the notes)	No		10.2

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		Observations	Notes	USP Reference(s)
	Preparation of Radiolabeled Blood Components		***Note to Inspector:*** *Handling blood and radiolabeling of blood components requires special attention to biological risks and need to be handled with standard precautions using aseptic technique to prevent the introduction of new microorganisms into the preparation that will be administered.*	10.3
288.00	The preparation BUD does not exceed 6 hours after the blood sample is obtained from the patient or blood bank.	Yes		10.3
289.00	Equipment and supplies are never shared with other activities unless they are first thoroughly cleaned and disinfected.	Yes	Equipment and supplies are never shared.	10.3
290.00	Do special precautions when radiolabeling of blood components for non-immediate use include the following?	Yes		10.3
290.01	There is complete physical separation (either fixed or non-fixed wall) of areas where blood products are handled from areas where non-blood products are handled. An ISO Class 5 BSC located in an ISO Class 7 buffer area is required for blood-labeling processes. If more than one ISO Class 5 PEC is located within the ISO Class 7 buffer area, policies and SOPs are in place to include certification that the SEC meets conditions of air quality at maximum occupancy under dynamic operating conditions.	Yes		10.3
290.02	One radiolabeling procedure per PEC at a time. Blood products from more than one patient are never manipulated at the same workstation at the same time. Each area has dedicated supplies, equipment, and waste disposal to eliminate sharing of these items or overlap in pathways.	Yes		10.3
290.03	Thorough cleaning and disinfection of the ISO Class 5 BSC and all reusable equipment within, occurs prior to starting another blood component radiolabeling procedure.	Yes		10.3
290.04	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator is used or the dose calibrator dipper and liner is cleaned and disinfected following the radioassay.	N/A	Dose calibrators are dedicated.	10.3

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		Observations	Notes	USP Reference(s)
290.05	Centrifuge is located within the ISO Class 7 buffer area that is dedicated for blood component radiolabeling processes.	Yes		10.3
290.06	Dedicated (per each radiolabeling procedure) consumable products (eg, 0.9% sodium chloride injection, diluent, tubes, syringes, and other supplies) necessary for each individual patient radiolabeling procedure.	Yes		10.3
290.07	All tubes and syringes in contact with the patient's blood components are clearly labeled with the patient's name and at least one additional identifier (eg, date of birth, medical record number, barcode).	Yes	A patient barcode is used in addition to the name.	10.3
290.08	Dedicated syringe shields and vial shields.	Yes		10.3
290.09	Any garb that enters the ISO Class 5 BSC is removed and replaced before handling anything else not related to performing this procedure.	Yes		10.3
290.10	Removal of all disposable items from the ISO Class 5 BSC is utilized in each radiolabeling procedure.	Yes		10.3
290.11	Cleaning and disinfection of all reusable equipment and components (eg, BSC, centrifuge, dose calibrator, syringe shields, vial shields, syringe transport shields and delivery cases) is done after each radiolabeling procedure prior to any further use. Policies and SOPs address cleaning and disinfection processes including the use of an EPA-registered (or equivalent) one-step disinfectant cleaner with activity against blood-borne pathogens followed by sterile 70% IPA. Sterile 70% IPA alone is not sufficient.	Yes		10.3
290.12	After the completion of blood radiolabeling procedures, 4.5 Hand Hygiene and Garbing requirements for Buffer Areas and segregated Radiopharmaceutical Processing Area are followed.	Yes		10.3

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		Observations	Notes	USP Reference(s)
	Preparation of Radiolabeled Red Blood Cells for Immediate Use			10.4
291.00	Is In vitro red blood cell labeling prepared with the following conditions?	N/A	There are no immediate use radiolabeled red blood cells.	10.4
291.01	A dedicated space for blood handling is designated through the entirety of the blood radiolabeling process. This area is free from clutter and not used for any other radiopharmaceutical preparation or handling until the completion of cleaning and disinfection.	N/A		10.4
291.02	Only one radiolabeling procedure is performed at a time or there are documented processes that maintain the integrity of samples and environment.	N/A		10.4
291.03	Dedicated equipment is used for blood radiolabeling procedure (eg, L-block, syringe shield, vial shield, forceps, needle recapper).	N/A		10.4
291.04	If a dedicated dose calibrator is not available, then a means of preventing the blood container(s) from contaminating the dose calibrator or a cleaning and disinfecting procedure with an appropriate product is used to decontaminate the dipper and liner of the dose calibrator following the radioassay	N/A		10.4
291.05	A cleaning and disinfecting procedure with an appropriate agent(s) is used to decontaminate the area and equipment prior to and after the radiolabeling is complete and all disposable components have been discarded	N/A		10.4
291.06	All requirements in 4.4 Hand Hygiene and Garbing for Immediate Use Preparations are followed.	N/A		10.4
291.07	The start time of the preparation begins with the initial container puncture or the exposure of a critical site (eg, syringe tip, needle hub or needle) to ambient air, whichever is first.	N/A		10.4
291.08	The compounded product has a BUD of 1 hour	N/A		10.4

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		Observations	Notes	USP Reference(s)
	Compounding		***Note to Inspector:*** *The combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides.*	11
292.00	Each compounding activity is based on a pre-established written procedure and includes maintenance of compounding records.	Yes		11
292.01	The compounding record provides traceability for components and person(s) involved.	Yes		11
293.00	All sterile compounding, using aseptic technique, is performed in an ISO 5 PEC. Compounding employees are using appropriate aseptic technique. May require inspector to garb and enter clean/buffer room. Pay attention to first air, entry and exit of materials in ISO Class 5 PEC, appropriate frequent sanitization of gloves, appropriate cleaning and cleanliness of the direct compounding area (DCA). ***When applicable, Compounding MUST be observed****. If compounding is not being performed at the time of survey mark item as "No"*	Yes		11
293.01	If compounding is not being performed at the time of survey, ask that a compounding pharmacist or technician prepare a compound for you to observe the compounding process. *If the pharmacy staff refuses or is unable to perform compounding for you to observe, document on the "**Denial of Authorization**" form. List individual who signs the Denial of Authorization.*	[redacted]	N/A	11
294.00	Compounding is not be performed for any radiopharmaceutical(s) that has been withdrawn from the market because of safety or lack of effectiveness, unless part of an institutional review board approved investigational study.	Yes		11
295.00	Radiopharmaceuticals that are essentially copies of marketed FDA-approved radiopharmaceuticals are not be compounded unless there is a change that produces a clinical difference for an identified individual patient, as determined by a prescriber.	Yes		11

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		Observations	Notes	USP Reference(s)
	Compounding Nonsterile Radiopharmaceuticals		***Note to Inspector:*** *Compounding nonsterile radiopharmaceuticals is the combining, mixing, diluting, pooling, reconstituting or otherwise altering a drug or bulk drug substance other than as provided by the manufacturer's package insert to create a nonsterile radiopharmaceutical.*	11.1
296.00	Areas designated for nonsterile compounding are cleaned, uncluttered and separated from areas designated for sterile radiopharmaceuticals.	Yes		11.1
297.00	*Recommendation: Compounding takes into account RAM licensing requirements for appropriate radiation safety considerations and utilize appropriate environmental controls, if applicable.*	Yes		11.1
298.00	The placement of equipment and materials are designed to prevent cross-contamination.	Yes		11.1
299.00	When feasible, disposable material is used to reduce the chance of cross-contamination.	Yes		11.1
300.00	Each compound has a unique MFR.	Yes		11.1
301.00	The preparation information is documented on a compounding record.	Yes		11.1
302.00	The MFR details the selection of all components.	Yes		11.1
303.00	**The ingredients obtained from sources in this preferential order:** FDA-approved product; FDA-registered facility; and lastly, if the ingredients for the compound are not available from either of these two sources, the MFR details the selection of a material that is suitable for the intended use.	Yes	Only FDA-approved products are used.	11.1
304.00	The MFR establishes the identity, strength, purity, and quality of the ingredients by validated means (eg, CoA).	Yes		11.1

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305.00	Requirements for nonsterile oral meal components are limited to common food grade description and are not required to establish identity by validated means.	N/A	There are no meal components compounded.	11.1
306.00	A BUD for the compounded radiopharmaceutical is validated, taking into account the stability of the ingredients, any intermediate containers, the final container, and the storage conditions.	Yes		11.1
306.01	A BUD cannot be extended past the labeled expiration date of any component in the compound.	Yes		11.1
306.02	If the compounded radiopharmaceutical(s) includes components from other preparations or preparations with minor deviations, the BUD of the final compounded radiopharmaceutical does not exceed the shortest remaining BUD of any of those components.	N/A		11.1
	Sterile Compounding		***Note to Inspector**: Kit-splitting (also referred to as "fractionation") may be used to meet patient need.*	11.2
307.00	Do personnel responsible for compounding consider all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (eg, osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD?	Yes		11.2
308.00	Do the compounding activities involve the addition of a conventionally manufactured drug product (eg, Ascorbic Acid Injection, Lidocaine Hydrochloride Injection, Sodium Bicarbonate Injection) approved by the appropriate regulatory agency to a radiopharmaceutical?	Yes	Lidocaine HCl injection may be used.	11.2
309.00	Does the pharmacy split conventionally marketed kits?	No		11.2
310.00	Do personnel responsible consider all possible interactions of kit components with these other containers (eg, container walls, closures), as well as possible alterations in stability (eg, physical stability, chemical stability) that may affect radiolabeling yields or performance parameters, when determining an appropriate BUD?	Yes	Corporate assigns all BUDs.	11.2
310.01	Systematic QC testing is performed to validate the appropriateness of a particular BUD.	N/A		11.2

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		Observations	Notes	USP Reference(s)
	Sterile Compounding Using Nonsterile Drug Substance or Components			11.3
311.00	Some sterile compounding activities involve the use of materials other than commercially marketed products, such as drug substances and/or radionuclides.	No	There is no nonsterile to sterile compounding performed.	11.3
311.01	If one or more materials or components are not certified to be sterile and pyrogen-free, a sterilization procedure (eg, filtration with bubble point testing) and testing described in <85> is performed. Record calibration date of the bubble test pressure gauge, as applicable.	N/A		11.3
312.00	The designated person for compounding is responsible for ensuring that the final preparation complies with pre-established standards or acceptance criteria for identity, quality, and purity.	N/A		11.3
313.00	The designated person considers all possible interactions between the components, such as altered chemical stability, radiochemical stability, solubility, or other parameters (eg, osmolality) related to changes in pH, excipients, or other factors, in determining an appropriate BUD.	N/A		11.3
313.01	Testing to validate the appropriateness of a particular BUD may be required.	N/A		11.3
314.00	If compounding involves a bulk drug substance, the radiopharmaceutical complies with standards of an applicable USP or NF monograph, if one exists, or be a component of an approved drug product.	N/A		11.3
314.01	A bulk drug substance includes a radionuclide, a ligand, or other substance, such as a precursor that becomes an active ingredient in the final radiopharmaceutical.	N/A		11.3
315.00	Each bulk drug substance is manufactured by drug establishments registered with FDA and be accompanied by a valid CoA or equivalent testing procedures.	N/A		11.3

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National Association of Boards of Pharmacy®
Verified Pharmacy Program® Inspection Form

Nuclear Pharmacy Inspection

The information and comments obtained are based on USP General Chapter <825>
Nuclear/Radiopharmaceuticals Preparation, Compounding, Dispensing and Repackaging

Facility Name: RLS (USA) Inc.
e-Profile ID: 1803196
Inspection Date: 04/29/2024 & 05/02/2024

		Observations	Notes	USP Reference(s)
316.00	If compounding involves excipients or other inactive ingredients, the excipients or other inactive ingredients comply with standards of an applicable USP or NF monograph, if one exists.	N/A		11.3
317.00	It is also acceptable that any excipients or other inactive ingredients be approved products, manufactured by a drug establishment registered with the FDA.	N/A		11.3
	Dispensing and Radioassay		*Note to Inspector: Dispensing refers to the manipulations necessary to transfer the prescribed or ordered amount of radiopharmaceutical into the final container (eg, syringe or vial).*	12.1
318.00	Labeling of the final patient-ready dose or ordered amount of a radiopharmaceutical is also a component of the dispensing process.	Yes		12.1
319.00	Except for an unopened manufacturer container, the final dose or ordered amount is radioassayed (ie, in a dose calibrator).	Yes		12.1
320.00	*Recommendation: The measured activity is mathematically corrected for radioactive decay to the time of scheduled administration (calibration time).*	Yes		12.1
321.00	The activity at calibration time is always be within federal, state, and local variance limits.	Yes		12.1
	Labeling			12.2
322.00	*Recommendation: All personnel distributing and/or dispensing radiopharmaceuticals verify that any labeling is in compliance with regulatory agencies.*	Yes		12.2
323.00	Is the inner container (eg syringe, vial) labeled with all of the following?	Yes		12.2
323.01	Standard radiation symbol	Yes		12.2
323.02	The words "Caution—Radioactive Material"	Yes		12.2

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		Observations	Notes	USP Reference(s)
323.03	For all therapeutic and blood-products, the patient name/identifier	Yes		12.2
323.04	Radionuclide and chemical form (generic name)	Yes		12.2
323.05	Radioactivity at the date and time of calibration	Yes		12.2
324.00	Is the outer shielding (eg, syringe or vial shielding) labeled with all the following?	Yes		12.2
324.01	Standard radiation symbol	Yes		12.2
324.02	The words "Caution—Radioactive Material"	Yes		12.2
324.03	For all therapeutic and blood-products, the patient name/identifier	Yes		12.2
324.04	The radionuclide and chemical form (generic name)	Yes		12.2
324.05	Radioactivity with units at time of calibration and the calibration time	Yes		12.2
324.06	Volume or number of units (eg, 2 capsules), as applicable	Yes		12.2
324.07	Product expiration or BUD, as applicable, and any special storage and handling requirements for non-immediate use (eg, refrigeration, resuspension)	Yes		12.2
324.08	Route of administration	Yes		12.2

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		Observations	Notes	USP Reference(s)
	Direct Infusion Systems			12.3
325.00	Do the operations of the direct infusion systems follow the "Instructions for Use" in the device labeling?	N/A	There are no direct infusion systems.	12.3
326.00	Are each of the following parameters considered by the operator of the system?	N/A		12.3
326.01	Setup attachment or needle-puncture should be performed in a defined environment	N/A		12.3
326.02	Aseptic handling in ambient air with a maximum BUD of 10 hours is allowed for these direct infusion systems	N/A		12.3
326.03	The 0.9% sodium chloride bag attached to the device may only be punctured once and may be used for no more than 10 hours. The bag is labeled with the date and time of puncture and the BUD	N/A		12.3
326.04	Any nonsterile parts of the device that may encounter the septum of the radiopharmaceutical vial is disinfected with sterile 70% IPA prior to puncturing the vial with the needle	N/A		12.3
326.05	The septum of any vial and the ports of any diluent bag is wiped with sterile 70% IPA prior to puncturing	N/A		12.3
326.06	When puncturing the vial in ambient air, it is only punctured once	N/A		12.3
326.07	If there are problems with the infusion device, no sterile container(s) associated with the system is repunctured or transferred to a PEC for further manipulations and the container, with contents, is discarded	N/A		12.3

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		Observations	Notes	USP Reference(s)
	Transporting Generators Between Facilities			12.4
327.00	Are the following standards followed if transporting generators between facilities?	N/A	There is no transportation of generators.	12.4
327.01	The generator needle and/or ports are capped in ISO Class 8 air or better with sterile protectors	N/A		12.4
327.02	The generator is packaged and transported in a manner to maintain the integrity and sterility of the generator system	N/A		12.4
	Repackaging			13
328.00	If the facility repackages, are the following applicable?	Yes		13
328.01	Removes conventionally manufactured radiopharmaceutical(s) from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product.	No		13
328.02	Places the contents of multiple containers of the same finished drug product into one container, as long as the container does not include other ingredients	Yes		13
329.00	Does the facility repackage nonsterile radiopharmaceuticals (eg, I-131 sodium iodide oral capsules)?	Yes		13
330.00	Does the facility repackage sterile radiopharmaceuticals (eg, thallous chloride Tl 201 injection)?	Yes	Indium-111 DTPA may be repackaged.	13
331.00	Unopened manufacturer dosage units (eg, capsules, Xe-133 vials) are not radioassayed.	No		13

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		Observations	Notes	USP Reference(s)
332.00	The repackaged radiopharmaceutical is radioassayed (ie, in a dose calibrator), if it is not an unopened manufacturer dosage unit.	Yes		13
333.00	*Recommendation: The inner container is labeled with all of the following:*	Yes		13
333.01	*Standard radiation symbol*	Yes		13
333.02	*The words "Caution—Radioactive Material"*	Yes		13
333.03	*The radionuclide and chemical form (generic name)*	Yes		13
333.04	*Radioactivity with units at time of calibration and the calibration time*	Yes		13
334.00	*Recommendation: The outer container is labeled with all of the following:*	Yes		13
334.01	*Standard radiation symbol*	Yes		13
334.02	*The words "Caution—Radioactive Material"*	Yes		13
334.03	*The radionuclide and chemical form (generic name)*	Yes		13
334.04	*Radioactivity with units at time of calibration and the calibration time*	Yes		13
334.05	*Volume, or number of units (eg, capsules), as applicable*	Yes		13
334.06	*Product expiration or BUD, as applicable*	Yes		13
334.07	*Special storage and handling instructions*	Yes		13

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		Observations	Notes	USP Reference(s)
	Quality Assurance and Quality Control			14
335.00	QA and QC programs are formally established and documented in SOPs that ensure that all aspects of the handling of radiopharmaceuticals are conducted in accordance with this chapter and applicable federal, state, and local laws and regulations.	Yes		14
336.00	A designated person ensures that the facility has formal, written QA and QC programs. *List this person in the notes.*	Yes	Janice Swett, a staff pharmacist, is the lead person for QA and QC and reports to Otha Bright, the designated person and PIC.	14
337.00	Do QA and QC programs establish a system which include of all of the following?	Yes		14
337.01	Adherence to procedures	Yes		14
337.02	Prevention and detection of errors and other quality problems	Yes		14
337.03	Evaluation of complaints and adverse events	Yes		14
337.05	Appropriate investigations and corrective actions	Yes		14
338.00	The SOPs describe the roles, duties, and training of the personnel responsible for each aspect of the QA program.	Yes		14
339.00	The overall QA and QC program is reviewed at least once every 12 months by the designated person. *List last date of review in notes.*	No	The PIC stated he reviews the QA and QC program monthly but was not able to find the last review.	14
340.00	The results of the review are documented, and appropriate corrective action taken, if needed.	No	The PIC stated that the program is reviewed monthly but there has been no documentation of the review.	14

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Facility Name: RLS (USA) Inc.
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		Observations	Notes	USP Reference(s)
	Notification About and Recall of Out-of-Specification Dispensed Radiopharmaceuticals			14.1
341.00	If a radiopharmaceutical is dispensed or administered before the results of release testing are known, does the facility have all of the following SOPs in place?	N/A	Radionuclidic potency and purity testing are performed before release. There is no other testing required.	14.1
341.01	Immediately notify the prescriber of a failure of specifications with the potential to cause patient harm (eg, sterility, strength, purity, bacterial endotoxin, or other quality attributes)	N/A		14.1
341.02	Determine whether a recall is necessary	N/A		14.1
342.00	Does the SOP for recall of out-of-specification dispensed radiopharmaceuticals contain all of the following procedures?	Yes		14.1
342.01	Determine the severity of the problem and the urgency for the implementation and completion of the recall	Yes		14.1
342.02	Determine the distribution of any affected radiopharmaceutical, including the date and quantity	Yes		14.1
342.03	Identify patients who have received the radiopharmaceutical	Yes		14.1
342.04	Outline the disposition and reconciliation of the recalled radiopharmaceutical	Yes		14.1
343.00	Does the facility document the implementation of the recall procedures?	Yes		14.1
344.00	Is the recall is reported to appropriate regulatory bodies as required by laws and regulations of the applicable regulatory jurisdiction (eg, state board of pharmacy, state health department)?	Yes		14.1

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		Observations	Notes	USP Reference(s)
	Complaint Handling			14.2
345.00	Has the nuclear pharmacy developed and implemented SOPs for handling complaints? Note: Complaints may include concerns or reports on the quality and container labeling of, or possible adverse reactions to, a specific radiopharmaceutical.	Yes		14.2
346.00	Does the designated person review all complaints to determine if they indicate potential quality problems with the radiopharmaceutical?	Yes		14.2
346.01	If a complaint indicates potential quality issues with radiopharmaceuticals, is an investigation into the potential cause of the issue completed?	Yes		14.2
346.02	Does the investigation consider whether the quality problem could extend to other radiopharmaceuticals?	Yes		14.2
346.03	Is corrective action, if necessary, implemented for all potentially affected radiopharmaceuticals?	Yes		14.2
346.04	Does the investigation consider whether to initiate a recall of potentially affected radiopharmaceuticals and whether to cease sterile compounding until all underlying problems have been identified and corrected?	Yes		14.2
347.00	Is a readily retrievable record (written or electronic) of each complaint kept by the facility, regardless of the source of the complaint (eg, e-mail, telephone, mail)?	Yes	Records of complaints are maintained electronically.	14.2
348.00	Does the record contain all of the following?	Yes		14.2
348.01	The name of the complainant	Yes		14.2
348.02	The date the complaint was received	Yes		14.2
348.03	The nature of the complaint	Yes		14.2
348.04	The response to the complaint	Yes		14.2

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		Observations	Notes	USP Reference(s)
348.05	If known, the name and strength of the radiopharmaceutical and the assigned internal identification number (eg, prescription, order, or lot number).	Yes		14.2
349.00	Does the record also include the findings of any investigation and any follow-up?	Yes		14.2
350.00	Are records of complaints easily retrievable for review and evaluation for possible trends?	Yes		14.2
351.00	Are records retained in accordance with the record keeping requirements?	Yes		14.2
352.00	Is a radiopharmaceutical that is returned in connection with a complaint quarantined until it is destroyed after completion of the investigation and in accordance with applicable jurisdictional laws and regulations?	Yes		14.2
	Adverse Event Reporting			14.3
353.00	Are adverse events potentially associated with the quality of radiopharmaceuticals reported in accordance with the facility's SOPs and all applicable jurisdictional laws and regulations?	Yes		14.3
354.00	*Recommendation: Adverse events potentially associated with the quality of the radiopharmaceutical preparation are reported to the applicable jurisdictional regulatory body (eg, state boards of pharmacy, state health departments, FDA's MedWatch program for human drugs).*	Yes		14.3

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An inspection against current Good Manufacturing Practices (cGMPs) was not conducted. There may be some overlap in concepts.

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Acronym	Definition
ACPH	Air changes per hour
ALARA	As low as reasonably achievable
ANDA	Abbreviated new drug application
ANP	Authorized nuclear pharmacist
AU	Authorized user
BLA	Biologics license application
BSC	Biological safety cabinet
BUD	Beyond-use date
CETA	Controlled Environment Testing Association
cfu	Colony-forming unit
CoA	Certificate of analysis
DPA	Direct processing area
EPA	Environmental Protection Agency
FDA	Food and Drug Administration
FDCA	Food, Drug, and Cosmetic Act
HEPA	High-efficiency particulate air
HVAC	Heating, ventilation, and air conditioning
IND	Investigational new drug
IPA	Isopropyl alcohol
ISO	International Organization for Standardization
LAFW	Laminar airflow workbench
MAA	Macroaggregated albumin
MEA	Malt extract agar
MFR	Master Formulation Record
NDA	New drug application
NRC	Nuclear Regulatory Commission
PEC	Primary engineering control
PET	Positron emission tomography
RAM	Radioactive material
RDRC	Radioactive drug research committee
RH	Relative humidity
SDA	Sabouraud dextrose agar
SEC	Secondary engineering control
SOP	Standard operating procedure
SRPA	Segregated radiopharmaceutical processing area
TSA	Trypticase soy agar

Term	Definition
Dispense/dispensing	Pursuant to a patient specific prescription, labeled with patient name at the pharmacy
Distribute/distributing	Delivered/sent to a practitioner or health care facility for office use or further dispensing, no prescription, not labeled with a patient name at the pharmacy.
Type of Practice: Central Fill/Processing/ Shared Services	Where part of the prescription processing and dispensing process occurs at another location
Type of Practice: Closed Door	Such as a mail order facility, prescriptions cannot be picked up at the facility, all are sent
Type of Practice: HMO/PBM only	Limited to only the beneficiaries of the specific insurance program - no cash patients
Type of Practice: Institutional	Such as a hospital or jail
Type of Practice: Internet Pharmacy	Pharmacy advertises on the internet, patients fill/refill prescriptions and revise patient profile information on-line.

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Type of Practice: Investigational Drugs, Clinical Trials or Research	Approved to handle investigational drugs
Type of Practice: Long Term Care	Nursing Home pharmacy
Type of Practice: Manufacturer	Registered with the FDA as a manufacturer
Type of Practice: Open to the Public	Patients are able to come into the pharmacy to pick up filled prescriptions and interact with a pharmacist
Type of Practice: Outsourcing Facility	Registered with the FDA as an Outsourcing Facility
Type of Practice: Provides Office Use	Distributes prescription and/or compounded preparations to providers for administration or resale. No prescription, not labeled with a patient name by the pharmacy.
Type of Practice: Specialty Pharmacy	Business is primarily with specialty drugs and works with specific disease states
Type of Practice: Telepharmacy	Pharmacy oversees a remote location staffed by a technician supervised via audio/visual system by a pharmacist at this facility.
Type of Practice: Traditional retail	Also known as Community Pharmacy.
Type of Practice: Veterinary Pharmacy	Pharmacy business is primarily or exclusively for animals.
Type of Practice: Wholesale Distributor	Pharmacy is licensed or registered as a wholesale distributor
Glossary	
Administration:	The direct and immediate application of a radiopharmaceutical to a patient by injecting, infusing, ingesting, or otherwise providing a radiopharmaceutical in its final form.
Airlock:	A space with interlocked doors, constructed to maintain air pressure control when items move between two adjoining areas.
Ante-room:	An ISO Class 8 or cleaner area with fixed walls and doors where personnel hand hygiene, garbing procedures, and other activities that generate high particulate levels are performed. The ante-room is the transition area between the unclassified area in a facility and the classified buffer area.
Aseptic processing or preparation:	A process by which separate, sterile components (eg, drugs, containers, or closures) are brought together under conditions that maintain their sterility.
Aseptic technique:	Methods utilized during the processing of radiopharmaceuticals to keep objects and areas free of microorganisms and thereby minimize infection risk to the patient. It is accomplished through practices that maintain the microbe count at a nearly irreducible number.
As low as (is) reasonably achievable (ALARA):	The effort to maintain exposures to ionizing radiation as far below the dose limits as practical. These efforts should be consistent with the purpose for which the licensed activity is undertaken, in relation to utilization of licensed materials in the public interest. Limiting exposure time, using adequate shielding, and maintaining the most distance possible from all radioactive sources (i.e., time, distance, shielding) are the basic principles for successfully following ALARA guidelines.
Authorized nuclear pharmacist (ANP):	A pharmacist recognized by the U.S. Nuclear Regulatory Commission or an Agreement State agency as having met training and experience requirements for the practice of nuclear pharmacy.
Authorized user (AU):	A physician recognized by the U.S. Nuclear Regulatory Commission or an Agreement State agency as meeting training and experience requirements for specified medical uses of radioactive material.
Beyond-use date (BUD):	The assigned date and time beyond which the radiopharmaceutical must not be administered.
Biological safety cabinet (BSC) Class II:	A ventilated cabinet with an open front and inward and downward unidirectional HEPA-filtered airflow and HEPA-filtered exhaust. The BSC is designed to provide worker protection from exposure to biohazardous material and to provide an ISO Class 5 or better environment for preparing sterile radiopharmaceuticals.
Blood components:	Any constituent of blood that is separated by physical or mechanical means (eg, red cells, white cells, platelets)
Buffer area:	An ISO Class 8 or cleaner area with fixed walls and doors where PEC(s) that generate and maintain an ISO Class 5 environment are physically located. The buffer area may only be accessed through the ante-room.
Chemical purity:	The fraction of the total chemical species present in the radiopharmaceutical as the specified chemical component(s). A chemical impurity is the presence of an unwanted non-radioactive chemical.
Classified area:	An area that maintains an air quality classification based on the ISO guidelines (i.e., ante-room, buffer area). See ISO class.
Cleaning agent:	A material for the removal of residues (eg, dirt, debris, microbes, and residual drugs or chemicals) from surfaces.
Compounding:	The combining, mixing, pooling, or otherwise altering (excluding preparation with minor deviations) of a conventionally manufactured radiopharmaceutical or synthesizing/formulating a radiopharmaceutical from bulk drug substances and radionuclides. See Preparation with minor deviations.
Container–closure system:	The packaging components that contain or come in contact with the radiopharmaceutical and maintain the integrity of the radiopharmaceutical contained within. Examples include (but are not limited to) vials, tubes and syringes.

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Critical site:	A location that includes any component or fluid pathway surface (eg, vial septa, injection ports) or openings (eg, needle hubs) that, when exposed is at risk for contamination by direct contact with air (eg, ambient area or HEPA-filtered), moisture (eg, oral and mucosal secretions), or touch.
Designated person:	One or more individuals assigned to be responsible and accountable for the performance and operation of the radiopharmaceutical processing facility and for personnel who prepare, compound, dispense, and repackage radiopharmaceuticals.
Direct infusion system:	An FDA-cleared medical device used to dispense and/or administer radiopharmaceuticals to multiple patients. The standards of this chapter pertain to devices with ambient air that lack and ISO Class 5 environment.
Direct processing area (DPA):	An area within the ISO Class 5 PEC where critical sites are exposed to unidirectional HEPA-filtered air, also known as first air.
Disinfectant:	A chemical or physical agent used on inanimate surfaces and objects to destroy microbiological contamination (eg, fungi, viruses, and bacteria) when used in the appropriate concentrations and for the appropriate contact times. Sporicidal disinfectant agents are considered a special class of disinfectants that also are effective against bacterial endospores and fungal spores.
Dispensing:	The manipulation or labeling of a radiopharmaceutical to render it in its final form for administration, typically obtained from a single-dose or multiple-dose container (eg, withdrawing a volume of finished product or preparation from a vial into a syringe). Dispensing is performed under the supervision of a physician or pharmacist and for radiopharmaceuticals includes dilution with an appropriate diluent or adjusting the activity in an individual dosage.
Dose pooling:	The combining of doses from two or more syringes to meet one patient's need, also see "repackaging".
Dose splitting:	The splitting of a patient-ready unit dose for use with more than one patient.
Dynamic operating conditions:	Conditions in the SRPA or classified area in which operating personnel are present and performing actual or simulated activities. The PEC should contain equipment and materials regularly used for radiopharmaceutical processing (eg, low-lint absorbent pads, dose calibrator, syringe shields).
Expiration date:	For conventionally manufactured radiopharmaceuticals, the specified date (and time) beyond which the product must not be administered. The expiration date is determined by the manufacturer.
First air:	The air exiting the HEPA filter in a unidirectional air stream.
Garb:	Gloves, gowns, shoe covers, head (covers ears and all hair) and facial hair covers, masks, and other items designed to reduce particle shedding from personnel and minimize the risk of microbiological contamination to radiopharmaceuticals.
High efficiency particulate air (HEPA) filtration:	Using a tested and certified air filter designed to remove 99.97% of airborne particles measuring 0.3-micron or greater in diameter from the air passing through it.
Hot-cell:	A device used for the shielding and containment of radioactive materials. The shielding material(s) (eg, lead) is generally incorporated into the structure of the unit itself. Radiopharmaceutical personnel carry out the majority of the tasks within the hot-cell from the exterior of the unit. This is accomplished by the use of remote manipulation systems (eg, manipulator arms, automated dispensing system) of various designs. Numerous air quality configurations of the hot-cell may exist, including integrated HEPA filtration systems to render all or a specified portion (DPA) of the device capable of certifying to a controlled ISO Class 5 environment. In other situations, the hot-cell offers only radiation protection and a laminar flow PEC, capable of achieving an ISO Class 5 environment, is placed within the enclosure to allow for safe aseptic manipulations. A hot-cell may also be referred to by other designations (eg, shielded isolator with laminar flow, PET dispensing station, manipulator hot-cell, shielded isolators for dispensing, radiopharmaceutical dispensing isolator).
Hot lab:	Unclassified radiopharmaceutical processing area located within a hospital or clinical site that is only appropriate for immediate use radiopharmaceuticals if there is not an ISO 5 PEC within SRPA located within the area.
Immediate use:	A preparation (including preparations with minor deviations) and/or dispensing of a sterile radiopharmaceutical that is limited for a single patient. Only sterile conventionally manufactured drug products (eg, NDA, ANDA) or drugs produced under an approved IND or RDRC protocol may be used. Administration must begin within 1 hour of the first container puncture or exposure of any critical site involved (eg, syringe tip, needle hub or needle) to ambient air, whichever is first.
Individual dose (unit dose):	A radiopharmaceutical in its final form ready for administration (eg, capsule, sterile solution in a syringe) consisting of the amount (dose) prescribed, ordered, or other intended for an individual patient or research subject.
Inverse square law:	The specified physical quantity or intensity of a radiation emission is inversely proportional to the square of the distance from the source of the emission.
ISO class:	A quality classification from the International Organization for Standardization based on quantity and size of particles per volume of air.
Kit:	Conventionally manufactured package containing all ingredients required to prepare a radiopharmaceutical with the exception of the radionuclide.

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Kit-splitting (fractionation):	The act of dividing the contents of a kit vial and transferring aliquots into other containers for storage and subsequent radiolabeling.
Ligand:	An ion or molecule that incorporates a metal atom to form a coordination complex.
Line of demarcation:	A visible line on the floor that separates the clean and less clean sides of the ante-room.
Low-lint wiper:	A wiper exhibiting few, if any, fibers or other particulates, visible without magnification, which are separate from, or easily removed from, the wiper material in a dry condition.
Master Formulation Record (MFR):	A document or set of documents specifying the starting materials with their quantities and the packaging materials, together with a description of the procedures and precautions required to produce a specified quantity of a finished preparations as well as the processing instructions, including the in-process controls.
Media-fill test:	A simulation used to qualify processes and personnel engaged in sterile radiopharmaceutical processing to ensure that the processes and personnel are able to prepare radiopharmaceuticals without microbiological contamination. Molar mass: The measured mass that is attained from a molar amount of a given substance (eg, element, compound).
Molar mass:	The measured mass that is attained from a molar amount of a given substance (eg, element, compound). It is generally expressed with units such as g/mol and kg/mol.
Multiple-dose container:	A container of a radiopharmaceutical for administration that is designed to contain more than one patient dose of the radiopharmaceutical.
Negative-pressure area:	An area that is maintained at lower pressure than the adjacent spaces, and therefore the net airflow is into the area. This area is appropriate for volatile or gaseous radionuclides and radiopharmaceuticals (eg, I-131 NaI, N-13 ammonia) and intended to lend a measure of protection for the radiation workers and the general public.
One-step disinfectant cleaner:	A product with an EPA-registered claim (or equivalent) that it can clean and disinfect a nonporous surface in the presence of light to moderate organic soiling without a separate cleaning step.
Pass-through:	An enclosure with sealed doors on both sides to ensure that both doors are not opened at the same time. The pass-through is positioned between two spaces creating an airlock for the purpose of minimizing particulate transfer while moving materials from one space to another.
Perimeter:	A visible demarcation on the floor that defines the boundaries of the SRPA.
Positive-pressure area:	An area that is maintained at higher pressure than the adjacent spaces, and therefore the net airflow is out of the area.
Preparation:	The act of combining a conventionally manufactured kit with a conventionally manufactured radionuclide following manufacturer's recommended instructions. Mixing, reconstituting, combining, diluting, or repackaging of a radiopharmaceutical, or other such acts, performed in accordance with directions contained in the FDA-approved labeling.
Preparation with minor deviations:	The act of preparing a conventionally manufactured kit with a conventionally manufactured radionuclide with volume, and/or radioactivity, and/or step-by-step deviations from the manufacturers recommended labeling while ensuring that the final preparation maintains appropriate radiochemical and radionuclidic purity for the entirety of the BUD. Examples of minor deviations include, but are not limited to, altering the amount of activity or volume added to the vial, changes in step-by-step operations (eg, dilute Tc-99m solution after, rather than before, addition to the vial, use of a venting needle or filter), using alternative devices or equipment (eg, a heating block rather than a hot water bath), and using alternative radiochemical purity testing methods.
Primary engineering control (PEC):	A device or zone that provides an ISO Class 5 air quality environment for sterile processing.
Pyrogen:	A substance that induces a febrile reaction in a patient.
Quality assurance (QA):	The system of procedures, activities, and oversight that ensures that radiopharmaceutical processing consistently meets quality standards.
Quality control (QC):	The sampling, testing, and documentation of results that, taken together, ensure that specifications have been met before release of the radiopharmaceutical.
Radioactive materials (RAM) license:	A document(s) issued by the US NRC or an Agreement State agency that authorizes various activities involving the use of radioactive materials. These uses can include possession, research and development, distribution, medical use, and other purposes not included in this list. Only those activities specifically authorized are allowed.
Radioassay:	Measurement of the quantity of radioactivity present in a container using a suitable and calibrated instrument, such as a well-type ionization chamber (i.e., dose calibrator).
Radiochemical purity:	The ratio, expressed as a percentage, of the radioactivity of the intended active radiopharmaceutical ingredient to the total radioactivity of all radioactive ingredients and impurities present in the radiopharmaceutical preparation (see Radioactivity <821>).
Radionuclidic purity:	The ratio, expressed as a percentage, of the radioactivity of the intended radionuclide to the total radioactivity of all radionuclides in the radiopharmaceutical preparation (see <821>).

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Radiopharmaceutical (radiopharmaceutical preparation/radioactive drug):	(See <821>.) A finished dosage form that contains a radioactive substance in association with one or more other ingredients and that is intended to diagnose, stage a disease, monitor treatment, or provide therapy. A radiopharmaceutical includes any non-radioactive reagent kit or radionuclide generator that is intended to be used in the preparation of any such substance. The terms "radiopharmaceutical" and "radioactive drug" are commonly used interchangeably.
Repackaging:	The act of removing a conventionally manufactured radiopharmaceutical from the container in which it was distributed by the original manufacturer and placing it into a different container without further manipulation of the product. Repackaging also includes the act of placing the contents of multiple containers (eg, vials) of the same finished drug product into one container, as long as the container does not include other ingredients. Radiopharmaceutical manipulation in any other way, including reconstitution, dilution, mixing, or combination with another ingredient, is not considered repackaging.
Restricted area:	Any area to which access is controlled for the protection of individuals from exposures to radiation and radioactive materials.
Secondary engineering control (SEC):	The area where the PEC is placed (eg, a classified area or an SRPA). It incorporates specific design and operational parameters required to minimize the risk of microbial contamination.
Segregated radiopharmaceutical processing area (SRPA):	A designated, unclassified space, area, or room with a defined (by facility procedures) perimeter that contains a PEC. An SRPA is only suitable for radiopharmaceutical preparation (with and without minor deviations), dispensing, and repackaging. If the SRPA is used to elute radionuclide generators it must have ISO Class 8 particle count non-viable particle count air quality.
Shielding:	Barriers of appropriate radiation attenuating material, used for radiopharmaceuticals, to protect the personnel. These barriers can be general in nature (eg, L-block, hot-cell), as to afford protection from a radiation field, or specific to a container used to hold a particular radiopharmaceutical (eg, syringe shield, vial shields, "pigs").
Single-dose container:	A container of a radiopharmaceutical for administration that is designed for use with a single patient as a single administration.
Specific activity:	The radioactivity of a radionuclide per unit mass of the compound involved with the radionuclide (see Radioactivity—Theory and Practice <821>). The units of specific activity involve those for the activity (eg, mCi, MBq, Ci, GBq)and those for the unit of mass (eg, µg, mmol)
Sporicidal agent:	A chemical or physical agent that destroys bacterial and fungal spores when used in sufficient concentration for a specified contact time. It is expected to kill all vegetative microorganisms.
Start of preparation:	Time at which a vial septum is punctured or a component container is opened (eg, removal of cap on a pre-filled syringe), whichever comes first.
Sterility:	The absence of viable microorganisms.
Strength:	The radioactivity concentration of the radiopharmaceutical at the calibration time (see <821>). Strength is expressed as the quantity of radioactivity on a volume basis (eg, mCi/mL or MBq/mL).
Unclassified space:	A space not required to meet any ISO air cleanliness classification.
Unrestricted area:	An area in which a person should not be exposed to radiation levels in excess of 2 millirems in any 1 h from external sources.
Use-by time:	For radiopharmaceuticals prepared from kits, the time period after preparation during which the radiopharmaceutical should be used or administered, as suggested or stated in the manufacturer's prescribing information.

Pharmacy Name:	RLS (USA) Inc.
Pharmacy Address:	945 N. Edgewood Ave., Suite A-1, Wood Dale IL 60191
NABP Business e-Profile ID:	1803196
VPP Inspection Date(s):	5/2/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)
Clarification or Further Explanation	30 of 96	59.01	RLS (USA) Inc. SOP 6.2.2 Aseptic Technique and Preparation requires disinfection of gloves by spraying with sterile 70% IPA prior to reentinering a PEC after touching non-sterile surfaces such as pens and paper. All pharmacists and technicians have been retrained on this procedure and training documentation is on file.	6/15/2024	Y	SOP 6.2.2 Aseptic Technique and Preparation
Clarification or Further Explanation	88 of 96	339.00	RLS (USA) Inc. SOP 4.4.4 Self-Inspections and Program Reviews requires site self-inspections and program reviews of the QA/QC, Radiation Safety, and Environmental Health and Safety programs on a routine basis. Completion of the QA Program review was last documented for this facility on 6/12/2023. However, site personnel were unable to locate the program review at the time of the inspection. A review of the location of the documentation associated with the site self-inspections and program reviews has been conducted to ensure all applicable staff are aware of the document location during an inspection. Documentation of this training is on file.	6/15/2024	Y	SOP 4.4.4 Self-Inspections and Program Reviews
Clarification or Further Explanation	88 of 96	340.00	RLS (USA) Inc. SOP 4.4.4 Self-Inspections and Program Reviews requires site self-inspections and program reviews of the QA/QC, Radiation Safety, and Environmental Health and Safety programs on a routine basis. This SOP also requries non-conformances are investigated, and CAPAs (if any are identified) are implemented to prevent reoccurance. Documentation of these inspections and program reviews including corrective actions taken to any identified non-conformances are maintained in the Joint Commission Tracers with AMP® tool. Completion of the QA Program review was last documented on 6/12/2023 and is readily available to all personnel. A review of the location of the documentation associated with the site self-inspections and program reviews shall be conducted to ensure all applicable staff are aware of the document location during an inspection. Documentation of this training is on file.	6/15/2024	Y	Joint Commission Resources Tracer Observation Detail Report

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

6166

Pharmacy Name:	RLS (USA) Inc.
Pharmacy Address:	945 N. Edgewood Ave., Suite A-1, Wood Dale IL 60191
NABP Business e-Profile ID:	1803196
VPP Inspection Date(s):	5/2/2024
Sharing Acknowledgment:	Yes — By typing "Yes" you acknowledge that all response documentation will be made available to the Boards of Pharmacy and state regulators upon their request

Facility Response to Verified Pharmacy Program® (VPP®) Inspection

Type of Response (Choose from Drop Down)	VPP Inspection Report Page No.	VPP Inspection Report Item No.	Facility Response/Corrective Action/Comments	Estimated Date of Completion For Corrective Action Taken	Attachment Included (Y/N)	Title of Document (Must be indicated at top of document attachment)

This VPP Inspection response and documentation has been provided directly by the pharmacy in response to its VPP Inspection. The content of this response has not been verified or modified by NABP at this point in time, except to check for completeness of any attachments provided.

Tracer Observation Detail Report

Quality Lead- Quarterly QA Program Review

Site: 535863 RLS (USA) Inc.

Program: Home Care

*Compliance percentage and totals display data from all questions in the observation.

100.0%

Total Numerator : 53 **Total Denominator :** 53 **Not Applicable Count :** 0 **Total Question Count :** 53

Observation Header

Tracer Instructions:	Review site quality program compliance on a quarterly basis. Reviews are due by the last day of each month following the calendar quarter. Corrective actions to non-compliant findings which do not require an investigation shall be documented by assigning as associated task in this tool. Findings requiring investigations to determine cause and implement effective corrective actions shall be entered into the SAP system for proper documentation and tracking to closure.
Observation Title: Quality Lead- Quarterly QA Program Review - Janice, Swett - 06/12/2023 10:23.740 AM	
Observation Status: Complete	**Regions:** West
Observation Date: 05/31/2023	**Department:** Wood Dale, IL
Total Completed Observations: 1	**Staff Interviewed:**
Survey Team:	**Unique Identifier:**
Medical Staff:	**Equipment Observed:**
Location:	**Contracted Service:**
Note:	

Questions (* = Required)

Cleaning/Maintenance and Infection Control

1.* Monthly quality self-inspection results been reviewed, corrective actions taken if required and corrective actions are appropriate and effective. ☐ N/A

Instructions: Review the monthly quality self-inspections for your facility to confirm compliance.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

2.* If the facility uses a third party vendor for cleaning the clean room, have all scheduled cleanings been completed per SOP, within the required time frame and documentation is clearly written and complete? ☐ N/A

Instructions: Review third party vendor clean room cleaning records for period under review, sign and date when review is completed. Confirm that the vendor has completed all scheduled cleanings on time (monthly cleaning every 30 days), appropriate cleaning agents are used per SOP and all records are complete, accurate, clearly written, signed as required and good documentation practices are followed.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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3.* Have all Clean Room equipment and environment filters been replaced or inspected as required by SOP and is proper documentation maintained? ☐ N/A

Instructions: Review Form 111 Filter Maintenance Record for timely completion of tasks required and proper documentation. LFH pre-filters are to be changed bi-annually unless otherwise required by local regulations, cart pass-thru filters are changed quarterly, air return filters (low wall air returns in clean rooms) are deep cleaned bi-annually.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

EQ.02.01.01 EP 1 - The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.

4.* Has quarterly HVAC service been completed as required by SOP and is Form 112 Maintenance Checklist on file? ☐ N/A

Instructions: Review HVAC maintenance records on file. Confirm that service is completed during each quarter, annual maintenance service schedule is completed once per year and service provider is completing Form 112 for each service.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

EQ.02.01.01 EP 1 - The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.
EQ.02.01.01 EP 2 - The organization performs basic safety and operational checks on medical equipment used by staff in the provision of care, treatment, or services, according to organization policy and the manufacturers' guidelines. The organization documents the performance of these checks.

5.* Have all laminar flow hoods LFH and biological safety cabinet BSC disinfection procedures been properly completed as required and documented accordingly? ☐ N/A

Instructions: Review Form 25 LFH and BSC disinfection logs for period under review. Confirm that all units were cleaned each day of use and frequency is appropriate as required by SOP and local regulations. Confirm an "A" agent for used daily, all entries are clearly written and good documentation practices are followed. Confirm that deep clean is performed at required frequency.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

6.* Aseptic processing areas are clean and uncluttered. All clean rooms have been cleaned each day of use as required by SOP and documented properly on Form 76. Monthly cleaning tasks performed timely and documented properly. ☐ N/A

Instructions: Review cleaning logs for period under review, sign and date when review is completed. Confirm that rooms were cleaned each day of use and monthly cleaning is performed. Confirm all documentation entries are complete and clearly written. Good documentation practices are followed.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

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EQ.02.01.01 EP 1 - The organization performs routine and preventive maintenance on medical equipment used by staff in the provision of care, treatment, or services at defined intervals and according to the manufacturers' guidelines. The organization documents the performance of these checks. Note: If the manufacturer does not have guidelines for routine and/or preventive maintenance, the organization establishes such guidelines. For example, the organization may choose to have discussions with the manufacturer, observe its own failure rates for the equipment, examine maintenance schedules of like products, or use any other method that is effective.
MM.05.01.07 EP 2 - Staff use clean or sterile techniques and maintain clean, uncluttered, and functionally separate areas for product preparation to avoid contamination of medications.

7.* Are ISO classified areas in good condition, no signs of wear, or deterioration? ☐ N/A

Instructions: Look through the clean room areas, looking for broken parts, breaks/tears/bubbling flooring, loss/deterioration of caulk, paint chips, buildup of cleaning agents, etc.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

8.* Has the restricted area been properly cleaned and maintained to aid in the control of the clean room environment? ☐ N/A

Instructions: Confirm maintenance is appropriate by observation of the restricted area for clutter and accumulation of dust/debris especially near the outer perimeter of the clean room. Documentation is not required.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

9.* Is storage of supplies in the clean room kept to a minimum, racks clean and neatly organized and opened syringes kept to 24 hour supply? ☐ N/A

Instructions: Visually observe the storage of supplies in the clean room. Confirm that supplies kept to a minimum and stored in containers that are easily cleanable when possible. No excessive supplies are stored in any area and the areas immediately surrounding the laminar flow hoods are clear of storage racks.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

10.* Hand hygiene practices follow the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5) ☐ N/A

Instructions: Verify that a legible copy of the WHO hand hygiene poster is posted at the hand hygiene sink.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

NPSG.07.01.01 EP 1 - Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) and/or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5)

11.* Verify hand hygiene compliance tracking has been completed each January and July using Form 141 and were compliance goals met during these observations? (See also IC.03.01.01, EP 3) ☐ N/A

Instructions: Minimum acceptable overall or individual compliance goal is 80%. If less than 80% compliance was observed was the individual or entire staff re-trained and re-observed? Were the most recent observation compliance rates compared with the previous tracker? Was an improvement goal of +2% or more observed for overall facility compliance from the previous tracker until ultimate goal of 100% compliance is achieved and maintained?

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

NPSG.07.01.01 EP 2 - Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)
NPSG.07.01.01 EP 3 - Improve compliance with hand hygiene guidelines based on established goals.

12.* Are all deliveries being handled in a manner to reduce the possible spread of infections? (See also IC.02.02.01, EP 4) ☐ N/A

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Instructions: Confirm by observation and interview that distribution personnel understand and comply with segregation or covering of return packages from delivery packages, hand hygiene and equipment sanitization procedures.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.01.01.01 EP 9 - The organization delivers medical equipment and supplies that are sanitary, clean, and undamaged.

13.* Do site distribution personnel reduce possible cross contamination of delivery packages by using proper segregation and/or coverings on return delivery packages? ☐ N/A

Instructions: Confirm by observation and interviews that distribution personnel understand and comply with measures to reduce cross contamination during delivery procedures.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.01.01.01 EP 9 - The organization delivers medical equipment and supplies that are sanitary, clean, and undamaged.
IC.02.02.01 EP 1 - The organization implements infection prevention and control activities when doing the following: Cleaning and performing disinfection of medical supplies and devices. * Note: Disinfection is used for items such as stethoscopes and blood glucose meters. Additional cleaning and disinfecting is required for medical equipment, devices, and supplies used by patients who are isolated as part of implementing transmission-based precautions. Footnote *: For further information regarding cleaning and performing disinfection of medical equipment, devices, and supplies, refer to the website of the Centers for Disease Control and Prevention (CDC) at https://www.cdc.gov/infectioncontrol/guidelines/disinfection/#r3. (See also EQ.01.05.01, EPs 3, 4)
IC.02.02.01 EP 3 - The organization implements infection prevention and control activities when doing the following: Disposing of medical equipment, devices, and supplies in accordance with law and regulation.
IC.02.02.01 EP 4 - The organization implements infection prevention and control activities when doing the following: Storing medical equipment, devices, and supplies. (See also EQ.01.05.01, EPs 1, 2, 3, 4, 5)

14.* Are proper supplies available for clean room entry hand hygiene? ☐ N/A

Instructions: Nail pics, hand soap in non-refillable dispensing containers, and low lint towels must be used for clean room entry hand hygiene.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

Environmental Controls and Monitoring

15.* Have the clean room and primary engineering control certification reports been reviewed for compliance and timely completion? ☐ N/A

Instructions: Confirm that third party certification reports are reviewed and all primary and secondary engineering control tests have been completed according to SOP, USP<797> and State BOP requirements. Confirm that any failures or out of compliance results are investigated and remediation actions/corrective actions are taken.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.02.01.01 EP 5 - The organization certifies laminar flow hoods and clean rooms every 12 months. The organization documents the performance of these checks. Note: There are many ways to document the certification, such as using bar coding equipment, check marks on a tag, or an inventory.

16.* Is equipment used in compounding and to ensure proper storage conditions in calibration if required? ☐ N/A

Instructions: Review all drug storage thermometers/hygrometers, cold drug storage (refrigerator) thermometers, heat block thermometers, centrifuges, velometer and tachometer to verify that equipment is in calibration. Calibration reports shall be signed and dated to document the initial site review. Verify that calibration certificates are maintained on file for equipment currently in use and prior certificates are maintained on file for a minimum of 5 years.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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EQ.02.01.01 EP 4 - The organization periodically inspects equipment used in compounding or preparing drugs for operational effectiveness and accuracy. The organization documents the performance of these checks.

17.* Have viable air samples been taken at the appropriate frequency, at all locations as required in SOP and confirmed to be within ISO classification limits? If samples exceeded action limits, was remediation conducted and properly documented with corrective actions? Was area retested to confirm state of control? ☐ N/A

Instructions: Review certification records for period under review to confirm that viable air samples have been completed as required and are within ISO classification requirements. Confirm Action limits are not exceeded. Confirm that any exceedences are reported, investigated and corrective actions if identified are implemented and communicated to applicable employees. Confirm that follow up activities to determine effectiveness of corrective actions taken are documented. If applicable, confirm that any reporting of excursions to State Board of Pharmacy was completed.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

18.* Has contact plate surface sampling been conducted at the required frequency and confirmed to be within ISO classification action limits? If exceedences are identified, was organism(s) ID'd, remediation conducted and properly documented? ☐ N/A

Instructions: Review records during period under review to confirm that contact plate tests for surface contamination have been completed as required and are within ISO classification requirements. Confirm that SOP action limits are not exceeded. Confirm that any exceedences are ID'd by a credentialed lab, reported, investigated and corrective actions if identified are documented and communicated to applicable employees. Confirm that follow ups activities to determine effectiveness of corrective actions taken are conducted and documented. If applicable, confirm that any required reporting of excursions to State Board of Pharmacy was conducted.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

EQ.02.01.01 EP 2 - The organization performs basic safety and operational checks on medical equipment used by staff in the provision of care, treatment, or services, according to organization policy and the manufacturers' guidelines. The organization documents the performance of these checks.

19.* Are temperature and humidity readings taken each day of operations in all drug and media storage locations and verified to be within required ranges? ☐ N/A

Instructions: Review temperature and humidity logs Form 28 for period under review. Confirm proper documentation each day of operations or as required by State regulations. Documentation is clearly written, and all temperatures and humidity readings are within appropriate ranges per SOP and State BOP guidance. If out of specification results are noted, were corrective actions needed to return the area to the proper range? Were corrective actions noted or documented?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.03.01.01 EP 2 - For organizations that store medications at their site(s): The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. Note: This element of performance is also applicable to sample medications.
MM.03.01.01 EP 4 - For organizations that store medications at their site(s): The organization follows a written process addressing the control of the medication between receipt by the organization and delivery to or administration at the designated site. Note: This element of performance is also applicable to sample medications.

20.* Are pressure differentials recorded each day of operations and verified to be within required ranges? ☐ N/A

Instructions: Review Form 82 pressure differential logs for period under review. Confirm that pressure differentials are documented at minimum once each day of operations, documentation is clearly written, and all pressure differentials are within appropriate ranges per SOP guidance. If out of specification results are identified, were corrective actions taken to remediate and properly documented?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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EQ.02.01.01 EP 2 - The organization performs basic safety and operational checks on medical equipment used by staff in the provision of care, treatment, or services, according to organization policy and the manufacturers' guidelines. The organization documents the performance of these checks.

21.* **Verify environmental monitoring results have been trended on the EM trending spreadsheet and evaluated for negative trends. Negative trends if any, have been identified and actions taken as needed.** ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

22.* **Are all drugs, components, drug kits, and environmental monitoring media stored correctly and are storage areas monitored using calibrated thermometers/hygrometers?** ☐ N/A

Instructions: Perform a review of the room drug storage area and drug product storage areas to ensure label storage conditions are met. If any of these products require refrigerator, freezer, or low humidity storage, these areas must be monitored using a calibrated monitoring device (thermometers and/or hygrometers). Ensure products are not stored outside of monitored areas.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

Employee Competencies and Process Validations

23.* **Have employees and third party vendors who perform duties in the clean room been visually observed for the duties they perform: initially and at frequencies as required by aseptic training policy?** ☐ N/A

Instructions: Review observational assessment Forms 114-118 on file. Confirm that initial and subsequent observational assessments have been completed on each site employee and third party vendors for all duties performed in the clean room in a timely manner. Confirm that no observational assessments are past due.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

24.* **Have all employees who perform compounding and drawing activities performed the applicable media fill validations initially prior to performing duties and been re-evaluated at the appropriate intervals in accordance with SOP?** ☐ N/A

Instructions: Review media fill records for the period under review for compliance to SOP. If a media fill failure is noted, have investigation procedures and re-evaluation as outlined been completed, documented and reported?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

25.* **Have all employees who perform WBC labels performed a WBC media fill validation initially prior to performing duties and been re-evaluated at the appropriate intervals in accordance with SOP?** ☐ N/A

Instructions: Review WBC media fill records for the period under review for compliance to SOP. If a media fill failure is noted, have investigation procedures and re-evaluation been completed, documented and reported?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

26.* **Have all employees who perform aseptic compounding or dose drawing performed gloved fingertip sampling as required by SOP? Initial GFT sampling must be completed on 3 separate and full garbing procedures. Re-evaluation GFTs are conducted as part of the media-fill process.** ☐ N/A

Instructions: Review gloved fingertip sampling records. Confirm that all applicable employees have completed initial triplicate fingertip sampling to verify proper garbing technique and fingertip samples during media fills to confirm aseptic technique prior to performing aseptic operations. Confirm that employees are sampled at appropriate frequency in compliance with SOP during a media fill operation. If action limits are exceeded, are investigations into the possible cause conducted, employees re-instructed, re-evaluated and properly documented in the reporting tool?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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27.* Has product sterility testing been completed annually as required by SOP or more frequently if required by local BOP rules? ☐ N/A

Instructions: Review Form 119 to confirm that sterility testing has been completed as required by SOP at minimum annually or as required by local BOP rules. If a positive sterility test was observed, was failure properly reported, investigated, corrective action if identified are implemented and communicated to applicable employees? Confirm that follow up activities to determine effectiveness of corrective actions taken are documented in the reporting tool.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

28.* Are all the staff's required licenses, certifications, or registrations, posted in the facility and not expired? Is Form 42 completed, and up-to-date? *If any licenses are due to expire within the upcoming calendar quarter, assign a TASK for that employee using this tracer, requiring them to provide proof of renewal prior to the expiration date. ☐ N/A

Instructions: Staff licenses, certifications, registrations required by the company, BOP or a State agency must be verified through the issuing agency website upon hire, and prior to each expiration. If you use floaters, their license must be checked prior to performing duties at your site, if the license has not been verified by their primary worksite site since the last renewal date. If your state requires the company maintains record of CE required for license/certification renewal, documentation must be presented to the PIC at the time of renewal and maintained on file.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

HR.01.01.01 EP 2 - The organization verifies and documents the following: - Credentials of staff using the primary source when licensure, certification, or registration is required by law and regulation to practice their profession. This is done at the time of hire and at the time credentials are renewed. - Credentials of staff (primary source not required) when licensure, certification, or registration is not required by law and regulation. This is done at the time of hire and at the time credentials are renewed. For home health agencies that elect to use The Joint Commission deemed status option: The organization maintains current licensure and qualifications in personnel records. Note 1: It is acceptable to verify current licensure, certification, or registration with the primary source via a secure electronic communication or by telephone, if this verification is documented. Note 2: A primary verification source may designate another agency to communicate credentials information. The designated agency can then be used as a primary source. Note 3: An external organization (for example, a credentials verification organization [CVO]) may be used to verify credentials information. A CVO must meet the CVO guidelines identified in the Glossary.

29.* Have the appropriate aseptic assessments been completed on any new hire or employees whos duties have changed to require entry ISO classified areas prior to entry? ☐ N/A

Instructions: All employees who enter an ISO classified area must be trained and then assessed on their aseptic techniques applicable to their assigned duties.
Entry requires: 1) Hand hygiene and garbing training and observational assessment
2) Initial Gloved fingertip tests on three separate hand hygiene and garbing entries
Cleaning/disinfecting requires: 1) Cleaning/disinfecting observational assessment for each area they are assigned duties
Product prep/dose drawing requires: 1) Aseptic technique assessment
2) Media fill/GFT testing for assigned duties

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

Training

30.* Have all employees completed the initial and annual USP training module in a timely manner? ☐ N/A

Instructions: Review training records to confirm that all new employees have completed the initial USP training module(s) appropriate to their job description and prior to performing clean room related tasks. Annual reviews are completed by all employees within the past year. No training is past due.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

31.* Are employee who perform WBC labeling and WBC Dual Verifications up to date on training required in SOP? ☐ N/A

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Instructions: Confirm by reviewing electronic and/or hard copy training records to confirm all employees who perform WBC labeling procedures and Dual Verifications are trained initially and annually thereafter as required by SOP.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

32.* Do all employees who perform Therapy Order Verifications have a Form 49 on file? ☐ N/A

Instructions: Confirm that all employees who perform therapy order verifications are initially trained (Form 49 on file).

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

33.* Are Management of Change MOC activities properly implemented and communicated to site employees? ☐ N/A

Instructions: Review site electronic and/or hard copy MOC documents including training records for the quarter under review. Confirm that employees have acknowledged training on Change packets or signed hard copy training records if changes were applicable to their job duties. Verify that MOC changes have been properly implemented and new forms and procedures are being utilized.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

34.* The PIC has reviewed SOPs associated with the overall QA/QC site program within the last 12 months against current employee practices and State BOP requirements. ☐ N/A

Instructions: This review is documented on Form 120. Corrective actions are taken to ensure SOPs reflect current practices and Fed/State regulatory requirements.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)

35. Confirm by review of change packet documentation that any program changes implemented during the quarter have been fully implemented and all applicable personnel have been trained on these program changes. ☐ N/A

Instructions: MOC training records are maintained on file either hard copy or electronically for all affected employees.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)

Compounding and Preparation

36.* Does the facility assign appropriate expiration dating to compounded drugs and drugs used in compounding procedures in compliance with policies and procedures? ☐ N/A

Instructions: Check pharmacy computer system for maximum activity and expiration times on all compounded drug products. Verify that the site has on file complete stability data by drug manufacturer for all drugs compounded beyond package insert activity and expiration time. Confirm that kit calibration times match actual compounding times within 15 minutes. Confirm that no new drugs or manufacturers were introduced during the period under review and if so, maximum activity and expiration times assigned are set to package insert or are supported by complete stability records on file. Confirm by observation and interviews that single use bag/vials of diluents used during compounding are labeled with open date/time if used during multiple runs or discarded at end of run. No single use vial or bag punctured inside an ISO 5 environment is used for more than 6 hours.

Compliant? ◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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37. Are medications and components stored in accordance with manufacturer's recommendations or, in the absence of such recommendations, in accordance with PIC's instructions? Are high alert medications, look-a-like/sound-a-like medications properly labeled, stored and handled as indicated in SOP 3.2.4? ☐ N/A

Instructions: Confirm compliance by inspecting drug storage areas. Observe procedures and review associated documentation for compliance (Y-90, Bexxar, therapy medication, WBC labeling, etc.). Confirm proper order processing and handling of look-a-like/sound-a-like drugs as described in SOP.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

MM.01.01.03 EP 1 - The organization identifies, in writing, its high-alert and hazardous medications. * Note: This element of performance is also applicable to sample medications. Footnote *: For a list of high-alert medications, see https://www.ismp.org/recommendations. For a list of hazardous drugs, see https://www.cdc.gov/niosh/docs/2016-161/pdfs/2016-161.pdf. (See also EC.02.02.01, EP 1)
MM.01.01.03 EP 2 - The organization follows a process for managing high-alert and hazardous medications. Note: This element of performance is also applicable to sample medications. (See also EC.02.02.01, EP 2)
MM.01.02.01 EP 1 - The organization develops a list of look-alike/sound-alike medications it stores, dispenses, or administers. Note 1: One source of look-alike/sound-alike medication name pairs is the Institute for Safe Medication Practices (https://www.ismp.org/recommendations/confused-drug-names-list). Note 2: This element of performance is also applicable to sample medications.
MM.01.02.01 EP 2 - The organization takes action to prevent errors involving the interchange of the medications on its list of look-alike/sound-alike medications. Note: This element of performance is also applicable to sample medications.
MM.01.02.01 EP 3 - The organization annually reviews and, as necessary, revises its list of look-alike/sound-alike medications. Note: This element of performance is also applicable to sample medications.
MM.03.01.01 EP 2 - For organizations that store medications at their site(s): The organization stores medications according to the manufacturers' recommendations or, in the absence of such recommendations, according to a pharmacist's instructions. Note: This element of performance is also applicable to sample medications.

38.* Are large volume parenterals divided in compliance with SOP, properly stored and labeled? ☐ N/A

Instructions: Confirm by observation that large volume parenterals are divided and labeled in compliance with SOP and given proper expiration dating.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

39.* Are drugs which have expired, are damaged, contaminated or have been recalled properly handled and quarantined in a designated area away from active product prior to final disposal in compliance with SOP? ☐ N/A

Instructions: Confirm by review of computer inventory that expired and recalled drugs are not in active inventory. Inspect quarantined product storage area for proper segregation.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

MM.03.01.01 EP 8 - All expired, damaged, and/or contaminated medications are removed from patient care areas and stored separately from medications available for administration. Note: This element of performance is also applicable to sample medications.
MM.05.01.17 EP 1 - The organization follows a written policy describing how it will retrieve and handle medications within the organization that are recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA). Note: This element of performance is also applicable to sample medications.
MM.05.01.17 EP 3 - For organizations that store or dispense medications: When a medication is recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA), the organization notifies the prescribers and those who dispense or administer the medication. Note: This element of performance is also applicable to sample medications.
MM.05.01.17 EP 4 - When required by law and regulation or organization policy, the organization informs patients that their medication has been recalled or discontinued for safety reasons by the manufacturer or the US Food and Drug Administration (FDA). Note: This element of performance is also applicable to sample medications.

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40. Confirm by review of local documents and observation that product information is properly confirmed at time of receipt and labeled with Auxiliary Control # labels and Auxiliary Barcode labels as required in SOP 3.2.2. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.02.01.01 EP 4 - The organization maintains a written list of medications, including strength and dosage, for dispensing and administering. The list of medications is readily available. Note: In some settings, the term "formulary" is used instead of "list of medications available for use." The terms are synonymous. (See also MM.03.01.01, EP 1)
MM.03.01.01 EP 1 - For organizations that store medications at their site(s): The organization stores only approved medications and medications selected by the organization. (See also MM.02.01.01, EP 4)
MM.03.01.01 EP 4 - For organizations that store medications at their site(s): The organization follows a written process addressing the control of the medication between receipt by the organization and delivery to or administration at the designated site. Note: This element of performance is also applicable to sample medications.

41.* Confirm by review of local documents and that a master formula is on file in hard copy or electronic copy for each product prepared with minor deviations or compounded as described in Policy 6.5. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

42.* Confirm by review of pharmacy computer system that all maximum activities and expiration times which exceed the manufacturers recommendations are supported by stability data required in SOP 6.5.2. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

43. Confirm by review of current inventory and inventory records that only appropriate, conventionally manufactured sterile products from FDA-registered facility are used in product preparation. ☐ N/A

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.02.01.01 EP 2 - The organization develops and approves criteria for selecting medications, which include the following: - Indications for use - Effectiveness - Drug interactions - Potential for errors and abuse - Adverse drug events - Sentinel event advisories - Other risks - Costs Note: This element of performance is also applicable to sample medications.
MM.02.01.01 EP 4 - The organization maintains a written list of medications, including strength and dosage, for dispensing and administering. The list of medications is readily available. Note: In some settings, the term "formulary" is used instead of "list of medications available for use." The terms are synonymous. (See also MM.03.01.01, EP 1)

44. All vial shields are properly labeled whenever radiopharmaceuticals are prepared. (See also MC.03.08.05, EP 1; MC.05.01.01, EPs 4 and 6; MM.06.01.01, EP 3) ☐ N/A

Instructions: Vial shield labels are undamaged, cleanable. Auxiliary control # labels are placed on shields prior to preparation.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.05.01.09 EP 1 - Medication containers are labeled whenever medications are prepared but not immediately administered. Note 1: This element of performance does not apply to segregated pill boxes that store medications by day and time of day. Note 2: An immediately administered medication is one that an authorized staff member prepares or obtains, takes directly to a patient, and administers to that patient without any break in the process. Note 3: This element of performance is also applicable to sample medications.

Quality Events/Performance Improvement

45.* Are all quality related events reported to the facility through customer or patient complaints such as the right dose, right drug, right patient/customer, right time, on time, and product safety events such as altered biodistribution, adverse events, patient complaints etc., being properly reported in the electronic database and being investigated for appropriate corrective actions? Are external reports being made as required by law or regulation? ☐ N/A

Instructions: Confirm by reviewing reported events for complete and clearly written documentation, references to all investigation activities, identification of corrective actions and follow up documentation showing effectiveness of corrective actions. Confirm external reports are timely if needed. Confirm that site personnel can retrieve supporting documents that are not supplied as attachments to the event.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

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LD.03.07.01 EP 2 - As part of performance improvement, leaders, or managers delegated by leaders, do the following: - Set priorities for data collection, performance improvement activities, and patient health outcomes - Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities Note: Examples of areas of risk include blood-borne infections, wound care, undetected urinary tract infections, oxygen-related fires, and patient handoff to or from the home care organization. - Identify the frequency of data collection for performance improvement activities - Reprioritize performance improvement activities in response to changes in the internal or external environment Note: For home health agencies and hospices that elect to use The Joint Commission deemed status option: The organization's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care. (See also PI.01.01.01, EPs 2, 12, 13; PI.02.01.01, EP 1)
PI.01.01.01 EP 12 - The organization collects data on the following: Significant medication errors. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 13 - The organization collects data on the following: Significant adverse drug reactions. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 15 - The organization collects data on the following: - Patient satisfaction with and complaints about products and services - Timeliness of response to patient questions, problems, and concerns - Impact of the organization's business practices on the adequacy of patient access to equipment, items, services, and information - Adverse events involving patients due to inadequate or malfunctioning equipment, supplies, or services (for example, injuries, accidents, signs and symptoms of infection, and hospitalizations)
PI.01.01.01 EP 2 - The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.03.07.01, EP 2)
PI.01.01.01 EP 41 - For specialty pharmacies: The organization collects data on medication errors including the following: - Incorrect drug - Incorrect recipient - Incorrect strength of medication - Incorrect dosage form - Incorrect instructions - Incorrect quantity - Near misses
PI.01.01.01 EP 42 - For specialty pharmacies: The organization collects data on the following: - Adherence rate - Turnaround time for patient delivery of medications and associated products supplied by the specialty pharmacy Note: The organization may choose to separate data for medications that require an intervention. - Billing and coding errors

46.* Are quality events and corrective actions being properly communicated to all affected employees and employee training completed? ☐ N/A

Instructions: Confirm that events are being properly communicated to affected employees by reviewing site communications documents such as monthly safety meeting minutes or completion of training record on Form 45.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

LD.03.07.01 EP 2 - As part of performance improvement, leaders, or managers delegated by leaders, do the following: - Set priorities for data collection, performance improvement activities, and patient health outcomes - Give priority to high-volume, high-risk, or problem-prone processes for performance improvement activities Note: Examples of areas of risk include blood-borne infections, wound care, undetected urinary tract infections, oxygen-related fires, and patient handoff to or from the home care organization. - Identify the frequency of data collection for performance improvement activities - Reprioritize performance improvement activities in response to changes in the internal or external environment Note: For home health agencies and hospices that elect to use The Joint Commission deemed status option: The organization's governing body is ultimately accountable for making sure that the priorities that are selected address improvements to the safety and quality of patient care. (See also PI.01.01.01, EPs 2, 12, 13; PI.02.01.01, EP 1)
PI.01.01.01 EP 12 - The organization collects data on the following: Significant medication errors. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 13 - The organization collects data on the following: Significant adverse drug reactions. (See also LD.03.07.01, EP 2; MM.08.01.01, EP 1)
PI.01.01.01 EP 15 - The organization collects data on the following: - Patient satisfaction with and complaints about products and services - Timeliness of response to patient questions, problems, and concerns - Impact of the organization's business practices on the adequacy of patient access to equipment, items, services, and information - Adverse events involving patients due to inadequate or malfunctioning equipment, supplies, or services (for example, injuries, accidents, signs and symptoms of infection, and hospitalizations)
PI.01.01.01 EP 2 - The organization collects data on the following: Performance improvement priorities identified by leaders. (See also LD.03.07.01, EP 2)

47.* Are corrective actions to quality events implemented and are follow ups conducted to confirm effectiveness? ☐ N/A

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Instructions: Confirm by reviewing events for identified corrective actions. Do documents and/or interviews with employees confirm that corrective actions have been implemented? Have re-occurrences of the event or similar events happened which may show lack of effectiveness?

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)
PI.04.01.01 EP 4 - The organization evaluates actions to confirm that they resulted in improvements. Note: For hospices that elect to use The Joint Commission deemed status option: The hospice's governing body is ultimately accountable for making sure that improvement actions are evaluated for effectiveness.
PI.04.01.01 EP 5 - The organization acts when it does not achieve or sustain planned improvements.

48.* Do site events show any re-occurrences or trends that have not been previously identified and that needs to be investigated for possible site or systemic corrective actions? Answer compliant if no re-occurrences or trends. ☐ N/A

Instructions: Confirm by review of site events for the period under review. Pay close attention to similar types events and look for trends that may show a breakdown of the quality system in place. If a trend is identified, an investigation into possible causes and corrective actions is to be initiated locally. If a systemic issue and corrective actions is identified a Management of Change shall be initiated.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

PI.03.01.01 EP 4 - The organization analyzes and compares internal data over time to identify levels of performance, patterns, trends, and variations.
PI.04.01.01 EP 5 - The organization acts when it does not achieve or sustain planned improvements.

49.* Have all product related complaints reported to or noted by pharmacy staff such as altered bio-distributions, adverse reactions and QC failures been reported to the drug manufacturer as required by SOP? ☐ N/A

Instructions: Review events entries for the period under review. Confirm that any product related complaints have been reported directly to the drug manufacturer.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

MM.07.01.03 EP 1 - The organization follows a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors. Note: This element of performance is also applicable to sample medications.
MM.07.01.03 EP 2 - The organization follows a written process addressing prescriber notification in the event of an adverse drug event, significant adverse drug reaction, or medication error. Note: This element of performance is also applicable to sample medications.
MM.07.01.03 EP 3 - The organization complies with internal and external reporting requirements for actual or potential adverse drug events, significant adverse drug reactions, and medication errors. Note: This element of performance is also applicable to sample medications.

50.* Has the site posted updated local communicable disease information for employees to review? ☐ N/A

Instructions: Confirm by observation that the local communicable disease postings are updated quarterly. The posting shall include influenza rates during the flu season. If an updated posting is not available, the current posting should be signed and dated as updated.

Compliant?	◉Yes ○No	Num: 1	Den: 1	Comp%: 100.00

IC.01.03.01 EP 1 - The organization identifies infection risks based on the following: - Its geographic location, community, and population served - The care, treatment, or services it provides - The analysis of its surveillance activities and other infection control data Note 1: Surveillance activities may address processes and/or outcomes. Note 2: For organizations that provide personal care and support services: Surveillance activities may include verification of infection control education for all employees and supervisor observations of employees' hand-washing techniques.
IC.01.03.01 EP 3 - The organization prioritizes the identified risks for acquiring and spreading infections. These prioritized risks are documented.

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51.* Has the facility completed the hand hygiene compliance tracker as required and does the facility meet company goals for hand hygiene compliance? ☐ N/A

Instructions: Confirm by reviewing local documents. If hand hygiene compliance did not meet goals, were corrective actions taken to promote compliance and were follow up observations made to confirm effectiveness of corrective actions? Current frequency is biannual (January/July of each year).

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

NPSG.07.01.01 EP 1 - Implement a program that follows categories IA, IB, and IC of either the current Centers for Disease Control and Prevention (CDC) and/or the current World Health Organization (WHO) hand hygiene guidelines. (See also IC.01.04.01, EP 5)
NPSG.07.01.01 EP 2 - Set goals for improving compliance with hand hygiene guidelines. (See also IC.03.01.01, EP 3)
NPSG.07.01.01 EP 3 - Improve compliance with hand hygiene guidelines based on established goals.

52.* Confirm the current year Organizational Goals are posted and all employees are aware/understand these goals. Do employees know how we improve our performance to our goals through Continuous Quality Improvement (CQI)? ☐ N/A

Instructions: When interviewed, can staff name a goal or a quality improvement change that was implemented within the last year, i.e., an SOP change, or local change made in response to site event trending or customer complaint?

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

LD.02.01.01 EP 1 - Leaders work together to create the organization's mission, vision, and goals, which guide the leaders' actions and are communicated to staff and the population(s) the organization serves.
PI.04.01.01 EP 2 - The organization acts on improvement priorities. (See also MM.08.01.01, EP 6)

53.* Are employees following Policy 4.3 and SOP 4.3.2 to respond to actual or potential adverse drug events, significant adverse drug reactions and medication errors? Staff Pharmacists follow procedures to notify affected prescribers. (See also MC.02.01.13, EP 2) ☐ N/A

Instructions: Verify by reviewing events and/or employee interviews.

Compliant?	Num: 1	Den: 1	Comp%: 100.00
◉Yes ○No			

MM.07.01.03 EP 1 - The organization follows a written process to respond to actual or potential adverse drug events, significant adverse drug reactions, and medication errors. Note: This element of performance is also applicable to sample medications.

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SOP 4.4.4 Quality and Safety Self-Inspections and Program Reviews

I. Purpose

To describe quality and safety compliance self-inspections and program reviews.

II. Scope

This applies to all Nuclear Pharmacy sites.

III. Responsibility

It is the responsibility of the Pharmacy Manager or designee to oversee policy compliance for personnel under his/her supervision.

IV. Definitions

PIC- Pharmacist in Charge

V. Related Forms

Form 120 Quality Policy and Procedures Review Log

VI. Equipment and Materials:

All equipment and materials used in aseptic processing

VII. Procedure

A. Site Self-Inspections

1. Periodic self-inspections shall be conducted by each facility to ensure ongoing program and regulatory compliance.
2. Tracers with AMP® shall be used to record and maintain documentation of self-inspections either electronically or by printing a hard copy.
3. Content and minimum frequency of the self-inspections shall be determined by the QA/RA, EHS departments.
4. Tracer names and minimum required frequencies are listed in Table 1.
5. Issues identified during the self-inspections shall be documented to include the following:
    a. Description of issue identified
    b. Investigation details including root cause(s) if identified
    c. Corrective action and preventative actions (CAPAs) taken to prevent reoccurrence
    d. CAPA effectiveness evaluation if deemed necessary

B. Site Ops Metrics and Quality Program Reviews

1. Each site PIC/Manager or designee will report all Ops Metrics data by using the Ops Metrics reporting tool link on the E-Reporting and Requesting document found on Teams: https://forms.monday.com/forms/62687754c09f36ac1fa30af545d54340?r=use1

a. Ops Metrics data should be reported by the 15th of each month for the previous month.

2. Quality policies and procedures shall be reviewed annually by the PIC and documented on Form 120 for site compliance and applicability.
    a. This review will include but is not limited to the following:
    - Policy 2.2 Dose Calibrator and all associated SOPs

- Policy 2.3 Radiation Detection Equipment and all associated SOPs
- Section 3: Medication Management
- Policy 4.3 Patient Safety Events & Product Complaints and associated SOPs
- Policy 4.4 Pharmacy Regulatory Events and Inspections and associated SOPs
- Section 6: Quality Assurance- Medication Compounding
- Section 7: Blood Procedures and Controls
- Section 9: Pharmacy Wholesale Distribution

b. Any discrepancies between written procedures and state regulations shall be identified by submitting a management of change request.

3. The site PIC or designee shall review all new or revised policies and procedures and develop a local implementation plan. Hard copy Form 45 or electronic training records of implementation shall be maintained.

Table 1:

Tracer Name	Minimum Frequency	Suggested Responsibility
Monthly Vehicle Safety Check	Monthly on each company vehicle	Courier/Driver
Monthly EHS Safety Self-Inspection	Monthly	Any trained staff member
Monthly Quality Self-Inspection	Monthly	Any trained staff member
RSO- Monthly Rad Safety Inspection	Monthly	RSO
Quality Lead- Quarterly QA Program Review	Each calendar quarter	Quality Lead or Manager/PIC
EHS Lead- Quarterly Program Review	Each calendar quarter	EHS Lead or Manager/PIC
Quarterly Radioactive Medical Waste (RMW) Self-Inspections- State specific checklists for California, Florida, and New York	Each calendar quarter for sites in specified States	RSO
Biannual Hazardous Material (HMT) Self-Inspection	Biannual	EHS Lead or Manager/PIC
Biannual Form 141 Hand Hygiene Tracer Results	Every January and July	Quality Lead or Manager/PIC
Biannual Emergency Drill Confirmation	Biannual	EHS Lead or Manager/PIC
Medication Management Compliance	Annually	Manager/PIC
Annual OSHA Work Related I&I Reporting/Posting	Each year by February 1st thru April 30th	Manager/PIC
Contract Courier Observational Assessment	Optional or as needed for finding corrective actions	Any trained staff member
Packing and Shipping RAM Observational Assessment	Optional or as needed for finding corrective actions	Any trained staff member

VIII. Training

Employees performing these duties shall be trained on the procedure and the documentation tools.

LIST OF ATTACHMENTS

None

Document History		
Version	Date	Brief Description of Change
1	1 June 2020	New Document
2	1 Dec 2020	Updating SOP to remove quality audit which are now covered in SOP 4.4.3, identify required periodic self-inspections, and include form 140 on self-inspections and moved SOP # from 6.1.1 to 4.4.4.
2.1	1 Nov 2021	Administrative
2.2	1 Jul 2022	Updated for self-inspections to be recorded in Tracers with AMP tool, remove reference to Form 140.
2.3	1 Nov 2022	JC Finding- Update to identify required self-inspections by name, location, and frequency. Update to include location and required completion of Ops Metrics.

SOP 6.2.2 Aseptic Techniques & Preparation

I. Purpose:

To describe the aseptic technique used while compounding and dispensing sterile radiopharmaceuticals and pharmaceuticals.

II. Scope:

This applies to all Nuclear Pharmacy sites. Aseptic technique procedures will be employed when preparing for, and during all sterile product processing.

III. Responsibility:

It is the responsibility of the Business Unit Manager or designee to oversee policy compliance for personnel under his/her supervision. All pharmacists and supervised pharmacy support staff who prepare sterile products will adhere to these procedures.

IV. Definitions:

A. **Air curtain** – is the air boundary at the face of a LFH and BSC
B. **ALARA** – As Low as Reasonably Achievable
C. **Beyond Use Date (BUD)**- The date or time after which a compounded product or component used in compounding shall not be used.
D. **Buffer Area** – The area where the primary engineering control that generates and maintains an ISO Class 5 environment is physically located.
E. **CR** – Clean Room, which refers to all ISO classified areas
F. **Critical Sites** – Locations that include any component or fluid pathway such as vial septa, injection ports, open ampules, syringe tips, needles and needle hubs that are exposed and at risk of direct contact with air or touch contamination
G. **Critical Work Area** – Central area within the laminar air flow hood
H. **CSP** – Compounded Sterile Preparation
I. **Direct Compounding Area (DCA)** – A critical area within the ISO Class 5 primary engineering control where critical sites are exposed to unidirectional HEPA filtered air (first air)
J. **First Air** – The unidirectional air exiting the HEPA filter that is essentially particle free
K. **Multiple-Dose Containers**- A multiple-dose container for articles or preparations intended for parenteral administration only and usually containing antimicrobial preservatives.
L. **Primary Engineering Control (PEC)** –Laminar flow hood (LFH) and Biological Safety Cabinet (BSC) which provide an ISO Class 5 environment for the exposure of critical sites
M. **Secondary Engineering Control (SEC)** – Clean Room ISO Class 8 ante and ISO Class 7 buffer areas which serve as a core for the location of the PEC
N. **Single-Dose Containers** - Single-dose containers are single-unit containers for articles or preparations intended for parenteral administration only.
O. **Restricted Area** – Radiation Restricted Area as defined for each individual facility

V. Related Documents:

None

VI. Equipment and Materials:

None

VII. Procedure:

A. All employees entering the clean room shall:

1. Maintain good personal hygiene
2. Perform thorough hand cleaning
3. Select and properly don appropriate garb
4. Clean and maintain the environment in accordance with the ISO classification of each area
5. Protect personnel and compounding environments from contamination
6. Offer guidance when observing incorrect procedures and report malfunctioning equipment.

B. All employees performing aseptic operations shall:
   1. Accurately and aseptically compound and dispense sterile products
   2. Properly label all CSP
   3. Inspect all CSP prior to release

C. To aid in maintenance of ISO classified air quality and first air:
   1. Only personnel directly involved in compounding or dispensing should be in the buffer rooms while aseptic processes are in progress.
   2. Dynamic occupancy rates tested during the current certification test should not be exceeded during aseptic operations.
   3. Verify LFH has proper air velocity prior to use by visual inspection of the airflow monitor or magnahelic gauge.
      a. If the LFH airflow monitor indicates the velocity is below the manufacturer's acceptable level for operation, the pre-filters shall be replaced. If the air velocity remains below the acceptable level after changing the pre-filters, the unit shall not be used.
   3. Verify BSC has proper air velocity prior to use each day by visual inspection of the magnahelic gauge and record the reading on Form 25.
      a. A significant change in the magnahelic gauge reading the time of calibration will indicate cause for concern and the unit shall not be used until service personnel can evaluate proper function.
   4. All personnel while working in the CR shall avoid excessive and fast movement that may compromise the air quality inside the ISO Class 5 PEC. This includes:
      a. Flapping of hands to dry gloves
      b. Quick movements near a PEC or through the air curtain at the face of the PEC
      c. Placement, pulling or swinging of the dose calibrator well dipper pulley in such a way that the pulley moves in and out of the ISO Class 5 air during aseptic operations
   5. Only essential personnel and items shall be in the immediate area of an ISO Class 5 PEC during aseptic processing. The immediate area shall be a minimum of 3 feet in front of any ISO Class 5 PEC.
   6. Talking shall be kept to a minimum and directed away from the PEC during aseptic processing.
   7. Operators shall not interfere with the first air flowing directly from the PEC HEPA filter to critical sites during manipulations.
      a. Radiation safety practices must be balanced with aseptic handling practices when handling radioactive materials. The use of flanged syringe shields and recessed vial shielding may disrupt direct first air contact with the vial septum during certain handling conditions.
      b. The operators' hands or any equipment shall not be allowed to block or interrupt HEPA filtered air to critical sites e.g., unsheathed needle, open centrifuge tube, exposed barrel tip and punctured vial septum when radiation safety practices are not a factor, e.g., drawing saline into a syringe.
   8. Only supplies critical to aseptic operations may be introduced into the PEC.
      a. Items placed in the PEC shall be disinfected using a sterile wiper and sterile 70% IPA.
      b. Unit dose pigs shall be cleaned and disinfected within 24 hours prior to the production run.
      c. Equipment and absorbent material shall not obstruct airflow return grates at the front and back of the work surface.

9. Saline bags and other products or devices shall be hung in the PEC to avoid obstructing first air to the DCA and to ensure critical sites are accessed at least 6 inches from the front edge and either side wall of the PEC.
10. A minimal number of absorbent pads may be used in the PEC for ALARA purposes and shall not block airflow grates at the front or back of the PEC.
11. Only supplies immediately necessary to kit compounding and dose dispensing activities shall be in the DCA.
12. Under normal operations, PECs should never be turned off. In the event of a power failure or shut down for maintenance or service, the unit must be:
    a. Turned on and allowed to run for a minimum of 30 minutes to allow purging of contaminated air and full circulation of first air.
    b. Cleaned with a List A agent and disinfected with sterile 70% IPA prior to use.

D. General Principles of Aseptic Technique
1. Aseptic principles are used during preparation of CSPs to ensure they are free of microorganisms, pyrogens, and particulate matter. It involves the manipulation of products, vials, syringes and the shielding necessary to reduce radiation exposure with consideration to airflow to produce a sterile final product.
2. All aseptic manipulations shall be conducted in a properly prepared ISO Class 5 PEC while wearing appropriate garb.
3. Compounding, dose dispensing, removing, changing, or adding a needle, and vial or bag punctures or any action that involves exposing a critical site to potential contamination shall be considered an aseptic manipulation.
4. Vial septa and bag injection ports shall be disinfected before puncturing, after being exposed to less than ISO 5 air, and if touch contamination is known or suspected. Disinfection shall be performed:
    a. inside the PEC prior to initial puncture
    b. using a new sterile 70% IPA swab
    c. by wiping three times in the direction of the operator
    d. prior to another needle puncture if vial shield top is closed or product is removed from the ISO 5 environment
    e. frequently whenever multiple punctures are occurring
5. Critical sites such as the needle shaft and tip, the syringe plunger ribs, and barrel tip cannot be disinfected and must be discarded if touch contamination is known or suspected.
6. Care must be taken to avoid touching the plunger ribs when drawing sterile products into syringes. If plunger ribs have been or are suspected to have touch contamination:
    a. You may continue with the action of pulling product into the syringe.
    b. You may eject one time as needed e.g., during kit preparation.
    c. You may NOT move the plunger back and forth to adjust activity/volume because the product may become contaminated.
7. Needles shall be used immediately upon removing the cap and promptly recapped or discarded after use.
8. Syringes containing diluents or sterile products for future use may not have the needles removed unless replaced with a sterile cap.
9. Syringes and needles must be discarded if needles are uncapped or removed from syringes in an environment other than ISO Class 5 air quality.
10. Operators shall disinfect their gloves by spraying all surfaces with Sterile 70% IPA:
    a. Immediately after donning sterile gloves.
    b. Prior to cleaning the PEC.

c. Immediately prior to each kit preparation after all disinfected components for compounding have been properly introduced into the PEC.
d. Immediately prior to each dose drawing activity after proper line clearance has been completed and the kit has been properly introduced into the PEC.
e. Immediately prior to initiating each WBC processing action conducted inside the BSC.
f. Prior to re-entering the PEC after touching non-sterile surfaces such as phones, barcode scanners, pens, paper, carts, generators, heat block containment box, tables, etc.
g. Periodically throughout prolonged sessions of compounding or dose drawing or when suspected or known contaminant has occurred.

D. Assignment of BUDs
1. Sterile and Non-sterile prepared products:
a. Shall not exceed the manufacturer's expiration date or time of the component(s) used in compounding.
b. Non-sterile shall be compliant with current USP<795> guidelines.
c. Sterile radiopharmaceutical shall be compliant with current USP<825> guidelines.
d. Sterile radiopharmaceuticals prepared from cold kits shall be compliant with SOP 6.5.2/CASOP 6.5.2 Stability Testing when applicable.
2. Single dose containers:
a. Must be punctured within an ISO Class 5 environment with proper aseptic technique.
b. Must be properly labeled with the BUD date and time.
(a) Single-dose containers used during a single production run not exceeding 6 hours and remaining under the control of a single operator, need not be labeled but must be discarded at the end of the single production run.
c. Maximum BUD is 6 hours and must be discarded 6 hours after the initial needle puncture.
3. Multiple dose containers:
a. Must be punctured within an ISO Class 5 environment with proper aseptic technique.
b. Must be properly labeled with initial puncture date and discard date.
c. Maximum BUD is 28 days after initial needle puncture unless otherwise specified by the manufacturer.
d. BUD shall not exceed the manufacturer's expiration date.

VIII. Training

All employees who perform aseptic operations shall be trained on this procedure.

LIST OF ATTACHMENTS
None

DOCUMENT HISTORY		
Version	**Date**	**Brief Description of Change**
1	1 June 2020	New Document
1.1	15 Sept 2021	Changed incorrect reference to sterility testing policy.
1.2	1 Nov 2021	Administrative
1.3	1 Nov 2022	Update C.4. in response to JC finding regarding dose calibrator dipper swinging in and out of ISO Class 5 air space during product preparation and dose drawing.

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NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

Change in Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Application

Non-Refundable $50.00 Fee

Rev (05/17/2023)

Section 1: Pharmacy Information

Pharmacy Name: RALEYS #120 License #: PH01276

Physical Address: 1201 S MAIN ST

City: TONOPAH State: NV Zip: 89049

Mailing Address (if different from physical address): _____

City: _____ State: _____ Zip: _____

Telephone: 775-482-6711 Toll Free # (NAC 639.708, NRS 639.23286): _____

Fax: 775-482-8767 Contact Email: 120PHARM@RALEYS.COM

Section 2: Previous Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Information

Pharmacist Name: FLORENCE BESONG-ASAH NV Pharmacist Registration #: 20532

State and End Date of the Managing Pharmacist/PIC/Supervising Pharmacist: 03/22/2025

Section 3: New Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Information

Pharmacist Name: THOMAS SCHOTIK NV Pharmacist Registration #: 08312

State Date as the Managing Pharmacist/PIC/Supervising Pharmacist: 03/22/2025

Personal and Professional History for the New Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your registration?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?		✓
3. Have you been the subject of a board citation or administrative action whether completed or pending in any state?	✓	
4. Has your license/registration been subjected to any discipline for violation of pharmacy or drug laws in any state?	✓	

If you marked YES to any questions above, include the following information and provide a signed statement of explanation. Copies of any documents that identify the circumstance or contain an order, agreement or other disposition is required.

Board Administrative Action:	State:	Date:	Case #:
RESTRICTION	NEVADA	09/04/2024	23-063-RPH-S0904

Criminal Action:	State:	Date:	Case #:	County:	Court:

Section 4: New Managing Pharmacist/Pharmacist in Charge/Supervising Pharmacist Acknowledgement

Managing Pharmacist Name: THOMAS SCHOTIK Pharmacist Registration #: 08312

Pharmacy Name: RALEYS #120 Pharmacy License #: PH01276

Initial each statement below to indicate you have read and agree with the following:

TS I understand that as the managing pharmacist I am responsible for compliance by the pharmacy and its personnel with all state and federal laws and regulations relating to the operation of the pharmacy and the practice of pharmacy. I understand my license can be revoked or that I can be subject of disciplinary action if such laws or regulations are knowingly violated in the pharmacy in which I am the managing pharmacist.

TS I understand within 48 hours after I report for duty as the managing pharmacist, I shall complete an inventory of all controlled substances of the pharmacy pursuant to 21 CFR Part 1304 and maintain a copy of the inventory in the file at the pharmacy.

TS I understand that if I cease to be managing pharmacist of the above-named pharmacy, I will jointly, with the new managing pharmacist, take an inventory of all controlled substances.

TS I understand that as the managing pharmacist I must ensure that all loss or theft of controlled substances are reported on forms provided by the Nevada State Board of Pharmacy and Department of Public Safety within 10 days after the date of discovery of theft or loss. NRS 453.568. Federal regulations require that registrants notify the Field Division Office of the Administration in his area, in writing, of the theft or significant loss of any controlled substance, disposal receptacles or listed chemicals within one business day of discovery of such loss or theft. The registrant shall also complete and submit to the Field Division Office in his area, DEA Form 106 regarding the loss or theft (21 C.F.R. §1301.76(b) and 21 U.S.C. §830(b)(1)(C)).

TS I understand that as the managing pharmacist I must notify the Nevada State Board of Pharmacy of all employment changes of pharmacy staff within 10 days of the change. NAC 639.540

I certify under penalty of perjury that the information I have provided on this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

THOMAS SCHOTIK

Print Name of New Managing Pharmacist



Original signature of New Managing Pharmacist (copies or stamps not accepted)

03/19/2025

Date

Board Use Only	Date Received: 4/1/25	Amount: $50 ck# 10192528

To who it may concern.

The only outstanding administrative action on my license is that I cannot be pharmacist in charge of a compounding pharmacy.

Signed:

3/19/2025

Thomas Schotik Rph. Lic. 08312

[redacted]

FILED
SEP 0 4 2024
NEVADA STATE BOARD OF PHARMACY

BEFORE THE NEVADA STATE BOARD OF PHARMACY

NEVADA STATE BOARD OF PHARMACY, **Petitioner,** v. **AMERICAN WELLNESS PHARMACY, Pharmacy License No. PH02705, and** **THOMAS SCHOTIK, RPH, Certificate of Registration No. 08312,** **Respondents.**	**CASE NOS. 23-063-PH-S** **23-063-RPH-S** **STIPULATION AND ORDER [SCHOTIK ONLY]**

J. David Wuest, in his capacity as Executive Secretary of the Nevada State Board of Pharmacy (Board), by and through General Counsel Brett Kandt, and Respondent Thomas Schotik, RPh, Certificate of Registration No. 08312, **HEREBY STIPULATE AND AGREE THAT:**

1. On or about June 18, 2024, Respondent was served with the Notice of Intended Action and Accusation (Accusation) on file in this matter together with the Statement to Respondent and Notice of Hearing.

2. On or about July 19, 2024, Respondent filed an Answer and Notice of Defense to the Accusation.

3. Respondent is fully aware of the right to seek the advice of counsel in this matter prior to entering into this Stipulation.

4. Respondent is aware of the right to a hearing on the matters alleged in the Accusation, the right to reconsideration, the right to appeal and any and all other rights which may be accorded to him pursuant to NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

5. Conditioned on the acceptance of this Stipulation by the Board, and with the exception of the right to challenge any determination that Respondent has failed to comply with

the provisions of this Stipulation, Respondent hereby knowingly and voluntarily waives the rights to a hearing, reconsideration, appeal and any and all other rights related to this action that may be accorded to him by NRS Chapter 233B (Nevada Administrative Procedure Act), NRS Chapter 622A (Administrative Procedure Before Certain Regulatory Bodies), and NRS Chapter 639 (Nevada Pharmacy Act).

6. Respondent does not contest the allegations in the Accusation, but acknowledges that Board staff prosecuting this case could present such evidence at an administrative hearing to establish a factual basis for the violations alleged therein, *to wit,* that:

A. American Wellness Pharmacy, Pharmacy License No. PH02705, compounded and sold drug products using active ingredients that (1) do not have a United States Pharmacopoeia-National Formulary monograph; (2) are not a part of an FDA approved drug product, or (3) are not authorized to be used in pharmacy compounding pursuant to 21 USC § 353a(b)(1) or the regulations adopted pursuant thereto;

B. American Wellness Pharmacy compounded and sold high-risk sterile products with beyond use dates (BUD's) listed on the product label in excess of USP-797 guidelines based on storage conditions without documentation to support the extended BUD;

C. American Wellness Pharmacy's personnel violated NAC 639.67019, NAC 639.67067, NAC 639.67071 and/or NAC 639.757 and related provisions of 21 U.S.C. § 353a;

D. As the managing pharmacist of American Wellness Pharmacy at the time of the violations, Schotik is responsible for those violations and subject to discipline pursuant to NRS 639.210(12) and (15), NRS 639.220(1), NAC 639.510 and/or NAC 639.702; and

E. Schotik engaged in unprofessional conduct as defined in NAC 639.945(1)((i) and is therefore subject to discipline pursuant to NRS 639.210(4).

7. Those violations are pled with particularity in the Accusation and grounds for action pursuant to NRS 639.210 and NRS 639.255.

8. To resolve this matter without incurring any further costs or the expense associated with a hearing, the Board and Respondent stipulate to the following penalties. Respondent Thomas

Schotik, RPh, Certificate of Registration No. 08312, is placed on probation pursuant to NRS 639.255(1)(b) for a period of one (1) year subject to the following conditions:

A. Pursuant to NRS 639.255(1)(f) and NAC 639.955(5), Schotik shall pay a fine of Two Thousand Dollars ($2000.00) for the violations, by personal, business, certified or cashier's check or money order made payable to "State of Nevada, Office of the Treasurer," to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024;

B. Pursuant to NRS 622.400, Schotik shall pay One Thousand Dollars ($1,000.00) to partially reimburse the Board for recoverable attorney's fees and recoverable costs incurred in investigating and prosecuting this matter, by personal, business, certified or cashier's check or money order made payable to the "Nevada State Board of Pharmacy" to be received by the Board's Reno office located at 985 Damonte Ranch Parkway – Suite 206, Reno, Nevada 89521, due and payable by December 1, 2024;

C. Schotik shall not work as managing pharmacist of any compounding pharmacy licensed by the Board while on probation;

D. Schotik shall not engage in the practice of compounding sterile drug products unless and until he completes twenty (20) extra hours of continuing education (CE) on sterile compounding, in addition to the CE hours he must otherwise complete to maintain licensure, and provides certificates demonstrating completion to the Board; and

E. Schotik shall complete ten (10) extra hours of continuing education (CE) on nonsterile compounding, in addition to the CE hours he must otherwise complete to maintain licensure, and provide certificates demonstrating completion to the Board.

Upon successful completion of probation, Respondent's Certificate of Registration No. 08312 will be fully restored.

9. Any failure by Respondent to comply with the terms of this Order may result in issuance by the Executive Secretary of an order to show cause pursuant to NAC 639.965 directing Respondent to appear before the Board at the next regularly scheduled meeting for a show cause hearing. If such a hearing results in a finding of a violation of this Order by Respondent, the Board

may impose additional discipline upon Respondent not inconsistent with the provisions of NRS Chapter 639.

10. General Counsel will present this Stipulation to the Board for approval pursuant to NRS 622.330 at the Board's regularly scheduled public meeting on September 4, 2024. Respondent will appear in person at the meeting to answer questions from the Board Members and/or Board Staff. The Board Members and Staff may discuss and deliberate regarding this Stipulation, even if Respondent or counsel are not present at the meeting.

11. The Board has discretion to accept this Stipulation, but it is not obligated to do so. If this Stipulation is approved by the Board, it shall be a public record pursuant to NRS 622.330 and shall be reported to the National Practitioner Data Bank pursuant to 42 USC § 1396r–2 and 45 CFR Part 60.

12. If the Board rejects any part or all of this Stipulation, and unless they reach an alternative agreement on the record during the hearing, the parties agree that a full hearing on the merits of this matter may be heard by the Board at a later date. The terms and admissions herein may not be used or referred to in a full hearing on the merits of this matter.

13. Subject to the approval of this Stipulation by the Board, the Board and Respondent agree to release one another from any and all additional claims arising from the facts set forth in the Accusation on file herein, whether known or unknown that might otherwise have existed on or before the effective date of this Order.

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this 5th day of SEPT 2024

THOMAS SCHOTIK, RPH
Certificate of Registration No. 08312

Signed this ___ day of _____ 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Thomas Schotik, RPh, Certificate of Registration No. 08312, in Case No. 23-063-RPH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this ___ day of September 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

Respondent has fully considered the charges and allegations contained in the *Notice of Intended Action and Accusation* in this matter, and the terms of this Stipulation, and have knowingly and voluntarily agreed to the terms set forth herein, and waived certain rights, as stated herein.

AGREED:

Signed this ___ day of _____ 2024

THOMAS SCHOTIK, RPH
Certificate of Registration No. 08312

Signed this 30 day of September 2024

BRETT KANDT, ESQ.
General Counsel
Nevada State Board of Pharmacy

ORDER

The Nevada State Board of Pharmacy hereby adopts the foregoing Stipulation as to Respondent Thomas Schotik, RPh, Certificate of Registration No. 08312, in Case No. 23-063-RPH-N, and hereby orders that the terms of the foregoing Stipulation be made immediately effective upon execution below.

IT IS SO ORDERED.

Entered this 1st day of September 2024.

Helen Park, Pharm.D.
President
Nevada State Board of Pharmacy

CERTIFICATE OF SERVICE

I certify that I am an employee of the Nevada State Board of Pharmacy, and that on this 9th day of September 2024, I served a true and correct copy of the foregoing document by Certified U.S. Mail and Standard U.S. mail to the following:

Thomas Schotik, RPH
[redacted]
Las Vegas, NV 89146

JESSETTE PHAYNARIKONE
ADMINISTRATIVE ASSISTANT I
BOARD COORDINATOR

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14A

[redacted]

NEVADA STATE BOARD OF PHARMACY

985 Damonte Ranch Parkway, Suite 206 - Reno, NV 89521 - (775) 850-1440

APPLICATION FOR ADVANCED PRACTICE REGISTERED NURSE TO PRESCRIBE

Rev (01/05/2023)

What types of drug(s) will you be prescribing?

☑ Dangerous Drugs ONLY (Non-Refundable $80 Fee) (PR)

☐ Dangerous Drugs AND Controlled Substances (CS) I, II, III, IV and/or V (Non-Refundable $200 Fee) (CS)
Select the Controlled Substance Schedules you are applying to prescribe

☐ Schedule I ☐ Schedule II ☐ Schedule III ☐ Schedule IV ☐ Schedule V

Section 1: Personal Information (NAC 639.850)

First: Leslie Middle: Erin Last: Kalyn

Date of Birth: [redacted] SSN or ITIN: [redacted] Sex: ☐ M ☒ F ☐ X

Home Address: [redacted]

City: [redacted] State: [redacted] Zip Code: [redacted]

Telephone: [redacted] Email: [redacted]

APRN License #: APRN001086 Specialty: Family

(A current license and active-PRESCRIBING status with the Nevada State Board of Nursing is required to apply for and maintain a Prescribe or a CS Registration.)

Section 2: Practice Information (A practice address is required for processing of your application.)

Practice Name: LIVE YOUR MAstery @ Trimcare.

Practice Address: 5052 S. Jones Blvd #145 Suite #:

City: Las Vegas, NV State: NV Zip: 89118

Telephone: [redacted] Fax: — Email: [redacted]

Section 3: NRS 632.237 (Complete this section if you are applying to also prescribe SCHEDULED II CS).

An advanced practice registered nurse may apply to prescribe CS listed in schedule II if they meet one of the following qualifications (please mark that apply):

☐ I have at least 2 years or 2,000 hours of clinical experience; OR

☐ The CS will be prescribed pursuant to a protocol approved by a collaborating physician. (If you marked this answer, provide the information as requested below per NAC 639.850.)

Collaborating Physician Name:

Collaborating Physician Practice Address: Suite #:

City: State: Zip:

Telephone: Fax: Email:

Section 4: Federally Mandated Requirement (NRS 425.520, NRS 639.129)	Yes	No
1. Are you the subject of a court order for the support of a child? (If "yes", answer question 2.)		✓
2. Are you in compliance with the order or the plan approved by the district attorney or other public agency enforcing the order for the repayment of the amount owed pursuant to the order?	N/A	

Section 5: Military Service (NRS 622.120)	Yes	No
1. Have you ever served on active duty in the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
2. Have you ever been assigned to duty for a minimum of 6 continuous years in the National Guard or a reserve component of the Armed Forces of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓
3. Have you ever served the Commissioned Corps of the United States Public Health Service or the Commissioned Corps of the National Oceanic and Atmospheric Administration of the United States in the capacity of a commissioned officer while on active duty in defense of the United States and separated from such service under conditions other than dishonorable? (Mark "Yes" if discharged honorably.)		✓

Section 6: Personal and Professional History	Yes	No
1. Have you been diagnosed or treated for any mental illness, including alcohol or substance abuse, or physical condition that would impair your ability to perform the essential functions of your license?		✓
2. Have you been charged, arrested or convicted of a felony or misdemeanor in any state?	✓	
3. Have you been the subject of a board citation or an administrative action whether completed or pending in any state?	✓	
4. Has your license been subjected to any discipline for violation of pharmacy or drug laws in any state?	✓	

Please use and make copies of this page (if necessary) to provide information regarding any questions, 1-4, you have marked "YES" to in section 6 of the application. A signed statement of explanation for each event and a copy of all documents that identify the circumstance or contain an order, agreement or other disposition for the event must be provided.

This is in response to Question # 2,3,4. Provide all the following *where applicable*:

Date of Event/Arrest	Disposition Date	State	City	County
June 1, 2018	Oct 20 20	NV	Las Vegas	Clark
Case #		**Governing, licensing, Arresting Presiding Body/Agency/Court**		
		Federal Government.		
Reason/Charge				
Illegal Health Care Remuneration..				
Plaintiff/Defendant/Claimant/Respondent			**Lawsuit/Arbitration/Bankruptcy**	
VS VS Kalyn.			—	
Name of Business/Industry/Entity				
—				

Provide explanation below:

Please Attached letter & A through H documents of Evidence. to support Reinstatement of My Dangerous Drugs ONLY prescribing license. Thankyou!

[redacted]

Original Signature (electronic, copies or stamps not accepted)

April 2/25.

Date

I certify under penalty of perjury that the information contained in this application is accurate, true and complete in all material respects. I understand that making any false representation in this application is a crime under NRS 639.281. I understand that, pursuant to NRS 239.010, this entire application and any portion thereof is a public record unless otherwise declared confidential by law, and will be considered by the Nevada State Board of Pharmacy at a public meeting pursuant to NRS 241.020. In the event this application is approved I agree to comply with all applicable federal and state statutes and regulations governing this license or registration and understand that any violation may result in discipline.

Leslie, Kalyn

Applicant Print Name (First, Last)

[redacted]

Original Signature (electronic, copies or stamps not accepted)

April 2/25

Date

COLLABORATING PHYSICIAN's name and signature per Section 3 of the application (if applicable):

Collaborating Physician's Print Name (First, Last)

Original Signature (electronic, copies or stamps not accepted)

Date

Board Use Only: Date Processed: 4/9/25 Amount: $80.00

LIVE YOUR MASTERY
Total Transformation

Date: April 2. 2025

Nevada State Board of Pharmacy
985 Damonte Ranch Parkway, St #206
Reno, NV, 89521

Dear Application/Reinstatement Department,

This is a letter explaining questions 2, 3 and 4 of section 6 of my application for reinstatement of my Board of Pharmacy Dangerous Drugs ONLY license.

1) I was indicted in June 2018 for a professional offense that occurred over a few short months at the end of 2016-early 2017, that was heavily influenced by domestic abuse I was suffering from with a co-worker I was working with and whom I was having romantic relations.
2) After 2.5 years in pre-trial with the federal government where I went through rigorous federal level checkin's, domestic abuse therapy, life/professional coaching, and other government restrictions & oversight, I was convicted on October 20/2020 of "illegal healthcare renumeration" in the amount of $4000 for prescribing creams and modafinil. Note, the basis for the conviction was because I had not reported the scheme my co-worked and romantic partner had unknowingly at first had pulled me into, and because there was life threatening domestic abuse (towards me and my two young children) that was silencing me from reporting.
3) I was sentenced to 3 years probation, zero months in prison, zero dollars in restitution, zero penalties, and 80 hours of community service. I was released after 1 year of federal probation since I was considered low risk and was fully in compliance with my 2.5 years of pre-trial and 1 year of probation. I was also placed on the Inspector Generals exclusion list for 5 years from November 2020 to December 2025.

[redacted]

4) I had surrendered my RN and APRN licenses In March 2021 because I did not trust myself or the medical community as a result of the drug scheme that was going on under my nose in the clinic I worked at with the person I had trusted and was in a romantic relationship with. In October 2023, after time away from nursing for more therapy and coaching, I applied for and was granted my RN license back with supervision for a period of 2 years.
5) February of this year, 2025, my RN supervision requirements were met and I was released from RN supervision and all restrictions.
6) March of this year, 2025, the Nevada State Board of Nursing fully reinstated my APRN license with prescribing privileges and without other restriction nor limitations for demonstrating compliance and growth personally and professional over the last 7 years since the incident.
7) The Inspector General is welcoming me back to accept Medicare and Medicaid without limitations, restrictions or penalty this year, December 2025, so I can serve their population of patients in the underserved community of Nevada and nationally.

Regarding the incidence that lead to my indictment that occurred 7 years ago that I had minimal involvement in (per the judges words), and the total 5.5 years of federal and other state/government oversight, I have shown complete and total compliance to the point that ALL governing agencies have come to consensus that I have been prepared and an fully ready to step back into my role as an APRN with prescribing privileges. The biggest reason for this, at this time, is also due to the trust in the federal governments rigorous and trusted due diligence to provide justice, and when requirements are met, the individual is released of consequence and be free to function in the world again, as in the second chance act. I am applying for my prescribing license back as the Nursing Board has supported and as the Federal Government's Inspector General is supporting me back to serve their clients in the full I was in prior to my removal.

The last license I need to meet my requirement to be prepared to accept Medicaid and Medicare again, per the Inspector General's letter, is for the Nevada State Board of Pharmacy to reinstate my Dangerous Drug ONLY prescribing License. To provide the

[redacted]

supporting facts to substantiate my application and explain questions 2, 3 & 4, please see the below documents.

A) Judgement of Conviction
B) My sentencing transcript where the judge state my minimal involvement and the domestic abuse perpetuating my conviction.
C) The letter from my federal probation officer from January 21 showing early probation release
D) The letter from my criminal defense attorney from 2020 giving an overview of my case
E) The RN supervision release letter from the Board of Nursing from February 2025
F) The APRN reinstatement letter from the Nevada State Board of Nursing from March 2025
G) The original Inspector General's letter showing they are welcoming me back to apply this year in (3 months before my 5 year exclusion date) in September this year (which is 5 months from now)
H) The email from the Inspector General's office stating, essentially, there would be no reason to deny or otherwise penalize or restrict me from being able to accept Medicare and Medicaid insurance, as long as all the criteria are met (**which I have met ALL criteria accept for having my prescribing license back from the Board of Pharmacy**).

I respectfully appreciate that you assist me, the Nevada State Board of Nursing, the Federal Government with reinstating my Dangerous Drugs Privileges without additional penalties nor consequence as per all of the governing bodies recommendation, so I can provide serve to the Medicare and Medicaid population as I am expected to come the end of this 2025 year.

If you have any questions or concerns, or require further information; my attorney, my nursing board representative, and the Inspector General's office, as would I, be more

[redacted]

then happy to provide you with what is needed to move forward with reinstating my license to prepare me to serve the nation.

In gratitude,

Leslie Kalyn, APRN-BC, DNP

[redacted]

[redacted]

Exhibit A

Judgement of Conviction

UNITED STATES DISTRICT COURT

District of Nevada

UNITED STATES OF AMERICA
v.
LESLIE KALYN, D.N.P./A.P.R.N., a/k/a LESLIE FETH

JUDGMENT IN A CRIMINAL CASE

Case Number: 2:18-cr-00169-JCM-NJK-3

USM Number: 54846-048

Peter S. Christiansen, Esq. and Kendelee Works, Esq.
Defendant's Attorney

THE DEFENDANT:

☑ pleaded guilty to count(s) One of the Superseding Information

☐ pleaded nolo contendere to count(s) which was accepted by the court.

☐ was found guilty on count(s) after a plea of not guilty.

The defendant is adjudicated guilty of these offenses:

Title & Section	Nature of Offense	Offense Ended	Count
42 U.S.C. § 1320a-7b(b)(1)(A)	Illegal Remunerations for Health Care Referrals	4/30/2017	1s

The defendant is sentenced as provided in pages 2 through 8 of this judgment. The sentence is imposed pursuant to the Sentencing Reform Act of 1984.

☐ The defendant has been found not guilty on count(s)

☑ Count(s) remaining ☐ is ☑ are dismissed on the motion of the United States.

It is ordered that the defendant must notify the United States attorney for this district within 30 days of any change of name, residence, or mailing address until all fines, restitution, costs, and special assessments imposed by this judgment are fully paid. If ordered to pay restitution, the defendant must notify the court and United States attorney of material changes in economic circumstances.

10/2/2020
Date of Imposition of Judgment

James C. Mahan
Signature of Judge

JAMES C. MAHAN, UNITED STATES DISTRICT JUDGE
Name and Title of Judge

October 5, 2020
Date

DEFENDANT: LESLIE KALYN, D.N.P./A.P.R.N., a/k/a LESLIE FETH
CASE NUMBER: 2:18-cr-00169-JCM-NJK-3

IMPRISONMENT

The defendant is hereby committed to the custody of the Federal Bureau of Prisons to be imprisoned for a total term of:

Zero months.

☐ The court makes the following recommendations to the Bureau of Prisons:

☐ The defendant is remanded to the custody of the United States Marshal.

☐ The defendant shall surrender to the United States Marshal for this district:

☐ at _____ ☐ a.m. ☐ p.m. on _____.

☐ as notified by the United States Marshal.

☐ The defendant shall surrender for service of sentence at the institution designated by the Bureau of Prisons:

☐ before 2 p.m. on _____.

☐ as notified by the United States Marshal.

☐ as notified by the Probation or Pretrial Services Office.

RETURN

I have executed this judgment as follows:

Defendant delivered on _____ to _____

at _____, with a certified copy of this judgment.

_____
UNITED STATES MARSHAL

By _____
DEPUTY UNITED STATES MARSHAL

DEFENDANT: LESLIE KALYN, D.N.P./A.P.R.N., a/k/a LESLIE FETH
CASE NUMBER: 2:18-cr-00169-JCM-NJK-3

SUPERVISED RELEASE

Upon release from imprisonment, you will be on supervised release for a term of:

Three (3) years.

MANDATORY CONDITIONS

1. You must not commit another federal, state or local crime.
2. You must not unlawfully possess a controlled substance.
3. You must refrain from any unlawful use of a controlled substance. You must submit to one drug test within 15 days of release from imprisonment and at least two periodic drug tests thereafter, as determined by the court, not to exceed 104 tests annually.
   ☐ The above drug testing condition is suspended, based on the court's determination that you pose a low risk of future substance abuse. *(check if applicable)*
4. ☐ You must make restitution in accordance with 18 U.S.C. §§ 3663 and 3663A or any other statute authorizing a sentence of restitution. *(check if applicable)*
5. ☑ You must cooperate in the collection of DNA as directed by the probation officer. *(check if applicable)*
6. ☐ You must comply with the requirements of the Sex Offender Registration and Notification Act (34 U.S.C. § 20901, *et seq.*) as directed by the probation officer, the Bureau of Prisons, or any state sex offender registration agency in the location where you reside, work, are a student, or were convicted of a qualifying offense. *(check if applicable)*
7. ☐ You must participate in an approved program for domestic violence. *(check if applicable)*

You must comply with the standard conditions that have been adopted by this court as well as with any other conditions on the attached page.

STANDARD CONDITIONS OF SUPERVISION

As part of your supervised release, you must comply with the following standard conditions of supervision. These conditions are imposed because they establish the basic expectations for your behavior while on supervision and identify the minimum tools needed by probation officers to keep informed, report to the court about, and bring about improvements in your conduct and condition.

1. You must report to the probation office in the federal judicial district where you are authorized to reside within 72 hours of your release from imprisonment, unless the probation officer instructs you to report to a different probation office or within a different time frame.
2. After initially reporting to the probation office, you will receive instructions from the court or the probation officer about how and when you must report to the probation officer, and you must report to the probation officer as instructed.
3. You must not knowingly leave the federal judicial district where you are authorized to reside without first getting permission from the court or the probation officer.
4. You must answer truthfully the questions asked by your probation officer.
5. You must live at a place approved by the probation officer. If you plan to change where you live or anything about your living arrangements (such as the people you live with), you must notify the probation officer at least 10 days before the change. If notifying the probation officer in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
6. You must allow the probation officer to visit you at any time at your home or elsewhere, and you must permit the probation officer to take any items prohibited by the conditions of your supervision that he or she observes in plain view.
7. You must work full time (at least 30 hours per week) at a lawful type of employment, unless the probation officer excuses you from doing so. If you do not have full-time employment you must try to find full-time employment, unless the probation officer excuses you from doing so. If you plan to change where you work or anything about your work (such as your position or your job responsibilities), you must notify the probation officer at least 10 days before the change. If notifying the probation officer at least 10 days in advance is not possible due to unanticipated circumstances, you must notify the probation officer within 72 hours of becoming aware of a change or expected change.
8. You must not communicate or interact with someone you know is engaged in criminal activity. If you know someone has been convicted of a felony, you must not knowingly communicate or interact with that person without first getting the permission of the probation officer.
9. If you are arrested or questioned by a law enforcement officer, you must notify the probation officer within 72 hours.
10. You must not own, possess, or have access to a firearm, ammunition, destructive device, or dangerous weapon (i.e., anything that was designed, or was modified for, the specific purpose of causing bodily injury or death to another person such as nunchakus or tasers).
11. You must not act or make any agreement with a law enforcement agency to act as a confidential human source or informant without first getting the permission of the court.
12. If the probation officer determines that you pose a risk to another person (including an organization), the probation officer may require you to notify the person about the specific risks posed by your criminal record and you must comply with that instruction. The probation officer may contact the person and confirm that you have notified the person about the specific risks posed by your criminal record.
13. You must follow the instructions of the probation officer related to the conditions of supervision.

U.S. Probation Office Use Only

A U.S. probation officer has instructed me on the conditions specified by the court and has provided me with a written copy of this judgment containing these conditions. For further information regarding these conditions, see *Overview of Probation and Supervised Release Conditions*, available at: www.uscourts.gov.

Defendant's Signature _____ Date _____

DEFENDANT: LESLIE KALYN, D.N.P./A.P.R.N., a/k/a LESLIE FETH
CASE NUMBER: 2:18-cr-00169-JCM-NJK-3

SPECIAL CONDITIONS OF SUPERVISION

1. Search and Seizure – You must submit your person, property, house, residence, office, vehicle, papers, computers (as defined in 18 U.S.C. § 1030(e)(1)), other electronic communications or data storage devices or media, to a search conducted by a United States Probation Officer. Failure to submit to a search may be grounds for revocation of release. You must warn any other occupants that the premises may be subject to searches pursuant to this condition.

The probation officer may conduct a search under this condition only when reasonable suspicion exists that you have violated a condition of supervision and that the areas to be searched contain evidence of this violation. Any search must be conducted at a reasonable time and in a reasonable manner.

2. Deportation Compliance – If you are ordered deported from the United States, you must remain outside the United States, unless legally authorized to re-enter. If you re-enter the United States, you must report to the nearest probation office within 72 hours after you return.

3. No Contact – You must not communicate, or otherwise interact, with any codefendant/coconspirators in the instant offense: Horace Paul Guerra, Nelson M. Mukuna, Robert D. Harvey, and Alejandro Alex Incera, either directly or through someone else, without first obtaining the permission of the probation office.

4. Community Service – You must complete 80 hours of community service within 24 months. The probation officer will supervise your participation in the program by approving the program (agency, location, frequency of participation, etc.). You must provide written verification of completed hours to the probation officer.

Note: A written statement of the conditions of release was provided to the Defendant by the Probation Officer in open court at the time of sentencing.

DEFENDANT: LESLIE KALYN, D.N.P./A.P.R.N., a/k/a LESLIE FETH
CASE NUMBER: 2:18-cr-00169-JCM-NJK-3

CRIMINAL MONETARY PENALTIES

The defendant must pay the total criminal monetary penalties under the schedule of payments on Sheet 6.

	Assessment	Restitution	Fine	AVAA Assessment*	JVTA Assessment**
TOTALS	$ 100.00	$ N/A	$ WAIVED	$ N/A	$ N/A

☐ The determination of restitution is deferred until _____. An *Amended Judgment in a Criminal Case (AO 245C)* will be entered after such determination.

☐ The defendant must make restitution (including community restitution) to the following payees in the amount listed below.

If the defendant makes a partial payment, each payee shall receive an approximately proportioned payment, unless specified otherwise in the priority order or percentage payment column below. However, pursuant to 18 U.S.C. § 3664(i), all nonfederal victims must be paid before the United States is paid.

Name of Payee	Total Loss***	Restitution Ordered	Priority or Percentage

TOTALS	$ 0.00	$ 0.00

☐ Restitution amount ordered pursuant to plea agreement $ _____

☐ The defendant must pay interest on restitution and a fine of more than $2,500, unless the restitution or fine is paid in full before the fifteenth day after the date of the judgment, pursuant to 18 U.S.C. § 3612(f). All of the payment options on Sheet 6 may be subject to penalties for delinquency and default, pursuant to 18 U.S.C. § 3612(g).

☐ The court determined that the defendant does not have the ability to pay interest and it is ordered that:

☐ the interest requirement is waived for the ☐ fine ☐ restitution.

☐ the interest requirement for the ☐ fine ☐ restitution is modified as follows:

* Amy, Vicky, and Andy Child Pornography Victim Assistance Act of 2018, Pub. L. No. 115-299.
** Justice for Victims of Trafficking Act of 2015, Pub. L. No. 114-22.
*** Findings for the total amount of losses are required under Chapters 109A, 110, 110A, and 113A of Title 18 for offenses committed on or after September 13, 1994, but before April 23, 1996.

DEFENDANT: LESLIE KALYN, D.N.P./A.P.R.N., a/k/a LESLIE FETH
CASE NUMBER: 2:18-cr-00169-JCM-NJK-3

ADDITIONAL TERMS FOR CRIMINAL MONETARY PENALTIES

IT IS ORDERED that this Court determined the documented loss amount for defendant Leslie Kalyn is less than $10,000.00.

DEFENDANT: LESLIE KALYN, D.N.P./A.P.R.N., a/k/a LESLIE FETH
CASE NUMBER: 2:18-cr-00169-JCM-NJK-3

SCHEDULE OF PAYMENTS

Having assessed the defendant's ability to pay, payment of the total criminal monetary penalties is due as follows:

A ☑ Lump sum payment of $ 100.00 due immediately, balance due

☐ not later than _____, or
☐ in accordance with ☐ C, ☐ D, ☐ E, or ☐ F below; or

B ☐ Payment to begin immediately (may be combined with ☐ C, ☐ D, or ☐ F below); or

C ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after the date of this judgment; or

D ☐ Payment in equal _____ *(e.g., weekly, monthly, quarterly)* installments of $ _____ over a period of _____ *(e.g., months or years)*, to commence _____ *(e.g., 30 or 60 days)* after release from imprisonment to a term of supervision; or

E ☐ Payment during the term of supervised release will commence within _____ *(e.g., 30 or 60 days)* after release from imprisonment. The court will set the payment plan based on an assessment of the defendant's ability to pay at that time; or

F ☐ Special instructions regarding the payment of criminal monetary penalties:

Unless the court has expressly ordered otherwise, if this judgment imposes imprisonment, payment of criminal monetary penalties is due during the period of imprisonment. All criminal monetary penalties, except those payments made through the Federal Bureau of Prisons' Inmate Financial Responsibility Program, are made to the clerk of the court.

The defendant shall receive credit for all payments previously made toward any criminal monetary penalties imposed.

☐ Joint and Several

Case Number Defendant and Co-Defendant Names *(including defendant number)*	Total Amount	Joint and Several Amount	Corresponding Payee, if appropriate

☐ The defendant shall pay the cost of prosecution.

☐ The defendant shall pay the following court cost(s):

☐ The defendant shall forfeit the defendant's interest in the following property to the United States:

Payments shall be applied in the following order: (1) assessment, (2) restitution principal, (3) restitution interest, (4) AVAA assessment, (5) fine principal, (6) fine interest, (7) community restitution, (8) JVTA assessment, (9) penalties, and (10) costs, including cost of prosecution and court costs.

Exhibit B

Sentencing Transcript- Judges Statement

THE COURT: All right.

All right. Having heard statements of counsel for the government, counsel for the defendant and the defendant's remarks, having read the presentence report submitted by the probation department, considering its contents and the contents of the plea agreement, the Court hereby accepts the terms of the plea agreement and will embody those terms in the sentence provided, of course overriding everything -- or the factors set forth in 18 U.S.C. Section 3553(a) which the Court always considers when determining an appropriate sentence.

So I'm going to impose a sentence of zero months, which is the low end of the guidelines. That sentence is -- is within the guide -- it's the low end of the guideline and the Court hereby adopts that. The defendant has no prior criminal record. She's been under supervision for I believe over two years and has complied with all conditions. And her role in the instant offense and the time frame of her involvement was minimal in comparison to codefendant, and she was of course in an unhealthy and abusive relationship with the codefendant during that offense -- during the commission -- during the time that that offense was committed. She -- she has two young children whom she supports and a felony conviction and probation are adequate punishment and deterrence. So zero months.

The -- let's see. That sentence is within the

Exhibit C

Official Early Probation Release

UNITED STATES DISTRICT COURT

DISTRICT OF NEVADA

* * *

UNITED STATES OF AMERICA, Plaintiff(s), v. LESLIE KAYLN, D.N.P./A.P.R.N. aka LESLIE FETH, Defendant(s).	Case No. 2:18-CR-169 JCM (NJK) ORDER

Presently before the court is Leslie Kalyn's motion for early termination of supervised release. (ECF No. 161). Neither probation (*Id.* at 1) nor the government oppose Ms. Kalyn's motion (ECF No. 163).

On July 2, 2020, pursuant to a plea agreement, Ms. Kalyn pled guilty to one count of illegal remunerations for health care referrals, a violation of 42 U.S.C. § 1320a-7b(b)(1)(A). On October 2, 2020, she was sentenced to three years of supervised release. No restitution was imposed.

Ms. Kalyn commenced her supervised release on October 2, 2020, and has been in full compliance in all areas of supervision. (ECF No. 161 at 2). Her probation officer, Matt Martinez has no objection to Ms. Kalyn's request for early release and defers to the court. (*Id.*).

After considering a subset of the 18 U.S.C. § 3553(a) sentencing factors, the court can terminate a defendant's supervised release after one year if "such action is warranted by the conduct of the defendant released and the interest of justice." 18 U.S.C. § 3583(e)(1). The subset of factors include: (1) the nature and circumstances of the offense and the history and

James C. Mahan
U.S. District Judge

characteristics of the defendant, (2) the need for deterrence, (3) the need to protect the public, (4) the need to provide the defendant with educational and vocational training or medical care, and (5) any pertinent Sentencing Commission policy statements. *Id.* The defendant need not show undue hardship stemming from his supervision. *U.S. v. Emmett*, 749 F.3d 817, 819–20 (9th Cir. 2014).

The court finds that early termination of Ms. Kalyn's supervision is warranted by her commendable conduct and the interest of justice. Ms. Kalyn has completed one year of her three-year term of supervised release with exemplary compliance. (ECF No. 161 at 3). She had a minimal role in the underlying offense, has no history of violence or recent arrests, and does not use any controlled substances. (*Id.* at 4). She does not have any special conditions requiring programming or counseling, has no outstanding restitution payments, is leading a law-abiding life, and has demonstrated successful reintegration into her community. (*Id.*)

In consideration of the § 3553(a) factors, the court grants her request.

Accordingly,

IT IS HEREBY ORDERED, ADJUDGED, and DECREED that Ms. Kalyn's motion for early termination of supervised release (ECF No. 161) be, and the same hereby is, GRANTED.

DATED December 21, 2021.

James C Mahan

UNITED STATES DISTRICT JUDGE

James C. Mahan
U.S. District Judge

Exhibit D

Criminal Defense Attorney Letter 2020

CHRISTIANSEN LAW OFFICES
TRIAL ATTORNEYS

PETER S. CHRISTIANSEN
PETER J. CHRISTIANSEN
R. TODD TERRY
KENDELEE LEASCHER WORKS
WHITNEY J. BARRETT
KEELY A. PERDUE

October 24, 2020

Re: Leslie Kalyn

To Whom it May Concern:

Please allow this letter to provide you background regarding Ms. Kalyn's recent felony conviction and the terms of her sentence. My office represented Ms. Kalyn with respect to charges filed against her in U.S. Federal District Court for the District of Nevada (Case No. 2:18-cr-00169-JCM-NJK-3. On July 2, 2020, pursuant to a plea agreement, Ms. Kalyn plead guilty to one count of Illegal Remunerations for Health Care Referrals, a violation of 42 U.S.C. §§ 1320a-7b(b)(1)(A). On October 1, 2020, the Court sentenced Ms. Kalyn to zero months incarceration and a period of supervised release not to exceed three years. While Ms. Kalyn's co-defendants will be held to answer for millions of dollars in losses and restitution, the Court could not determine a total loss amount to be attributable to Ms. Kalyn's case, instead concluding only that it could not find such amount to be any more than $10,000. Ms. Kalyn will not be required to pay any amount of restitution.

The court based its decision to afford Ms. Kalyn exceptional leniency on several mitigating factors surrounding her background and lesser role in the charged offense, as well as recommendations from both the United States Attorney's Office and the United States Probation Office for the District of Nevada. More specifically, Ms. Kalyn holds a doctorate in nursing practice and is an advance practice registered nurse. She has no prior criminal convictions, and at the time of the instant offense was on the heels of a tumultuous divorce. Vulnerable and financially unstable, Ms. Kalyn became romantically involved with Co-Defendant [redacted] which was the conduit for her becoming a party to the conduct that gave rise to the underlying charges against her. Ms. Kalyn's relationship with [redacted] was frought with manipulation and verbal abuse. She has long since cut all ties with [redacted] who is now in prison.

In requesting leniency, Ms. Kalyn expressed great regret for her actions and took full responsibility for her violations of the law, which are an exception in an otherwise law-abiding life. Ms. Kalyn also provided the court with letters from her supporters, including prior patients, who time and again, reiterated that the instant conduct is a significant departure from her character and life history. Perhaps more importantly, each of them also noted that Ms. Kalyn is focused on working to change the patterns and relationships that lead her to such a place so that these behaviors are never again repeated.

Although the Government asserted the court had the discretion to sentence Ms. Kalyn to 30-37 months in prison, it conceded that such a punishment did not fit her role in the alleged conduct. The United States Probation Office recommended that the court depart from the numeric

federal sentencing guidelines and impose a sentence of probation. The court agreed, finding that a period of supervised release is all that is needed to meet the ends of justice in Ms. Kalyn's case.

It is my understanding that Ms. Kalyn is now seeking to renew her professional licenses in order to continue moving forward in a manner that will have a positive impact on her community and patients. In the event you require additional information, please do not hesitate to contact my office.

Sincerely,

CHRISTIANSEN LAW OFFICES

[redacted]

PETER S. CHRISTIANSEN, ESQ.

Exhibit E

Nevada State Board of Nursing RN Supervision Release Letter

Nevada State Board of
NURSING

February 3, 2025

Leslie Kalyn
[redacted]

Dear Ms. Kalyn:

Congratulations! You have successfully completed all requirements of the Order for Probation executed on October 10, 2022 by the Nevada State Board of Nursing. You may review the current status of your license, which is now active and unencumbered through nvbn.boardsofnursing.org/licenselookup.

If you should have any questions or need assistance in the future, please do not hesitate to contact me.

Thank you,
Nevada State Board of Nursing

[redacted]
Elaine Ralph, MSN, RN, FN-CSp
Monitoring and Probation Investigator
[redacted]

Exhibit F

Nevada State Board of Nursing- APRN FULL Reinstatement of License Letter

STATE OF NEVADA

JOE LOMBARDO
Governor

DR. KRISTOPHER SANCHEZ
Director

PERRY FAIGIN
NIKKI HAAG
MARCEL F. SCHAERER
Deputy Directors

CATHY DINAUER
Executive Director

DEPARTMENT OF BUSINESS AND INDUSTRY
OFFICE OF NEVADA BOARDS, COMMISSIONS AND COUNCILS STANDARDS

NEVADA STATE BOARD OF NURSING

March 24, 2025

Leslie Kalyn
[redacted]

Dear Ms. Kalyn:

The Nevada State Board of Nursing at its March 19, 2025, meeting accepted your reinstatement application for licensure as an Advanced Practice Registered Nurse (APRN).

Your application has been processed. You may access your most current licensure information through the license verification portal at https://nvbn.boardsofnursing.org/licenselookup

If you have any questions please do not hesitate to contact me in writing, or by telephone at [redacted]

Sincerely,
Nevada State Board of Nursing

[redacted]

Elaine Ralph, MSN, RN, FN-CSp
Monitoring and Probation Investigator
[redacted]

Exhibit G

Original Inspector General's Letter of Exclusion Expiring December 2025

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

November 30, 2020

Leslie Kalyn
[redacted]

Dear Leslie Kalyn:

Re: OIG File Number L-18-40030-9

This is to notify you that you are being excluded from participation in any capacity in the Medicare, Medicaid, and **all** Federal health care programs as defined in section 1128B(f) of the Social Security Act (Act) for the minimum statutory period of 5 years. The Act defines a Federal health care program as any plan or program that provides health benefits, whether directly, through insurance, or otherwise, which is funded directly, in whole or in part, by the United States Government (other than the Federal Employees Health Benefits Program). State health care programs are defined in section 1128(h) and include plans and programs under titles XIX, V, XX, and XXI of the Act. The scope of this exclusion is broad and will have a significant effect on your ability to work in the health care field.

This action is being taken under section 1128(a)(1) of the Act and is effective 20 days from the date of this letter. See 42 U.S.C. 1320a-7(a), 42 C.F.R. 1001.101(a). This exclusion is due to your conviction as defined in section 1128(i) (42 U.S.C. 1320a-7(i)), in the United States District Court, District of Nevada, of a criminal offense related to the delivery of an item or service under the Medicare or a State health care program, including the performance of management or administrative services relating to the delivery of items or services, under any such program.

This exclusion will affect your ability to claim payment from these programs for items or services that you render; it will NOT affect your right to collect benefits under any Federal health care program such as Medicare, Medicaid, or Social Security. You may find more information regarding exclusions on the Office of Inspector General's (OIG) website, including Frequently Asked Questions and the Special Advisory Bulletin about the Effect of Exclusion. To access this site, go to http://oig.hhs.gov, click on EXCLUSIONS DATABASE, and then choose the item you would like to access.

A detailed explanation of the authority for this exclusion, its effect, and your appeal rights is enclosed and is incorporated as part of this notice by specific reference. You should read this document carefully, act upon it as necessary, and retain it for future reference.

REINSTATEMENT IS NOT AUTOMATIC. You must apply to the OIG and be granted reinstatement. Obtaining a provider number from a Medicare contractor, a State agency, or a Federal health care program does not reinstate your eligibility to participate in those programs.

Sincerely,

WILLIAM ECHOLS Digitally signed by WILLIAM ECHOLS

William T. Echols
Reviewing Official
Exclusions Branch

Enclosures

cc: Leslie Kalyn
[redacted]

/vb

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

Please read carefully and retain; it contains important information about your exclusion

You are excluded from participation in any capacity in the Medicare, Medicaid, and **all** Federal health care programs as defined in section 1128B(f) of the Social Security Act. See 42 U.S.C. § 1320a-7b(f); 42 C.F.R. § 1001.2.

This exclusion significantly limits your ability to work in any capacity in the health care field in the United States. No payment will be made by any Federal health care program (such as Medicare, Medicaid, Veterans Health Administration, TRICARE, Military Direct Care System, etc.) for any items or services furnished, ordered, or prescribed by you in any capacity. For example, you are prohibited from submitting or causing claims to be submitted to Federal health care programs for items or services which you provide, and you are also prohibited from being employed to provide items or services which are billed to a Federal health care program. Such items or services could include administrative, clerical, and other activities that do not directly involve patient care or the provision of any health care related services.

An excluded person cannot be employed by a provider to perform functions paid for, in whole or in part, by any Federal health care program. Generally speaking, with rare exceptions, you may not be employed by a hospital, nursing home, or any other institutional provider that participates in Federal health care programs.

This exclusion does not affect your rights or the rights of your family members to collect benefits to which you or they may be entitled as a beneficiary under any Federal program such as Medicare, Medicaid, or Social Security.

Under 42 U.S.C. § 1320a-7(d), the Office of Inspector General (OIG) is required to notify all applicable State agencies of your exclusion. The OIG's exclusion is in addition to any sanction an individual State or other Federal agency may impose under its own authority. Notice will be provided to the public and other parties in accordance with 42 U.S.C. §§ 1320a-7(c), (d), and (e).

Any service you provide is a non-covered service. Therefore, notwithstanding 42 U.S.C. 1395w-4(g)(4), you cannot submit claims or cause claims to be submitted for payment under any Federal health care program. Violations of the conditions of your exclusion may subject you to criminal prosecution and/or the imposition of civil monetary penalties and the denial of your reinstatement to the programs. See 42 U.S.C. § 1320a-7a(a)(1)(D); 42 U.S.C. § 1320a-7b(a)(3); 42 C.F.R. § 1001.3002(a)(2).

YOUR REINSTATEMENT IS NOT AUTOMATIC. You will not be reinstated at the conclusion of the minimum period of exclusion, or anytime thereafter, UNLESS YOU APPLY TO THE OIG AND ARE GRANTED REINSTATEMENT to the Medicare and all Federal health care programs under the provisions of 42 U.S.C. § 1320a-7(g) and 42 C.F.R. §§ 1001.3001–.3005. If you were excluded because you lost your license, you may not apply for reinstatement until (1) your license has been restored by the licensing board or agency which originally took the disciplinary action against you, (2) you have obtained a professional health care license in any State, or (3) have been excluded as a result of this action for a minimum of 3 years. See 42 C.F.R. 1001.501(c) for details and exceptions. The request must be made in writing and emailed to sanction@oig.hhs.gov or faxed to (202) 691-2298. Upon receipt of the request, the OIG will notify you of the information and documentation it requires to reach a decision on your reinstatement.

Obtaining a license, moving to another State, or obtaining a provider number from a Medicare contractor, a State agency, or a Federal health care program does not reinstate your eligibility to participate in those programs.

(04/20 Edition)

DEPARTMENT OF HEALTH AND HUMAN SERVICES

OFFICE OF INSPECTOR GENERAL

WASHINGTON, DC 20201

HOW TO APPEAL YOUR EXCLUSION

If you disagree with this action, you may request a hearing before an administrative law judge (ALJ). You may file a request for a hearing before an ALJ only on the issues of: (i) whether the Inspector General has a basis for the imposition of the sanction, and/or (ii) whether the length of exclusion is unreasonable.

A request for hearing must be made in writing within 60 days of receiving the Office of Inspector General's (OIG) notice of exclusion. The date you receive the OIG's notice of exclusion will be presumed to be five (5) days after the date of such notice unless there is a reasonable showing to the contrary.

Your request for hearing must be accompanied by a copy of the OIG's notice of exclusion, a statement as to the specific issues or findings with which you disagree, along with the basis for your contention that the specific issues and/or findings are incorrect.

Your request for hearing should be filed with the Departmental Appeals Board electronic filing system website (DAB E-File) at https://dab.efile.hhs.gov. To file a new appeal using DAB E-File, you must first register a new account, by: (1) clicking "Register" on the DAB E-File home page; (2) entering the information requested on the "Register New Account" form; then (3) clicking "Register Account" at the bottom of the form. If you have more than one representative, each representative must register separately to use DAB E-File on your behalf.

The e-mail address and password provided during registration must be entered on the login screen https://dab.efile.hhs.gov/login to access DAB E-File. A Registered User's access to DAB E-File is restricted to the appeals for which he or she is a party or authorized representative. Once registered, you may file your appeal by:

- Clicking the "File New Appeal" link on the "Manage Existing Appeals" screen, then clicking "Civil Remedies Division" (CRD) on the "File New Appeal" screen; and
- Entering and uploading the requested information and documents on the "File New Appeal – Civil Remedies Division" form.

All documents must be submitted in Portable Document Format (PDF). Any document, including a request for hearing, will be deemed to have been filed on a given day, if it is uploaded to DAB E-File on or before 11:59 p.m. eastern time of that day. A party that files a request for hearing via DAB E-File will be deemed to have consented to accept electronic service of appeal-related documents that OIG files, or CRD issues on behalf of the ALJ, via DAB E-File. Correspondingly, OIG will also be deemed to have consented to electronic service. More detailed instructions on DAB E-File for CRD cases can be found on the link to CRD E-File Procedures on the File New Appeal Screen for CRD appeals.

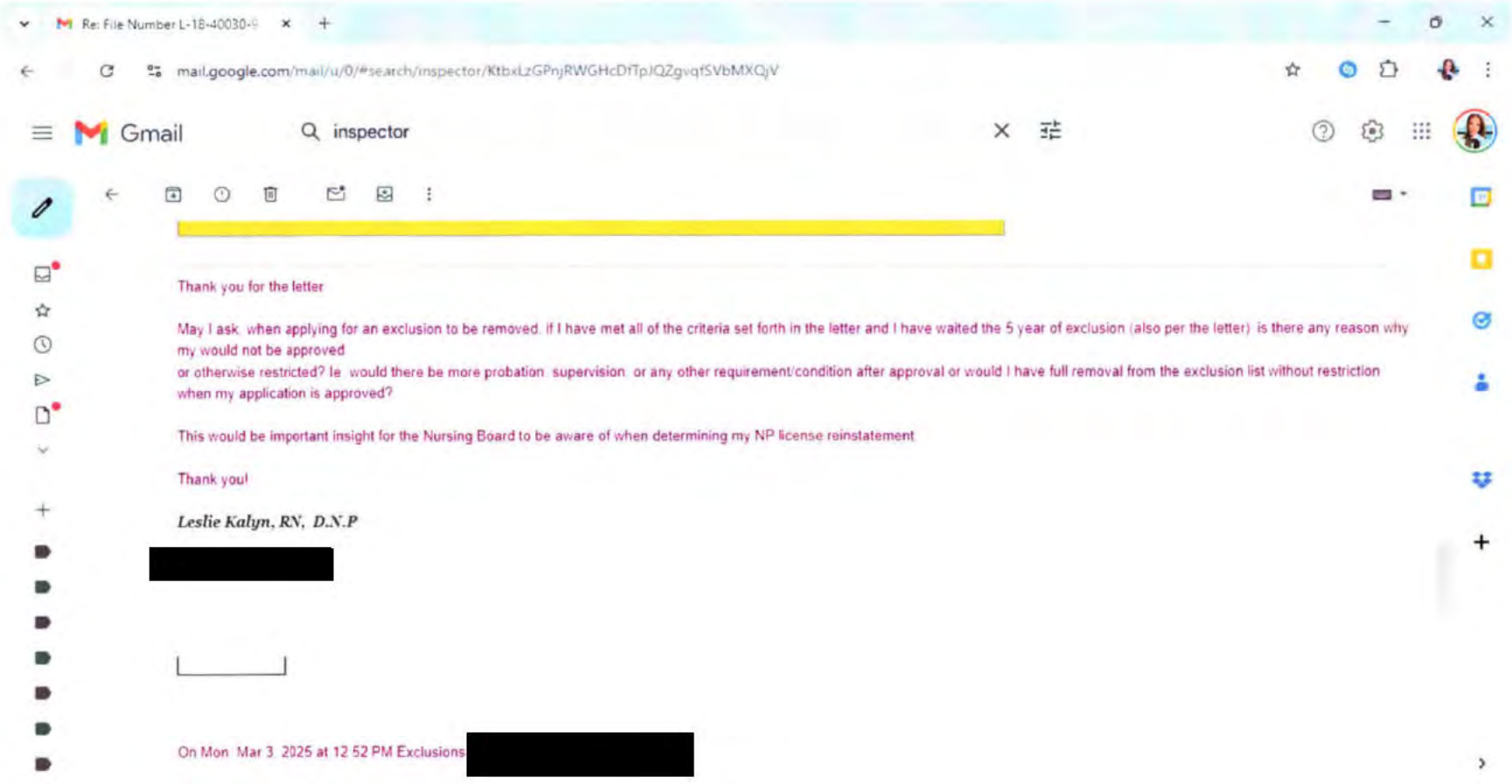
In the event you are unable to file a hearing request using the DAB E-File system, you may submit all of the required information by mail to:

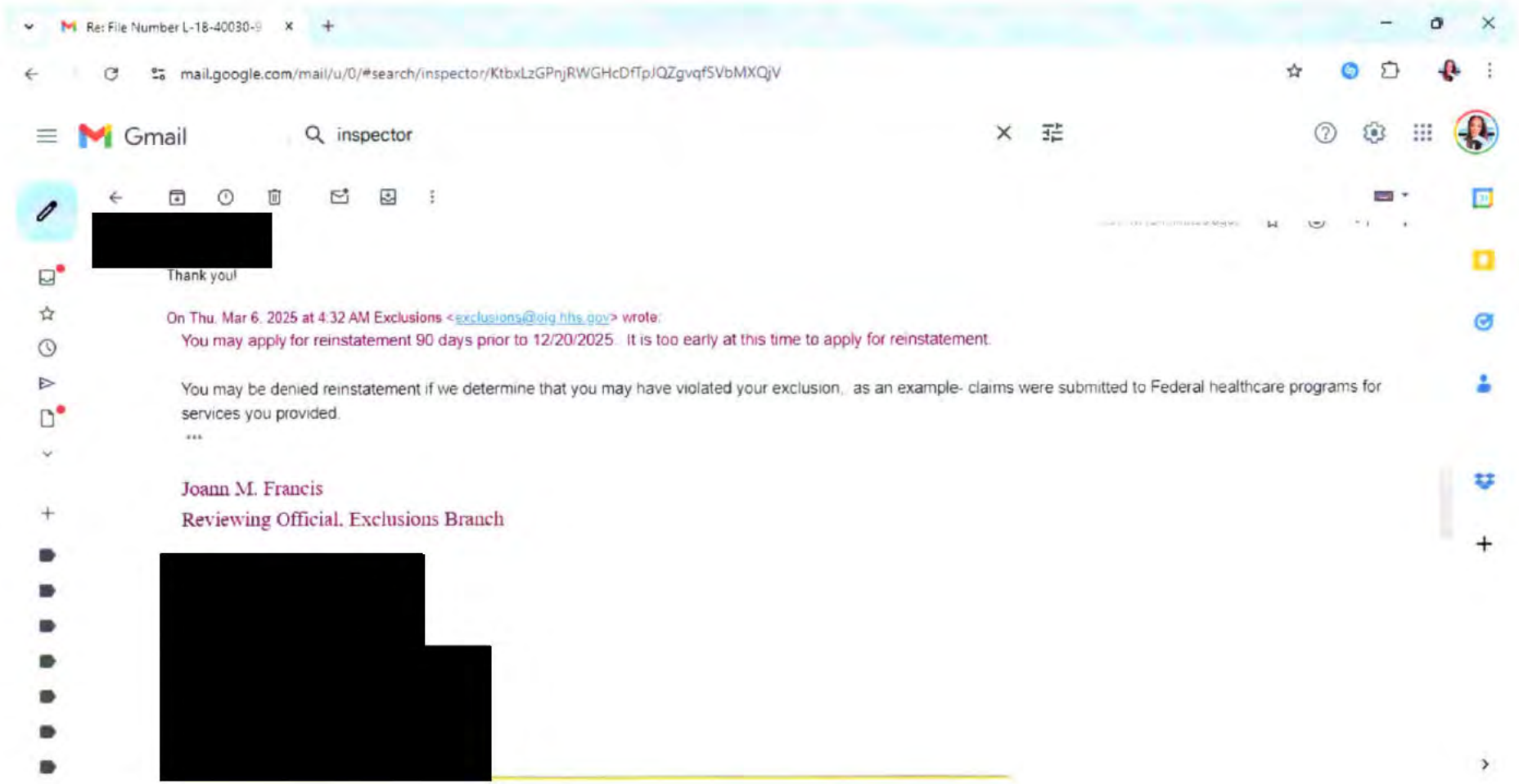
Director, Civil Remedies Division
Departmental Appeals Board, MS 6132
Room G-644, Cohen Building
330 Independence Avenue, SW
Washington, D.C. 20201

(04/20 Edition)

Exhibit H

Email from Inspector General's Office confirming no further limitations


Re: File Number L-18-40030-9
mail.google.com/mail/u/0/#search/inspector/KtbxLzGPnjRWGHcDfTpJQZgvqfSVbMXQjV
Gmail
inspector
Thank you for the letter
May I ask: when applying for an exclusion to be removed: if I have met all of the criteria set forth in the letter and I have waited the 5 year of exclusion (also per the letter): is there any reason why my would not be approved
or otherwise restricted? Ie: would there be more probation: supervision: or any other requirement/condition after approval or would I have full removal from the exclusion list without restriction when my application is approved?
This would be important insight for the Nursing Board to be aware of when determining my NP license reinstatement
Thank you!
Leslie Kalyn, RN, D.N.P
[redacted]
On Mon, Mar 3, 2025 at 12:52 PM Exclusions [redacted]


Re: File Number L-18-40030-9
mail.google.com/mail/u/0/#search/inspector/KtbxLzGPnjRWGHcDfTpJQZgvqf5VbMXQjV
Gmail
inspector
[redacted]
Thank you!
On Thu, Mar 6, 2025 at 4:32 AM Exclusions <exclusions@oig.hhs.gov> wrote:
You may apply for reinstatement 90 days prior to 12/20/2025. It is too early at this time to apply for reinstatement.
You may be denied reinstatement if we determine that you may have violated your exclusion, as an example- claims were submitted to Federal healthcare programs for services you provided.
***
Joann M. Francis
Reviewing Official, Exclusions Branch
[redacted]

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline

Primary Source Board of Nursing Discipline/Final Orders
Contact the boards of nursing for any questions

- **Discipline/Final Orders state:** NV
- **Date action was taken:** 03/24/2021

NPDB

Basis for action

- **Violation Code:** 19 - Criminal Conviction
- **Violation Code:** D8 - Other Unprofessional Conduct, Specify **- Unprofessional Conduct**

- **Initial Action Code:** 1145 - Voluntary Surrender of License

- **Initial action date:** 03/24/2021
- **Effective date(s):** 03/24/2021 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):** No
- **Official primary source board order(s). Also check with the board of nursing for any subsequent or superseding orders.**
- Voluntary Surrender of License in Lieu of Other Di

Primary Source Board of Nursing Discipline/Final Orders
Contact the boards of nursing for any questions

- **Discipline/Final Orders state:** NV
- **Date action was taken:** 11/10/2022

NPDB

Basis for action

- **Violation Code:** 19 - Criminal Conviction
- **Violation Code:** D8 - Other Unprofessional Conduct, Specify **- Unprofessional Conduct**

- **Initial Action Code:** 1125 - Probation of License **-**

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline

- **Initial action date:** 11/10/2022
- **Effective date(s):** 11/10/2022 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):** No
- **Official primary source board order(s). Also check with the board of nursing for any subsequent or superseding orders.**
- Order of Probation

- **Revision action date:** 03/19/2025
- Effective date(s): 03/19/2025 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):**

- **Revision action date:** 02/03/2025
- Effective date(s): 02/03/2025 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):**

NPDB Specific Revision

Basis for action

- Revision Action Code: 1280 -License Restored or Reinstated, Complete

---

- **Revision action date:** 02/03/2025
- Effective date(s): 02/03/2025 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):**

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
KALYN, LESLIE ERIN	APRN-CNP	TAPN700469	Expired	09/10/2008	03/10/2009	NO

Primary Source Board of Nursing Messages & Notifications

- This temporary license is issued until the applicant meets all of the licensure requirements for a permanent license. A temporary license may not be extended or renewed.

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: NO
  - Expiration Date: 03/10/2009
  - Original Issuance Date: 09/10/2008
  - Current Issue Date: 09/10/2008
  - Certification expiration date:

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
KALYN, LESLIE ERIN	APRN-CNP	APRN001086	Active - Prescribing	10/24/2008	05/02/2027	YES

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline

Primary Source Board of Nursing Discipline/Final Orders
Contact the boards of nursing for any questions

- **Discipline/Final Orders state:** NV
- **Date action was taken:** 03/24/2021

NPDB

Basis for action

- **Violation Code:** 19 - Criminal Conviction
- **Violation Code:** D8 - Other Unprofessional Conduct, Specify **- Unprofessional Conduct**

- **Initial action date:** 03/24/2021
- **Effective date(s):** 03/24/2021 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):** No
- **Official primary source board order(s). Also check with the board of nursing for any subsequent or superseding orders.**
- Voluntary Surrender of License in Lieu of Other Di

Primary Source Board of Nursing Discipline/Final Orders
Contact the boards of nursing for any questions

- **Discipline/Final Orders state:** NV
- **Date action was taken:** 11/10/2022

NPDB

Basis for action

- **Violation Code:** 19 - Criminal Conviction
- **Violation Code:** D8 - Other Unprofessional Conduct, Specify **- Unprofessional Conduct**

- **Initial Action Code:** 1125 - Probation of License **-**

- **Initial action date:** 11/10/2022
- **Effective date(s):** 11/10/2022 - Indefinite/Unspecified

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline

- **Is license automatically reinstated after the effective date(s):** No
- **Official primary source board order(s). Also check with the board of nursing for any subsequent or superseding orders.**
- Order of Probation

NPDB Specific Revision

Basis for action

- Revision Action Code: 1280 -License Restored or Reinstated, Complete

---

- **Revision action date:** 03/19/2025
- Effective date(s): 03/19/2025 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):**

NPDB Specific Revision

Basis for action

- Revision Action Code: 1280 -License Restored or Reinstated, Complete

---

- **Revision action date:** 02/03/2025
- Effective date(s): 02/03/2025 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):**

- **Revision action date:** 02/03/2025
- Effective date(s): 02/03/2025 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):**

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline

Advanced Practice license/recognition information

- Population Focus / Specialty:
  - Focus/Specialty: Family Across the Lifespan
  - Has discipline: YES
  - Expiration Date: 05/02/2027
  - Original Issuance Date: 10/24/2008
  - Current Issue Date: 04/07/2025
  - Certification expiration date: 12/05/2029
  - **Discipline/Final Orders state:** NV
  - **Date action was taken:** 03/24/2021

NPDB

Basis for action

- **Violation Code:** 19 - Criminal Conviction
- **Violation Code:** D8 - Other Unprofessional Conduct, Specify - **Unprofessional Conduct**

- **Initial Action Code:** 1145 - Voluntary Surrender of License

---

- **Initial action date:** 03/24/2021
- Effective date(s): 03/24/2021 - Indefinite/Unspecified
- **Is license automatically reinstated after the effective date(s):** No
- **Official primary source board order(s). Also check with the board of nursing for any subsequent or superseding orders.**
- Voluntary Surrender of License in Lieu of Other Di

License type information

- **RN:** Registered Nurse
- **PN:** Practical Nurse (aka Licensed Practical Nurse (LPN), Vocational Nurse (VN), Licensed Vocational Nurse (LVN))
- **CNP:** Certified Nurse Practitioner
- **CNS:** Clinical Nurse Specialist

Nevada State Board of
NURSING
Primary Source License Verification

ViewReportHeaderTitle

Primary Source Board of Nursing Report Summary for

LESLIE ERIN KALYN [NCSBN ID: 20482095]

Wednesday, April 09 2025 02:22:13 PM

The legend below provides details related to the statuses for advanced practice registered nurses (APRNs) only

Active– *ascribed to APRNs who meet the requirements for licensure, but do not meet the requirements, or have not applied for, prescribing privileges.*

Active Prescribing– *ascribed to all APRNs who have been granted authority to prescribe all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL – *ascribed to all APRNs who have been granted authority to prescribe within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

Active Prescribing -D– *ascribed to all APRNs who have been granted authority to prescribe and dispense all legend drugs and may include Schedule CIII-V*

Active Prescribing – CII – D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and is not required to obtain a protocol with a collaborative physician.*

Active Prescribing-CII-COLL –D *ascribed to all APRNs who have been granted authority to prescribe and dispense within the Schedule CII-V category, and have provided a copy of his/her current protocol with a collaborative physician.*

APRNs must also apply with the Nevada State Board of Pharmacy and/or DEA before they can prescribe in Nevada.

If an APRN wishes to remove the protocol requirement they must submit a letter on letterhead from their employer to the Nevada State Board of Nursing verifying that they have worked a minimum of 2 years or 2,000 hours as an APRN.

Details related to License / Certificate Status can be found at the bottom of this page.

Name on License	License / Certificate Type	License / Certificate Number	License Status	Original Issue Date	Current Expiration Date	Discipline
KALYN, LESLIE ERIN	RN	RN53224	Active	09/21/2006	05/02/2027	YES

15

AARON D. FORD
Attorney General

CRAIG A. NEWBY
First Assistant Attorney General

CHRISTINE JONES BRADY
Second Assistant Attorney General



TERESA BENITEZ-THOMPSON
Chief of Staff

LESLIE NINO PIRO
General Counsel

HEIDI PARRY STERN
Solicitor General

STATE OF NEVADA

OFFICE OF THE ATTORNEY GENERAL

100 North Carson Street
Carson City, Nevada 89701

March 26, 2025

OPINION NO. 2025-01

BOARD OF PHARMACY; CONTROLLED SUBSTANCES; DRUGS/DRUG ADDICTS; FOOD AND DRUG; HEALTH; HEALTH CARE PROVIDERS; HOMEOPATHIC MEDICINE; LICENSES; MEDICINE; OSTEOPATHY; STATE BOARD OF HOMEOPATHIC MEDICAL EXAMINERS: Nevada law, specifically NRS 453, 454 and 639 do allow a licensed homeopathic physician in Nevada to possess, administer, prescribe, and dispense controlled substances and dangerous drugs. However, the administration and prescription of said drugs and substances is strictly limited to only the drugs and substances used in accepted homeopathic medicine practice, and only in the very limited amounts permitted in accepted homeopathic practice.

Helen Park, Pharm.D., President
Nevada State Board of Pharmacy
985 Damonte Ranch, Pkwy #206
Reno, Nevada 89521

Dear President Park,

Pursuant to NRS 228.150, you have requested an opinion from this office regarding Nevada's pharmacy and controlled substance statutes, including Nevada Revised Statutes ("NRS") 453, 454 and 639. Specifically, you have asked whether a licensed homeopathic physician, who is not otherwise licensed as an allopathic or osteopathic physician in Nevada, may possess, administer, prescribe, and dispense controlled substances and dangerous drugs under Nevada law. This letter addresses that question.

QUESTION

Whether a licensed homeopathic physician, who is not otherwise licensed as an allopathic or osteopathic physician in Nevada, may possess, administer, prescribe, and dispense controlled substances and dangerous drugs under Nevada law.

SHORT ANSWER

Current Nevada law allows singly licensed homeopathic providers, who are not also licensed as either an allopath or osteopath, to possess, administer, and prescribe both dangerous drugs and controlled substances. However, the administration and prescription of said drugs and substances by a singly licensed homeopathic provider are strictly limited to only the drugs and substances used in accepted homeopathic medicine practice, and only in the very limited amounts permitted in accepted homeopathic practice. For example, common homeopathic practice generally limits utilization of a controlled substance to heavy dilution of a single pill of the drug, versus common allopathic or osteopathic practice, which may allow for the prescription of dozens of pills of the same drug. Various legal mechanisms are in place to monitor and enforce these limits to drugs and dosage.

For dangerous drugs, the prescription of drugs that are (1) not recognized for use in homeopathic medical practice, or (2) are in amounts/dosages beyond what is commonly allowed, is policed and enforced as part of the Nevada Board of Homeopathic Medical Examiners' (NBHME) supervision of its licensees. Failure of any singly licensed provider to adhere to the appropriate limitations would likely be considered malpractice and subject the licensee to disciplinary action from NBHME, which could include revocation of the provider's license to practice.

For controlled substances, the singly licensed homeopathic provider must obtain a controlled substances registration from the Nevada Board of Pharmacy. The Board of Pharmacy has wide discretion and considers numerous factors to determine if any single provider is apt to safely prescribe and utilize controlled substances. For example, a singly licensed homeopathic provider (or any licensed provider for that matter) who has a history of malpractice and/or past disciplinary action may be properly denied a controlled substance registration. Even if a singly licensed homeopathic provider is granted a controlled substance registration, the Board of Pharmacy may continue to closely monitor that provider to ensure that it is utilizing and prescribing controlled substances consistent with accepted homeopathic

practice. Any utilization of non-approved substances and/or use of approved substances in amounts that exceed the generally accepted practice of homeopathic medicine would be grounds for the Board of Pharmacy to initiate disciplinary action against the provider.

ANALYSIS

Background

Under NRS 0.040, the definition of "physician" includes a "homeopathic physician" and the practice of homeopathy. NRS 454.000958 defines "practitioner" to include a "physician…who holds a valid license to practice his or her profession in this State[.]" "Homeopathic medicine" and "homeopathy", as currently defined and described in NRS 630A.040, mean a system of medicine "employing substances of animal, vegetable, chemical or mineral origin[.]" This includes "Nosodes and sarcodes," which are generally defined as inactivated disease products of human, animal, or vegetable origin, or cultures of microorganisms. For the purposes of this opinion, a homeopathic provider who is not at present time concurrently licensed as either an allopathic or osteopathic provider is determined and referred to as "singly licensed."

Definitions

Dangerous Drugs. "Dangerous drugs," as defined in NRS 454.201, generally include drugs, other than controlled substances, that can only be dispensed via prescription because they present a danger if used in an unsupervised manner. Under NRS 454.213, persons authorized to "possess and administer a dangerous drug," include a "practitioner." NRS 454.215 also allows a "practitioner" to dispense "dangerous drugs." Since the statutory definition of "practitioner" includes a "physician," and the statutory definition of a "physician" includes a licensed homeopathic physician, current Nevada law does allow a licensed homeopathic physician to possess, administer, and/or dispense (*i.e.*, prescribe) "dangerous drugs." In accordance with previous Attorney General and Counsel opinions, however, a singly licensed homeopathic provider's ability to possess, administer, and/or prescribe dangerous drugs is limited to only those drugs and in only those amounts generally allowed in homeopathic practice pursuant to The Homeopathic Pharmacopoeia of the United States (HPUS).

There is no separate registration or license for "dangerous drugs" in Nevada. Monitoring and enforcement for ensuring that a singly licensed homeopathic provider only prescribes substances and amounts in accordance

with generally accepted homeopathic medicine practice comes directly from NBHME.

Controlled Substances. The possession, administration, and/or prescription of "controlled substances" by a singly licensed homeopathic provider requires examination of NRS 453, Nevada's "Uniform Controlled Substances Act." Nevada law requires physicians to register with the Nevada State Board of Pharmacy to possess, administer, prescribe or dispense a controlled substance.[1] NRS 630A.370(3) states that one of the grounds for the Board of Pharmacy to initiate disciplinary proceedings against a homeopathic licensee is "[a]dministering, dispensing or prescribing any controlled substance, except as authorized by law." *Id.* (emphasis added). The emphasized language at the end of NRS 630A.370(3) appears to assume that there is some legal means for a homeopathic licensee to prescribe controlled substances.

"Practitioners" who can possess, administer, and dispense controlled substances included homeopathic providers. *See* NRS 453.375, NRS 453.377. Per NRS 453.226, any practitioner who wishes to engage in the dispensing of any controlled substance within the State of Nevada must obtain registration from the Board of Pharmacy on a biennial basis. The Nevada Board of Pharmacy has wide discretion to determine on a case-by-case basis whether an applying practitioner is suitable to receive the required registration to administer, dispense, or prescribe a controlled substance. *See* NRS 453.231 (listing various factors for consideration, including "any" factors relevant to and consistent with public health and safety).

Under NRS 453.231, the Nevada Board of Pharmacy may exempt controlled substances listed as schedule I and/or II even if it otherwise grants a controlled license registration to a particular practitioner under NRS 453.231. NRS 453.236 also allows the Nevada Board of Pharmacy to suspend or restrict a registrant's ability to possess, administer and prescribe certain controlled substances as part of disciplinary action. Finally, a practitioner looking to prescribe controlled substances must obtain and maintain a federal Drug Enforcement Agency license that must be renewed every 3 years, as well as create a Nevada Prescription Monitoring Account.

[1] See NRS 453.126, 453.226(1), NRS 453.375(1)(a), 453.377(1) and (3), 639.23505, 454.213(1)(a), and 454.215(1) and (3).

Previous Attorney General Opinions

Since the time "homeopathic physicians" were added to the statutory definition of "physician" in 1985, two Nevada Attorney General opinions have addressed the question of whether these practitioners can legally possess, dispense, and/or administer controlled substances and/or dangerous drugs. AGO 93-21 (1993) concluded that homeopathic physicians could possess, dispense and administer drugs, but only those that are found in the HPUS. This conclusion was largely based on the language of NRS 630A.040, which limited the authority of homeopathic physicians to write prescriptions to only substances in the HPUS and in only the dosages found in the HPUS. AGO 93-21 concluded, based on the definitions found in the HPUS, that "[n]o known allopathic drugs regularly stocked by Nevada pharmacists would be 'sarcodes'".

A 1999 Attorney General Opinion, AGO 99-06, similarly determined that a NBHME regulation that allowed singly licensed homeopathic physicians to prescribe "pharmaceutical preparations"[2] exceeded the grant of authority delegated to NBHME and was therefore invalid. The regulation in question sought to allow licensed homeopathic providers to prescribe the same drugs and in the same doses as allopathic or osteopathic licensed providers. The reasoning behind the regulation was that all licensed homeopathic providers had received allopathic or osteopathic training sufficient to meet the prescription requirements in at least one state or country. AGO 99-06 expressly endorsed its 1993 opinion and again concluded that the ability of singly licensed homeopathic providers to "possess, dispense and administer controlled substances and dangerous drugs" should be limited to only those substances, and in only those limited doses, expressly approved and allowed by the HPUS.

Legislative Counsel Opinion

In 2000, considering the same NBHME regulation, the State Legislative Counsel (the "Counsel") issued an opinion finding that homeopathic physicians could prescribe controlled substances and dangerous drugs within the course of practicing certain alternative therapies.[3] The Counsel recognized that Attorney General opinions are non-binding and disclaimed the ability of such

[2] This term was expressly limited to exclude "narcotic drugs or opiates that are listed as schedule II-controlled substances pursuant to chapter 453 of NRS, except as those substances may be described for use in the official [HPUS]".

[3] Legislative Counsel Opinion date 1/31/2000.

opinions to invalidate regulations otherwise properly adopted in compliance with the provisions of NRS 233B and filed with the Nevada Secretary of State.

The Counsel's opinion is limited, however, and ultimately aligns with the previous Attorney General opinions in its conclusions and effect. In allowing for the prescription of scheduled controlled substances as medically appropriate in practicing an approved alternative therapy, the Counsel specifically exempts the prescription of "narcotic drugs and opiates that are listed as schedule II-controlled substances pursuant to chapter 453 of NRS, except as those substances may be described for use in the official Homeopathic Pharmacopoeia of the United States[.]" The Counsel's opinion states that, even if a homeopathic provider had the authority and ability to prescribe drugs as a licensed allopathic or osteopathic provider (*i.e.* "a doctor of medicine"), it would not be in the same doses as those providers. Finally, the Counsel concludes that the allowable extent of a singly licensed homeopathic provider prescribing controlled substances and/or dangerous drugs is strictly limited to the substances expressly recognized in common homeopathic practice (*i.e.*, the HPUS) and only in the intentionally and significantly limited doses called for in those therapies, such as the "one-pill rule."

The Counsel also notes that, in its opinion, the NBHME regulation at issue did not purport to grant a singly licensed homeopathic provider *carte blanche* authority to prescribe controlled substances and dangerous drugs, but rather in only the very limited doses and manners necessary for alternative therapies recognized in the HPUS. The opinion thus fairly aligns with the Attorney General opinions of 1993 and 1999, which discussed explicit and significant limitations on the ability of singly licensed homeopathic providers to prescribe certain drugs.

District Court Ruling

A relatively recent Nevada District Court decision—in which the court held that a physician who held an active allopathic or osteopathic license at the time of application for a homeopathic license does not need to have an active allopathic or osteopathic license at the time they seek to renew the homeopathic license—is likewise consistent with the 1993 and 1999 Attorney General opinions.[4] The Court found that, based on statutory construction and differently listed requirements for a homeopathic license "application" versus a homeopathic license "renewal", (NRS 630A.230 vs. NRS 630A.325,

[4] *See Gerber, H.D.M. v. State of Nevada ex rel.*, 2JD, Case No. CV-17-02142 (2018).

respectively), an applicant for initial homeopathic licensure must be licensed as either an allopathic or osteopathic provider but need not still be a licensed allopathic or osteopathic provider at the time they seek to renew their homeopathic license.

This case does not interfere with the Pharmacy Board's authority, under NRS 630A.225, to initiate disciplinary proceedings and/or revoke the homeopathic license of a provider who has had any other medical license or certificate in another jurisdiction revoked for gross medical negligence.

CONCLUSION

Singly licensed homeopathic physicians in Nevada may prescribe "dangerous drugs" as defined in NRS 454.201, but only as long as said "dangerous drugs" are recognized and included in the Homeopathic Pharmacopoeia of the United States (HPUS) and generally accepted homeopathic medical practice. Singly licensed homeopathic providers are also limited in the amounts/dosages of "dangerous drugs" they can utilize or prescribe to an amount not exceeding accepted homeopathic medical practice. Any deviation from accepted practice could and should be grounds for the initiation of disciplinary action by the Board of Homeopathic Medical Examiners.

Similarly, singly licensed homeopathic providers may use and prescribe controlled substances, but only after obtaining required registrations from the Nevada Board of Pharmacy and DEA, and only as is expressly allowed in the HPUS and generally accepted homeopathic practice. Even singly licensed homeopathic providers who have obtained the required Board of Pharmacy registration may only use and prescribe certain substances, and only in the limited doses allowed for in the HPUS. Failure of a singly licensed homeopathic provider to strictly adhere to these limitations on controlled substances subjects said provider to disciplinary action by the Board of Pharmacy, up to and including revocation of the provider's controlled substance registration.

AARON D. FORD
Attorney General

By: _____
TODD M. WEISS
Senior Deputy Attorney General

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Executive Secretary Report

A. Financial Report
B. Issuance of Temporary Licenses and Registrations
C. Change of Address Business List
D. Meetings with Other Health Care Regulatory Boards
E. Licensing Activities Report
F. Citations & Fines issued pursuant to NRS 632.2895
G. Legislative Update
H. Nevada Law Examination Update

June 2025 - Temporary License since last Board Meeting

Pharmacist Name	License #
Amanda Chan	24535
Tahsin Hossain	24540
Marti Henry	24541
Emily Lancaster	24544
Marisa Diefenthaler	24553

Business Name	License #
Urgo Medical North America, LLC	WH03816
UPS Supply Chain Solutions, Inc	WH03817
Boxout, LLC	WH03818

Regulation Tracking Log

Regulation Number and Topic	Workshop Propose To Bd	30 Days To LCB W/Letter	LCB R Number Issued	LCB Return Date	30 Days Post Public Hearing	Public Hearing Meeting Date	To LCB Final W/ Cov./Info	Secretary of State File Date
NAC 639.520: Security of Pharmacies	09/07/23 Dave to meet with industry							
Amendment to Nevada Administrative Code (NAC). The proposed amendments establish the minimum staffing standards in a pharmacy and modify the number of pharmaceutical technicians and pharmaceutical technicians in training a pharmacist may supervise.	5/29/24	6/3/24	R113-24	6/25/24 – To Yenh/Dave for review 7/15/24 –sent revised version to Dave/Yenh	12/10/24	1/16/25 – This public hearing was withdrawn from the agenda and will be heard at a future BM. 4/17/25 – To be heard at a future BM		
Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for treatment with narcotics and provide other matters properly relating thereto.	10/17/24	10/21/24	R197-24					

Amendment to the Nevada Administrative Code ("NAC") 639. The proposed amendments relate to the licensing requirements for facilities for intermediate care or facilities for skilled nursing licensed by the State Board of Health pursuant to NRS 449.0303 and provide other matters properly relating thereto.	12/5/24	12/9/24	R203-24					
Amendment to the Nevada Administrative Code ("NAC") 639.742. The proposed amendments relate to removing the requirement that Dispensing Practitioners must personally dispense at a facility and provide other matters properly relating thereto. The change would allow Dispensing Practitioners to mail prescriptions to individual patients in their care as allowed by the Center for Medicare and Medicaid Services.	12/5/24 – Waiting for the federal reg to pass. The Board would like to see at a future meeting.							
A REGULATION relating to controlled substances adding ethylphenidate and 2-methyl AP-237 to the controlled substances listed in Schedule I; and providing other matters properly relating thereto.	12/5/24	12/9/24	R204-24					

Amendment to Nevada Administrative Code NAC 454. The proposed amendment revises the ability of an advanced emergency medical technicians to possess and administer dangerous drugs upon the order of a practitioner in a license hospital when practicing under their scope of practice as determined by the State of Nevada Health Department.	4/17/25	4/28/25	R004-25					

Citations & Fines issued pursuant to NRS 639.2895 (Since last Board Meeting)

- **Cease & Desist/Citation –**
  - **Unlicensed Practice: 17**
  - **Other: 1**
- **Citation & Fine –**
  - **Unlicensed Practice: 1**
  - **Misfill: 0**
  - **Other: 29 (prescribing with expired registration, administering incorrect dose of vaccine, allowing employee to work on expired license, prescribing without certificate of registration, improper access to dangerous drugs, non-compliance with PMP, failure to maintain administrator, dispensing without valid prescriber authorization)**

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